

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 24, 2017

Findings Date: February 24, 2017

Project Analyst: Bernetta Thorne-Williams

Assistant Chief: Martha J. Frisone

Project ID #: J-11228-16

Facility: Carolina Dialysis - Lee County

FID #: 110959

County: Lee

Applicant(s): Carolina Dialysis, LLC

Project: Add four dialysis stations for a total of 17 dialysis stations and develop a peritoneal and home hemodialysis training program upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Carolina Dialysis, LLC (Carolina Dialysis) d/b/a Carolina Dialysis - Lee County (CD-Lee County) proposes to add four dialysis stations for a total of 17 certified dialysis stations and develop a peritoneal and home hemodialysis training program upon project completion.

Need Determination

The 2016 State Medical Facilities Plan (2016 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2016 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of nine dialysis stations in Lee County. However, the applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. The applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for CD-Lee County in the July 2016 SDR is 3.4615 patients per station per week, or 86.54% ($3.4615 / 4 \text{ patients per station} = 0.86537$). This utilization rate was calculated based on 45 in-center dialysis patients and 13 certified dialysis stations ($45 \text{ patients} / 13 \text{ stations} = 3.4615 \text{ patients per station per week}$).

Application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table:

OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/15		86.5%
Certified Stations		13
Pending Stations		0
Total Existing and Pending Stations		13
In-Center Patients as of 12/31/15 (July 2016 SDR) (SDR2)		45
In-Center Patients as of 6/30/15 (Jan 2016 SDR) (SDR1)		41
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	4
	Multiply the difference by 2 for the projected net in-center change	8
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/15	0.1951
(ii)	Divide the result of Step (i) by 12	0.0163
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/14 until 12/31/15)	0.1951
(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	53.7805
(v)	Divide the result of Step (iv) by 3.2 patients per station	16.8064
	and subtract the number of certified and pending stations to determine the number of stations needed	3.8064

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is four stations. Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established . . . , up to a maximum of ten stations.*” The applicant proposes to add four new stations, therefore the application is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2016 SMFP which is applicable to this review. *POLICY GEN-3: BASIC PRINCIPLES* on page 39 of the 2016 SMFP is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

“A certificate of need 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 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 certificate of need 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 certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B.4, pages 13-14, and Section O, pages 57-62. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B.4, page 14, Section C, pages 20-21, Section L, pages 50-54, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4, page 15, Section C, pages 18-24, Section N, page 56, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. Therefore, the application is consistent with Policy GEN-3.

Conclusion

In summary, the applicant adequately demonstrates that the proposal is consistent with the facility need methodology in the July 2016 SDR and Policy GEN-3. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to add four dialysis station for a total of 17 certified dialysis stations and develop a peritoneal and home hemodialysis training program at CD-Lee County upon project completion.

Patient Origin

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

In Section C, page 23, the applicant provides a table showing the historical patient origin for in-center (IC) patients served by CD-Lee County, as shown below:

Dialysis Patients as of 6/30/2016

COUNTY	IC PATIENTS
Lee	28
Chatham	1
Cumberland	1
Harnett	17
Moore	1
Total	48

In Section C, page 18, the applicant identifies the patient population it proposes to serve during the first two years of operation which includes home hemodialysis (HH) and peritoneal dialysis (PD) patients, following project completion, as illustrated in the table below:

COUNTY	OPERATING YEAR 1 CY 2019			OPERATING YEAR 2 CY 2020			COUNTY PATIENTS AS % OF TOTAL	
	IC	HH	PD	IC	HH	PD	OY 1	OY 2
Lee	33.6	1.00	1.00	34.0	2.00	2.00	62.3%	63.3%
Chatham	1.0	0.0	0.0	1.0	0.0	0.0	1.7%	1.7%
Cumberland	1.0	0.0	0.0	1.0	0.0	0.0	1.7%	1.7%
Harnett	18.5	0.0	0.0	19.0	0.0	0.0	32.4%	31.7%
Moore	1.0	0.0	1.0	1.0	0.0	0.0	1.7%	1.7%
Total	55.1	1.00	1.00	56.0	2.0	2.0	100.0%	100.0%

The applicant provides the assumptions and methodology for the projections above on pages 18-21.

The applicant adequately identifies the population it proposes to serve.

Analysis of Need

The applicant proposes to add four dialysis stations to the existing CD-Lee County facility for a total of 17 certified dialysis stations and to develop a peritoneal and home hemodialysis training program upon project completion. In Section B.2, page 10, the applicant states the application is filed pursuant to the facility need methodology in the 2016 SMFP utilizing data from the July 2016 SDR. In Section C.1, pages 18-20, the applicant provides the assumptions used to demonstrate the need for the project. The facility's patients who reside in Lee County have increased at a rate commensurate with the Five-Year Average Annual Change Rate for Lee County, which is 7.1%. Additionally, the applicant projects that the Harnett County patients, which represent approximately 35 percent of CD-Lee County's patient population, will grow at the Harnett County Five Year Average Annual Change Rate of 2.5%. The applicant does not project growth of any patients residing outside of Lee or Harnett counties; those existing patients were added to the projected Lee and Harnett counties patients at appropriate points in the methodology.

Operating Year 1 (OY1) = Calendar Year (CY) 2019
OY2 = CY2020

Projected Utilization

In Section C, page 19, the applicant provided the methodology used to project in-center utilization, as illustrated in the following table,

Begin with the Lee and Harnett County patients dialyzing at CD-Lee County as of June 30, 2016.	Lee County 28 pts Harnett County 17 pts
Project the patient population forward for six months to December 31, 2016.	Lee $[28 \times (.071 / 12 \times 6)] + 28 = 29.0$ Harnett $[17 \times (.025 / 12 \times 6) + 17 = 17.2$
Project Lee and Harnett County patient population forward one year to December 31, 2017.	Lee $(29.0 \times .071) + 29 = 31.1$ Harnett $(17.2 \times .025) + 17.2 = 17.6$
Project Lee and Harnett County patient population forward one year to December 31, 2018.	Lee $(31.1 \times .071) + 31.1 = 33.3$ Harnett $(17.6 \times .025) + 17.6 = 18.0$
Add three patients from other counties. This is the beginning census.	$33.3 + 18.0 + 3 = 54.3$
Project Lee and Harnett County patient population forward one year to December 31, 2019.	Lee $(33.3 \times .071) + 33.3 = 35.6$ Harnett $(18 \times .025) + 18 = 18.5$
Subtract two Lee County patients projected to change modality to home based dialysis.	Lee $35.6 - 2 = 33.6$ Harnett 18.5
OY1: Add three patients from outside Lee and Harnett counties. This is the projected ending census for OY1.	$33.6 + 18.5 + 3 = 55.1$
Project Lee and Harnett County patient population forward one year to December 31, 2020.	Lee $(33.6 \times .071) + 33.6 = 36$ Harnett $(18.5 \times .025) + 18.5 = 19$
Subtract two patients projected to change modality to home based dialysis.	$36 - 2 = 34$ Harnett 19
OY2: Add three patients from outside Lee and Harnett counties. This is the projected ending census for OY2.	$34 + 19 + 3 = 56.0$

The applicant projects that CD-Lee County will serve a total of 55 in-center patients at the end of OY1 for a utilization rate of 80.88% or 3.24 patients per station per week (55 patients / 17

stations = $3.2352 / 4 = 0.8088$ or 80.88%). The projected utilization of 3.24 patients per station per week at the end of OY1 meets the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Projected utilization for the in-center patients is based on reasonable and adequately supported assumptions regarding continued growth.

Home Hemodialysis and Peritoneal Dialysis

On page 19 of the application, the applicant projects that in each of the first two years that two patients would transition from in-center dialysis care: one home hemodialysis and one peritoneal dialysis patient. This is the only explanation offered in the application as submitted to support the need to develop a home hemodialysis and peritoneal dialysis training program as part of this project.

Therefore, the applicant does not adequately explain in the application as submitted:

- 1) Why home hemodialysis and peritoneal dialysis training and support services need to be developed as part of this project; and
- 2) The basis for its assumptions regarding the number of home hemodialysis and peritoneal dialysis patients.

Access

In Section L, pages 51-52, the applicant states Carolina Dialysis and Fresenius Medical Care Holdings, Inc., (FMC) have a long history of providing care and services to a population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, and other traditionally underserved persons. The applicant provides its historical payor mix for CY2014 on page 54, as illustrated below.

Payment Source	Percent of Total Patients
Self Pay/ Indigent/ Charity	1.6%
Medicare	66.77%
Medicaid	2.36%
Commercial Insurance	10.97%
Medicare / Commercial	11.24%
Misc. (VA)	7.06%
Total	100.0%

On page 51, the applicant projects that 90.35% of its patients will be Medicare or Medicaid recipients. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

Conclusion

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need that population has for the proposed in-center stations and the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion subject to Condition 3 which is found in Criterion (4).

- (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 E-1, page 26, the applicant discusses the alternatives considered prior to submitting this application, which include:

1. Maintain the Status Quo - the applicant states that this option would result in higher utilization rates given the historical growth rate of the facility (19.5% over the last six months as reflected in the July and January 2016 SDRs).
2. Apply for Fewer Stations - Application of the facility need methodology indicated a need for an additional four stations based on the continued growing need for dialysis services at CD-Lee County.
3. Relocate Stations from Carolina Dialysis-Sanford County (CD-Sanford County) - The applicant states the facility operated at 75.0% utilization as of June 30, 2016. The facility's in-center census increased by eight patients within six months, which is nearly a 16% growth rate from its December 31, 2015 census. Thus, the applicant concluded it would be unreasonable to relocate stations from CD-Sanford County.

The applicant states the project as proposed in the application would ensure that the facility addresses the issues of growth and access to dialysis services by its patients. Therefore, the applicant believes that adding four dialysis stations at CD-Lee County is the most effective alternative to meet the identified need.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that this proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1. Carolina Dialysis, LLC d/b/a Carolina Dialysis Center - Lee County shall materially comply with all representations made in the certificate of need application except as modified by the conditions of approval.**
 - 2. Carolina Dialysis, LLC d/b/a Carolina Dialysis Center - Lee County shall develop and operate no more than four additional dialysis stations at Carolina Dialysis Center - Lee County for a total of no more than 17 certified dialysis stations which shall include any isolation or home hemodialysis training stations upon project completion.**
 - 3. Carolina Dialysis, LLC d/b/a Carolina Dialysis Center – Lee County shall not develop a home hemodialysis and peritoneal dialysis training program as part of this project.**
 - 4. Carolina Dialysis, LLC d/b/a Carolina Dialysis Center - Lee County shall install plumbing and electrical wiring through the walls for no more than four additional dialysis stations, which shall include any isolation or home hemodialysis training stations.**
 - 5. Carolina Dialysis, LLC d/b/a Carolina Dialysis Center - Lee County shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

Carolina Dialysis proposes to add four dialysis stations for a total of 17 certified dialysis stations and develop a peritoneal and home hemodialysis training program at CD-Lee County upon project completion.

Capital and Working Capital Costs

In Section F, page 28, the applicant projects the capital cost for the proposed project, as summarized in the table below:

Projected Capital Costs	
Dialysis machines	\$60,000
Water treatment equipment	\$3,000
Equipment/furniture not included above	\$12,000
Total	\$75,000

In Section F, page 31, the applicant states that there are no working capital needs for the proposed project since CD-Lee County is an existing facility.

Availability of Funds

In Section F, page 29, the applicant states that accumulated reserves will be used to finance the proposed project. In Exhibit F-1, the applicant provides a letter dated September 15, 2016 from the Chairman of the Board of Managers of UNC Hospitals which owns 67% of Carolina Dialysis committing to fund the project’s capital needs with its cash reserves. The remaining 33% of Carolina Dialysis is owed by Renal Research Institute. Renal Research Institute is wholly owned by Fresenius Medical Care Holdings, Inc.

Exhibit F-2 contains a copy of Carolina Dialysis, LLC’s balance sheet. As of December 31, 2015, Carolina Dialysis Center had \$273,583 in cash, \$31,587,516 in total assets and \$27,587,393 in net assets (total assets less total liabilities).

The applicant adequately demonstrated the availability of sufficient funds for the capital needs of the project.

Financial Feasibility

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

CD-Lee County	Operating Year 1 CY2019	Operating Year 2 CY2020
Total Treatments	8,002	8,151
Total Gross Revenues (Charges)	\$32,502,200	\$34,276,860
Total Net Revenue	\$3,103,358	\$3,221,849
Total Operating Expenses (Costs)	\$2,935,374	\$3,039,554
Net Profit	\$167,984	\$182,294

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section R of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based on reasonable projections of costs and charges.

Conclusion

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

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

C

Carolina Dialysis proposes to add four dialysis stations for a total of 17 certified dialysis stations and a peritoneal and home hemodialysis training program at CD-Lee County following project completion.

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

The July 2016 SDR indicates there are two dialysis facilities in Lee County, as follows:

**Lee County Dialysis Facilities
as of December 31, 2015**

Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
Carolina Dialysis - Lee County	CD	45	Sanford	13	0	86.54%
Carolina Dialysis - Sanford	CD	100	Sanford	36	0	69.4%

As shown in the table above both the facilities in Lee County are operated by Carolina Dialysis. Based on the most recent SDR, Carolina Dialysis - Sanford (CD-Sanford) operated at 69.4% of capacity as of December 31, 2015. However, the applicant states on page 26 that CD-Sanford

was serving 108 patients as of June 30, 2016 which is a utilization rate of 75.0%. Thus, all of the dialysis facilities are reasonably well utilized.

In Section C, pages 18-20, the applicant demonstrates that CD-Lee County will serve a total of 55 in-center patients at the end of OY1 for a utilization rate of 80.88% or 3.24 patients per station (55 patients / 17 stations = 3.235 / 4 = .8088 or 80.88%). The projected utilization of 3.24 patients per station per week for Operating Year One meets the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b). The applicant adequately demonstrates the need to add four additional stations at CD-Lee County based on the number of in-center patients it projects to serve.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved dialysis services in Lee County. Consequently, the application is conforming to this criterion.

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

C

In Section H, page 37, the applicant provides current and projected staffing in full time equivalents (FTEs) for CD-Lee County, as shown in the table below.

POSITION	CURRENT # FTEs	# FTEs POSITIONS ADDED/ DELETED	PROJECTED # FTEs
Registered Nurse	2.00	1.00	3.00
Technician (PCT))	5.00	1.00	6.00
Home Training Nurse		1.00	1.00
Clinical Manager	1.00		1.00
Administrator	0.15		0.15
Dietician	0.60		0.60
Social Worker	0.50		0.50
Chief Tech	0.15		0.15
Equipment Tech	0.67		0.67
In-Service	0.15		0.15
Clerical	0.75		0.75
Total	10.97	3.00	13.97

In Section H, page 39, the applicant provides the projected direct care staff for CD-Lee County in OY2, as shown below in the table:

DIRECT CARE POSITIONS	# FTES	HOURS PER YEAR PER FTE	TOTAL ANNUAL FTE HOURS	TOTAL ANNUAL HOURS OF OPERATION	# FTE HOURS PER HOUR OF OPERATION
Registered Nurse	3.00	2,080	6,240	3,432	1.82
Technician (PCT)	6.00	2,080	12,480	3,432	3.64
Home Training RN	1.00	2,080	2,080	3,432	0.61
Total	10.0	2,080	20,800	3,432	606

In Section I, page 41, the applicant identifies Dr. Pankaj Jawa as the Medical Director of the facility. In Exhibit I-5, the applicant provides a signed letter from Dr. Jawa of UNC Health Care Kidney Center supporting the project and confirming his commitment to serve as Medical Director. Exhibit I-6 contains a copy of Dr. Jawa’s curriculum vitae. In Section H, pages 38, the applicant describes the methods used to recruit and fill vacant or new positions.

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

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

C

In Section I, page 40, the applicant includes a list of providers of the necessary ancillary and support services. Exhibit I-5 contains a letter from the medical director of the facility expressing his support for the proposed project. The applicant discusses coordination with the existing health care system on pages 42-43. Exhibits I-2 through I-4, respectively, contain copies of agreements for Spectra laboratories services, UNC Hospitals, and UNC Hospitals Center for Transplant Care for transplant services. The information in Section I and Exhibits I-2, I-3 and I-4 is reasonable and adequately supports a finding of conformity with this criterion.

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

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates:
- (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and
 - (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
 - (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

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 L, page 54, the applicant reports that 80.37% of the patients who received treatments at CD-Lee County had some or all of their services paid for by Medicare or Medicaid in CY 2014, as illustrated in the table below.

Payment Source	Percent of Total Patients
Self Pay/ Indigent/ Charity	1.6%
Medicare	66.77%
Medicaid	2.36%
Commercial Insurance	10.97%
Medicare / Commercial	11.24%
Misc. (VA)	7.06%
Total	100.00%

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for Lee County, Harnett County and statewide.

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Lee	15%	51%	42%	19%	10%	21%
Harnett	11%	51%	37%	21%	10%	19%
Statewide	15%	51%	36%	17%	10%	15%

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

*Excludes "White alone" who are "not Hispanic or Latino"

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

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

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

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

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

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

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

C

In Section L.3, page 53, the applicant states:

“Carolina Dialysis-Lee County facilities do not have any obligation to provide uncompensated care or community service under any federal regulations.”

In Section L.6, page 53, the applicant states that there have been no patient civil rights complaints filed against CD-Lee County in the past five years.

The application is conforming to this criterion.

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

C

In Section L.1, page 50, the applicant states:

“It is Carolina Dialysis, LLC and Fresenius policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”

In Section L, page 51, the applicant projects that 90.35% of all in-center patients will have all or part of their services paid for by Medicare and or Medicaid.

**CD-Lee County
 Projected Payor Mix OY2**

Payor Type	Percent of Total Patients	Percent of IC	Percent of HH	Percent of PD
Self Pay/ Indigent/ Charity	1.00%	1.00%	0.0%	0.0%
Medicare	72.94%	72.94%	100.0%	100.0%
Medicaid	4.70%	4.70%	0.0%	0.0%
Commercial Insurance	4.83%	4.83%	0.0%	0.0%
Medicare/Commercial	12.71%	12.71%	0.0%	0.0%
VA	3.81%	3.81%	0.0%	0.0%
Total	100.0%	100.0%	100.0%	100.0%

The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

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In Section L.4, page 53, 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-Lee County has an open policy, which means that any Nephrologist may apply to admit patient to the facility. The attending physicians receive referrals from other physicians or Nephrologists or hospital emergency rooms. ... Transient patients are accepted upon proper coordination of care with the patient’s regular nephrologist and a physician with staff privileges at the facility.”

The applicant adequately demonstrates that it will offer a range of means by which patients will have access to the proposed services. Therefore, the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

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In Section M.1, page 55, the applicant states that CD-Lee County offered the facility as a site for clinical rotations for Central Carolina Community College’s nursing students. Exhibit M.I contains a copy of a letter from Fresenius Kidney Care to the Nursing Department Chair of Central Carolina Community College documenting the offer. The information provided in Section M.1 and Exhibit M-1 is reasonable and credible and supports a finding of conformity to this criterion.

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

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Carolina Dialysis proposes to add four dialysis stations for a total of 17 certified dialysis stations as well as adding a peritoneal and home hemodialysis training program at CD-Lee County.

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

The July 2016 SDR indicates there are two dialysis facilities in Lee County, as follows:

**Lee County Dialysis Facilities
as of December 31, 2015**

Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
Carolina Dialysis - Lee County	CD	45	Sanford	13	0	86.54%
Carolina Dialysis - Sanford	CD	100	Sanford	36	0	69.4%

As shown in the table above both the facilities in Lee County are operated by Carolina Dialysis. Based on the most recent SDR, Carolina Dialysis - Sanford (CD-Sanford) operated at 69.4% of capacity as of December 31, 2015. However, the applicant states on page 26 that CD-Sanford was serving 108 patients as of June 30, 2016 which is a utilization rate of 75.0%. Thus, all of the dialysis facilities are reasonably well utilized.

In Section N, page 56, the applicant discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. The applicant states:

“Carolina Dialysis, LLC does not expect this proposal to have effect on the competitive climate in Lee County. At the present time, there are three [sic] other dialysis facilities in the county, each serving patients of Lee and surrounding counties. Carolina Dialysis, LLC does not project to serve dialysis patients currently being served by another provider. The projected patient population for Carolina Dialysis-Lee County facility begins with patients currently served by Carolina Dialysis-Lee County, and a growth of that patient population consistent with the facility [sic] historical growth. ... This proposal will ... enhance the quality of the ESRD patients’ lives by offering another convenient venue for dialysis care and treatment.”

See also Sections C, F, G, H, L and P where the applicant discusses cost-effectiveness, quality and access.

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

- The applicant adequately demonstrates the need for the proposed in-center dialysis stations and that it is an effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that CD-Lee County will continue to provide quality dialysis services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates that CD-Lee County will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1), (3) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

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In Section B, pages 13-14, Section O, pages 57-59, and Exhibit O-1, the applicant discusses the methods it uses to ensure and maintain quality. In Section O, pages 60-62, the applicant states that out of more than 100 facilities located in North Carolina operated by the applicant or a related entity only the three facilities listed below were not in compliance with Medicare conditions of participation during the 18 months prior to submission of the application.

BMA QUALITY CARE			
FACILITY	SURVEY DATE	BACK IN COMPLIANCE	
		Yes	5/29/2015
BMA Lumberton	5/6/2015	Yes	5/29/2015
BMA East Charlotte	8/11/2015	Yes	9/9/2015
RAI West College	3/15/2016	Yes	4/11/2016

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

(21) Repealed effective July 1, 1987.

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

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- CD-Lee County 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.

-C- In Section C, pages 18-20, the applicant demonstrates that CD-Lee County will serve a total of 55 in-center patients at the end of OY1 for a utilization rate of 80.88% or 3.24 patients per station per week ($55 \text{ patients} / 17 \text{ stations} = 3.235 / 4 = .8088$ or 80.88%). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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

- C- In Section C.1, pages 18-20, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.