

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: November 5, 2013
PROJECT ANALYST: Celia C. Inman
SECTION CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: J-10190-13 / Carolina Dialysis, LLC d/b/a Carolina Dialysis-Siler City / Add four dialysis stations for a total of 22 certified stations upon completion of this project / Chatham 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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Carolina Dialysis, LLC d/b/a Carolina Dialysis-Siler City proposes to add four dialysis stations for a total of 22 certified dialysis stations upon completion of this project. The facility is located at 192 Campus Drive in Siler City, Chatham County. The 2013 State Medical Facilities Plan (2013 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2013 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of one dialysis station in Chatham County, but does not indicate additional stations are needed based on the county need methodology. However, the applicant is eligible to apply for additional stations based on the facility need methodology because the utilization rate reported for Carolina Dialysis-Siler City in the July 2013 SDR is 3.28 patients per station. This utilization rate was calculated based on 59 in-center dialysis patients and 18 certified dialysis stations. (59 patients / 18 stations = 3.2778 patients per station).

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

OCTOBER 1 REVIEW-JULY 2013 SDR

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/12		81.9%
Certified Stations		18
Pending Stations		0
Total Existing and Pending Stations		18
In-Center Patients as of 12/31/12 (SDR2)		59
In-Center Patients as of 6/30/12 (SDR1)		41
Step	Description	
	Difference (SDR2 - SDR1)	18
(i)	Multiply the difference by 2 for the projected net in-center change	36
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/12	0.8780
(ii)	Divide the result of Step (i) by 12	0.0732
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/11 until 12/31/12)	0.8780
(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	110.8049
(v)	Divide the result of Step (iv) by 3.2 patients per station	34.6265
	and subtract the number of certified and pending stations as recorded in SDR2 [# of stations] to determine the number of stations needed	17

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 17 stations, up to a maximum of 10. 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 and, therefore, is consistent with the facility need determination for dialysis stations.

Policy GEN-3: Basic Principles, page 42, of the 2013 SMFP 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

In Section II.3, pages 33-36, the applicant discusses insuring and maintaining quality care. On page 33, the applicant states:

“Carolina Dialysis-Siler City has a well-defined Quality Improvement program whose purpose is to establish an outcome focused review and evaluation of the quality, safety and effectiveness of patient care. The program’s work is conducted by the Continuous Quality Improvement Team and coordinated by the Clinical Manager and the Regional Quality Manager. The primary method of review is patient care audits and monitoring of critical patient indicators. Audits will be conducted monthly and results presented to the Quality Improvement Team for evaluation and recommendation. Other audits include Patient Satisfaction Surveys and chart audits. CQI membership includes the Medical Director, Area Manager, Clinical Manager, Chief Technician, Social Worker and Dietitian. The committee will meet monthly. Individual teams may be assigned to individual projects to gather data as needed to conduct the “Check, Plan, Do, and Check, Act” process for addressing the improvement opportunities.”

See Exhibit 13 for copies of the Quality Assessment and Performance Improvement for FMS Inpatient Services Programs.

In Section II.1, page 24, the applicant states:

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

In Section 1.13, page 5-9, the applicant discusses the quality of services provided at Carolina Dialysis-Siler City, attributing much of its success in providing quality services to the expertise of its healthcare leaders: UNC Hospitals and Fresenius Medical Care (FMC), parent company to National Medical Care, Inc, parent to Bio-Medical Applications of North Carolina. On page 5, the applicant states, *“The excellence in patient care and patient outcomes facilitated by Carolina Dialysis, LLC is a direct result of the culture Carolina Dialysis, LLC, fosters among its staff and physicians.”* The applicant states that Carolina Dialysis, LLC and UNC Hospitals have chosen Renal Research Institute (RRI) as the contracted manager for the facility. The applicant further states that FMC offers a strong corporate structure and extensive management background to the Carolina Dialysis-Siler City facility, specifically its

Clinical Services Department, Technical Services Department, Regulatory Affairs and Law Departments, and other management resources as discussed, in part, below.

- Clinical Services Department
 - Serves as a central resource for the entire FMC network
 - Provides facilities with the best procedures and equipment available
 - Assist facility managers and medical personnel with questions and concerns on clinical operations
 - Provides ongoing Clinical Review Program, guidelines for comprehensive training, and Quality Assurance Program

- Technical Services Department
 - Oversees the technical and mechanical aspects of dialysis
 - Supported by a research and quality control team that leads the industry in dealing with technically complex issues facing dialysis providers

- Regulatory Affairs and Law Departments
 - Deal with legal and regulatory issues
 - Provides interpretation of legislation and government policy to ensure compliance

- Other Management Resources, including but not limited to:
 - Revenue Operations – draws experience through interaction with more than 13 Medicare intermediaries and numerous third-party carriers
 - Accounting and Budget – tailored to ensure effective financial management of dialysis treatment centers
 - Facility Design and Maintenance – experienced architectural staff promotes development of efficiently designed facilities
 - Human Resources – develops productivity standards, job descriptions, staff performance reviews, personnel policies and procedures and employee relations.
 - Information Systems – develops comprehensive facility automation including enhanced software for clinical management to support delivery of high quality care
 - Operations Department – ensures effective transition of acquired programs in the division, the training of all field staff on systems applications, and the efficiency of facility administrative support
 - Health, Safety, and Risk Management – provides regulatory information used to ensure compliance in the dialysis setting and provides risk management services.
 - Renal Research Institute – a wholly-owned subsidiary of FMCNA, initiates a wide range of research activities including the development and evaluation of the latest technology with the

- goal of creating innovative clinical protocols for improved renal care.
- Regional Vice Presidents – provide operational direction and monitoring of daily operations.

In Section II.3, pages 33-36, the applicant continues to address quality in a discussion of its Quality Improvement program, staff orientation and training, Continuous Quality Improvement teams, regional quality teams, and core indicators of quality.

In Section V, page 49, the applicant states that its facilities have done an excellent job of containing costs while providing outstanding care and treatment to patients. The applicant further states it has eliminated the re-use concept in its facilities and provides every patient a new dialyzer at each treatment.

The applicant adequately demonstrates that the proposal will promote quality and safety.

Promote Equitable Access

In Section II, page 26, the applicant states:

“Carolina Dialysis-Siler City has removed the economic barriers with regard to access to treatment. The overwhelming majority of dialysis treatments are covered by Medicare / Medicaid; in fact, within this application, Carolina Dialysis-Siler City is projecting that 91.3% of the In-Center dialysis treatments will be covered by Medicare or Medicaid. An additional 2.2% is expected to be reimbursement from VA. Thus, 93.5% of the In-Center revenue is derived from government payors.”

The applicant states that Carolina Dialysis-Siler City is also keenly sensitive to the second element of “equitable access” – time and distance barriers. The applicant says it is an advocate of community based treatment delivery when possible and appropriate.

In Section VI.1, page 51, the applicant states:

“The Carolina Dialysis facilities have a long history of providing dialysis services to the underserved populations of North Carolina. Carolina Dialysis currently operates five dialysis facilities in North Carolina. Each of our facilities has a homogeneous patient population, including low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.”

The applicant further states, *“It is the 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 patients as underserved.”*

The applicant states Medicare represented 84.8% of North Carolina dialysis patients in FMC facilities in FY 2012 with Medicaid representing an additional 4.56%.

The applicant adequately demonstrates that the proposal will promote equitable access.

Maximize Healthcare Value

In Section II, page 26, the applicant states it is projecting a capital expenditure of \$105,600 for this project and is not seeking State or Federal monies; rather, parent company, Carolina Dialysis, LLC is taking on the financial burden to bring dialysis treatment closer to the patient homes. The applicant goes on to state:

“As an additional consideration, Carolina Dialysis-Siler City notes that the overwhelming majority of dialysis treatments are reimbursed through Medicare, Medicaid, or other government payor sources. ... The point here is that government payors are working from a fixed payment schedule, often at significantly lower reimbursement rates than the posted charges. As a consequence, Carolina Dialysis-Siler City must work diligently to control costs of delivery for dialysis. Carolina Dialysis-Siler City does.”

In Section V, page 49, the applicant states that its facilities have done an excellent job of containing costs while providing outstanding care and treatment to patients. The applicant adequately demonstrates that the proposal will maximize healthcare value. Consequently, the applicant demonstrates that the projected volumes for the proposed service incorporate the basic principles in meeting the needs of the patients to be served. The application is consistent with the facility need determination in the July 2013 SDR and Policy GEN-3. Therefore, the application is conforming to this criterion.

Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES is not applicable to this review because the applicant is not proposing a capital expenditure greater than \$2 million.

- (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.

The applicant, Carolina Dialysis, LLC proposes to add four dialysis stations to the existing Carolina Dialysis-Siler City ESRD facility for a total of 22 dialysis stations upon completion of the project.

Population to be Served

In Section IV.1, page 43, the applicant states the number of in-center patients served at Carolina Dialysis-Siler City as of June 30, 2013 as follows:

County	In-center Patients	Percent
Chatham	50	84.7%
Randolph	9	15.3%
Total	59	100.0%

In Section 111.7, page 40, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, as summarized in the table below:

Projected Dialysis Patient Origin

COUNTY	OPERATING YEAR 1 2015		OPERATING YEAR 2 2016		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	In-center Patients	Home	In-center Patients	Home	Year 1	Year 2
Chatham	62.4	0	66.4	0	87.4%	88.1%
Randolph	9	0	9	0	12.6%	11.9%
Total	71.4	0	75.4	0	100.0%	100.0%

The applicant adequately identified the population it proposes to serve.

Demonstration of Need

The applicant proposes to add four dialysis stations to the existing Carolina Dialysis-Siler City facility for a total of 22 dialysis stations. In Section II, pages 15-17, and Section III. 7, pages 38-41, the applicant provides the assumptions and methodology it uses to project the proposed in-center patient utilization of the existing Carolina Dialysis-Siler City facility

The assumptions and methodology are summarized below:

- Carolina Dialysis-Siler City projects the project will be complete December 31, 2015. Operating year 1 is Calendar Year (CY) 2016, January 1, 2016 through December 31, 2016.

- The July 2013 SDR reports that Carolina Dialysis-Siler City utilization was 81.94% with 59 patients dialyzing on 18 dialysis stations.
- Carolina Dialysis-Siler City assumes that the patient population of Chatham County will grow at the Chatham County five year average annual change rate as published in the July 2013 SDR. That rate is 6.5%.
- Carolina Dialysis-Siler City does not project any increase in the patient population residing in Randolph County and dialyzing at Carolina Dialysis-Siler City.

On pages 16 and 39, the applicant states, “*Projections of future patient populations of Carolina Dialysis-Siler City are derivative of the facility patient population census as of June 30, 2013. ... The following table demonstrates the calculations used to arrive at the projected census for Operating Years One and Two.*”

Carolina Dialysis-Siler City	In-Center Patients
Carolina Dialysis-Siler City begins with Chatham County patients utilizing Carolina Dialysis-Siler City as of June 30, 2013	50
Carolina Dialysis-Siler City projects growth of this patient population using a rate of 6.5% for six months to December 31, 2013.	$[50 \times (.065 / 12 \times 6)] + 50 = 51.6$
Carolina Dialysis-Siler City projects growth of Chatham County patient population using a rate of 6.5% for one year to December 31, 2014.	$(51.6 \times .065) + 51.6 = 55.0$
Carolina Dialysis-Siler City projects growth of Chatham County patient population using a rate of 6.5% for one year to December 31, 2015.	$(55 \times .065) + 55 = 58.6$
Carolina Dialysis-Siler City adds 9 Randolph County Patients. This is the projected beginning census for this project.	$58.6 + 9 = 67.6$
Carolina Dialysis-Siler City projects growth of Chatham County patient population using a rate of 6.5% for one year to December 31, 2016.	$(58.6 \times .065) + 58.6 = 62.4$
Carolina Dialysis-Siler City adds 9 Randolph County Patients. This is the projected ending census for this Operating Year 1.	$62.4 + 9 = 71.4$
Carolina Dialysis-Siler City projects growth of Chatham County patient population using a rate of 6.5% for one year to December 31, 2017.	$(62.4 \times .065) + 62.4 = 66.4$
Carolina Dialysis-Siler City adds 9 Randolph County Patients. This is the projected ending census for Operating Year 2.	$66.4 + 9 = 75.4$

At the end of operating year one, Carolina Dialysis-Siler City is projected to have an in-center patient census of 71 patients for a utilization rate of 80.7% or 3.2 patients per station. At the end of operating year two, Carolina Dialysis-Siler City is projected to

have an in-center patient census of 75 patients for a utilization rate of 85.2% or 3.4 patients per station.

Projected patient utilization at the end of Year One is 3.2 in-center patients per station per week which satisfies the 3.2 in-center patients per station required by 10A NCAC 14C .2203(b); and the number of in-center patients projected to be served is based on reasonable and supported assumptions regarding future growth.

The applicant adequately demonstrates the need the population it proposes to serve has for the proposed project.

Access to Services

In Section VI.1(a), page 51, the applicant states:

“It is clear that Carolina Dialysis-Siler City provides service to historically underserved populations. It is 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.”

The applicant projects that 93.4% of its patients will be covered by Medicare, Medicaid or VA. The applicant adequately demonstrates the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

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

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

NA

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

In Section III.9, page 42, the applicant discusses the alternatives considered prior to the submission of its application, which include:

- 1) Maintain the Status Quo – The applicant states that not applying for additional stations to increase capacity at its existing facility would remove patient choice of dialysis facility. The facility is already operating at 82% utilization as reported in the July 2013 SDR; therefore the applicant states this is not a viable option.
- 2) Ask patients to transfer to the other dialysis facility in Chatham County at Pittsboro – The applicant states that forcing patients to transfer across the county or to a facility not of their choosing is not a viable option.
- 3) Chosen alternative – Increase capacity at the existing Carolina Dialysis-Siler City facility. The applicant states:

“The facility census is growing steadily. If we are to continue to meet the need of the ESRD population of Chatham County, then expansion is the only viable option.”

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

- Carolina Dialysis-Siler City cannot accommodate future growth in capacity.
- The July 2013 SDR reports that Carolina Dialysis-Siler City utilization was 81.94% with 59 patients dialyzing on 18 dialysis stations.
- Minimal capital will be required to expand the existing facility.

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

In summary, the applicant adequately demonstrates that its proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions and the condition in Criterion (5):

- 1. Carolina Dialysis, LLC d/b/a Carolina Dialysis-Siler City shall materially comply with all representations made in the certificate of need application.**

- 2. Carolina Dialysis, LLC d/b/a Carolina Dialysis-Siler City shall develop and operate no more than four additional dialysis stations for a total of no more than twenty-two (22) certified dialysis stations which shall include any home hemodialysis training stations or isolation stations.**
 - 3. Carolina Dialysis, LLC d/b/a Carolina Dialysis-Siler City shall install plumbing and electrical wiring through the walls for no more than twenty-two (22) dialysis stations which shall include any home training or isolation stations.**
 - 4. Carolina Dialysis, LLC d/b/a Carolina Dialysis-Siler City 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.

CA

In the table in Section VIII, page 59, the applicant shows the capital cost of the project is \$105,600, which includes the purchase of dialysis machines totaling \$72,500, other equipment and furniture totaling \$31,600 and \$1,500 for water treatment equipment. In Section IX, page 63, the applicant states that because the project is for additional stations at an existing facility, there are no associated startup or initial operating expenses.

On page 61, the applicant states, *“This project will be financed with accumulated reserves.”* The applicant further states, *“Please refer to Exhibit 24 for letter of commitment from Carolina Dialysis LLC.”* Exhibit 24 contains a letter from the Chairman of the Board of Managers of Carolina Dialysis, LLC, confirming Carolina Dialysis’ commitment of cash reserves in the sum of \$105,600 for the capital needs of the project.

In Section VIII.8(b), page 62, the applicant states:

“Carolina Dialysis LLC has one other CON related project at this time. Carolina Dialysis has proposed to develop Carolina Dialysis-Lee County by relocating 13 dialysis stations from Carolina Dialysis-Sanford. The total capital expenditure was \$1,634,298 and was funded by the LLC as a whole, not by the Siler City operating entity.”

In Section VIII.7(a), page 61, the applicant states, “Please refer to Exhibit 10 for copies of financial reports for Carolina Dialysis, LLC.” In Section VIII.7(b), page 61, the applicant states, “Please refer to Exhibit 10 for copies of Carolina Dialysis-Siler City financial Balance Sheet. The balance sheet reflects more than \$2.3 million in current assets. Carolina Dialysis-Siler City has sufficient funds to undertake this project.” Exhibit 10 contains three copies of a one-page balance sheet entitled “Siler City Balance Sheet”, which shows cash of \$200 and retained earnings of -\$734,163, as of June 30, 2013. This balance sheet does not document availability of funds to develop the project. Exhibit 10 does not contain copies of financial reports for Carolina Dialysis, LLC. Thus, the applicant does not adequately demonstrate the availability of adequate funds to develop the project.

Based on information provided by the applicant in Section X.1, page 64, the dialysis facility’s projected allowable charges per treatment for each payment source are as follows:

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

Based on the calculations presented in Section X.3, page 67, the facility reimbursement is as follows:

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

The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services.¹ In Sections X.2-X.4, pages 65-69, the applicant reported projected revenues and expenses as follows:

¹ http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/End-Stage_Renal_Disease_Pro prospective_Payment_System_ICN905143.pdf and <http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-Sheets/2013-Fact-Sheets-Items/2013-07-012.html>

	OPERATING YEAR 1	OPERATING YEAR 2
Total Net Revenue	\$ 3,083,280	\$ 3,271,042
Total Operating Costs	\$2,871,900	\$3,028,883
Net Profit	\$211,380	\$242,159

The applicant projects that revenues 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.3, page 66 of the application for the applicant's assumptions on number of treatments (3 treatments/week, 52 weeks/year, and 6.5% missed treatments). Note: on page 71, the applicant demonstrates a net positive 2016 and 2017 operating income in the event that Medicare reduces reimbursement by as much as 9%.

The applicant's projections of treatments and revenues are reasonable based on the number of in-center patients projected for the first two operating years. In Section VII.1, page 56 and Section X.5, page 70, the applicant provides projected staffing and salaries. The applicant states compliance with all staffing requirements in 42 C.F.R. Section 494 (formerly 405.2100) on page 57. Staffing by shift is provided on page 58. The applicant provides adequate staffing to provide dialysis treatments for the number of patients projected.

In summary, the applicant adequately demonstrates the projections are based on reasonable projections of revenues and operating costs; therefore, the applicant adequately documents the financial feasibility of the project, assuming adequate funding is available. Therefore, the application is conforming to this criterion, subject to the following condition:

Prior to issuance of the certificate of need, Carolina Dialysis, LLC d/b/a Carolina Dialysis-Siler City shall provide the CON Section with adequate documentation demonstrating the availability of funds for the proposed project.

- (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

The applicant proposes to add four dialysis stations to its existing facility for a total of 22 certified dialysis stations upon completion of the proposed project. According to the July 2013 SDR, the county need methodology shows there is a deficit of one dialysis station in Chatham County. There is no county need determination for additional dialysis stations or facilities in Chatham County. However, the applicant is eligible to apply for additional stations based on the facility need methodology because the utilization rate reported for Carolina Dialysis-Siler City in the July 2013 SDR is 3.28 patients per station. This utilization rate was calculated based on 59 in-center dialysis patients and

18 certified dialysis stations. ($59 \text{ patients} / 18 \text{ stations} = 3.2777 \text{ patients per station}$). The applicant is applying for additional stations based on the facility need methodology. According to the July 2013 SDR, Carolina Dialysis-Siler City was operating at 81.9% capacity ($59 / 18 = 3.2777$; $3.2777 / 4 = 0.8194$ or 81.9%). The target utilization is 80% or 3.2 patients per station per week as of the end of the first operating year of the facility. Based on the calculations above, the applicant is eligible to expand its facility and may apply for additional stations. Upon completion of the proposed project, the facility will have 22 stations serving 71 in-center patients (end of year 1) which is a utilization rate of 80.7% ($71 / 22 = 3.22$; $3.2 / 4 = .8068$ or 80.7%). Therefore, the applicant is conforming with the required performance standard in 10A NCAC 14C .2203.

Chatham County has a second dialysis facility, which is located in Pittsboro, approximately 16 miles and 21 minutes from Carolina Dialysis-Siler City. Chatham County, with 709 square miles and a population of 63,505 has two distinct population centers: Siler City and Pittsboro. Siler City and Pittsboro have an east/west orientation along US Hwy 64. Siler City on the western side of the county comprises 12% of the population and Pittsboro in eastern Chatham County, approximately 6%, with the rest of the population being rural. Per the July 2013 SDR, Carolina Dialysis-Pittsboro is operating 10 dialysis stations at 60% of utilization. However, Pittsboro is near Jordan Lake and Chapel Hill, via US 15-501, which increases its likelihood of long-term growth and increased future utilization of its existing stations.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the 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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The following table illustrates the projected staffing for Carolina Dialysis-Siler City, as provided by the applicant in Section VII.1, page 56.

Position	Total FTE Positions
RN	4.00
Tech	7.00
Clinical Mgr	1.00
Chief Tech	0.30
MD	
Admin	0.20
Dietician	0.60
Social Worker	0.60
Clerical	1.00
In-Service Tech	0.30
Equipment Tech	1.00
Total	16.00

As shown in the above table, the applicant proposes to employ a total of 16 full-time equivalent (FTE) positions to staff the Carolina Dialysis-Siler City facility upon completion of the proposed project. In Section VII.1, page 57, the applicant states,

“Carolina Dialysis LLC anticipates no difficulties in filling staff positions.”

The following table shows the projected number of direct care staff for each shift offered at Carolina Dialysis-Siler City after the addition of the four dialysis stations.

	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	5:00 am to 9:30 am	8	8	8	8	8	8
Afternoon	10:00am to 4:30 pm	8	8	8	8	8	8
Evening	N/A	0	0	0	0	0	0

In Section V.4, page 48, the applicant states that Vimal Derebail, M.D., of UNC Kidney Center will serve as Medical Director of the proposed facility. Exhibit 21 contains a letter signed by Dr. Derebail, expressing support for the addition of four stations and agreeing to continue his relationship with the facility. In Section VII, page 58, the applicant states there are 14 nephrologists providing coverage at the facility, with each one maintaining privileges at one or more of the following hospitals: UNC Medical Center, Central Carolina Community Hospital, Alamance Regional Hospital and Chatham Hospital. The 14 nephrologists expressing a willingness to provide coverage are listed on page 48 of the application.

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 45, the applicant provides a list of providers of the necessary ancillary and support services. Acute dialysis in an acute care setting, transplantation (Exhibit 17), psychological counseling, pediatric nephrology and vascular surgery will be provided by UNC Medical Center. Emergency care, diagnostic evaluation services, X-ray services, and blood bank will be provided by Chatham Hospital (Exhibit 16). Spectra will provide laboratory services (Exhibit 18). Self care training, including hemodialysis, peritoneal dialysis, CAPD and CCPD will be provided by Carolina Dialysis Carrboro or Carolina Dialysis Sanford (Exhibit 20). The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health system. Therefore, the application is conforming to this criterion.

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

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates:

- (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and

NA

- (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

- (i) would be available under a contract of at least 5 years duration;
- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

NA

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

C

In Section VI.1(a), page 51, the applicant states that Carolina Dialysis operates five dialysis facilities in North Carolina, each with a homogenous patient population, including underserved persons. The applicant says the patient population of Carolina Dialysis-Siler City is comprised of the following:

Facility	Medicaid/Low Income	Elderly(65+)	Medicare	Women	Racial Minorities
Carolina Dialysis-Siler City	50.8%	27.1%	98.0%	28.8%	64.4%

On page 52, the applicant further states:

“The historical performance does not change as new patients are admitted. Commercial insurance for patients generally covers the patient for a period of 30 months from the beginning of treatment; thereafter, Medicare provides coverage for the patient. The commercial insurance population is therefore constantly changing. In addition, not

every patient beginning dialysis has commercial insurance. Thus, the payor mix should be considered dynamic and not fixed.”

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

	2011 Total # of Medicaid Eligibles as % of Total Population *	2011 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Chatham County	12%	4.10%	19.3%
Randolph County	19%	7.20%	19.5%
Statewide	17%	6.71%	19.7%

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

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

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

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

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

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

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

Additionally, the United States Renal Data System, in its 2012 USRDS Annual Data Report provides these national statistics for FY 2010: “On December 31, 2010, more than 376,000 ESRD patients were receiving hemodialysis therapy.” Of the 376,000 ESRD patients, 38.23% were African American, 55.38% were white, 55.65% were male and 44.65% were 65 and older. The report further states:

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

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

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

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

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

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

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

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

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

The applicant demonstrates that it 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 VI.1(f), page 53, 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

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

Medicaid, Title XIX, Carolina Dialysis Facilities are obligated to meet federal requirements of the Civil Rights Act, Title VI and the Americans with Disabilities Act.”

In Section VI.6 (a), page 54, the applicant states, “*There have been no Civil Rights complaints lodged against any Carolina Dialysis LLC facilities 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 VI.1(d), page 53, the applicant states:

“Carolina Dialysis LLC-Siler City 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]

On page 52, Carolina Dialysis-Siler City reports that it expects 91.2% of the patients who received treatments at Carolina Dialysis-Siler City to have some or all of their services paid for by Medicare or Medicaid as indicated below.

CAROLINA DIALYSIS-SILER CITY PAYOR MIX	
SOURCE OF PAYMENT	PERCENTAGE
Medicare	80.1%
Medicaid	11.1%
Commercial Insurance	6.5%
VA	2.2%
Total	100.0%

Totals may not sum due to rounding.

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

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

C

In Section VI.5, page 54, the applicant states that:

“Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. Carolina Dialysis-Siler City 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 provides a range of means by which a person can access 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.

CA

In Section V.3, page 47, the applicant states,

“All health related education and training programs are welcomed 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 of the patient with end stage renal disease.”

The applicant further states that Exhibit 19 contains a letter from the facility Director of Operations inviting Central Carolina Community College’s nursing program students to utilize Carolina Dialysis-Siler City for clinical rotations. The information provided in Section V.3 is reasonable and credible and supports a finding of conformity with this criterion.

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

C

The applicant proposes to add four dialysis stations for a total of 22 certified dialysis stations upon completion of this project. According to the July 2013 Semiannual Dialysis Report (SDR), Chatham County has two dialysis centers, one in Pittsboro and one in Siler City, both Carolina Dialysis facilities. Carolina Dialysis-Pittsboro is operating at 60% utilization while Carolina Dialysis-Siler City is operating at 82%.

In Section V.7, pages 49-50, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The applicant states its proposal should have no effect on the competitive climate in Chatham County. The applicant further states:

“Carolina Dialysis is the only provider of dialysis services in Chatham County, operating both the Pittsboro and Siler City facilities.

...

Therefore, with fixed reimbursement rates, Carolina Dialysis facilities are compelled to operate at maximum dollar efficiency.

...

Our facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients.

...

This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients’ lives.

...

This facility will have added value stemming from the strength of our relationship with the nephrology physicians at UNC-CH. ... The UNC-CH Division of Nephrology and Hypertension brings together the collaborative efforts of the entire department of very qualified nephrologists to provide care for the patients choosing to dialyze at the Carolina Dialysis-Siler City facility.”

See also Sections II, III, V, VI, and VII. The information provided by the applicant in each of these sections is reasonable, credible, and adequately demonstrates that the expected effects of the proposal on competition include a positive impact on cost effectiveness, quality, and access to dialysis services in Chatham County.

This determination is based on a review of the information in the sections of the application referenced above and the following analysis:

- The applicant adequately demonstrates the need to add four dialysis to its existing Carolina Dialysis-Siler City facility;
- The applicant adequately demonstrates that the proposed project is a cost-effective alternative to meet the need to provide additional access to dialysis care in Chatham County;
- The applicant will continue to provide quality services; and
- The applicant will continue to provide adequate access to medically underserved populations.

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

Carolina Dialysis-Siler City currently provides dialysis services. According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the Carolina Dialysis-Siler City facility operated in compliance with the Medicare Conditions of Participation within the 18 months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

G.S. 131E-183(b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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

Services promulgated in 10A NCAC 14C Section .2200. The specific findings are discussed below.

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

.2202 INFORMATION REQUIRED OF APPLICANT

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

(1) *Utilization rates;*

-C- In Section II.1, page 13, the applicant states the utilization rate is reported in the July 2013 SD. The July 2013 SDR utilization rate of 81.9% was calculated based on 59 in-center dialysis patients and 18 certified dialysis stations as of December 31, 2012 (59 patients / 18 stations = 3.28 patients per station; 3.28 patients per station / 4.00 patients per station = 81.9%). In Section III.7, page 41, the applicant projects serving 71 dialysis patients on 22 stations for a utilization rate of 80.7% ($71 / 22 = 3.23 / 4 = 80.7\%$) in year 1 and 75 dialysis patients on 22 stations for a utilization rate of 85.2% ($75 / 22 = 3.41 / 4 = 85.2\%$) in year 2.

(2) *Mortality rates;*

-C- In Section IV.2, page 43, the applicant reports the 2010, 2011 and 2012 facility mortality rates as 11.0%, 14.6% and 9.4%, respectively.

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

-C- In Section IV.3, page 43, the applicant states, “*Carolina Dialysis-Siler City is not certified to provide home dialysis training and support. Patients desiring to dialyze at home are referred to Carolina Dialysis-Carrboro home training program.*”

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

-C- In Section IV.4, page 43, the applicant provides information showing Carolina Dialysis-Siler City referred 5 and 11 patients for transplant in 2011 and 2012, respectively and had 0 transplants performed.

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

-C- In Section IV.5, page 43, the applicant states, “*Carolina Dialysis-Siler City has two patients on the transplant waiting list.*”

- (6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
- C- In Section IV.6, page 44, the applicant states that there were 75 hospital admissions in 2012, 15 (20%) of which were dialysis related and 60 (80%) non-dialysis related.
- (7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*
- C- In Section IV.7, page 44, the applicant provides information that shows there were 0 patients dialyzing at Carolina Dialysis-Siler City with Hepatitis B Conversions during 2010 and 2011. The applicant further shows 0 current patients with Infectious Disease (Hepatitis B), as of December 31, 2012. The number of patients treated with infectious disease who have converted to infectious status within the last year is 0. The patient with Hepatitis B utilizes the isolation station for dialysis treatments.
- (b) *An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:*
- (1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.*
- NA- The applicant states, “*Not applicable; this is not an application for a new facility. However, a copy of the Hospital Agreement is included at Exhibit 16.*”
- (2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*
- (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
- (B) *composition of the assessment/evaluation team at the transplant center,*
- (C) *method for periodic re-evaluation,*
- (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and*

(E) *signatures of the duly authorized persons representing the facilities and the agency providing the services.*

-NA- The applicant states, “*Not applicable; this is not an application for a new facility. However, a copy of the Transplant Agreement is included at Exhibit 17.*”

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

-NA- The applicant states, “*Not applicable; Carolina Dialysis-Siler City is an existing and operational dialysis facility.*”

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

-C- See Exhibit 12, in which the applicant provides copies of written policies and procedures for back up procedures in the event of a power outage.

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

-NA- This is not an application for a new facility.

(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*

-C- In Section II, page 15, the applicant states:

“Carolina Dialysis, LLC will provide all services approved by the Certificate of Need in conformity with applicable laws and regulations. The facility staffing consistently meets CMS and State guidelines for dialysis staffing. Fire safety equipment, the physical environment, water supply and other relevant health and safety equipment will be appropriately installed and maintained at Carolina Dialysis-Siler City.”

In Section XI.6(g), page 74, the applicant states, “*Information detailing conformity can be found in Sections II and VII and exhibits referenced therein.*”

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

-C- The applicant provides the following projected patient origin on pages 17 and 40 of the application, as shown below.

Projected Dialysis Patient Origin

COUNTY	OPERATING YEAR 1 CY2016		OPERATING YEAR 2 CY2017		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CENTER	HOME	IN-CENTER	HOME	YEAR 1	YEAR 2
Chatham	62.4	0	66.4	0	87.4%	88.1%
Randolph	9	0	9	0	12.6%	11.9%
Total	71.4	0	75.4	0	100.0%	100.0%

See Section III.7, pages 38-41 of the application and the discussion in Criterion (3) with regard to the methodology and assumptions the applicant uses to project patient origin which is incorporated hereby as if set forth fully herein.

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

-NA- The applicant is not proposing a new facility.

(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*

-C- In Section II, page 18, the applicant states,

“Carolina Dialysis-Siler City 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.”

.2203 PERFORMANCE STANDARDS

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

-NA- The applicant proposes to add stations to an existing facility.

- (b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- C- The applicant projects it will serve 71 patients on 22 stations at the end of the first operating year. $71 / 22 \text{ stations} = 3.23$.

.2204 SCOPE OF SERVICES

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

- (1) *diagnostic and evaluation services;*
- C- The table in Section V.1, page 45, states patients will be referred to Chatham Hospital or UNC Medical Center for diagnostic and evaluation services.
- (2) *maintenance dialysis;*
- C- The table in Section V.1, page 45, states the applicant will provide in-center maintenance dialysis.
- (3) *accessible self-care training;*
- C- On page 21, the applicant states, *“The facility will provide self-care training when deemed appropriate by the nephrologists.”* The table in Section V.1, page 45, states patients will receive in-center hemodialysis, intermittent peritoneal dialysis, CAPD and CCPD at Carolina Dialysis Carrboro or Carolina Dialysis Sanford.
- (4) *accessible follow-up program for support of patients dialyzing at home;*
- C- The applicant addresses accessible follow-up program for support of patients dialyzing at home in Section V, Question 2(d), page 46, stating,
- “Those patients who desire to perform home dialysis are trained and followed by the Carolina Dialysis Home Training Clinics at Carrboro. Patients who are candidates for home dialysis are referred by their attending nephrologists to the appropriate Home Training Clinic, depending upon patient choice of programs. The applicant will provide back-up hemo-dialysis treatments to any home patient in need of temporary hemo-dialysis. Services offered*

to home patients include home visitation, assistance with problems that patients have with catheters; diagnosis of infections and assistance with placing orders of needed supplies. Social work and dietary assessments are provided for those patients on an ongoing basis. Patients are given EPO at the facility or taught to administer it to themselves at home. Laboratory testing of blood samples may be provided by the facility as prescribed by the physician. Please refer to Section IIA.1.i. Exhibit 20 includes a Home Training Agreement.”

(5) *x-ray services;*

-C- The table in Section V.1, page 45, states patients will be referred to Chatham Hospital or UNC Medical Center for x-ray services.

(6) *laboratory services;*

-C- The table in Section V.1, page 45, states Carolina Dialysis-Siler City will use Spectra Laboratories, Inc. for routine and special laboratory services. Exhibit 18 contains a laboratory services agreement.

(7) *blood bank services;*

-C- The table in Section V.1, page 45, states patients will be referred to Chatham Hospital for blood bank services.

(8) *emergency care;*

-C- The table in Section V.1, page 45, states patients will be transported to Chatham Hospital by ambulance for emergency care beyond that available from the trained staff and fully stocked crash cart on site.

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

-C- The table in Section V.1, page 45, states patients will be referred to UNC Medical Center for acute dialysis in an acute care setting.

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

-C- The table in Section V.1, page 45, states dialysis patients will be referred to UNC Medical Center, Triangle Surgical in Cary, or Pinehurst Surgical for vascular surgery.

(11) *transplantation services;*

-C- The table in Section V.1, page 45, states patients will be referred to UNC Medical Center for transplantation services. See Exhibit 17 for documentation from UNC Healthcare.

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

-C- The table in Section V.1, page 45, states patients will be referred to local Vocational Rehabilitation services.

(13) *transportation.*

-C- The table in Section V.1, page 45, states patients will be referred to Chatham Transit for transportation.

.2205 STAFFING AND STAFF TRAINING

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

-C- In Section VII.1, page 56, the applicant provides the proposed staffing for Carolina Dialysis-Siler City. On page 57, the applicant states, “*Carolina Dialysis-Siler City will comply with all staffing requirements as stated in 42 C.F.R. Section 494 (formerly 405.2100).*” See additional staffing details in Section 1.13 (c), page 10 and Section II.2. A, pages 29-30.

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

-C- In Section VII.5, pages 57-58, the applicant refers to Exhibit 14 for a copy of the training program description/outline. Exhibit 15 contains a copy of the outline of continuing education programs.