

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DATE: January 23, 2015

PROJECT ANALYST: Fatimah Wilson

TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: J-10335-14/ Carolina Dialysis, LLC d/b/a Carolina Dialysis Sanford (CDS) / Add 3 dialysis stations for a total of 36 stations upon project completion / Lee County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Carolina Dialysis, LLC d/b/a Carolina Dialysis-Sanford, also referred to as CDS, proposes to add three dialysis stations to the facility for a total of 36 certified dialysis stations upon project completion. CDS is an existing 33-station dialysis facility in Lee County, located at 1922 KM Wicker Drive, Sanford.

Effective March 30, 2012, Carolina Dialysis-Lee County, also referred to as CD-Lee County, was issued a certificate of need (CON) to establish a new 13-station dialysis facility at 3236 NC Hwy 87 South, Sanford, by relocating thirteen stations from the 39 station CDS facility (Project I.D. #J-8767-11). Based on documentation received by the CON Section, the CD-Lee County facility was certified for 13 stations, effective June 25, 2014, according to documentation from the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation (DHSR). The certification of the new CD-Lee County facility resulted in a total of 26 (39 - 13 =26) certified dialysis stations remaining at the CDS facility. Effective March 1, 2013, CDS was issued a CON, Project I.D. #J-10050-12, to add seven stations to its facility for a total of 33 certified stations upon completion of this project and Project I.D. #J-8767-

11. Based on documentation received by the CON Section, the CDS facility was certified for 33 stations, effective June 24, 2014, according to documentation from the Acute and Home Care Licensure and Certification Section, DHSR.

Need Determination

The 2014 State Medical Facilities Plan (2014 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2014 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of six (6) dialysis stations in Lee County; therefore, based on the county need methodology, there is no need for additional stations in Lee 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 Sanford (CDS), in the July 2014 SDR is 92.3% and 3.69 patients per station. This utilization rate was calculated based on 144 in-center dialysis patients and 39 certified dialysis stations. (144 patients / 39 stations = 3.69 patients per station / 4 = 0.923).

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

OCTOBER 1 REVIEW-JULY 2014 SDR

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/13		92.3%
Certified Stations		39
Pending Stations		7
Total Existing and Pending Stations		46
In-Center Patients as of 12/31/13 (SDR2)		144
In-Center Patients as of 6/30/13 (SDR1)		138
Step	Description	
	Difference (SDR2 - SDR1)	6
(i)	Multiply the difference by 2 for the projected net in-center change	12
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/13	0.0870
(ii)	Divide the result of Step (i) by 12	0.0072
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/12 until 12/31/13)	0.0870
(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	156.5217
(v)	Divide the result of Step (iv) by 3.2 patients per station	48.9130
	and subtract the number of certified and pending stations as recorded in SDR2 [46] to determine the number of stations needed	3

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 3 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 three new stations and, therefore, is conforming with the facility need determination for dialysis stations.

Policies

Policy GEN-3: BASIC PRINCIPLES, page 38 of the 2014 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.”

The applicant addresses Policy GEN-3 beginning on page 19 of the application.

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section I, pages 5-9, Section II, pages 19-20, Section V, pages 38-42, and referenced exhibits. 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 II, pages 20-21, Section III, pages 31-35, Section V, pages 38-42, Section VI, page 43, 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 II, pages 21-22, Section III, pages 31-35, Section V, pages 41-42, 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.

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.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with the facility need determination in the July 2014 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 three dialysis stations to the existing CDS dialysis facility for a total of 33 dialysis stations upon project completion.

Population to be Served

In Section IV.1, page 36, the applicant states the number of patients who are currently being served at the CDS facility, as of June 30, 2014:

County	# Patients Dialyzing at Home	# Patients Dialyzing In-Center
Lee	5	107
Chatham	0	3
Cumberland	2	1
Harnett	2	12
Hoke	1	0
Moore	2	2
Randolph	1	0
Total	13	125

End-Stage Renal Disease (ESRD) facilities are required to provide data collection forms to the Medical Facilities Planning Branch (MFPB) to determine current utilization of in-center dialysis stations services and the percentage of patients receiving home dialysis in the state to project future need for new dialysis stations and facilities. On page 5 of the June 2014 ESRD data collection forms for CDS, the facility states the number of patients who were being served at the CDS facility, as of June 30, 2014:

County	# Patients Dialyzing at Home	# Patients Dialyzing In-Center
Lee	5	98
Chatham	0	3
Cumberland	2	0
Harnett	2	9
Moore	3	2
Other States	0	2
Rutherford	1	0
Total	13	114

As shown in the tables above, the information submitted by the applicant in the application and on the June 2014 ESRD data collection forms do not reconcile for the same time period, June 30, 2014. In Section II, page 14 and Section III.7, page 33, the applicant states the facility had 107 Lee County patients dialyzing at the facility as of June 30, 2014 and the June 2014 ESRD data collection forms state the facility had 98 Lee County patients dialyzing at the facility as of June 30, 2014. In clarifying information, the applicant states that the information provided by the facility on the June 2014 ESRD data collection forms is the more accurate number.

The applicant proposes to add three dialysis stations to the existing CDS dialysis facility for a total of 36 certified dialysis stations upon project completion. In Section II, page 13 and Section III.7, page 32, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, December 31, 2017, as summarized in the table below:

**Projected Dialysis Patient Origin
 January 2016 – December 2017**

COUNTY	OPERATING YEAR 1		OPERATING YEAR 2		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	In-Center	Home Peritoneal	In-Center	Home Peritoneal	Year 1	Year 2
Lee	123.5	5.9	130.8	6.3	83.28%	92.57%
Chatham	3	0	3	0	1.93%	2.03%
Cumberland	1	2	1	2	1.93%	2.03%
Harnett	12	2	12	2	9.00%	0.00%
Hoke	0	1	0	1	0.64%	0.00%
Moore	2	2	2	2	2.57%	2.70%
Randolph	0	1	0	1	0.64%	0.68%
Total	141.5	13.9	148.8	14.3	100.00%	100.00%

The data in the table above was projected based on 107 Lee County in-center patients that were dialyzing at the facility as of June 30, 2014, which was determined to be incorrect. The project analyst recalculated the projected patient origin based on 98 in-center patients dialyzing at the facility as of June 30, 2014, as shown in the following table:

**Projected Dialysis Patient Origin
 January 2016 – December 2017**

COUNTY	OPERATING YEAR 1		OPERATING YEAR 2		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	In-Center	Home Peritoneal	In-Center	Home Peritoneal	Year 1	Year 2
Lee	113.2	5.9	120.9	6.3	84.41%	85.25%
Chatham	3	0	3	0	2.13%	2.01%
Cumberland	0	2	0	2	1.42%	1.34%
Harnett	9	2	9	2	7.80%	7.37%
Hoke	0	1	0	1	0.71%	0.67%
Moore	2	2	2	2	2.83%	2.68%
Randolph	0	1	0	1	0.71%	0.67%
Total	127.2	13.9	134.9	14.3	100.00%	100.00%

Despite discrepancies in the facility's patient origin data, the project analyst can still reasonably assume that the current and projected patient origin for the facility is and will be Lee County and surrounding counties.

Analysis of Need

As discussed in Criterion (1), based on the facility need methodology for adding dialysis stations, the potential number of stations needed is three stations. The applicant proposes to add three stations.

In Section II, pages 13-14, and Section III.7, pages 32-22, the applicant provides the assumptions and methodology it uses to determine the need for additional stations and to project CDS's proposed patient utilization.

The assumptions and methodology are summarized below:

- The applicant states in the application that the facility is currently serving 107 in-center patients residing in Lee County.
- The applicant assumes that the Lee County patient population at its CDS facility will increase at a rate commensurate with the Lee County Five Year Average Annual Change Rate (AACR) of 5.9%, as published in the July 2014 SDR.
- On page 13 and 32 the applicant states that the facility is currently serving 18 in-center patients residing in Chatham, Cumberland, Harnett and Moore County. CDS does not project any increase in this segment of the population, but projects that these out-of-county patients will continue to dialyze at the facility.
- The project is projected to be complete on December 31, 2015, with Operating Years 1 and 2 being from January 1, 2016 through December 31, 2016 and January 1, 2017 through December 31, 2017, respectively.

Projected Utilization

The following table demonstrates the applicant's calculations used to arrive at the projected patient census for Operating Years One and Two, as illustrated in the following table:

CDS	In-Center Patients
CDS begins with the Lee County patient population dialyzing at the facility as of June 30, 2014.	107
CDS uses one half of the Lee County Five Year Average Annual Change Rate to project the census forward for 6 months to December 31, 2014.	$[107 \times (.059 / 12 \times 6)] + 107 = 110.2$
CDS projects this patient population forward for 1 year to December 31, 2015.	$(110.2 \times .059) + 110.2 = 116.7$
CDS adds the 18 patients residing in other counties. This is the projected beginning census.	$116.7 + 18 = 134.7$
CDS projects the Lee County patient population forward for 1 year to December 31, 2016.	$(116.7 \times .059) + 116.7 = 123.5$
CDS adds the 18 patients residing in other counties. This is the projected ending census for Operating Year 1, December 31, 2016.	$123.5 + 18 = 141.5$
CDS projects the Lee County patient population forward for 12 months to December 31, 2017.	$(123.5 \times .059) + 123.5 = 130.8$
CDS adds the 18 patients residing in other counties. This is the projected ending census for Operating Year 2, December 31, 2017.	$130.8 + 18 = 148.8$

CDS	PD Patients
CDS begins with the Lee County patient population dialyzing at the facility as of June 30, 2014.	5
CDS uses one half of the Lee County Five Year Average Annual Change Rate to project the census forward for 6 months to December 31, 2014.	$[5 \times (.059 / 12 \times 6)] + 5 = 5.1$
CDS projects this patient population forward for 1 year to December 31, 2015.	$(5.1 \times .059) + 5.1 = 5.5$
CDS adds the 18 patients residing in other counties. This is the projected beginning census.	$5.5 + 8 = 13.5$
CDS projects the Lee County patient population forward for 1 year to December 31, 2016.	$(5.5 \times .059) + 5.5 = 5.8$
CDS adds the 18 patients residing in other counties. This is the projected ending census for Operating Year 1, December 31, 2016.	$5.8 + 8 = 13.8$
CDS projects the Lee County patient population forward for 12 months to December 31, 2017.	$(5.8 \times .059) + 5.8 = 6.1$
CDS adds the 18 patients residing in other counties. This is the projected ending census for Operating Year 2, December 31, 2017.	$6.1 + 8 = 14.1$

At the end of Operating Year One, CDS is projecting a patient census of 141 patients for a utilization rate of 97.92% or 3.92 (141 patients / 36 stations = 3.92) patients per station. At the end of operating Year Two, CDS is projected to have an in-center patient census of 148 patients for a utilization rate of 102.8% or 3.89 (148 patients / 36 stations = 4.11) patients per station.

As shown in the table above, the applicant states that the facility will have a beginning census of 107 Lee County patients and 18 patients residing in other counties, as of June 30, 2014. However, the applicant states in the June 2014 ESRD data collection forms that the facility is was serving 98 in-center patients residing in Lee County, 14 patients residing in other counties and two patients residing out-of-state, as of June 30, 2014. Thus, the project analyst recalculated projected in-center patient utilization as follows, utilizing the same methodology as the applicant:

CDS	In-Center Patients
CDS begins with the Lee County patient population dialyzing at the facility as of June 30, 2014.	98
CDS uses one half of the Lee County Five Year Average Annual Change Rate to project the census forward for 6 months to December 31, 2014.	$[98 \times (.059 / 12 \times 6)] + 98 = 100.9$
CDS projects this patient population forward for 1 year to December 31, 2015.	$(100.9 \times .059) + 100.9 = 106.9$
CDS adds the 14 patients residing in other counties. This is the projected beginning census.	$106.9 + 14 = 120.9$
CDS projects the Lee County patient population forward for 1 year to December 31, 2016.	$(106.9 \times .059) + 106.9 = 113.2$
CDS adds the 14 patients residing in other counties. This is the projected ending census for Operating Year 1, December 31, 2016.	$113.2 + 14 = 127.2$
CDS projects the Lee County patient population forward for 12 months to December 31, 2017.	$(113.2 \times .059) + 113.2 = 119.9$
CDS adds the 14 patients residing in other counties. This is the projected ending census for Operating Year 2, December 31, 2017.	$119.9 + 14 = 133.9$

Based on the project analyst's calculations, at the end of Operating Year One, CDS is projecting a patient census of 127 patients for a utilization rate of 88.19% or 3.53 (127 patients / 36 stations = 3.53) patients per station. At the end of operating Year Two, CDS is projected to have an in-center patient census of 134 patients for a utilization rate of 93.06% or 3.72 (134 patients / 36 stations = 3.72) patients per station.

Projected patient in-center utilization at the end of Year One is 3.58 in-center patients per station per week which satisfies the 3.2 in-center patients per station required by 10A NCAC 14C .2203(b).

Projected utilization is based on reasonable and supported assumptions regarding continued growth. The applicant adequately identifies the population it proposes to serve and adequately demonstrates the need that population has for the proposed services.

Access

In Section VI.1(a), page 43, the applicant states:

“It is clear that CDS provides service to historically underserved populations. It is CDS 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.”

On page 43, the applicant states that the patient population of CDS is comprised of the following:

Facility	Medicaid/Low Income	Elderly(65+)	Medicare	Women	Racial Minorities
CDS	42.0%	36.2%	63.0%	39.1%	51.4%

Note: The Medicare percentage here represents the percentage of patients receiving some type of Medicare benefit. This is not to say that 94.8% of the facility treatment reimbursement is from Medicare.

On pages 44 and 59, the applicant projects that 61.13% of its patients will be covered by some form of Medicare or Medicaid and an additional 13.10% will be covered by VA. The applicant adequately demonstrates 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.

Conclusion

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need that population has for the proposed project based on reasonable and supported utilization projections and assumptions and demonstrates the extent to which all residents of the area, and in particular, underserved groups, are likely to have access to the services. 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, pages 34-35, 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 would not resolve the growing ESRD patient population at the facility. The July 2014 SDR indicates the facility utilization rate exceeded 80% threshold allowing it to qualify for additional stations. In this application, the facility projects to exceed 80% utilization at the end of the first year of operations of the project.
- 2) Applying for fewer stations – the applicant states that the utilization of the facility exceeding the 80% threshold mandates that CDS apply for more stations.
- 3) Relocate stations from another facility – Carolina Dialysis—Lee County is a new 13-station facility in Lee County. The development of this facility was due to a relocation of stations from CDS. In addition, this facility has been dialyzing 32 patients on 13 stations since the opening of the facility. Between both facilities, Lee County is dialyzing 157 patients on 46 stations, a county utilization rate of 85.3%, or 3.41 patients per station ($157 / 46 = 3.41$; or 0.8525).

The applicant states that the chosen alternative to apply to expand the existing CDS facility by adding three stations is the most effective and least costly alternative for meeting the needs of the patients projected to receive treatment at the Carolina Dialysis—Sanford facility.

The applicant adequately demonstrates that the proposed alternative is the most effective or least costly alternative based on the on the continued growth of CDS's patient population. See the discussion regarding need in Criterion (3) which is incorporated herein by reference.

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:

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

- 2. Carolina Dialysis, LLC d/b/a Carolina Dialysis Sanford shall develop and operate no more than three additional dialysis stations for a total of no more than 36 certified dialysis stations upon project completion, which shall include any home hemodialysis training or isolation stations.**
 - 3. Carolina Dialysis, LLC d/b/a Carolina Dialysis Sanford shall install plumbing and electrical wiring through the walls for no more than three additional dialysis stations for a total of no more than 36 dialysis stations, which shall include any isolation stations.**
 - 4. Carolina Dialysis, LLC d/b/a Carolina Dialysis Sanford shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII.5, page 52, the applicant states, *“The facility will not incur any capital costs to add these three stations back to the facility.”*

The letter in Exhibit 21 from Carolina Dialysis’s Chairman of the Board of Managers states in part:

“Carolina Dialysis is submitting a Certificate of Need Application to add three dialysis stations to the Carolina Dialysis—Sanford facility for a total of 36 stations upon completion of this project. This project does not require any capital expenditure on behalf of Carolina Dialysis, LLC.”

Based on information provided by the applicant in Section X.1, page 55, the dialysis facility’s projected allowable charges per treatment for each payment source are as follows:

SOURCE OF PAYMENT	ALLOWABLE CHARGE PER TREATMENT
Private Pay	\$1,425.00
Commercial Insurance	\$1,425.00
Medicare	\$239.00
Medicaid	\$140.23
Medicare/Medicaid	\$239.00
Medicare/Commercial	\$239.00
State Kidney Program	\$100.00
VA	\$231.12
Other: Self/Indigent	\$1,425.00

On page 56, the applicant states:

“In November 2013, Medicare announced further cuts to reimbursement for dialysis treatment. These cuts amount to a 12% reduction in revenues and will be phased in over several years. The following table demonstrates the projected Medicare reimbursement by calendar year. CDS will use these rates within in the application and its projections of revenues.”

**Table X.1-2
 Anticipated Medicare Reimbursement by Year**

YEAR	MEDICARE RATE
2014	\$239.02
2015	\$239.02
2016	\$229.46
2017	\$220.28
2018	\$211.47
2019	\$211.47

In Sections X.2-X.4, pages 57-64, the applicant reports projected revenues and expenses as follows:

	OPERATING YEAR 1 1/1/16-12/31/16	OPERATING YEAR 2 1/1/17-12/31/17
Total Net Revenue	\$12,221,064	\$12,742,549
Total Operating Costs	\$8,289,358	\$8,618,941
Net Profit	\$3,931,706	\$4,123,607

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. See Section X.3, page 58 for the applicant’s assumptions on number of treatments (3 treatments/week, 52 weeks/year, and 5.9% missed treatments) for in-center patients.

As previously stated, the applicant incorrectly projected patient origin for the proposed project. Patient origin and patient utilization is needed in order to correctly project revenue. In a request for clarifying information, the applicant states,

“As you might expect, the number of projected patients to be served will be less than indicated in the CON application. Thus, there will be fewer treatments, which necessarily effects the revenue stream. Fewer treatments will also affect the expenses of the facility, but only in the variable expense. Fixed expenses such as rent would of course remain the same.”

The applicant acknowledges that incorrect projected patient origin data has resulted in incorrect revenue projections for the proposed project. The applicant incorrectly projected the number of procedures the facility will serve in operating years one and two. Thus, the project analyst recalculated projected net revenue based on the recalculated projected utilization in Criterion (3), as shown in the following table:

	OPERATING YEAR 1 1/1/16-12/31/16	OPERATING YEAR 2 1/1/17-12/31/17
Total Net Revenue	\$9,742,616	\$10,279,611
Total Operating Costs	\$8,289,358	\$8,618,941
Net Profit	\$1,453,258	\$1,660,670

Source: Net revenue is based on 127 in-center patients in operating year one (2017) and 134 in-center patients in operating year two (2017)

As shown in the tables above, projected revenue and profit for the facility will actually be less than the applicant originally projected, as a result of fewer procedures to be performed. Operating costs were not recalculated to reflect the fewer procedures to be performed, however, even without adjusting operating costs, the facility will still yield a profit in operating years one (2016) and two (2017). There is no capital expenditure for the proposed project and even with less patients to be served, the proposed project will still be financially feasible. See Criterion (3) for further discussion on the applicant’s assumptions for projections which is incorporated herein by reference.

In Section VII.1, page 48, the applicant provides projected staffing and salaries. The financials in Sections X.4-5, pages 63-65, provide operating costs adequate to cover projected staffing.

In summary, the applicant adequately demonstrates that the financial feasibility of the project is based on reasonable projections of revenues and operating costs, including the proposed staffing.

- (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 following table identifies the existing and approved kidney disease treatment centers located in Lee County as reported in the July 2014 SDR.

LEE COUNTY DIALYSIS CENTERS		
FACILITY	LOCATION	UTILIZATION
Carolina Dialysis Lee County*	Sanford	0.00%
Carolina Dialysis Sanford	Sanford	92.31%

Source: July 2014 SDR, Table A.

*New Site, no data reported

As shown in the table above, there are only two dialysis facilities located in Lee County, both of which are owned and operated by the applicant. The Carolina Dialysis—Lee County facility was certified for 13 dialysis stations as of June 25, 2014, thus no data was reported in the July 2014 SDR. CDS, the only other existing facility in Lee County was operating above 80% utilization (3.2 patients per station).

CDS was serving 125 patients weekly on 33 certified stations, which is 3.79 patients per station or 94.7% of capacity, as of December 31, 2013. Dialysis facilities that operate four shifts per week (2 per day on alternate days) have a capacity of four patients per station. The applicant does not propose to establish a new facility. The applicant provides reasonable projections for the in-center patient population it proposes to serve. The growth projections are based on a projected 5.9% average annual change rate in the number of dialysis patients at the CDS facility. At the end of Operating Year Two, CDS projects the utilization will be 3.72 in-center patients per station (134 patients / 36 dialysis stations = 3.72), which is 93.06% of capacity.

The applicant adequately demonstrates the need to develop three additional dialysis stations at the existing facility based on the number of in-center patients it proposes to serve. 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.

C

The following table illustrates the projected staffing for CDS, as provided by the applicant in Section VII.1, page 48.

Position	Total FTE Positions
RN	6.00
LPM	2.50
Tech	16.00
Clinical Manager	1.00
Admin.	0.25
Dietician	1.50
Social Worker	1.50
Home Training Nurse	1.20
Medical Records	1.00
Chief Tech	0.30
Equipment Tech	1.00
In-Service	0.30
Clerical	1.00
Total	33.55

As shown in the above table, the applicant proposes to employ a total of 33.55 full-time equivalent (FTE) positions to staff the CDS facility upon completion of the proposed project. In Section VII.4, page 49, the applicant states, “CDS anticipates no difficulties in filling staff positions.”

The following table shows the projected number of direct care staff for each shift offered at CDS after the addition of three stations.

	Shift Times	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	7:00 am to 12:00 pm		11	11	11	11	11	11
Afternoon	12:00 pm to 5:00 pm		11	11	11	11	11	11
Nocturnal	5:00 pm to 10:00 pm		3		3		3	

The applicant provides adequate staffing to provide dialysis treatments for the number of patients projected. In fact, the applicant states that the above staffing represents sufficient number of dialysis direct care staff for the 36 station facility and further states,

“The facility will operate a third shift on Monday-Wednesday-Friday from the beginning of the second operating year when the facility is projected to exceed 100% utilization.”

In Section V.4, page 40, the applicant states that Edwin Fuller, III, M.D. will serve as Medical Director for the CDS facility. Exhibit 18 contains a letter signed by Dr. Fuller,

of UNC Health Care Kidney Center, expressing support for the addition of dialysis stations and agreeing to continue his relationship as Medical Director with the facility. In Section V, page 41, the applicant lists 11 nephrologists who have expressed a willingness to provide medical coverage for ESRD patients at the facility. In Section VII.8, page 50, the applicant states that the nephrologists have admitting privileges at:

*“Carolina Dialysis Carrboro Carolina Dialysis Pittsboro
Carolina Dialysis Siler City Carolina Dialysis Sanford
Carolina Dialysis Lee County Carolina Dialysis Mebane
FMC Burlington”*

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

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

C

In Section V.1, page 38, the applicant provides a list of providers of the necessary ancillary and support services. Central Carolina Hospital (CCH) or University of North Carolina Hospital (UNCH) will provide acute dialysis in an acute care setting and CCH will provide blood bank services. See Exhibit 22 for the back-up hospital services agreement with UNCH. CCH or UNCH will provide diagnostic evaluation and X-ray services. Transplantation services will be provided by UNCH (Exhibit 23). CCH or UNCH will provide psychological counseling. Pediatric nephrology will be provided onsite. Vascular surgery will be provided by UNCH, Pinehurst Surgical, or Carolina Vascular Access. All CDS staff are trained to respond to emergencies and there is a fully stocked crash cart available on-site. If needed, patients will be transported by ambulance to the hospital for further acute care. Spectra will provide laboratory services (Exhibit 15). Self care training, including hemodialysis, peritoneal dialysis, CAPD and CCPD will be provided on site. Hemodialysis will be referred to Carolina Dialysis—Carrboro. 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 43, the applicant states that Fresenius Medical Care Holdings, Inc., co-parent company to CDS, currently operates 102 dialysis facilities in 42 North Carolina counties (including affiliations with RRI facilities). The applicant further states, *“Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.”* The patient population of the CDS facility is comprised of the following:

Facility	Medicaid/Low Income	Elderly(65+)	Medicare	Women	Racial Minorities
CDS	42.0%	36.2%	63.0%	39.1%	51.4%

Note: The Medicare percentage represents patients receiving some type of Medicare benefit. This is not to say 94.8% of the treatment reimbursement is from Medicare.

On pages 43, the applicant further states:

“CDS notes that the historical performance as reported here represents the payor mix for CDS as of June 30, 2014. The historical performance is not a guarantee of future performance as the payor source does 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 Section VI.1(b), page 44, the applicant reports that 61.13% of the patients who were receiving treatments at Carolina Dialysis—Sanford as of June 30, 2014, had some or all of their services paid for by Medicare or Medicaid in the past year. The following table illustrates the historical and projected payment source for the facility.

CAROLINA DIALYSIS--SANFORD PAYOR MIX

SOURCE OF PAYMENT	% OF TOTAL
Commercial Insurance	24.16%
Medicare	51.54%
Medicaid	3.06%
VA	13.10%
Medicare/Commercial	6.53%
Other (Self/Indigent)	1.61%
Total	100.00%

Totals may not sum due to rounding.

The Division of Medical Assistance (DMA) maintains a website which provides the number of persons eligible for Medicaid in North Carolina, and estimates

the percentage of uninsured people for each county. The following table illustrates those percentages for Lee County and statewide.

	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Lee County	19.5%	7.2%	21.5%
Statewide	16.5%	6.7%	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 2013 only 6.6% of all newly-diagnosed ESRD patients in North Carolina were under the age of 35, according to the ESRD Network 6 2013 Annual Report. (*ESRD Network 6 2013 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 1/1/2013 – 12/31/2013, page 99*).¹

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

Additionally, The United States Renal Data System, in its *2013 USRDS Annual Data Report*, pages 216-223, provides the following national statistics for FY 2011:

*“The December 31, 2011 prevalent population included 430,273 patients on dialysis ...”*² (p. 216)

The report also provided the incidence of dialysis patients in 2011, adjusted by age, gender and race, which showed that 65.4% were White, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian, and 1.2% were Native American (p. 218). Moreover, the prevalence of ESRD for the 65-74 year old population grew by 31% since 2000 and by 48% for those aged 75 and older (p. 223). The report further states:

“In the 2011 prevalent population, 84 percent of hemodialysis patients and 81 percent of those on peritoneal dialysis had some type of primary Medicare coverage, compared to just 53 percent of those with a transplant.”(p. 216)

¹<http://www.esrdnetwork6.org/utills/pdf/annualreport/2013%20Network%206%20Annual%20Report.pdf>

² www.usrds.org/adr.aspx

The 2013 USRDS Annual Data Report provides 2011 ESRD spending by payor, as follows:

ESRD SPENDING BY PAYOR*		
PAYOR	SPENDING IN BILLIONS	% OF TOTAL SPENDING
Medicare Paid	\$30.7	62.4%
Medicare Patient Obligation	\$4.7	9.6%
Medicare HMO	\$3.6	7.3%
Non-Medicare	\$10.2	20.7%
TOTAL	\$49.2	100.0%

The Southeastern Kidney Council (SKC) Network 6 2013 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 101, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race, and Gender 2013		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	65	0.4%
20-34	766	5.0%
35-44	1,498	9.7%
45-54	2,746	17.8%
55-64	4,039	26.2%
65+	6,275	40.8%
Gender		
Female	6,845	44.5%
Male	8,544	55.5%
Race		
African-American	9,559	62.1%
White/Caucasian	5,447	35.4%
Other	383	2.5%

Source: SKC Network 6. Table includes North Carolina statistics only.³

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

³<http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

- (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 45, the applicant states,

“CDS of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. ... The applicant will treat all patients the same regardless of race or handicap status.”

In Section VI.6 (a), page 46, the applicant states, *“There have been no Civil Rights complaints lodged against any CDS North Carolina 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(c), page 44, the applicant provides the projected payor mix for the proposed services at CDS, which is shown below:

CAROLINA DIALYSIS--SANFORD PAYOR MIX

SOURCE OF PAYMENT	% OF TOTAL
Commercial Insurance	24.16%
Medicare	51.54%
Medicaid	3.06%
VA	13.10%
Medicare/Commercial	6.53%
Other (Self/Indigent)	1.61%
Total	100.00%

Totals may not sum due to rounding.

The applicant projects no change from the current payor mix for in-center dialysis services, which is 61.13% Medicare and Medicaid.

In Section VI.1(d), page 45, the applicant states:

“CDS 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]

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 46, 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. CDS 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.

Patients cannot self-refer for dialysis and dialysis treatment does require orders from an attending physician with staff privileges at the facility. 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 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.

C

In Section V.3, pages 39-40, the applicant states:

“Exhibit 19 [16] contains letters to Central Carolina Community College encouraging the school to include the CDS facility in their clinical rotations for nursing students.

...

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 for the patient with end stage renal disease.”

Exhibit 16 contains a copy of a letter from Carolina Dialysis to the Nursing Program at Central Carolina Community College inviting the college to include Carolina Dialysis—Sanford (CDS) in the clinical rotation for its nursing students. The information provided in Section V.3 is reasonable and credible and supports a finding of conformity with this criterion.

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

C

Carolina Dialysis Sanford proposes to add three dialysis stations to the existing facility for a total of 36 stations upon project completion. The applicant operates the only two dialysis facilities in Lee County, as shown in the table below.

Lee County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/13	% Utilization	Patients Per Station
Carolina Dialysis Lee County	0	0.00%	0.00
Carolina Dialysis—Sanford*	39	92.31%	3.69

Source: July 2014 SDR, Table A.

*New site, no data reported in July 2014 SDR

As shown in the table above, Carolina Dialysis of Lee County is a new facility with no data to report as of the July 2014 SDR. CDS was operating above 80% utilization (3.2 patients per station), at the time of this report.

In Section V.7, page 42, 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,

“CDS does not expect this proposal to have effect on the competitive climate in Lee County. According to the July 2014 SDR there are currently two dialysis facilities operating within Lee County; both are operated by Carolina Dialysis, LLC. CDS seeks the opportunity to continue providing dialysis care and treatment to the patients of the area.

Consider the choices available to the patients, and that Medicare and Medicaid reimbursement rates are fixed as established by the respective agencies. Therefore, with fixed reimbursement rates, Carolina Dialysis facilities are compelled to operate at maximum dollar efficiency. The majority of our patients rely upon Medicare and Medicaid to cover the expense of their treatments. In this application, we project that greater than 74% [61.13%] of the in-center patients will be relying upon either Medicare or Medicaid. The facility must capitalize upon every opportunity for efficiency.

Our facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients. Again, we have eliminated the re-use concept in our facilities and provides every patient a new dialyzer at each treatment. Every effort is made to (a) ensure that the applicant thoroughly plans for the success of a facility prior to submitting a CON application, and, (b) that once the project is completed, all staff members work toward the clinical and financial success of the facility. This facility will be no different. This proposal will certainly [sic] 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 UNCH. UNCH is a premier teaching institution and offers patients access to the latest developments in healthcare; in fact, many nephrology protocols employed across the country can be traced to the UNCH Division of Nephrology and Hypertension. The UNCH Division of Nephrology and Hypertension brings together the collaborative efforts of six very qualified nephrologists to provide care for the patients choosing to dialyze at the Carolina Dialysis—Sanford facility.”

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that any enhanced competition in the service area will have a positive impact on 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 to add three dialysis stations at the Carolina Dialysis—Sanford facility and that it is a cost-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 it will continue to provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.
- ◆ The applicant demonstrates that it will continue to provide adequate access to medically underserved populations. The discussion regarding access found in Criterion (1) and (13) is incorporated herein by reference.

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—Sanford, also referred to as CDS, currently provides dialysis services. According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the CDS facility operated in compliance with the Medicare Conditions of Participation within the 18 months immediately preceding the date of the 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.

CA

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 11, the applicant states that the utilization rate is reported in the July 2014 SDR. The July 2014 SDR shows a utilization rate of 92.31% for Carolinas Dialysis—Sanford. The rate was calculated based on 144 in-center dialysis patients and 39 certified dialysis stations as of December 31, 2013 (144 patients / 39 stations = 3.69 patients per station; 3.69 patients per station / 4.00 patients per station = 0.9231).

(2) *Mortality rates;*

-C- In Section II, page 11, the applicant reports the 2011, 2012 and 2013 facility mortality rates as 17.3%, 16.4% and 5.9%, respectively.

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

-C- In Section II, page 11, the applicant states, “CDS currently has 13 peritoneal dialysis patients dialyzing at home.”

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

-C- In Section II, page 11, the applicant provides information showing CDS referred 57 patients for transplant in 2012 and 53 patients in 2013; 5 transplants were performed in 2012, and 1 transplant was performed in 2013.

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

-C- In Section II, page 11, the applicant states, “CDS has seven patients on the transplant waiting list.”

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

-C- In Section II, page 11, the applicant states that there were 192 hospital admissions in 2013, 32 (16.7%) of which were dialysis related and 160 (83.3%) 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 II, page 12, the applicant provides information that shows there were no patients dialyzing at CDS with Hepatitis B Conversions during 2012 and 2013 and no current patients with infectious disease (Hepatitis B).

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

(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*

- (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
- (B) *composition of the assessment/evaluation team at the transplant center,*
- (C) *method for periodic re-evaluation,*
- (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and*
- (E) *signatures of the duly authorized persons representing the facilities and the agency providing the services.*

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

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

-NA- This is not an application for a new or replacement 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, including 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 13, the applicant states:

“CDS will provide all services approved by the Certificate of Need in conformity with applicable laws and regulations. CDS 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 CDS.”

In Section XI.6(g), page 70, the applicant states, *“CDS of North Carolina provides and will continue to provide services in conformity with applicable laws and regulations pertaining to staffing, fire safety and equipment, physical environment and other relevant health and safety requirements. Information detailing conformity can be found in Sections II and VII and exhibits referenced therein. Additionally, this applicant has confirmed its commitment to provide services in conformity with the law on the Certification page provided in the front of the application.”*

(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 projected patient origin for the first two operating years in Section II, page 13 and Section III, page 32, as incorporated herein by reference. However, the applicant incorrectly projected patient origin. The recalculated projected patient origin is in Criterion (3), as incorporated herein by reference.

(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 15, the applicant states,

“CDS 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 provides the projected utilization for the first two operating years in Section II, page 13 and Section III, page 32. However, the applicant incorrectly projected utilization. The recalculated projected utilization is greater than 3.2 patients per station per week as of the end of the first operating year. The recalculated projected utilization is in Criterion (3), as incorporated herein by reference.

.2204 SCOPE OF SERVICES

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

- (1) *diagnostic and evaluation services;*
 - C- Section II, page 17 and the table in Section V.1, page 38 state patients will be referred to Central Carolina Hospital or UNC Hospital for diagnostic and evaluation services.
- (2) *maintenance dialysis;*
 - C- Section II, page 17 and the table in Section V.1, page 38, state the applicant will provide in-center maintenance dialysis.
- (3) *accessible self-care training;*
 - C- In Section II, page 17, the applicant states, “*Patients who are candidates for self-care are referred to the CDS home training department.*” The table in Section V.1, page 38, shows patients will receive in-center hemodialysis at Carolina Dialysis—Carrboro and intermittent peritoneal dialysis, CAPD and CCPD on site at CDS.
- (4) *accessible follow-up program for support of patients dialyzing at home;*
 - C- In Section II, page 17, the applicant states, “*Patients who are candidates for home dialysis are referred to the CDS facility home training department.*” The applicant addresses accessible follow-up program for support of patients dialyzing at home in Section V, Question 2(d), page 39, stating,

“Currently, patients who desire to perform home peritoneal dialysis will be trained and referred to the CDS facility home training program; patients who desire to perform home hemodialysis will be trained and referred to the Carolina Dialysis—Carrboro facility home training program. Patients who are candidates for home dialysis are referred by their attending nephrologists to the appropriate Carolina Dialysis facility home training program. 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.”

(5) *x-ray services;*

-C- Section II, page 17 and the table in Section V.1, page 38, state patients will be referred to Central Carolina Hospital or UNC Hospital for x-ray services.

(6) *laboratory services;*

-C- Section II, page 17 and the table in Section V.1, page 38, state the facility provides on-site laboratory services through contract with Spectra Labs. Exhibit 15 contains a laboratory services agreement.

(7) *blood bank services;*

-C- Section II, page 17 and the table in Section V.1, page 38, state patients will be referred to Central Carolina Hospital for blood bank services.

(8) *emergency care;*

-C- Section II, page 17 and the table in Section V.1, page 38, state emergency care is provided on site from the trained staff and fully stocked crash cart. Emergency services will be summoned via phone call to 911 in the event transport by ambulance to a hospital is required.

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

-C- Section II, page 17 and the table in Section V.1, page 38, state patients will be referred to Central Carolina Hospital for acute dialysis in an acute care setting.

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

-C- Section II, page 18 and the table in Section V.1, page 38, state dialysis patients will be referred to UNC Hospitals, Pinehurst Surgical or Carolina Vascular Access for vascular surgery.

(11) *transplantation services;*

-C- In Section II, page 18, the applicant states, “CDS will have a transplant agreement with UNC Hospital. A copy of an executed transplant agreement is included in Exhibit 26.”

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

-C- Section II, page 18 and the table in Section V.1, page 38, state patients will be referred to Lee County Vocational Rehabilitation for vocational counseling and services.

(13) *transportation.*

-C- Section II, page 18 and the table in Section V.1, page 38, states transportation services for patients are provided by the County of Lee Transit System (COLTS), or, Sister to Sister.

.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 48, the applicant provides the proposed staffing for Carolina Dialysis—Sanford. On page 49, the applicant states, “CDS 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, pages 5-9 and Section II.2. A, pages 23-24.

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

-C- In Section VII.5, page 49, the applicant refers to Exhibit 9 for an outline of the training program and Exhibit 10 for an outline of continuing education programs. The applicant also states that each new employee will be required to successfully complete a 10-week training program, including training in the clinical aspects of their job, facility and corporate policies and procedures, safety precautions, OSHA regulations, and CPR.