

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DATE: June 28, 2013
PROJECT ANALYST: Gregory F. Yakaboski
ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: O-10110-13 / Total Renal Care of North Carolina, LLC d/b/a Cape Fear Dialysis Center / Add four dialysis stations for a total of 32 certified stations upon completion of this project / New Hanover 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

Total Renal Care of North Carolina, LLC (TRC) d/b/a Cape Fear Dialysis Center ("Cape Fear Dialysis Center"), whose ultimate parent company is DaVita Healthcare Partners Inc., (DaVita), proposes to add 4 dialysis stations for a total of 32 certified dialysis stations upon completion of this project. 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 January 2013 Semiannual Dialysis Report (SDR), Table B, the county need methodology shows there is a projected deficit of two dialysis stations and no county station need determination in New Hanover County. However, the applicant is eligible to apply for additional stations based on the facility need methodology because the utilization rate reported for Cape Fear Dialysis Center in the January 2013 SDR is 117.86% or 4.71 patients per station. This utilization rate was calculated based on 132

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in-center dialysis patients dialyzing in the facility on June 30, 2012 and 28 certified dialysis stations. (132 patients / 28 stations = 4.71 patients per station).

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

Required SDR Utilization		80%
Center Utilization Rate as of 6/30/12		117.86%
Certified Stations		28
Pending Stations		0
Total Existing and Pending Stations		28
In-Center Patients as of 6/30/12 (SDR2)		132
In-Center Patients as of 12/31/11 (SDR1)		132
Difference (SDR2 - SDR1)		0
Step	Description	
(i)	Multiply the difference by 2 for the projected net in-center change	0
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/11	0
(ii)	Divide the result of Step (i) by 12	0
(iii)	Multiply the result of Step (ii) by 6 (the number of months from 6/30/12 to 12/31/12)	0
(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	132.0000
(v)	Divide the result of Step (iv) by 3.2 patients per station	41.2500
	and subtract the number of certified and pending stations as recorded in SDR2 [28] to determine the number of stations needed	13

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 13 stations. Step (C) of the facility need methodology states *“The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.”* The applicant proposes to add only four new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policy GEN-3: Basic Principles, pages 42-43, 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.”

Safety and Quality- The applicant describes how its proposal will promote safety and quality in Section I.13, pages 7-8, Section II, pages 10-17, Section V, pages 25-29, Section VII, pages 34-37, and Exhibits 4, 8, 10, 11, 12, 14, 15, 16, 18, 23, 24 and 25. The information provided by the applicant is reasonable, credible and supports the determination that the applicant’s proposal will promote safety and quality.

Equitable access- The applicant describes how its proposal will promote equitable access in Section VI, pages 30-33, and Exhibit 15 (Business and Admissions Policy). The information provided by the applicant is reasonable, credible and supports the determination that the applicant’s proposal will promote equitable access.

Maximize Health Care Value- The applicant describes how its proposal will maximize health care value for resources expended in Section III, pages 18-24, Section VIII, pages 38-42, and Section X, pages 45-49. The information provided by the applicant is reasonable, credible and supports the determination that the applicant’s proposal will maximize health care value.

The applicant adequately demonstrates how its proposal will promote safety and quality, equitable access and maximize health care value for resources expended. Therefore, the application is consistent with Policy GEN-3. 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 January 2013 SDR and Policy GEN-3. Therefore, the application is conforming to this criterion.

- (2) Repealed effective July 1, 1987.

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- (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 January 2013 SDR indicates a total of 28 certified dialysis stations at Cape Fear Dialysis Center as of June 30, 2012. In this application, Cape Fear Dialysis Center proposes to add 4 dialysis stations based on facility need for a total of 32 dialysis stations at the facility. The dialysis stations proposed in this application are projected to be operational by January 1, 2014.

Population to be Served

In Section IV.1, page 23, the applicant identifies Cape Fear Dialysis Center’s historical patient origin as of December 31, 2012, as illustrated in the table below.

County of Residence	# of patients dialyzing in-center
New Hanover	111
Pender	13
Brunswick	5
Columbus	3
Total	132

In Section III.7, page 20, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, as illustrated in the following table.

County	Operating Year 1 2013/2014		Operating Year 2 2014/2015		County Patients as a % of TOTAL	
	Home	In-Center	Home	In-Center	Year 1	Year 2
New Hanover	0	121	0	127	85.2%	85.8%
Pender	0	13	0	13	9.2%	8.8%
Brunswick	0	5	0	5	3.5%	3.4%
Columbus	0	3	0	3	2.1%	2.0%
Total	0	142	0	147	100%	100%

The applicant adequately identified the population to be served.

Need Analysis

Cape Fear Dialysis Center proposes to add four additional dialysis stations to its facility at 2722 Exchange Drive, Wilmington for a total of 32 dialysis stations upon project completion. On pages 20-21, the applicant indicates that the following assumptions and methodology were used to project the future patient population of the facility.

Assumptions

- The proposed project will be completed and certified as of January 1, 2014.
- Operating Year 1 is January 1, 2014 through December 31, 2014.
- Operating Year 2 is January 1, 2015 through December 31, 2014.
- The calculations for growth of the patient population begin from the date of the most recent SDR (January 2014).
- The number of patients projected are rounded down to the nearest whole number.
- The project is not anticipating the transfer of any patients from other facilities.
- The applicant utilized the Average Annual Change Rate for the Past Five Years of 4.8% for New Hanover County for the 111 in-center patients from New Hanover County.
- The applicant did not apply a growth rate to the current in-center patients residing in counties other than New Hanover County.
- The period of growth was calculated from January 1, 2013 through the end of Year 2, December 31, 2015.

Projected Utilization:

January 1, 2013 – December 31, 2013: 111 New Hanover County patients x 1.048 = 116.328.

Year 1: January 1, 2014 – December 31, 2014: 116.328 New Hanover County patients x 1.048 = 121.911744.

Year 2: January 1, 2015 – December 31, 2015: 121.911744 New Hanover County patients x 1.048 = 127.763.

Year 1 projected patients: 121 New Hanover County patients (+) 13 Pender County patients (+) 5 Brunswick County patients (+) 3 Columbus County patients = 142 projected patients.

Year 2 projected patients: 127 New Hanover County patients (+) 13 Pender County patients (+) 5 Brunswick County patients (+) 3 Columbus County patients = 148 projected patients.

Operating Year 1 (CY 2014): The applicant projects to serve 142 in-center patients or 4.44 patients per station ($142 / 32 = 4.44$) by the end of Year 1, which is a utilization rate of 111% ($4.44 / 4 = 1.109$ or 111.0%).

Operating Year 2 (CY 2015): The applicant projects to serve 148 in-center patients or 4.63 patients per station ($148 / 32 = 4.625$) by the end of Year 2, which is a utilization rate of 115.6% ($4.625 / 4 = 1.156$ or 115.6%) for the proposed 32 station facility.

The projected 4.44 patients per station per week at the end of Operating Year 1 exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable, credible and supported assumptions regarding continued growth.

Access

In Section VI, page 30, the applicant states,

“Cape Fear Dialysis Center, by policy, has always made dialysis services available to all residents in its service area without qualifications. We have served and will continue to serve without regard to race, sex, age, handicap, or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.”

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In the past year, 45.4% of all payments came from Medicare, 6.8% from Medicaid, 38.0% from Medicare/Medicaid and 3.0% from the VA. The applicant states in Section VI, pages 30-32, that they will provide services regardless of financial situation or socioeconomic status and that the facility will be handicapped accessible according to all state and local requirements. Home training services for patients living in New Hanover County and surrounding counties is provided by SEDC-Wilmington. The applicant is not certified to provide home training services. [See application page 23.] The applicant demonstrates adequate access for the underserved to its services.

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for four additional stations at Cape Fear Dialysis Center, and demonstrates the extent to which all residents of the area, including medically underserved groups, 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 21, the applicant discusses the alternatives considered prior to the submission of this application, which include:

1. Maintain the Status Quo—Do Nothing. The applicant states that this alternative was dismissed because of the growing in-center population of dialysis patients. The facility's utilization rate exceeds 100% and the facility needs 13 additional stations to operate at 80% of capacity without any increases in the number of patients. The applicant is only asking for four additional stations at this time.
2. Add four dialysis stations for a total of 32 stations at Cape Fear Dialysis Center. The applicant proposes to add four additional stations to the existing treatment space at Cape Fear Dialysis Center to improve access to dialysis services which

is necessitated by the current and projected demand for dialysis services at the facility.

The applicant adequately demonstrates the need for four additional stations based on the current utilization and continued growth of the ESRD patient population of New Hanover County. See Criterion (3) for additional discussion regarding need which is incorporated hereby as if set forth fully herein.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable.

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

1. **Total Renal Care of North Carolina, LLC d/b/a Cape Fear Dialysis Center shall materially comply with all representations made in the certificate of need application.**
 2. **Total Renal Care of North Carolina, LLC d/b/a Cape Fear Dialysis Center shall develop no more than four additional stations for a total of no more than 32 stations, which includes any isolation stations or home hemodialysis training stations.**
 3. **Total Renal Care of North Carolina, LLC d/b/a Cape Fear Dialysis Center shall install plumbing and electrical wiring through the walls for no more than four additional dialysis stations for a total of no more than 32 stations, which shall include any isolation stations or home hemodialysis training stations.**
 4. **Total Renal Care of North Carolina, LLC d/b/a Cape Fear Dialysis Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

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In Section VIII.1, page 39, the applicant projects a capital cost of \$63,352 for the four station addition. In Section IX, page 43, the applicant states there will be no start-up or initial operating expenses associated with the proposed project.

In Section VIII.2, page 40, the applicant states that this project will be funded from cash reserves. Exhibit 19 includes a letter dated March 15, 2013 from the Chief Accounting Officer of DaVita Healthcare Partners, Inc. which states:

“I am the Chief Accounting Officer of DaVita Healthcare Partners Inc., the parent and 100% owner of Total Renal Care, Inc. I also serve as the Chief Accounting Officer of Total Renal Care, Inc. which owns 85% of the ownership interests in Total Renal Care of North Carolina, LLC.

We are submitting a Certificate of Need Application to expand our Cape Fear Dialysis Center facility by four dialysis stations. The project calls for a capital expenditure of \$199,411. This letter will confirm that DaVita Healthcare Partners, Inc. has committed cash reserves in the total sum of \$199,411 for the project capital expenditure. DaVita Healthcare Partners, Inc. will make these funds, along with any other funds that are necessary for the development of the project, available to Total Renal Care of North Carolina, LLC.”

The letter commits \$199,411 for the capital needs of the project which exceeds the projected capital cost. In Exhibit 20, the applicant provides a United States Securities and Exchange Commission Form 10-K for DaVita Healthcare Partners, Inc. for the year ended December 31, 2012. As of December 31, 2012, DaVita Healthcare Partners, Inc. had cash and cash equivalents totaling \$195,037,000 with \$12,823,766,000 in total assets. [See page F-60.] The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the proposed project.

Based on information provided by the applicant in Section X.1, page 45, the applicant projects the following charge per treatment for each payment source:

**Applicant Projected Allowable
In-Center Charges**

Payor	In-center
Medicare	\$240
Medicaid	\$143
Medicare/Medicaid	\$240
Commercial	\$1,442
VA	\$193
Medicare/Commercial	\$240

The applicant projects revenues in Section X.2, page 45, of the application and operating expenses in Section X.4, page 48, of the application. The applicant projected revenues in excess of operating expenses in both the first and second operating year following completion of the project, as illustrated in the table below and supported by the accompanying assumptions.

**Cape Fear Dialysis Center
Projected Net Revenues, Operating Expenses and Net Profit
2014/2015**

	Operating Year 1	Operating Year 2
Net revenue	\$6,389,002	\$6,640,362
Operating expenses	\$4,963,780	\$5,143,026
Profit	\$1,425,222	\$1,497,336

Assumptions:

1. Patients would be seen three times a week, 52 weeks per year.
2. Patients would miss 5% of treatments in the first operating year.
3. The actual number of treatments was multiplied by the patient payment percentage by source of revenue to obtain how many treatments would be from each source of revenue.
4. The amount paid by each source of revenue was multiplied by the treatment number by source of revenue to obtain the operating revenue totals.
5. Calendar Year 2013 revenue projections include an average of 134.5 in-center patients being treated during the year. The number of in-center patients is based on 132 in-center patients being treated at the beginning of the year with a growth during the year to 137 in-center patients.
6. The operating year one (CY 2014) revenue projections include an average of 139.5 in-center patients being treated during the year. The number of in-center patients is based on 137 in-center patients being treated at the beginning of the year with a growth during the year to 142 in-center patients.
7. The operating year two (CY 2015) revenue projections include an average of 145 in-center patients being treated during the year. The number of in-center patients is based on 142 in-center patients being treated at the beginning of the year with a growth during the year to 148 in-center patients.

In Section VII.1, page 34, the applicant provides projected staffing and salaries. On page 34, the applicant states Cape Fear Dialysis Center will comply with all staffing requirements as stated in 42 C.F.R. Section 405.2100 (now 42 C.F.R. Section 494). Projected staffing by shift is provided on pages 36-37. The applicant projects adequate staffing to provide dialysis treatments for the number of patients projected.

The applicant adequately demonstrates the financial feasibility of the proposal is based on reasonable projections of costs and revenues. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to add four dialysis stations to the existing facility for a total of 32 stations upon completion of the proposed project. Upon completion of this project the total number of dialysis stations in New Hanover County will increase from 57 to 61 dialysis stations. The applicant adequately demonstrates the need for four additional stations based on the number of in-center patients currently served and projected to be served. Per the January 2013 SDR, as of June 30, 2012, the 28-station facility was operating at 117.86% of capacity ($132/28 = 4.71$; $4.71/4 = 1.1785$ or 117.86%). The target utilization rate is 80%. The applicant therefore is eligible to expand its facility and could have applied for as many as 10 stations. See Criterion (1) for discussion which is incorporated hereby as if set forth fully herein. Upon completion of this project, the facility will have 32 stations serving 142 patients (end of operating year 1) which is a utilization rate of 111.0% ($142/32 = 4.44$; $4.44/4 = 1.109$ or 111.0%). Therefore the application is conforming with the requirement in 10A NCAC 14C .2203.

The applicant has a second dialysis facility in New Hanover County, SEDC-Wilmington, located at 2215 Yaupon Drive in Wilmington. SEDC-Wilmington is located approximately 9.96 miles from Cape Fear Dialysis Center which is located at 2722 Exchange Drive in Wilmington. Even factoring in the proposed four dialysis station expansion, Cape Fear Dialysis Center is projected to be operating at 111.0% of capacity (four patients per station per week, assuming two shifts per day). Cape Fear Dialysis Center will offer a third shift on Monday, Wednesday and Friday. As of 6/30/12, SEDC-Wilmington had 72 in-center patients and 29 certified stations with a utilization rate of 62.07%. New Hanover County has no other dialysis provider or dialysis facilities. In Section III.7, page 21, the applicant acknowledges that the SEDC-Wilmington is currently underutilized. However, the applicant states that this is because SEDC-Wilmington is in the midst of a complete renovation project which is expected to be completed later this year. The applicant anticipates that some Cape Fear Dialysis Center patients will transfer to the newly renovated SEDC-Wilmington facility upon completion of the renovation project. On page 377, the 2013 SMFP states, "*Patient Access to In-Center ESRD Services: As a means of making ESRD services more accessible to patients, one of the goals of the N.C. Department of Health and Human Services is to minimize patient travel time to and from the center.*"

The applicant adequately demonstrates the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the application is conforming to this criterion.

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

C

In Section VII.1, page 34, the applicant provides the current and projected number of full-time equivalent (FTE) positions following completion of the proposed project, as illustrated in the table below:

Position	Current # of FTEs	Total Positions to be Filled	Total FTE Positions Upon Completion
RN	4	1	5
PCT	12	2	14
Bio-Med Tech	1	0	1
Medical Director	Contract position; not an FTE of the facility		
Administrator	1	0	1
Dietitian	1	0	1
Social Worker	1	0	1
Unit Secretary	1	0	1
Other- Reuse	1.5	0	1.5
Total	22.5	3	25.5

Analysis of the salaries budgeted in the operating expense statements on pages 48-49 confirms the use of 25.5 FTE positions in the projected salary expense.

In Section VII.10, page 36, the applicant provides the direct care staff for each shift offered in the facility after project completion as shown in the table below:

	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	6:00am to 10:30pm	8	8	8	8	8	8
Afternoon	11:00pm to 4:00pm	8	8	8	8	8	8
Evening	8:00pm to 9:00am	5	0	5	0	5	0

On page 37 the applicant states *“The charts above only indicate patient care technicians, who are the direct care teammates. We staff each shift Monday thru Saturday from 6 am to*

4 pm with two Registered Nurses. We staff each evening shift on Monday, Wednesday and Friday with at least one Registered Nurse.”

The applicant states in Section V.4 (c), page 27, that Dr. Robert Moore is the Medical Director for the facility. Exhibit 14 contains a letter from Dr. Moore in which he states that he is the Medical Director for the Cape Fear Dialysis Center and supports the proposed expansion of the facility. The information regarding staffing provided in Section VII is reasonable and credible and supports a finding of conformity with 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 25 of the application, the applicant lists the providers of the necessary ancillary and support services. Exhibits 10-12 contain a copy of the laboratory agreement, patient transfer agreement and transplant agreement. Exhibit 14 contains a copy of the medical director's letter. Exhibits 18, 24 and 25 contain copies of the professional training programs. Section V.4(b), page 27, contains a list of physicians who have expressed support for the addition of 4 dialysis stations at Cape Fear Dialysis Center and who have expressed a willingness to provide medical coverage for ESRD patients. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care 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 30, the applicant discusses Cape Fear Dialysis Center’s history of providing dialysis services to the underserved populations. The applicant states:

“Cape Fear Dialysis Center, by policy, has always made dialysis services available to all residents in its service area without qualifications. We have served and will continue to serve without regard to race, sex, age, or handicap, or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.

Cape Fear Dialysis Center makes every reasonable effort to accommodate all of its patients; especially those with special needs such as the handicapped, patients attending school or patients who work. Cape Fear Dialysis Center provides dialysis six days per week with three patient shifts per day on Monday, Wednesday, and Friday and two patient shifts per day on Tuesday, Thursday and Saturday to accommodate patient need.

Cape Fear Dialysis Center does not require payment upon admission to its services; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons. Cape Fear Dialysis Center works with patients who need transportation, when necessary.”

In Section VI.1, page 30, the applicant indicates that historically, 83.4% percent of patients at Cape Fear Dialysis Center have some or all of their services paid for by Medicare. An additional 3.0% are covered by VA. As illustrated in the table below, 93.2% of the center revenue is derived from government payors. The table below illustrates the current historical payor mix for the facility.

Historical Payor Source- Last Year

Payor Source	In-Center
Medicare	9.8%
Medicaid	6.8%
Medicare/Medicaid	38.0%
Commercial Insurance	6.8%
VA	3.0%
Medicare/Commercial	35.6%
Total	100.0%

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 New Hanover, Pender,

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Brunswick and Columbus counties and statewide. More current data, particularly with regard to the estimated uninsured percentages, was not available.

	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)
New Hanover	13.0%	5.7%	20.4%
Pender	17.0%	7.4%	21.0%
Brunswick	7.0%	2.8%	19.8%
Columbus	28.0%	13.1%	20.4%
Statewide	17%	6.71%	19.7%

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 Cape Fear Dialysis Center. In fact, only 5.8% of all 2011 Incident ESRD patients in North Carolina's Network 6 were under the age of 35.

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 and 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 or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The Centers for Medicare & Medicaid Services (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 standing.

...

Almost half (46.6%) of the incident patients in 2004 were between the ages of 60 and 70. 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.”¹

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.”

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

ESRD Spending by Payor		
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 demonstrating the following:

¹www.cms.gov/medicare/end-stage-renal-disease/esrdnetworkorganizations/downloads/esrdnetworkprogrambackgroundpublic.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	1,529	16.4%
55-64	2,370	25.4%
65-74	2,258	24.2%
75+	1,872	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	2.30%
Total	9,342	100.0%

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

The applicant demonstrates it 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 31, the applicant states:

“Cape Fear Dialysis Center has no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons except those obligations

which are placed upon all medical facilities under Section 504 of the Rehabilitation Act of 1973 and its subsequent amendment in 1993.”

In Section VI.6(a), page 33, the applicant states,

“There have been no civil rights equal access complaints filed within the last five years.”

The application is conforming to this criterion.

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

C

In Section VI.1(c), page 31, the applicant provides the projected payor mix for the facility, as illustrated in the table below.

Payor Source	In-Center
Medicare	9.8%
Medicaid	6.8%
Medicare/Medicaid	38.0%
Commercial Insurance	6.8%
VA	3.0%
Medicare/Commercial	35.6%
Total	100.0%

The applicant does not anticipate any changes in the payor mix as a result of the proposed project.

As shown in the table above, the applicant projects 83.4% of all in-center patients will have some or all of their services paid for by Medicare with VA covering another 3.0%.

In Section II.1, page 12, the applicant states:

“Total Renal Care of North Carolina, LLC d/b/a Cape Fear Dialysis Center will admit and provide dialysis services to patients who have no insurance or other source of payment if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”

The applicant demonstrates it will provide adequate access to elderly and medically underserved populations. Therefore, the application is conforming to this criterion.

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

C

In Section VI.5(a), page 32, the applicant states:

“Patients with End Stage Renal Disease will have access to dialysis services upon referral to a Nephrologist with privileges at Cape Fear Dialysis Center. These referrals most commonly come from primary care physicians or specialty physicians in New Hanover County. Patients, families and friends can obtain access by contacting a Nephrologist with privileges at the facility. Should a patient contact Cape Fear Dialysis Center directly or indirectly, the patient is referred to a qualified Nephrologist for evaluation and subsequent admission if medically necessary. Patients from outside the Cape Fear Dialysis Center catchment area requesting transfer to this facility are processed in accordance with the Cape Fear Dialysis Center transfer and transient policies which comprise Exhibit 15.”

The applicant adequately demonstrates that it will provide a range of means by which a person can access 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, page 26, the applicant states that it has established agreements with Cape Fear Community College. Exhibit 13 contains a copy of the “*Student Training Agreement*” between Cape Fear Community College and Total Renal Care of North Carolina, LLC. The applicant adequately demonstrates that the facility will accommodate the clinical needs of health professional training programs in the service area. The application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.

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- (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 to its existing facility for a total of 32 certified stations upon completion of the proposed project. The January 2013 SDR shows there is a deficit of (2) two dialysis stations in New Hanover County.

There are two existing dialysis facilities in New Hanover County:

- SEDC-Wilmington; (also a Total Renal Care of North Carolina, LLC facility); and
- Cape Fear Dialysis Center.

The dialysis facilities are located in different areas of Wilmington.

In Section V.7, page 28, the applicant states that all qualified Nephrologists can admit their patients to Cape Fear Dialysis Center and that the determining factor with respect to which facility is selected by the patient is which provider “*gives them the highest quality service and best meets their needs.*”

In Section V.7, pages 28-29, 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

“The effect upon competition is unknown. ... The only non Total Renal Care of North Carolina facility that operates in a contiguous county to New Hanover County is the Fresenius facility in Supply in Brunswick County. The FMC facility is located 35 miles from Cape Fear Dialysis Center. The expansion of the Cape Fear Dialysis Center that has a 117% utilization rate and is applying to add four dialysis stations is not in competition with the FMC Supply facility.” [See pages 28]

See also Sections II, III, V, VI and VII. The information the applicant provides in those sections is reasonable and credible and adequately demonstrates that adding four dialysis

stations to the existing facility will have a positive impact on cost-effectiveness, quality and access to the proposed service because:

- The applicant adequately demonstrates the need, based on “Facility Need”, to add four dialysis stations for a total of 32 certified dialysis stations following completion of this project. The applicant also demonstrates that the proposed project is a cost-effective alternative to meet the need to provide additional access to Cape Fear Dialysis Center patients.
- The applicant adequately documents that it will provide quality care and services. The information regarding staffing provided in Section VII is reasonable and credible and demonstrates adequate staffing for the provision of quality care services in accordance with 42 C.F.R., Section 494 (formerly 405.2100). The information regarding ancillary and support services and coordination of services with the existing health care system in Sections V.1, V.2, V.4, V.5 pages 25-28 and referenced in exhibits is reasonable and credible and demonstrates the provision of quality care services.

On page 17, the applicant describes the systems and methods in place to insure quality care at Cape Fear Dialysis Center.

- The applicant has and will continue to provide adequate access to medically underserved populations. In Section VI.1, page 30, the applicant states:

“Cape Fear Dialysis Center does not require payment upon admission to its services; therefore, services are available to all patients including, low-income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons. Cape Fear Dialysis Center works with patients who need transportation, when necessary.”

The applicant states on page 30 that it has served and will continue to serve all of the people in its service area without qualifications including continuing to serve without regard to race, age, ethnicity, handicap, gender, or socioeconomic groups.

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.

The applicant has been providing dialysis services at Cape Fear Dialysis Center since December 31, 2011. According to the files in the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, Cape Fear Dialysis has operated in compliance with all Medicare Conditions of Participation and there were no incidents resulting in a determination of immediate jeopardy during the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

- (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 promulgated in 10A NCAC 14C .2200 are applicable to this review. The proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services in 10A NCAC 14C .2200. The specific findings are discussed below.

10A NCAC 14C .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 10, and Exhibit 7, the applicant provides the utilization rate as reported in the January 2013 SDR which was 117.86% or 4.71 patients per station [$132/28 = 4.71$ patients per station; $4.71/4 = 1.1775$ or 117.86%].

(2) *Mortality rates;*

-C- In Section IV.2, page 23, the applicant state the mortality rate at Cape Fear Dialysis Center was 14.1% during 2012.

- (3) *The number of patients that are home trained and the number of patients on home dialysis;*
- C- In Section IV.3, page 23, the applicant states that Cape Fear Dialysis Center is not certified to provide home training services. SEDC-Wilmington provides the home training services for patients living in New Hanover County and surrounding counties.
- (4) *The number of transplants performed or referred;*
- C- In Section IV.4, page 24, the applicant states Cape Fear Dialysis Center referred 20 patients for transplant evaluation in 2012. One patient received a transplant in 2012.
- (5) *The number of patients currently on the transplant waiting list;*
- C- In Section IV.5, page 24, the applicant states that Cape Fear Dialysis Center has 9 patients on the transplant waiting list.
- (6) *Hospital admission rates, by admission diagnosis, i.e., dialysis versus non-dialysis related;*
- C- In Section IV.6, page 24, the applicant documents that Cape Fear Dialysis Center had 243 hospital admissions in 2012. Fifteen were dialysis related and 228 were 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 24, the applicant states that within the last year no patients were treated with infectious disease or converted to infectious status. In addition, Cape Fear Dialysis Center states that as of December 31, 2012, there were no patients with hepatitis B and three patients with AIDS.

- (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- Cape Fear Dialysis Center is an existing 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- Cape Fear Dialysis Center is an existing facility.

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

-NA- Cape Fear Dialysis Center is an existing facility.

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

-C- See Exhibit 8 for a copy of Cape Fear Dialysis Center's manual which has policies and procedures for testing the generator that provides back-up electrical service 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- Cape Fear Dialysis Center is an existing 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 regulations.*
- C- In Section XI.6(g), pages 54-55, the applicant documents 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 regulations
- (7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C- See Section III.7, page 20, for the methodology and assumptions the applicant uses to project patient origin as presented in the following table.

County	Operating Year 1 2014		Operating Year 2 2015		County patients as a % of TOTAL	
	Home	In-Center	Home	In-Center	Year 1	Year 2
Brunswick	0	121	0	127	85.2%	85.8%
Pender	0	13	0	13	9.2%	8.8%
Brunswick	0	5	0	5	3.5%	3.4%
Columbus	0	3	0	3	2.1%	2.0%
Total	0	142	0	148	100.0%	100.0%

Also see discussion in Criterion (3) 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- Cape Fear Dialysis Center is an existing 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.1, page 12, the applicant states:

“Total Renal Care of North Carolina, LLC d/b/a Cape Fear Dialysis Center will admit and provide dialysis services to patients who have no insurance or other source of payment if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”

10A NCAC 14C .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 stations 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- Cape Fear Dialysis Center does not propose to establish a new End Stage Renal Disease 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 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- Cape Fear Dialysis Center projects utilization of 4.44 patients per station per week as of the end of the first operating year. As of 6/30/12, the utilization rate was 4.71 patients per station or 117.86% of capacity. Assumptions are provided in Section II.1, pages 12-14, and Section III.7, pages 20-21. See discussion in Criterion (3) regarding historical and projected utilization which is incorporated hereby as if set forth fully herein.

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

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected in Section II.1, pages 12-14, and Section III.7, pages 20-21, Additionally, see discussion in Criterion (3) which is incorporated hereby as if set forth fully herein.

10A NCAC 14C .2204 SCOPE OF SERVICES

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

(1) *diagnostic and evaluation services;*

-C- In Section V.1, page 25, the applicant documents that diagnostic and evaluation services will be provided by New Hanover Regional Medical Center.

(2) *maintenance dialysis;*

-C- In Section V.1, page 25, the applicant documents that Cape Fear Dialysis Center Southport will provide maintenance dialysis at its own facility.

(3) *accessible self-care training;*

-C- In Section II., page 25, the applicant states self-care training is provided by SEDC-Wilmington.

(4) *accessible follow-up program for support of patients dialyzing at home;*

-C- In Section II.2, page 25, the applicant states that a follow-up program for support of patients dialyzing at home is provided by SEDC-Wilmington.

(5) *x-ray services;*

-C- In Section V.1, page 25, the applicant documents that x-ray services will be provided by New Hanover Regional Medical Center.

(6) *laboratory services;*

-C- In Section V.2, page 25, the applicant states that Dialysis Laboratories will provide laboratory services for Cape Fear Dialysis Center patients.

(7) *blood bank services;*

-C- In Section V.1, page 25, the applicant states that blood bank services will be provided by New Hanover Regional Medical Center.

(8) *emergency care;*

-C- In Section V.1, page 25, the applicant states that emergency care services will be provided by New Hanover Regional Medical Center.

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

-C- In Section V.1, page 25, the applicant documents that blood bank services will be provided by New Hanover Regional Medical Center.

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

-C- In Section V.1, page 25, the applicant documents that vascular surgery services will be provided by New Hanover Regional Medical Center.

(11) *transplantation services;*

-C- In Section V.1, page 25, the applicant states that transplantation services will be provided by “*Carolinas Medical Center*”. In Exhibit 12 the applicant provided a copy of a “*Kidney Transplant Affiliation Agreement*” with Duke University Hospital.

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

-C- In Section V.1, page 25, the applicant documents that vocational rehabilitation counseling and services will be provided by the N.C. Department of Vocational Rehabilitation.

(13) *transportation.*

-C- In Section V.1, page 25, the applicant documents that transportation services will be provided by “*Cape Fear Public Transportation Authority*”.

10A NCAC 14C .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., page 34, the applicant states that Cape Fear Dialysis Center will comply with all staffing requirements as stated in 42 C.F.R. Section 494 (formerly 405.2100). See Criterion (7) for further discussion on staffing which is incorporated hereby as if set forth fully herein.

(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 II., page 17, the applicant states DaVita's "*Quality Management Program includes ... Staff and Patient education program-ensuring continuous updates and training to ensure high quality patient care.*" Exhibit 18 contains a copy of the training program outlines and programs for new patient care provider teammates. Exhibit 24 contains a copy of the *Health and Safety Policy and Procedure Manual*. Exhibit 25 contains a copy of the *Cape Fear Dialysis Center Annual In-Service Calendar*.