

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 29, 2015

Findings Date: July 29, 2015

Project Analyst: Mike McKillip

Team Leader: Fatimah Wilson

Project ID #: O-11022-15

Facility: Cape Fear Dialysis Center

FID #: 342685

County: New Hanover

Applicant: Total Renal Care of North Carolina, LLC

Project: Add two dialysis stations for a total of 32 certified stations upon completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Total Renal Care of North Carolina, LLC d/b/a Cape Fear Dialysis Center [CFDC] proposes to add two dialysis stations for a total of 32 certified dialysis stations upon completion of the project and Project I.D. # O-10324-14 (relocate two stations to New Hanover Dialysis).

Need Determination

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The 2015 State Medical Facilities Plan (2015 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2015 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of one dialysis station in New Hanover County; therefore, based on the county need methodology, there is no need for additional stations in New Hanover County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology, because the utilization rate reported for CFDC in the January 2015 SDR is 3.59 patients per station. This utilization rate was calculated based on 115 in-center dialysis patients and 32 certified dialysis stations as of June 30, 2014 (115 patients / 32 stations = 3.59 patients per station). Application of the facility need methodology indicates nine additional stations are needed for this facility, as illustrated in the following table.

APRIL 1 REVIEW-JANUARY SDR

Required SDR Utilization		80%
Center Utilization Rate as of 6/30/14		88.16%
Certified Stations		32
Pending Stations		0
Total Existing and Pending Stations		32
In-Center Patients as of 6/30/14 (SDR2)		115
In-Center Patients as of 12/31/13 (SDR1)		101
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	14
	Multiply the difference by 2 for the projected net in-center change	28
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/13	0.2772
(ii)	Divide the result of step (i) by 12	0.0231
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/14 until 12/31/14)	0.1386
(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	130.9406
(v)	Divide the result of step (iv) by 3.2 patients per station	40.9189
	and subtract the number of certified and pending stations as recorded in SDR2 to determine the number of stations needed	9

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

Policies

Policy GEN-3: BASIC PRINCIPLES, page 38 of the 2015 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 as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section I.13, pages 6-10, Section II.3, pages 19-20, Section XI.6(g), pages 57-58, 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 VI, pages 32-36, 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 III.9, page 25, and Section V.7, page 31. 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 January 2015 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, Cape Fear Dialysis Center (CFDC), proposes to add two dialysis stations to its existing facility for a total of 32 certified dialysis stations upon completion of this project and Project I.D. # O-10324-14 (relocate two stations to New Hanover Dialysis).

Population to be Served

On page 361, the 2015 SMFP defines the service area for dialysis stations as the county where they are located. Thus, in this application, the service area is New Hanover County. Dialysis facilities may serve residents of counties not included in their service area.

In Section IV.1, page 26, the applicant provides a table showing the patient origin of the 116 in-center patients served at CFDC as of December 31, 2014, which is summarized below:

County of Residence	In-Center Patients
New Hanover	98
Pender	6
Brunswick	8
Columbus	1
Bladen	1
Other States	2
Total	116

In Section III.7, page 23, the applicant provides the projected patient origin for CFDC for in-center patients for the first two years of operation following completion of the project as follows:

Projected Patient Origin

County	Year 1 CY2016	Year 2 CY2017	County Patients as a Percent of Total	
	In-center Patients	In-center Patients	Year 1	Year 2
New Hanover	93	99	84.5%	85.3%
Pender	9	9	8.2%	7.8%
Brunswick	8	8	7.3%	6.9%
Total	110	116	100.0%	100.0%

The applicant adequately identified the population CFDC proposes to serve.

Analysis of Need

In Section III.2, page 21, the applicant states the application is filed pursuant to the facility need methodology in the 2015 SMFP utilizing data from the January 2015 SDR, and it proposes to add two dialysis stations to CFDC for a total of 32 stations at that facility. The applicant used the following assumptions:

1. The project is scheduled for completion and certification of stations on December 31, 2015, projecting calendar year 2016 as Operating Year 1, and calendar year 2017 as Operating Year 2.
2. On June 30, 2014, CFDC was providing dialysis treatment for 115 in-center patients. Of the 115 patients, 94 were residents of New Hanover County, 9 patients were residents of Pender County, 8 patients were residents of Brunswick County, and 4 patients were residents of Columbus County.
3. CFDC assumes the New Hanover County ESRD in-center patient population utilizing the facility will increase at 5.5% per year, which is equal to the New Hanover County Five Year Average Annual Change Rate as reported in the January 2015 SDR. On page 23, the applicant states,

“Total Renal Care of North Carolina, LLC submitted a CON application on August 15, 2014 to transfer two stations from the Cape Fear Dialysis Center to New Hanover Dialysis (Project ID# O-10324-14), a new facility projected to be certified by January 1, 2016. That CON was approved, which will leave the Cape Fear Dialysis Center with 30 dialysis stations. ... This application is for a two station expansion of the Cape Fear Dialysis Center, increasing the station capacity from 30 stations to 32 stations (32

current stations – 2 stations transferring to New Hanover Dialysis + 2 stations in this CON application = 32 stations).

The January 2015 SDR indicates that the five year average annual change rate for New Hanover County was 5.5%. It is reasonable to assume a 5.5% growth rate for the patients living in New Hanover County, since that is the five-year average change rate for the county. The growth is based on the 94 in-center patients living in New Hanover County.”

Projected Utilization

Application of the applicant’s assumptions and methodology is illustrated in the following table.

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	In-Center
CFDC begins with the facility census of New Hanover County in-center residents as of June 30, 2014.	94 patients
The census of New Hanover County patients is increased by 2.75% for six months to December 31, 2014.	$(94 \times 0.0275) + 94 = 96.585$
The census of New Hanover County patients is increased by 5.5% for one year to December 31, 2015, which is the projected completion date for the project.	$96.585 \times 1.055 = 101.897175$
CFDC subtracts 12 patients residing in New Hanover that are projected transfer to New Hanover Dialysis (Project I.D. #O-10324-14) to project the total beginning census of New Hanover patients at CFDC.	$101 - 12 = 89$
CFDC adds 9 Pender County patients and 8 Brunswick County patients for a total beginning census at CFDC. The four Columbus County patients are projected to transfer to Leland Dialysis (Project I.D. #O-10305-14).	$89 + 9 + 8 = 106$
The census of New Hanover County patients is again increased by 5.5% for one year to December 31, 2016.	$89 \times 1.055 = 93.895$
CFDC adds 9 Pender County patients and 8 Brunswick County patient for a total ending census for Operating Year 1.	$93 + 9 + 8 = 110$
The census of New Hanover County patients is again increased by 5.5% for one year to December 31, 2017.	$93.895 \times 1.055 = 99.059225$
CFDC adds 9 Pender County patients and 8 Brunswick County patients for a total ending census for Operating Year 2.	$99 + 9 + 8 = 116$

The applicant projects to serve 110 in-center patients or 3.4 patients per station ($110/32 = 3.4$) by the end of Operating Year 1 and 116 in-center patients or 3.6 patients per station ($116/32 = 3.6$) by the end of Operating Year 2 for the 32-station facility. This 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). Both the July 2014 and the January 2015 SDR indicate that CFDC operated at a utilization rate of 90 percent during the time period. In this application, the applicant assumes a

projected annual rate of growth of 5.5 percent for the New Hanover County in-center patient census at CFDC, which is consistent with the New Hanover County Five Year Average Annual Change Rate. Projected utilization is based on reasonable and supported assumptions regarding continued growth.

Access

In Section VI.1(a), page 32, the applicant states that CFDC makes dialysis services available to all residents of the service area without restrictions or qualifications, including low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons. The applicant projects 89% of its in-center patients will be covered by Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for two additional stations at CFDC, and demonstrates the extent to which all residents of the area, including 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 25, the applicant discusses the alternatives considered prior to the submission of this application. The applicant states the only alternative it considered was to maintain the status quo, but rejected this alternative because it would not address the growing demand for dialysis services at CFDC.

The applicant adequately demonstrates the need for two additional stations based on the facility's projected utilization. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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

In summary, the applicant adequately demonstrates that the 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 and operate no more than two additional dialysis stations for a total of no more than 32 certified stations upon completion of this project and Project I.D. #O-10324-14, which shall include any isolation or home hemodialysis stations.**
 3. **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 Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII.1, page 41, the applicant states no capital expense will be incurred for the proposed project. In Section IX, page 46, the applicant states there will be no start-up or initial operating expenses associated with the proposed project.

In Section X.1, page 47, the applicant projects the following charge per treatment for each payment source:

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Payer	In-Center Charge
Commercial	\$1,275.00
Medicare	\$239.43
Medicaid	\$143.00
VA	\$193.00
Medicare/Medicaid	\$239.43
Medicare/Commercial	\$239.43

In Section X.4, page 51, the applicant reported projected revenues and expenses as follows:

Cape Fear Dialysis Center		
	Operating Year 1 CY2016	Operating Year 2 CY2017
Total Net Revenue	\$4,810,862	\$5,032,811
Total Operating Costs	\$4,050,665	\$4,212,019
Net Profit	\$760,198	\$820,792

The applicant projects that revenue will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro forma financial statements, including the number of projected treatments, are reasonable. See Section X of the application for the applicant's assumptions. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

In summary, the applicant also adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of revenues (charges) and operating costs. Therefore, the application is conforming to this criterion.

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

C

On page 361, the 2015 SMFP defines the service area for dialysis stations as the county where they are located. Thus, in this application, the service area is New Hanover County. Dialysis facilities may serve residents of counties not included in their service area.

CFDC proposes to add two in-center dialysis stations for a total of 32 dialysis stations upon project completion. CFDC was serving 115 patients weekly on 32 stations, which is 3.6 patients per station or 88% of capacity, as of June 30, 2014. 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 on pages 23-24 of the

application. The growth projections are based on a projected 5.5% average annual growth rate in the number of New Hanover County dialysis patients at the CFDC facility. At the end of Operating Year Two, CFDC projects the utilization will be 3.6 in-center patients per station (116 patients / 32 dialysis stations = 3.6), which is 90% of capacity.

The applicant operates two dialysis centers in New Hanover County, and has been approved to develop a third. There are no other providers of dialysis services in New Hanover County. See the table below.

New Hanover County Dialysis Facilities

Dialysis Facility	Certified Stations 6/30/14	% Utilization	Patients Per Station
Cape Fear Dialysis Center	32	89.84%	3.59
Southeastern Dialysis-Wilmington	29	121.55%	4.86
New Hanover Dialysis*	0	NA	NA

Source: January 2015 SDR, Table A.

*New Hanover Dialysis is a new 12-station dialysis facility that was approved on November 4, 2014 (Project I.D. # O-10324-14) and is currently under development. Ten stations will be relocated from Southeastern Dialysis Center-Wilmington and two stations will be relocated from Cape Fear Dialysis Center. Thus, the development of New Hanover Dialysis does not result in an increase in the total number of dialysis stations.

As shown in the table above, both of the two operational New Hanover County dialysis facilities is operating above 80% utilization (3.2 patients per station).

The applicant adequately demonstrates the need to develop two 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 shows current and projected staffing for CFDC, as provided by the applicant in Section VII.1, page 37:

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Cape Fear Dialysis Center			
Position	Current FTEs	# of FTE Positions to be Added	Total FTE Positions
RN	5.00	0.00	5.00
PCT	12.00	0.00	12.00
Bio-Med Technician	0.50	0.00	0.50
Medical Director	Contracted Position		
Admin.	1.00	0.00	1.00
Dietician	1.00	0.00	1.00
Social Worker	1.00	0.00	1.00
Unit Secretary	2.00	0.00	2.00
Reuse	1.00	0.00	1.00
Total	23.50	0.00	23.50

As shown in the above table, the applicant proposes to employ a total of 23.5 full-time equivalent (FTE) positions to staff CFDC upon completion of the proposed project. In Section V.4, page 30, the applicant states that Douglas Hamerski, M.D., a board-certified nephrologist, will serve as medical director of the facility. Exhibit 13 contains a copy of a letter from Dr. Hamerski expressing his support for the project and his intention to continue as the medical director for CFDC.

In Section VII.10, page 39, the applicant provides the following table showing the projected number of direct care staff for each shift offered at CFDC after the addition of the two dialysis stations.

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

The applicant has documented 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 28, the applicant includes a list of providers of the necessary ancillary and support services. Exhibit 13 contains a letter from the medical director of the facility expressing his support for the proposed project. 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
 - (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(b), page 32, the applicant reports that 89% of the in-center patients who received treatments at CFDC had some or all of their services paid for by Medicare or Medicaid in the past year. The table below shows the historical payment source of the facility:

Payment Source	In-Center
Commercial Insurance	7.63%
Medicare	16.95%
Medicaid	8.47%
VA	3.39%
Medicare/Medicaid	28.81%
Medicare/Commercial Insurance	34.75%
Total	100.00%

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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 New Hanover 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 *	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
New Hanover County	13%	5.7%	20.4%
Statewide	17%	6.7%	19.7%

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

Although the majority of Medicaid eligibles are children under the age of 21, they represent a very small percentage of those who utilize the services offered by dialysis facilities. In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).¹

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, as well as data sorted by age, race or gender. But it does not include information on the number of elderly, handicapped, minorities or women utilizing health services.

However, the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report* provides prevalence data on North Carolina dialysis patients by age, race and gender on page 59, summarized as follows:

¹<http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

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

Source: Southeastern Kidney Council Network 6 Inc. 2014 Annual Report.²

The applicant demonstrates that 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;

²<http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

C

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. On page 34, 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 36, the applicant states there have been no civil rights access complaints filed within the last five years. Therefore, 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 33, the applicant provides the projected payment source for the proposed services at CFDC, which is shown below:

Payment Source	In-Center
Commercial Insurance	7.63%
Medicare	16.95%
Medicaid	8.47%
VA	3.39%
Medicare/Medicaid	28.81%
Medicare/Commercial Insurance	34.75%
Total	100.00%

The applicant projects no change from the current payment source for in-center dialysis services, which is 89% Medicare and Medicaid. The applicant demonstrates that medically underserved populations would 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 35, the applicant states,

“Patients with End Stage Renal Disease have access to dialysis services upon referral to a Nephrologist with privileges at the Cape Fear Dialysis Center. These referrals most commonly come from primary care physicians or specialty physicians in New Hanover County or transfer referrals from other Nephrologists outside the immediate area.”

The applicant adequately demonstrates that CFDC will provide a range of means by which a person can access the services. Therefore, the application is conforming to this criterion.

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

C

In Section V.3, page 29 the applicant states, *“The Cape Fear Dialysis Center has an established Student Training Agreement with Cape Fear Community College.”* Exhibit 12 contains a copy of a *“Student Training Agreement”* between the applicant and James Sprunt Community College in Kearsville (Duplin County). The information provided in Section V.3 is reasonable and credible and supports a finding of conformity to this criterion.

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

C

On page 361, the 2015 SMFP defines the service area for dialysis stations as the county where they are located. Thus, in this application, the service area is New Hanover County. Dialysis facilities may serve residents of counties not included in their service area.

The applicant operates two dialysis centers in New Hanover County, and has been approved to develop a third. There are no other providers of dialysis services in New Hanover County.

New Hanover County Dialysis Facilities

Dialysis Facility	Certified Stations 6/30/14	% Utilization	Patients Per Station
Cape Fear Dialysis Center	32	89.84%	3.59
Southeastern Dialysis-Wilmington	29	121.55%	4.86
New Hanover Dialysis*	0	NA	NA

Source: January 2015 SDR, Table A.

*New Hanover Dialysis is a new 12-station dialysis facility that was approved on November 4, 2014 (Project I.D. # O-10324-14) and is currently under development. Ten stations will be relocated from Southeastern Dialysis Center-Wilmington and two stations will be relocated from Cape Fear Dialysis Center. Thus, the development of New Hanover Dialysis does not result in an increase in the total number of dialysis stations.

As shown in the table above, both of the two operational New Hanover County dialysis facilities is operating above 80% utilization (3.2 patients per station).

The applicant adequately demonstrates the need to add two dialysis stations to Cape Fear Dialysis Center and that it would not result in an unnecessary duplication. The discussions regarding analysis of need and unnecessary duplication found in Criteria (3) and (6), respectively, are incorporated herein by reference.

In Section V.7, page 31, the applicant discusses how any enhanced competition in the service area will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states,

“The proposed expansion of the facility is an effort to provide dialysis services to this community and is not intended to be a competitive venture. The bottom line is that patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs. The Cape Fear Dialysis Center provides access to all qualified Nephrologists to admit his or her patients.”

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 dialysis services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need for the proposed project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates 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 it will continue to provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (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

In Section I.13 and referenced Exhibits, the applicant identifies the kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the

Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

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

.2202(a)(1) Utilization rates;

-C- See Section IV.1, page 26, which indicates the facility had 116 in-center patients and a 91% utilization rate as of December 31, 2014.

.2202(a)(2) Mortality rates;

-C- In Section IV.2, page 26, the applicant reports 2012, 2013 and 2014 facility mortality rates of 14.0%, 14.5% and 11.1%, respectively.

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

-NA- In Section IV.3, page 26, the applicant states that CFDC does not currently operate a home dialysis program.

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

-C- In Section IV.4, page 27 the applicant states CFDC referred 32 patients for transplant evaluation in 2014, and had one patient receive a transplant in 2014.

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

-C- In Section IV.5, page 27, the applicant states that CFDC has 19 patients on the transplant waiting list.

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

-C- See Section IV.6, page 27, the applicant reports a total of 218 hospital admissions in 2014; 187 were non-dialysis related and 31 were dialysis-related.

.2202(a)(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.*

-C- In Section IV.7, page 27, the applicant reports that in 2014 there were three patients with an infectious disease, and no patients converted to infectious status in 2014.

(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:*

.2202(b)(1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100*

-NA- CFDC is an existing facility.

.2202(b)(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*

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

-NA- CFDC is an existing facility.

- .2202(b)(3) For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- NA- CFDC is an existing facility.
- .2202(b)(4) Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C- Exhibit 8 contains a copy of written policies and procedures for back up for electrical service in the event of a power outage.
- .2202(b)(5) For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*
- NA- CFDC is an existing facility.
- .2202(b)(6) Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*
- C- See Section XI.6(g), pages 57-58 and referenced Exhibits.
- .2202(b)(7) The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C- In Section III.7, page 23, CFDC provides projected patient origin based on historical experience for the first two years of operation following completion of the project.
- .2202(b)(8) For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
- NA- CFDC is an existing facility.
- .2202(b)(9) A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement for such services.*

- C- In Section II.1, page 13, the applicant states, “*Total Renal Care of North Carolina 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.*”

10 NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- CFDC is an existing facility.

.2203(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*

-C- In Section II.1, page 15, the applicant projects to serve 110 in-center patients by the end of Operating Year 1, which is 3.4 patients per station ($110 / 32 = 3.4$). The discussion regarding utilization assumptions found in Criterion (3) is incorporated herein by reference.

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

-C- In Section II.1, pages 14-15 and Section III.7, pages 23-24, the applicant provides the assumptions and methodology used to project utilization of the proposed facility. The discussion regarding utilization assumptions found in Criterion (3) is incorporated herein by reference.

10 NCAC 14C .2204 SCOPE OF SERVICES

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

.2204(1) *Diagnostic and evaluation services;*

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- C- These services are provided by New Hanover Regional Medical Center. See Section V.1, page 28.
- .2204(2) *Maintenance dialysis;*
- C- Provided at CFDC. See Section V.1, page 28.
- .2204(3) *Accessible self-care training;*
- C- Provided by referral to SEDC-Wilmington currently. See Section V.2(d), page 29.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
- C- Provided by referral to SEDC-Wilmington currently. See Section V.2(d), page 29.
- .2204(5) *X-ray services;*
- C- These services are provided by New Hanover Regional Medical Center. See Section V.1, page 28.
- .2204(6) *Laboratory services;*
- C- Provided by Dialysis Laboratories, Inc. See Section V.1, page 28.
- .2204(7) *Blood bank services;*
- C- Provided by New Hanover Regional Medical Center. See Section V.1, page 28.
- .2204(8) *Emergency care;*
- C- Provided by New Hanover Regional Medical Center. See Section V.1, page 28.
- .2204(9) *Acute dialysis in an acute care setting;*
- C- Provided by New Hanover Regional Medical Center. See Section V.1, page 28.
- .2204(10) *Vascular surgery for dialysis treatment patients*
- C- Provided by New Hanover Regional Medical Center. See Section V.1, page 28.
- .2204(11) *Transplantation services;*

-C- Provided by Duke University Medical Center and East Carolina University Medical Center. See Section V.1, page 28.

.2204(12) *Vocational rehabilitation counseling and services; and,*

-C- Provided by referral to Division of Vocational Rehabilitation. See Section V.1, page 28.

.2204(13) *Transportation*

-C- Provided by Cape Fear Public Transportation Authority. See Section V.1, page 28.

10 NCAC 14C .2205 STAFFING AND STAFF TRAINING

.2205(a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R. Section 405.2100.*

-C- In Section VII.1, page 37, the applicant provides the proposed staffing. In Section VII.2, pages 37-38, the applicant states the proposed facility will comply with all staffing requirements set forth in 42 C.F.R. Section 405.2100. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

.2205(b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*

-C- See Section VII.5, page 39, and Exhibits 17 and 24.