

ATTACHMENT – REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA – Conditional

NC – Nonconforming

NA = Not Applicable

Decision Date: June 15, 2015

Findings Date: June 15, 2015

Project Analyst: Tanya S. Rupp

Assistant Chief: Martha Frisone

Project ID #: N-11021-15

Facility: Southeastern Dialysis Center - Elizabethtown

FID #: 955448

County: Bladen

Applicant: Total Renal Care of North Carolina, LLC

Project: Add two dialysis stations for a total of 26 stations upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center – Elizabethtown (SEDC - Elizabethtown) is currently certified for 24 in-center dialysis stations. In this application, the applicant proposes to add two stations for a total of 26 stations upon project completion.

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 no need for an additional dialysis facility or for any additional dialysis stations in Bladen County. However, according to the facility need methodology, an applicant for dialysis stations is eligible to apply for additional dialysis stations if the utilization rate for the dialysis facility, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. In this

application, SEDC - Elizabethtown is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate is 3.25 patients per station or 81.25%. This utilization rate was calculated based on 78 in-center dialysis patients and 24 certified dialysis stations as of June 30, 2014 (78 patients / 24 stations = 3.25 patients per station). See the following table, from Section III.1, page 23 of the application:

APRIL 1 REVIEW-JANUARY SDR

Required SDR Utilization		80%
Center Utilization Rate as of 6/30/14		81.25%
Certified Stations		24
Pending Stations		
Total Existing and Pending Stations		24
In-Center Patients as of 6/30/14 (SDR2)		78
In-Center Patients as of 12/31/13 (SDR1)		73
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	5
	Multiply the difference by 2 for the projected net in-center change	10
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/13	0.1370
(ii)	Divide the result of step (i) by 12	0.0114
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/14 until 12/31/14)	0.0685
(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	83.3425
(v)	Divide the result of step (iv) by 3.2 patients per station	26.0445
	and subtract the number of certified and pending stations as recorded in SDR2 to determine the number of stations needed	2

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.”* As shown in the table above, based on the facility need methodology for dialysis stations, SEDC - Elizabethtown has a need for two additional stations. The applicant proposes to add two new stations and, therefore, the application is consistent with the facility need determination for dialysis stations.

There is one policy in the 2015 SMFP that is applicable to this review: Policy GEN-3. Policy GEN-3, on page 38 of the 2015 SMFP, states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing

healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Promote Safety and Quality - The applicant describes how it believes the proposed project would promote safety and quality in Section II, pages 19 - 20, Section XI.6(g) pages 58 - 59, 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 to dialysis services in Section VI, pages 32 - 35, 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, pages 24 - 25 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the need identified in the 2015 SMFP. Therefore, the application is consistent with Policy GEN-3.

Conclusion

In summary, the applicant adequately demonstrates that its proposal to add two dialysis stations to its existing facility 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

SEDC - Elizabethtown proposes to add two dialysis stations for a total of 26 stations upon project completion. In addition to providing in-center dialysis services, the applicant also

provides home hemodialysis support and training at SEDC – Elizabethtown, and will continue to provide those services following completion of this project. The January 2015 SDR indicates that, as of June 30, 2014, SEDC - Elizabethtown was certified for 24 in-center dialysis stations and was dialyzing 78 in-center patients.

Population to be Served

In Section III.7, page 23, the applicant identifies the patient population to be served during the first two years of operation following the addition of the two stations, as illustrated in the following table:

COUNTY	OPERATING YEAR 1 (CY 2016)		OPERATING YEAR 2 (CY 2017)		PATIENTS AS % OF TOTAL	
	IN-CTR. PTS.	HOME PTS.	IN-CTR. PTS.	HOME PTS.	OPERATING YEAR 1	OPERATING YEAR 2
Bladen	76	9	79	10	81.7%	82.4%
Sampson	6	0	6	0	5.8%	5.6%
Columbus	3	10	3	10	12.5%	12.0%
Total	85	19	88	20	100.0%	100.0%

The applicant adequately identifies the population it proposes to serve.

Analysis of Need

In-Center Patients

In Section III.7, pages 23 - 24, the applicant describes the assumptions and methodology used to project utilization through the first two project years. The applicant states:

“The July 2014 Semiannual Dialysis Report indicated that SEDC-Elizabethtown had 73 in-center patients as of December 31, 2013, an increase of 5 in-center patients or a growth rate of 6.8% in a six-month period or an annualized growth rate of 13.6%.

As of June 30, 2014, 69 of the patients lived in Bladen County, 6 of the patients lived in Sampson County and 3 patients lived in Columbus County. This application is for a two-station expansion of SEDC-Elizabethtown, increasing the station capacity from 24 stations to 26 stations.

Based on the calculations below, SEDC-Elizabethtown is projected to have at least 85 in-center patients by the end of operating year 1 for a utilization rate of 81.7% or 3.27 patients per station and at least 88 in-center patients by the end of operating year 2 for a utilization rate of 84.6% or 3.38 patients per station. This information is based on the calculations below.

The period of the [sic] growth begins with June 30, 2014 forward to December

31, 2017. The following are the in-center patient projections using a conservative growth rate of 4% or less than one third of the calculated annual growth rate of 13.6% for SEDC-Elizabethtown:

*June 30, 2014 – December 31, 2014 – 69 patients X 1.02 = 70.38
January 1, 2015 - December 31, 2015 – 70.38 patients X 1.04 = 73.1952
January 1, 2016 – December 31, 2016 – 73.1952 X 1.04 = 76.123008
January 1, 2017 – December 31, 2017 – 76.123008 X 1.04 = 79.16792852*

Operating Year One is projected to begin January 1, 2016 and end on December 31, 2016.

Operating Year Two is projected to begin January 1, 2017 and end on December 31, 2017.

No growth was calculated for the patients living in Sampson and Columbus Counties.”

The applicant projects to serve 85 in-center patients on 26 dialysis stations at the end of Operating Year One, which is a utilization rate of 82% [$85 / 26 = 3.269$; $3.269 / 4 = 0.8173$]. In addition, the applicant projects to serve 88 in-center patients on 26 dialysis stations at the end of Operating Year Two, which is a utilization rate of 85% [$88 / 26 = 3.384$; $3.384 / 4 = 0.8462$].

With regard to in-center patients, on page 24, the applicant states that it assumes a 4% growth rate, which is “*less than one third of the calculated annual growth rate of 13.6% for SEDC – Elizabethtown.*” The Five Year Average Annual Change Rate (AACR) for Bladen County published in the July 2015 SDR is negative 1%. The analyst reviewed SEDC-Elizabethtown’s historical utilization as published in the last four SDRs (January 2013, July 2013, January 2014 and July 2014). The data in the SDRs shows the number of in-center patients increased 22% between June 30, 2012 and June 30, 2014. Therefore, the applicant’s use of a 4% growth rate is reasonable based on the historical growth rate of the facility.

Projected utilization of the 26 in-center dialysis stations at SEDC – Elizabethtown is based on reasonable and adequately supported assumptions.

Home Trained Patients

In Section III.7, page 24, the applicant provides the assumptions and methodology used to project the number of home trained patients projected to be served at SEDC – Elizabethtown. As of June 30, 2014, SEDC – Elizabethtown had 17 home trained patients. Six lived in Sampson County and three lived in Columbus County. The applicant projects the number of home trained patients during the first two Operating Years, as follows:

“It is reasonable to assume that the SEDC-Elizabethtown home-training program will grow at a rate of at least one patient during the current operating year and operating years one and two. SEDC - Elizabethtown had a total of 17 home-trained patients as of June 30, 2014. It is projected that the census will grow to 18 home-trained patients in 2015, 19 home-trained patients in 2016 and 20 home-trained patients in 2017.

...

Current Year begins with 17 patients and ends with 18 patients for an average of 17.5 patients.

OY1 begins with 18 patients and ends with 19 patients for an average of 18.5 patients.

OY2 begins with 19 patients and ends with 20 patients for an average of 19.5 patients.

The number of patients calculated above was rounded down to the nearest whole number.”

In the Data Collection Forms for End-Stage Renal Disease Facilities submitted to the Agency in December 2013, SEDC-Elizabethtown reported 16 patients who were home-trained, which increased to 17 patients in June 2014 as reported by the applicant. Projected utilization is based on reasonable and adequately supported assumptions.

The applicant adequately demonstrates the need the population proposed to be served has for the addition of two dialysis stations at SEDC – Elizabethtown.

Access to Services

In Section VI, page 32, the applicant states,

“SEDC – Elizabethtown, 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.”

In Section VI.1(c), page 33, the applicant projects that 83.13% of its in-center patients will be covered by Medicare or Medicaid. With regard to its home trained patients, the applicant projects that 87.5% will be covered by Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services.

Conclusion

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

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

NA

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

CA

In Section III.9, pages 24 - 25, the applicant describes the alternatives it considered prior to submitting this application. The applicant states:

“There were only two alternatives of meeting the needs of the proposed project considered. The first was to do nothing. This alternative was dismissed since the facility is experiencing growth. The second was to apply for the two-station expansion. We chose the second alternative in order to help meet the growing demand for dialysis services at the SEDC - Elizabethtown.”

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

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

- 1. Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center - Elizabethtown shall materially comply with all representations made in the certificate of need application.**
- 2. Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center - Elizabethtown shall add no more than two dialysis stations for a total of no more**

- than 26 stations upon project completion, which shall include any home hemodialysis training or isolation stations.**
- 3. Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center - Elizabethtown shall install plumbing and electrical wiring through the walls for no more than two additional dialysis stations.**
 - 4. Prior to the issuance of a certificate of need, Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center – Elizabethtown shall demonstrate that transportation services will be available.**
 - 5. Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center - Elizabethtown 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 42, the applicant states that the total capital cost of the project is projected to be \$33,708 which includes \$25,000 for dialysis machines, \$2,360 for other equipment/furniture, \$2,270 for dialysis chairs, \$3,000 for televisions, and \$1,078 for patient computer systems.

In Section IX.3, page 46, the applicant projects no start-up or initial operating expenses associated with the proposed project, since the facility is currently operational and the application is for the addition of two stations.

In Section VIII.2, page 43, the applicant states that the capital needs of the project will be funded from cash reserves.

In Exhibit 18, the applicant provides a March 10, 2015 letter from the Vice President of Tax for DaVita Healthcare Partners, the applicant's ultimate parent, which states in part:

“I am the Vice President of Tax of DaVita Healthcare Partners, Inc., the parent and 100% owner of Total Renal Care, Inc. I serve as the Vice President of Tax 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 the Southeastern Dialysis Center-Elizabethtown by two ESRD dialysis stations. The project calls for a

capital expenditure of \$33,708. This letter will confirm that DaVita HealthCare Partners Inc. has committed cash reserves in the total sum of \$33,708 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.”

In Exhibit 19, the applicant provides the audited financial statements for DaVita Healthcare Partners, Inc. for the fiscal year ended December 31, 2014. As of December 31, 2014, DaVita Healthcare Partners, Inc. had \$965,241,000 in cash and cash equivalents, \$17,942,715,000 in total assets and \$5,360,311,000 in total equity. The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

In Section X.1, page 47, the applicant provides the allowable charges per treatment for each payment source, as illustrated below in the table.

SOUTHEASTERN DIALYSIS CENTER-ELIZABETHTOWN	
PAYOR	CHARGE /TREATMENT
Medicare	\$239.43
Medicaid	\$143.00
Medicare/Medicaid	\$239.43
Commercial Insurance	\$1,275.00
VA	\$193.00
Medicare/Commercial	\$239.43

The applicant projects revenues in Section X.2, page 48, and operating expenses in Section X.4, pages 52 - 53, as illustrated in the following table:

SOUTHEASTERN DIALYSIS CENTER-ELIZABETHTOWN		
	OPERATING YEAR 1	OPERATING YEAR 2
Total Net Revenue	\$5,108,141	\$5,307,278
Total Operating Costs	\$4,029,718	\$4,173,492
Net Profit	\$1,078,423	\$1,133,786

The applicant projects that revenues will exceed operating expenses in each of the two operating years following project completion. The assumptions used in preparation of the pro formas, including projected number of treatments, are reasonable and adequately supported. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

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

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

C

Total Renal Care of North Carolina, LLC d/b/a SEDC - Elizabethtown proposes to add two dialysis stations to the existing facility for a total of 26 in-center dialysis stations upon project completion. SEDC - Elizabethtown is the only existing or approved dialysis facility located in Bladen County.

The applicant adequately demonstrates the need to add two stations to the existing facility to serve the number of patients expected to utilize the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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

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

C

In Section VII.1, page 37, the applicant provides projected staffing during Operating Year Two, as illustrated in the following table:

FULL TIME EQUIVALENT (FTE) POSITIONS	
RN	4.0
HT RN	2.0
PCT	10.0
Bio-Med Tech	1.0
Admin.	1.0
Dietician	1.0
Social Worker	1.0
Unit Secretary	1.0
Reuse	1.0
Total FTEs	22.0

The applicant proposes to employ a total of 22.0 FTE positions. The applicant proposes to add one FTE RN position and one FTE PCT position as a result of the project. In Section V.4, page 30, the applicant identifies the Medical Director for SEDC - Elizabethtown as Dr. James McCabe. In Exhibit 13, the applicant provides a March 13, 2015 letter from Dr. McCabe indicating his support for the project and his role as Medical Director of the facility.

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

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

C

In Sections V.1 and V.2, pages 28 - 29, the applicant lists the providers of the necessary ancillary and support services that will be available for patients dialyzing at SEDC - Elizabethtown. The applicant states that New Hanover Regional Medical Center will provide emergency services, acute hemodialysis services, diagnostic and evaluation services, X-ray services, blood bank services, and vascular surgery services. In addition, the applicant provides supporting documentation regarding ancillary services in Exhibits 9 and 10. The applicant discusses coordination with the existing health care system in Sections V.2 – V.6, pages 29 - 31. The information provided in those sections and exhibits is reasonable and credible and supports a finding of conformity with this criterion.

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

NA

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

NA

- (11) Repealed effective July 1, 1987.

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

NA

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

C

In Section VI.1, page 32, the applicant states

“SEDC - Elizabethtown, 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.”

The applicant’s dialysis policies, procedures, and guidelines with regard to accepting patients for dialysis care are provided in Exhibit 14.

The table below illustrates the historical payor mix for the facility, as reported by the applicant in Section VI.1, page 32.

SEDC – ELIZABETHTOWN HISTORICAL PAYOR MIX		
PAYOR SOURCE	IN-CENTER	HOME TRAINED
Medicare	14.29%	12.50%
Medicaid	3.90%	0.00%
Medicare/Medicaid	40.26%	31.25%
Commercial Insurance	11.69%	6.25%
VA	5.19%	6.25%
Medicare/Commercial	24.68%	43.75%
Total	100.0%	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 Franklin 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) *
Bladen County	25%	12%	19%
Statewide	17%	7%	20%

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

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by dialysis facilities. In fact, in 2013 only 6.6% of all newly-diagnosed ESRD patients in North Carolina were under the age of 35, according to the ESRD Network 6 2013 Annual Report. (*ESRD Network 6 2013 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 1/1/2013 – 12/31/2013, page 99*).¹

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

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

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

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

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

² www.usrds.org/adr.aspx

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

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

ESRD Spending by Payor		
Payor	Spending in Billions	% of Total Spending
Medicare Paid	\$30.7	62.4%
Medicare Patient Obligation	\$4.7	9.6%
Medicare HMO	\$3.6	7.3%
Non-Medicare	\$10.2	20.7%
Total	\$49.2	100.0%

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

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

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

The applicant demonstrates that medically underserved populations currently have adequate access to services available at SEDC - Elizabethtown. Therefore, the application is conforming to this criterion.

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

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

C

In Section VI.1(f), page 34, the applicant states, "*SEDC – Elizabethtown has no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons....*" In Section VI.6(a), page 36, 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 33, the applicant provides the projected payor mix for the proposed dialysis services at SEDC - Elizabethtown. The applicant projects 83.13% of the in-center patients who will receive treatments at SEDC - Elizabethtown and 87.5% of the home-trained patients will have some or all of the services paid for by Medicare or Medicaid.

In Section VI.2, pages 34 - 35, the applicant states the facility currently satisfies all state requirements and local building codes to provide access to handicapped persons, adding that "*many of our patients are severely handicapped.*" The applicant further states that the staff members are all trained to assist handicapped persons.

The applicant demonstrates that the elderly and medically underserved populations will continue to have adequate access to the proposed dialysis 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, pages 35 - 36, the applicant describes the range of means by which patients will have access to the proposed dialysis services. The information provided

in Section VI.5 is reasonable and credible and supports a finding of conformity with 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(c), page 30, the applicant states SEDC - Elizabethtown has an existing clinical training agreement with Bladen Community College. Exhibit 12 contains a copy of an existing agreement between DaVita and James Sprunt Community College in Kenansville to provide opportunities for nursing students to use SEDC - Elizabethtown as a clinical training site. The applicant adequately demonstrates that the facility will accommodate the clinical needs of health professional training programs in the area. The application is conforming 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

SEDC –Elizabethtown is the only dialysis facility located in Bladen County. The applicant proposes to add two dialysis stations for a total of 26 stations based on the Facility Need methodology and the number of in-center patients it projects to serve. The January 2015 SDR reports that as of June 30, 2014, SEDC - Elizabethtown was operating at 81.25% capacity with 78 in-center patients dialyzing on 24 stations [$78 / 24 = 3.25$; $3.25 / 4 = 0.8125$]. The target utilization is 80% or 3.2 patients per station per week as of the end of the first operating year of the facility.

In Section V.7, page 31, the applicant discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. See also Sections II, III, V, VI and VII, in which the applicant discusses the impact of the project on cost-effectiveness, quality and access to the proposed services.

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

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

CA

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 or conditionally conforming to all applicable Criteria and Standards for End Stage Renal Disease Services. 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 III.7, page 23, the applicant states the utilization rate at SEDC - Elizabethtown was 81.25% as of June 30, 2014.
- (2) *Mortality rates;*
-C- In Section IV.2, page 26, the applicant states the mortality rates were 18.54%, 11.43% and 8.79% in 2012, 2013 and 2014, respectively.
- (3) *The number of patients that are home trained and the number of patients on home dialysis;*
-C- In Section IV.3, page 26, the applicant states: “*SEDC Wilmington provides home training for patients living in Bladen County under an agreement with SEDC-Elizabethtown.*” This is an application for SEDC – Elizabethtown, not SEDC Wilmington. However, in Section II, page 16, and Section III, page 24, the applicant states that, as of June 30, 2014, SEDC – Elizabethtown had 17 patients who were home trained.
- (4) *The number of transplants performed or referred;*
-C- In Section IV.4, page 26, the applicant states SEDC - Elizabethtown referred 12 patients for transplant evaluation in 2014. The applicant states three transplants were actually performed in 2014.
- (5) *The number of patients currently on the transplant waiting list;*
-C- In Section IV.5, page 27, the applicant states SEDC - Elizabethtown has 14 patients currently on the transplant waiting list.
- (6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
-C- In Section IV.6, page 27, the applicant states that there were 98 total hospital admissions in CY 2014, 17 of which were dialysis related (17.3%) and 81 of which were non-dialysis related (82.7%).

- (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 27, the applicant states that, as of December 31, 2014, there was one patient with AIDS and one patient with Hepatitis-B. The applicant states that during CY 2014 there was one patient who required the use of an isolation station for treatment. There were no other patients with any other infectious diseases dialyzing at the facility.
- (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- SEDC - Elizabethtown is an existing facility.
- (2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with 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- SEDC - Elizabethtown is an existing facility.
- (3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- NA- SEDC - Elizabethtown 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 the policies and procedures for back-up electrical service in the event of a power outage for SEDC - Elizabethtown.
- (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- SEDC - Elizabethtown 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 requirements.*

-C- In Section XI.6(g), page 58, the applicant states, “*SEDC - Elizabethtown has and will continue to operate within the applicable laws and regulations pertaining to staffing and fire safety equipment, physical environment and other relevant health safety requirements.*”

(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, pages 23 - 24, the applicant provides the methodology and assumptions used to project patient origin, as shown in the following table:

COUNTY	OPERATING YEAR 1		OPERATING YEAR 2		COUNTY PATIENTS AS PERCENT OF TOTAL	
	IN-CTR.	HOME	IN-CTR.	HOME	YEAR 1	YEAR 2
Bladen	76	9	79	10	81.7%	82.4%
Sampson	6	0	6	0	5.8%	5.6%
Columbus	3	10	3	10	12.5%	12.0%
Total	85	19	88	20	100.0%	100.0%

The discussion regarding population to be served found in Criterion (3) is incorporated herein by reference.

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

-NA- SEDC - Elizabethtown 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 13, the applicant states, “*Total Renal Care of North Carolina d/b/a SEDC - Elizabethtown 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 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- SEDC - Elizabethtown is an existing facility.
- (b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- C- SEDC - Elizabethtown projects to serve 3.2 patients per station per week as of the end of the first operating year. Assumptions are provided in Section III.7, pages 23 - 24. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.
- (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 III.7, pages 23 - 24. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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 28, the applicant states New Hanover Regional Medical Center will provide diagnostic and evaluation services.
- (2) *maintenance dialysis;*
- C- In Section V.1, page 28, the applicant states patients will receive maintenance dialysis services at the facility.
- (3) *accessible self-care training;*
- C- In Section III, pages 24, the applicant states SEDC - Elizabethtown trains those patients who are candidates for home training.
- (4) *accessible follow-up program for support of patients dialyzing at home;*
- C- In Section II.1, page 29, the applicant states SEDC - Elizabethtown provides services for those patients who are home trained.
- (5) *x-ray services;*

- C- In Section V.1, page 28, the applicant states x-ray services will be provided by New Hanover Regional Medical Center.
- (6) *laboratory services;*
- C- In Section V.1, page 28, the applicant states laboratory services will be provided by Dialysis Laboratories.
- (7) *blood bank services;*
- C- In Section V.1, page 28, the applicant states blood bank services will be provided by New Hanover Regional Medical Center.
- (8) *emergency care;*
- C- In Section V.1, page 28, the applicant states 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 28, the applicant states acute dialysis services will be provided by New Hanover Regional Medical Center.
- (10) *vascular surgery for dialysis treatment patients;*
- C- *In Section V.1, page 32, the applicant states vascular surgery services will be provided by Maria Parham Medical Center and WakeMed.*
- (11) *transplantation services;*
- C- In Section V.1, page 28, the applicant states transplantation services will be provided by Carolinas Medical Center, Duke or Vidant. See Exhibit 10 for copies of the agreements with these facilities.
- (12) vocational rehabilitation counseling and services; and
- C- In Section V.1, page 28, the applicant states vocational rehabilitation counseling and services will be provided by “*Vocational Rehabilitation.*”
- (13) *transportation.*
- CA- In Section V.1, page 28, the applicant states transportation services will be provided by Cape Fear Public Transportation Authority, which is located an hour away. The analyst assumes this representation was meant for a different proposal. Therefore, this application is conforming to this Rule subject to Condition (4) in Criterion (4).

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.1, page 37, the applicant states that all staffing requirements will be met as stated in 42 C.F.R. Section 494 (formerly 405.2100). The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

- (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 Exhibit 17 the applicant provides a copy of the applicant's training program outline for dialysis nurses and technicians.