

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 5, 2015

Findings Date: June 5, 2015

Project Analyst: Jane Rhoe-Jones

Assistant Chief: Martha J. Frisone

Project ID #: P-11014-15

Facility: Wallace Dialysis Center

FID #: 060249

County: Duplin

Applicant: Total Renal Care of North Carolina, LLC

Project: Add no more than two dialysis stations for a total of no more than 16 stations upon completion of this project and Project ID# O-10348-14 (relocate three stations to Southeastern Dialysis Center – Burgaw)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Agency 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 Wallace Dialysis Center proposes to add two dialysis stations for a total of 16 certified dialysis stations upon completion of this project and Project ID# O-10348-14 (relocate three stations to Southeastern Dialysis Center – Burgaw). Prior to this application being submitted, Project ID #O-10348-14 was approved on February 15, 2015.

Need Determination

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 surplus of ten dialysis stations in Duplin County. However, an applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. Thus, 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 Wallace Dialysis Center in the January 2015 SDR is 3.4375 patients per station, or 85.9% ($3.4375/4 \text{ patients per station} = 0.859375$). This utilization rate was calculated based on 55 in-center dialysis patients and 16 certified dialysis stations ($55 \text{ patients} / 16 \text{ stations} = 3.4375 \text{ patients per station}$).

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

WALLACE DIALYSIS CENTER-APRIL 1 REVIEW-JANUARY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/14		85.94%
Certified Stations		16
Pending Stations		1
Total Existing and Pending Stations*		17
In-Center Patients as of 6/30/14 (SDR2)		55
In-Center Patients as of 12/31/13 (SDR1)		49
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	6
	Multiply the difference by 2 for the projected net in-center change	12
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/13	0.2449
(ii)	Divide the result of step (i) by 12	0.0204
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/14 until 12/31/14)	0.1224
(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	61.7347
(v)	Divide the result of step (iv) by 3.2 patients per station	19.2921
	and subtract the number of certified and pending stations as recorded in SDR2 to determine the number of stations needed	2

*Pursuant to the certificate of need for Project ID# O-10348-14, three stations will be relocated to SEDC-Burgaw leaving only 14 stations at Wallace Dialysis Center.

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

Policies

Policy GEN-3: BASIC PRINCIPLES, on page 38 of the 2015 State Medical Facilities Plan (SMFP) is applicable to this review. Policy GEN-3 states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Promote Safety and Quality - The applicant describes how it believes the proposed project would promote quality in Section II.3, pages 17-18, and referenced exhibits. The applicant describes how it believes the proposed project would promote safety in Section XI.6(g), pages 64-65, 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 33-38. 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, pages 24-25. 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 it has identified. 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

Total Renal Care of North Carolina, LLC d/b/a Wallace Dialysis Center proposes to add two dialysis stations, for a total of 16 certified dialysis stations upon completion of this project and Project ID# O-10348-14 (relocate three stations to Southeastern Dialysis Center – Burgaw). Prior to this application being submitted, Project ID #O-10348-14 was approved on February 15, 2015.

Population to be Served

In Section IV.1, page 26, the applicant identifies the population to be served, as of December 31, 2014, as illustrated below in the table:

WALLACE DIALYSIS CENTER		
County of Residence	# of In-Center Patients	# of Home Dialysis Patients
Duplin	45	2
Pender	8	3
Sampson	1	0
Wayne	1	0
TOTAL	55	5

In Section III.7, pages 22-23, the applicant identifies the patient population it proposes to serve during the first two years of operation following project completion, as illustrated below in the table:

WALLACE DIALYSIS CENTER: Projected Patient Origin						
County	Operating Year 1 2016		Operating Year 2 2017		County Patients as a Percent of Total	
	In-Center Patients	Home Dialysis Patients	In Center Patients	Home Dialysis Patients	Year 1	Year 2
Duplin	54	4	56	5	81.7%	82.3%
Pender	8	3	8	3	15.5%	14.9%
Sampson	1	0	1	0	1.4%	1.4%
Wayne	1	0	1	0	1.4%	1.4%
TOTAL	64	7	66	8	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 22-23, the applicant provides the assumptions and methodology used to project utilization; which are summarized below:

- Operating Year One is CY 2016
- Operating Year Two is CY 2017
- Based on the facility need methodology, Wallace Dialysis Center meets the requirements for a two-station expansion.
- There was a 24.4% annual increase in in-center patients during the first six months of 2014 due to an increase of six patients.
- There will be a 4% (or less) Average Annual Change Rate for Wallace Dialysis Center, based on patient growth from January 2014 to June 2014.
- The applicant expects no growth for patients that live outside of Duplin County.

The applicant states:

“The Wallace Dialysis Center had 55 in-center patients as of June 30, 2014 based on information included in Table A of the January 2015 Semiannual Dialysis Report (SDR). This is a station utilization rate of 80.1% based on 17 certified stations. Total Renal Care of North Carolina, LLC submitted a CON application on September 15, 2014 to transfer 3 stations from the Wallace Dialysis Center to SEDC-Burgaw. That CON application was approved, leaving the Wallace Dialysis Center with 14 dialysis stations.

The July 2014 Semiannual Dialysis Report indicated that the Wallace Dialysis Center had 49 in-center patients as of December 31, 2014, an increase of 6 in-center patients or a growth rate of 12.2% in a six-month period or an annualized growth rate of 24.4%.

As of June 30, 2014, 45 of the in-center patients lived in Duplin County, 8 of the in-center patients lived in Pender County, one in-center patient lived in Sampson County and one in-center patient lived in Wayne County. This application is for a two-station expansion of the Wallace Dialysis Center, increasing the station capacity from 14 stations to 16 stations (17 current stations – 3 stations transferring to SEDC-Burgaw + 2 stations in this CON application = 16 stations).

Based on calculations below, the Wallace Dialysis Center is projected to have at least 85 [sic] 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 [sic] in-center patients by the end of operating year 2 for a utilization rate of 84.6% or 3.38 patients per station. ...

The period of the 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 sixth of the calculated annual growth rate of 24.4% for the Wallace Dialysis Center:

June 30, 2014-December 31, 2014-49 patients X 1.02 = 49.98

January 1, 2015-December 31, 2015-49.98 patients X 1.04 = 51.9792

January 1, 2016-December 31, 2016-51.9792 patients X 1.04 = 54.058368

January 1, 2017-December 31, 2017-54.058368 patients X 1.04 = 56.22070272”

Home-Trained Patients

The applicant’s assumptions are summarized as follows:

- Wallace Dialysis Center home-trained patients will increase by one new patient for this current year and one for each of the next two operating years.
- During the one and one-half years that the home training program has been operational, it has grown to five patients as of June 30, 2014.
- The home-trained patient census will grow to six patients in 2015, seven in 2016 and 8 in 2017.
- There is no growth anticipated for patients residing outside of Duplin County.

By the end of Year One, the applicant projects to serve 54 in-center patients from Duplin County and 10 in-center patients living outside of Duplin County dialyzing on 16 stations for a utilization rate of 100% or four patients per station [$64 / 16 = 4.0 / 4.0 = 1.0$ or 100%]. The applicant projects 56 in-center patients from Duplin County and 10 in-center patients living outside of Duplin County at the end of Year Two for a utilization rate of 103.1% or 4.125 patients per station [$66 / 16 = 4.125 / 4.0 = 1.031$ or 103.1%]. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A

NCAC 14C .2203(b). Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Access to Services

In Section VI.1, page 33, the applicant states:

“The Wallace Dialysis Center, by policy, makes dialysis services available to all residents in its service area without qualifications. We serve patients without regard to race, sex, age, or handicap. We serve patients regardless of ethnic and socioeconomic situation.

...

The Wallace Dialysis Center does not require payment upon admission to its services; therefore, services are available to all patients including low-income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons.”

On page 34, the applicant projects no change as a result of this project in the current percentage of its in-center patients that have all or part of their services covered by Medicare and/or Medicaid (81.7%). The applicant adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the services proposed.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need that population has for the proposed project and the extent to which all residents of the area, 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 24, the applicant discusses the alternatives considered for Wallace Dialysis Center, which include:

1. Maintain the Status Quo - the applicant dismissed this alternative based on the continued growth at the facility. Therefore, doing nothing would not be in the best interest of the patients of Wallace Dialysis Center.
2. Add two stations - the applicant concluded that the proposal to add two additional dialysis stations was its most effective alternative to meet the growing need for dialysis services at the Wallace dialysis facility. Thus, the applicant concludes that the project as proposed is its least costly and most effective alternative.

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 applicable statutory and regulatory review criteria, and thus is approvable. An application that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that the proposal is its least costly or most effective alternative to meet the need. Consequently, 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 Wallace 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 Wallace Dialysis Center shall develop no more than two additional stations for a total of no more than 16 stations upon completion of this project and Project ID # O-10348-14 (relocate three dialysis stations to a Southeast Dialysis Center-Burgaw), which shall include any home hemodialysis training or isolation stations.**
 - 3. Total Renal Care of North Carolina, LLC d/b/a Wallace 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, page 43, the applicant projects that there will be no capital costs associated with the proposed project. In Section IX, page 48, the applicant projects no initial start-up costs or initial operating expenses because Wallace Dialysis Center is an existing facility.

In Section X.1, page 50, the applicant provides the allowable charges per treatment for each payment source for Wallace Dialysis Center, as illustrated below in the table:

Wallace Dialysis Center	
Payor	
Medicare	\$239.43
Medicaid	\$143.00
Medicare/Medicaid	\$239.43
Commercial Insurance	\$1,275.00
Medicare/Commercial	\$239.43
VA	\$193.00

On page 50, the applicant states that the reimbursement rates are the same for both in-center and home-trained patients and includes further details about charges and reimbursement rates.

In Section X.2-X.4, pages 51-58, the applicant projects revenues and operating expenses for Wallace Dialysis Center, as illustrated below in the table:

Wallace Dialysis Center		
	Operating Year 1	Operating Year 2
Total Net Revenue	\$3,556,664	\$3,722,250
Total Operating Costs	\$2,772,649	\$2,885,972
Net Profit	\$784,015	\$836,278

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable and adequately supported. See Section X, pages 50-56, for the applicant's assumptions. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges to provide the proposed health services. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to add two dialysis stations to its existing facility for a total of 16 certified dialysis stations upon completion of the proposed project and Project ID# O-10348-14. Although the January 2015 SDR shows there is a surplus of ten dialysis stations in Duplin County, in this application, the applicant is applying for additional stations based on the facility need methodology.

The applicant adequately demonstrates the need for two additional stations based on the number of in-center patients it currently serves and proposes to serve. The growth projections are based on Duplin County's projected five-year average annual growth rate in the number of dialysis patients.

According to Table A in the January 2015 SDR, as of June 30, 2014, Wallace Dialysis Center was operating at 85.9% of capacity, with 55 in-center patients on 16 stations ($55 / 16 = 3.4375$; $3.4375 / 4 = 0.859375$). The target utilization rate is 80% or 3.2 patients per station, per week, at the end of the first operating year. The utilization rate projected for Wallace Dialysis Center at the end of the first operating year is four patients per station, or 100% ($4/4$ patients per station = 1.0). This utilization rate was calculated based on 64 in-center dialysis patients and 16 certified dialysis stations ($64 \text{ patients} / 16 \text{ stations} = 4 \text{ patients per station}$). This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year required by *10A NCAC 14C .2203(b)*. Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

According to the January 2015 SDR, there are three existing dialysis facilities in Duplin County. Wallace Dialysis Center is one of two existing dialysis facilities in Duplin County owned by the same parent company, DaVita Healthcare Partners, Inc. The other DaVita facility in Duplin County is Southeastern Dialysis Center in Kenansville (SEDC-Kenansville). The third facility, RAI-West College in Warsaw, is owned by Fresenius Medical Care (FMC).

SEDC-Kenansville is certified for 17 stations and is currently serving 46 in-center patients, which is a utilization rate of 67.65% ($46/17 = 2.7059$; $2.7059/4 = 0.67647$ or 67.65%).

RAI-West College in Warsaw is certified for 16 stations and is currently serving 24 in-center patients, which is a utilization rate of 37.50% ($24/16 = 1.5$; $1.5/4 = 0.375$ or 37.50%).

Travel between Wallace and Warsaw can take 23 minutes (21.9 miles) to 32 minutes (26.7 miles) depending on the route traveled. (*Google Maps*)

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

In Section VII.1, page 39, the applicant states that Wallace Dialysis Center currently employs 14.5 full-time equivalent (FTE) positions. The applicant does not propose to hire additional

staff as a result of the proposed project. The applicant further states on page 40, “*The facility complies with all staffing requirements as stated in 42 C.F.R. Section 405 .2100 [sic].*”

In Section VII.10, page 42, the applicant provides the current and projected number of direct care staff (patient care technicians) per shift offered, as shown below:

WALLACE DIALYSIS CENTER							
	Shift Times	Mon	Tue	Wed	Thu	Fri	Sat
Morning	6am to 11am	4	4	4	4	4	4
Afternoon	11am to 4pm	4	4	4	4	4	4

In Section V.3, page 30, Section VII.4, page 40, and Exhibit 13, the applicant states that Dr. Brian Donner, M.D., currently serves as the Medical Director of Wallace Dialysis Center and he has expressed his willingness to continue serving in that role.

In Section VII, page 39, the applicant documents the availability of adequate health manpower and management personnel, including the medical director, for the 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 Section V.1, page 28, the applicant lists the providers of the necessary ancillary and support services. Acute dialysis in an acute care setting, emergency care, diagnostic evaluation services, X-ray services, blood bank and vascular surgery are provided by New Hanover Regional Medical Center. See Exhibit 9 for a copy of the Hospital Transfer Agreement with New Hanover Regional Medical Center and Exhibit 10 for a copy of the Transplantation Agreement with Vidant Medical Center (ECU). The applicant adequately demonstrates the necessary ancillary and support services are available and that the proposed services will be coordinated with the existing healthcare 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 42, the applicant reports that 81.7% of its in-center patients had some or all of their services paid for by Medicare and/or Medicaid, as illustrated in the following table.

WALLACE DIALYSIS CENTER IN-CENTER PATIENT UTILIZATION BY PAYOR SOURCE	
PAYOR SOURCE	PERCENT UTILIZATION BY PAYOR SOURCE
Medicare	21.67%
Medicaid	10.00%
Medicare/Medicaid	13.33%
Commercial Insurance	15.00%
Medicare/Commercial	36.67%
VA	3.33%
TOTAL	100.00%

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 Duplin, Pender, Sampson and Wayne counties and statewide.

County	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) *
Duplin	20.3%	7.6%	24.6%
Pender	16.6%	7.4%	21.0%
Sampson	25.4%	10.1%	24.0%
Wayne	20.2%	8.3%	20.3%
Statewide	16.5%	6.7%	19.7%

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

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

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, 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:

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

“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:

“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:

² www.usrds.org/adr.aspx

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 the elderly and other medically underserved groups have adequate access to its existing services. Therefore, the application is conforming to this criterion.

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

C

In Section VI.1(f), page 36, the applicant states:

“The Wallace 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. The Wallace Dialysis Center has no obligation under the Hill Burton Act.”

In Section VI.6(a), page 37, 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.

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

- (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(a), page 33, the applicant states:

“The Wallace Dialysis Center, by policy, makes dialysis services available to all residents in its service area without qualifications. We serve patients without regard to race, sex, age, or handicap. We serve patients regardless of ethnic or socioeconomic situation.

...

The Wallace Dialysis Center, does not require payment upon admission to its services; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons.”

In Section VI.1(c), page 34, the applicant projects that 81.7% of its in-center patients will have some or all of their services paid for by Medicare or Medicaid, as illustrated in the following table.

WALLACE DIALYSIS CENTER IN-CENTER PATIENT UTILIZATION BY PAYOR SOURCE	
PAYOR SOURCE	PERCENT UTILIZATION BY PAYOR SOURCE
Medicare	21.67%
Medicaid	10.00%
Medicare/Medicaid	13.33%
Commercial Insurance	15.00%
Medicare/Commercial	36.67%
VA	3.33%
TOTAL	100.00%

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, pages 36-37, the applicant describes the range of means by which patients will have access to the proposed services. The information the applicant provides in Section VI.5 is reasonable and credible and supports a finding of conformity 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.2(b), page 30, the applicant states “*The Wallace Dialysis Center has offered the facility as a clinical learning site for nursing students from James Sprunt Community College (See Exhibit 12).*” The applicant provides a copy of the training agreement in Exhibit 12. 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

DaVita HealthCare Partners, Inc., the parent company of Total Renal Care of North Carolina, LLC is one of two providers of dialysis services in Duplin County. The two DaVita facilities are Wallace Dialysis Center and SEDC-Kenansville. The third dialysis facility, RAI Care Center West College is owned by Fresenius Medical Care.

Wallace Dialysis Center proposes to add two dialysis stations to its existing facility for a total of 16 certified dialysis stations upon completion of this project and Project ID# O-10348-14 (relocate three stations to SEDC-Burgaw).

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

In Section V.7, pages 31-32, the applicant discusses how any enhanced competition in the service area will promote the cost effectiveness, quality and access to the proposed services. The applicant states:

“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. ...

... However, patient selection is the determining factor ...

... However, we do feel that accessibility to our services by the patients living in the service area identified will be enhanced.”

See also Sections I (pages 7-10), II (pages 13, 17-18), III (pages 24-25), V (pages 29-32), VI (pages 33-38), VII (pages 40-42) and referenced exhibits, where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in the application is reasonable 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 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 analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that it will continue to provide quality services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates that 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 Exhibit, 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 application is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services. The specific criteria are discussed below.

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

.2202 INFORMATION REQUIRED OF APPLICANT

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

(1) *Utilization rates;*

-C- In Section II.1, page 11, the applicant states the utilization rate as reported in the January 2015 SDR is provided in Exhibit 7. As of June 30, 2014, the utilization rate at Wallace Dialysis Center was 3.4 patients per station. This utilization rate was calculated based on 55 in-center dialysis patients and 16 certified dialysis stations (55 patients / 16 stations = 3.4375 patients per station).

(2) *Mortality rates;*

-C- In Section IV.2, page 26, the applicant reports the 2012, 2013 and 2014 facility mortality rates were 0.0%, 7.9% and 5.5%, 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 that as of June 30, 2014, Wallace Dialysis Center had five home-trained dialysis patients.

- (4) *The number of transplants performed or referred;*
- C- In Section IV.4, page 27, the applicant states that in 2014, Wallace Dialysis Center referred two patients for transplant evaluation and had one patient receive a transplant.
- (5) *The number of patients currently on the transplant waiting list;*
- C- In Section IV.5, page 27, the applicant states the facility has five patients on the transplant waiting list.
- (6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
- C- In Section IV.6, page 27, the applicant states that Wallace Dialysis Center had 49 hospital admissions in 2014; 10 (20.4%) of which were dialysis related and 39 (79.6%) of which were non-dialysis related.
- (7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*
- C- In Section IV.7, page 27, the applicant states that there was one patient dialyzing at the facility with an infectious disease (AIDS) as of December 31, 2014. The applicant also states that there were no patients who converted to infectious status within the last year.
- (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- Wallace Dialysis Center is an existing facility.
- (2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*
- (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
- (B) *composition of the assessment/evaluation team at the transplant center,*

- (C) *method for periodic re-evaluation,*
- (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and*
- (E) *signatures of the duly authorized persons representing the facilities and the agency providing the services.*

-NA- Wallace Dialysis Center is an existing facility.

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

-NA- Wallace Dialysis Center is an existing facility.

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

-C- See Exhibit 8, in which the applicant provides copies of written policies and procedures for back up electrical service in the event of a power outage.

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

-NA- Wallace Dialysis Center is an existing facility.

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

-C- In Section XI.6(g), page 64, the applicant states, “*Wallace Dialysis Center 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 22-23, the applicant provides the projected patient origin, including all assumptions and the methodology by which the patient origin is projected, as illustrated below in the table.

WALLACE DIALYSIS CENTER: Projected Patient Origin						
County	Operating Year 1 2016		Operating Year 2 2017		County Patients as a Percent of Total	
	In-Center Patients	Home Dialysis Patients	In Center Patients	Home Dialysis Patients	Year 1	Year 2
Duplin	54	4	56	5	81.7%	82.3%
Pender	8	3	8	3	15.5%	14.9%
Sampson	1	0	1	0	1.4%	1.4%
Wayne	1	0	1	0	1.4%	1.4%
TOTAL	64	7	66	8	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- Wallace Dialysis Center is an existing facility.

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

-C- In Section II.1, page 13, the applicant states, *“Total Renal Care of North Carolina, LLC d/b/a Wallace Dialysis Center admits and provides 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.”*

.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- Wallace Dialysis Center 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- By the end of Year One, the applicant projects to serve 64 in-center patients dialyzing on 16 stations for a utilization rate of 100% or 4.0 patients per station [$64 / 16 = 4.0 / 4.0 = 1.0$ or 100%]. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

.2204 SCOPE OF SERVICES

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

- (1) *diagnostic and evaluation services;*
 - C- The table in Section V.1, page 28, states patients will be referred to New Hanover Regional Medical Center for diagnostic and evaluation services.
- (2) *maintenance dialysis;*
 - C- The table in Section V.1, page 28, states the applicant will provide in-center maintenance dialysis at Wallace Dialysis Center.
- (3) *accessible self-care training;*
 - C- The table in Section V.1, page 28, states in-center hemodialysis, CAPD and CCPD will be provided by Wallace Dialysis Center.
- (4) *accessible follow-up program for support of patients dialyzing at home;*
 - C- The applicant addresses its accessible follow-up program for support of patients dialyzing at home in Section V.2(d), page 29.
- (5) *x-ray services;*
 - C- The table in Section V.1, page 28, states patients will be referred to New Hanover Regional Medical Center for x-ray services.
- (6) *laboratory services;*
 - C- The table in Section V.1, page 28, states patients will be referred to Dialysis Laboratories for routine and special laboratory services.
- (7) *blood bank services;*

-C- The table in Section V.1, page 28, states patients will be referred to New Hanover Regional Medical Center for blood bank services.

(8) *emergency care;*

-C- The table in Section V.1, page 28, states patients will be referred to New Hanover Regional Medical Center for emergency care.

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

-C- The table in Section V.1, page 28, states patients will be referred to New Hanover Regional Medical Center for acute dialysis in an acute care setting.

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

-C- The table in Section V.1, page 28, states dialysis patients will be referred to New Hanover Regional Medical Center for vascular surgery.

(11) *transplantation services;*

-C- The table in Section V.1, page 28, states patients will be referred to Duke University Medical Center and East Carolina University/Vidant Medical Center for transplantation services.

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

-C- The table in Section V.1, page 28, states patients will be referred to Vocational Rehabilitation for vocational rehabilitation counseling and services.

(13) *transportation.*

-C- The table in Section V.1, page 28, states patients will be referred to the Department of Social Services and various transportation providers.

.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 [sic].*

-C- In Section VII.1, page 39, the applicant provides the current staffing for Wallace Dialysis Center. On page 40, the applicant states, “*The facility complies with all staffing requirements as stated in 42 C.F.R. Section 405.2100 [sic] as evidenced below.*” Wallace Dialysis Center plans to continue having two dialysis shifts including direct care staffing of four direct care personnel per shift on Monday through Saturday for both shifts. (See application, page 42.)

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

-C- In Section VII.5, page 41, the applicant refers to Exhibit 17 for a copy of the training program description/outline. Exhibit 17 contains a copy of DaVita's Training Programs for New Patient Care Provider Teammates. Exhibit 23 contains a copy of the Safety Training Outline and Exhibit 24 contains the Annual In-Service Calendar for Wallace Dialysis Center.