

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 23, 2016

Findings Date: May 23, 2016

Project Analyst: Jane Rhoe-Jones

Team Leader: Fatimah Wilson

Project ID #: P-11157-16

Facility: Wallace Dialysis

FID #: 060249

County: Duplin

Applicant: Total Renal Care of North Carolina, LLC

Project: Add two dialysis stations for a total of 15 stations upon completion of this project and Project I.D. #O-11086-15 (relocate three stations)

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 (TRC) d/b/a Wallace Dialysis (“the applicant”), proposes to add two dialysis stations for a total of 15 stations at Wallace Dialysis upon completion of this project and Project I.D. #O-11086-15 (relocate three stations to Southeastern Dialysis Center- Burgaw (SEDC-Burgaw)).

Need Determination

The 2016 State Medical Facilities Plan (2016 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2016 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of four dialysis stations in Duplin County; thus the applicant cannot apply to add additional stations based on the county need methodology given that the minimum number of stations an applicant can apply for is ten. 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%. 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 in the January 2016 SDR is 3.4706 patients per station per week (as of June 30, 2015), or 86.76% (3.4706 / 4 patients per station per week = .867). This utilization rate was calculated based on 59 in-center dialysis patients and 17 certified dialysis stations (59 patients / 17 stations = 3.4706 patients per station per week).

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

WALLACE DIALYSIS APRIL 1 REVIEW-JANUARY 2016 SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/15		86.76%
Certified Stations		16
Pending Stations		0
Total Existing and Pending Stations		16
In-Center Patients as of 6/30/15 (SDR2)		59
In-Center Patients as of 12/31/14 (SDR1)		60
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	-1
	Multiply the difference by 2 for the projected net in-center change	-2
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/14	-0.0333
(ii)	Divide the result of step (i) by 12	-0.0028
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/15 until 12/31/15)	-0.0167
(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	58.0167
(v)	Divide the result of step (iv) by 3.2 patients per station	18.1302
	and subtract the number of certified and pending stations to determine the number of stations needed	2

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

There is one policy in the 2016 SMFP which is applicable to this review. POLICY GEN-3: BASIC PRINCIPLES on page 39 of the 2016 SMFP is applicable to this review because the facility need methodology 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 safety and quality in Section B-4(a), pages 9-10, Section O, page 50, 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 B-4(b), page 10, Section L, pages 43-47 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 B-4(c), page 11, Section F, pages 23-26, and Section N, page 49. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

Conclusion

In summary, the applicant adequately demonstrates that the proposal is consistent with the facility need methodology in the January 2016 SDR and Policy GEN-3. Therefore, the application is conforming to this criterion.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to add two new stations at Wallace Dialysis, an existing facility located at 5650 NC 41 Highway in Wallace. Upon completion of this project and Project I.D. #O-11086-15 (relocate three stations to SEDC-Burgaw), Wallace Dialysis will be certified for 15 dialysis stations.

Population to be Served

On page 369, the 2015 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Duplin County. Facilities may also serve residents of counties not included in their service area.

In Section C-8, page 19, the applicant identifies the population served as of June 30, 2015 (as reported in the January 2016 SDR), and illustrated below in the table:

WALLACE DIALYSIS Patient Origin - June 30, 2015			
County	# of In-Center Patients	# of Home Dialysis Patients	# PD Patients
Duplin	48	0	10
Pender	8	0	4
Sampson	1	0	1
Wayne	1	0	0
Other States	1	0	0
Onslow	0	0	1
TOTAL	59	0	16

PD=Peritoneal Dialysis.

In Section C-1, page 13, the applicant identifies the in-center patient population it proposes to serve during the first two years of operation following completion of this project and Project I.D. #O-11086-15 (relocate three stations to SEDC-Burgaw), as illustrated below in the table:

WALLACE DIALYSIS PROJECTED PATIENT ORIGIN OPERATING YEAR 1- OPERATING YEAR 2						
County	OY1 2018		OY2 2019		County Patients as Percent of Total	
	In-Center Patients	PD Patients	In-Center Patients	PD Patients	Year 1	Year 2
Duplin	55	13	57	14	80.0%	80.7%
Pender	8	4	8	4	14.1%	13.6%
Sampson	1	1	1	1	2.4%	2.3%
Wayne	1	0	1	0	1.2%	1.1%
Other States	1	0	1	0	1.2%	1.1%
Onslow	0	1	0	1	1.2%	1.1%
TOTAL	66	19	68	20	100.0%	100.0%

The applicant does not project to serve any home hemodialysis at Wallace Dialysis. The applicant provides the assumptions and methodology for the above in-center patient projections on pages 13-14, and for the peritoneal dialysis patient projections on pages 14-15.

The applicant adequately identifies the population it proposes to serve.

Analysis of Need

In Section B-2, page 7, the applicant states the proposed project is based on the facility need methodology. The discussion regarding the need determination found in Criterion (1) is incorporated herein by reference.

Projected Utilization

In Section C-1, pages 13-14, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- The applicant projects to serve 66 in-center dialysis patients at the end of the first operating year, which is 4.4 patients per station per week or a 110% utilization rate.
- Based on the January 2016 SDR, Wallace Dialysis had 59 in-center patients and 17 stations for a station utilization rate of 86.76%, as of June 30, 2015. Forty-eight of the 59 patients were residents of Duplin County. On page 13 of the application, the applicant states that Wallace Dialysis had 16 certified stations for a utilization rate of 86.76%. However 16 stations yield 3.687 patients per station, and a utilization rate of 92.18%.]
- The applicant proposed in Project I.D. # O-11086-15 to relocate three stations from Wallace Dialysis to SEDC-Burgaw.

- The applicant used a 4.1% annual growth rate commensurate with the Duplin County Five Year Average Annual Change Rate (5-Year AACR) as reported in the January 2016 SDR to project future growth at Wallace Dialysis from January 1, 2016 – December 31, 2019.
- The applicant projects to continue to serve 11 patients who reside outside of Duplin County. The applicant did not project growth for those 11 patients who are non-Duplin County residents.
- The applicant projects to have 66 in-center patients by the end of OY1 with a utilization rate of 110% or 4.4 patients per station per week and 68 in-center patients by the end of OY2, for a projected utilization rate of 113% or 4.5 patients per station per week.
- To ensure that the needs of the patients dialyzing at Wallace Dialysis will continue to be met, the applicant states on page 14 that certificate of need applications will be submitted based on facility need to accommodate the projected utilization growth at Wallace Dialysis.
- OY1 is Calendar Year 2018
- OY2 is Calendar Year 2019

WALLACE DIALYSIS CENTER IN-CENTER PATIENT GROWTH									
	Duplin County Patients	x	Growth Rate	=	Duplin County Patients Year End	+	Non- Duplin County Patients	=	Year End Census
Beginning census 6/30/2015	48								
Interim 7/1/2015	48	x	1.025	=	48.984	+	11	=	59.984
Interim 7/1/2016	48.984	x	1.041	=	50.992	+	11	=	61.992
Interim 7/1/2017	50.992	x	1.041	=	53.083	+	11	=	64.083
OY1 1/1/18– 12/31/18	53.083	x	1.041	=	55.259	+	11	=	66.259
OY2 1/1/19– 12/31/19	55.259	x	1.041	=	57.525	+	11	=	68.527

As shown in the previous table, the applicant projects an in-center patient census of 66 patients, for a utilization rate of 110% or 4.4 patients per station per week at the end of OY1 (2018). At the end of OY2 (2019), the applicant projects an in-center patient census of 68 patients, which is a utilization rate of 113% or 4.5 patients per station per week. The projected utilization of 4.4 patients per station per week for OY1 satisfies the 3.2 in-center patients per station per week as required by 10A NCAC 14C .2203(b).

The applicant adequately demonstrates that projected utilization is based on reasonable and adequately supported assumptions regarding continued growth in the dialysis patient population in Duplin County.

Access

In Section C-3, page 15, the applicant states:

“By policy, the proposed services will be made available to all residents in its service area without qualifications. The facility will serve patients without regard to race, sex, age, or handicap ... regardless of ethnic or socioeconomic situation.”

In Section L.7, page 47, the applicant provides its historic payor mix which indicates that Medicare and Medicaid represented 95.7% of all its dialysis services in 2015. The applicant projects, in Section L.1, page 44, that 95.7% of all dialysis services will also be covered by Medicare and Medicaid in OY1 and OY2 of the proposed project. The applicant confirms that low income and medically underinsured persons will continue to have access to all services provided by DVA and that the facility will conform to all federal, state and local codes and standards for handicapped access.

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 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 E-1, page 22, the applicant discusses the three alternatives considered prior to submitting this application, which include:

1. Maintain the Status Quo - The applicant states that this option would not support the growth rate at the facility.
2. Relocate stations from another DaVita facility – The other DaVita facility in Duplin County is SEDC-Kenansville, which is operating less than 80% capacity as reported in the January 2016 SDR. The applicant states that to relocate stations from SEDC-Kenansville could negatively impact the three day per week patient dialysis schedule there.
3. Apply to add two stations – the applicant states the two station expansion would help to meet the growing demand for dialysis services at Wallace Dialysis.

After considering the alternatives listed above, the applicant states it believes the most effective alternative is to add two stations to the existing facility to address growth and adequate access for the Wallace Dialysis patients. The applicant further states that in its experience, a third shift tends to be inconvenient for patients. The applicant projects that the utilization rate at Wallace Dialysis will exceed 100% and in Section C-1, page 14, discusses applying for more stations under the facility need methodology to meet the growing demand for dialysis services at Wallace Dialysis.

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

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

- 1. Total Renal Care of North Carolina, LLC. d/b/a Wallace Dialysis 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 shall add no more than two dialysis stations for a total of no more than 15 certified dialysis stations upon completion of Project I.D. # O-11086-15 (relocate three stations) and this project, which shall include any home hemodialysis training or isolation stations.**
 - 3. Total Renal Care of North Carolina, LLC. d/b/a Wallace Dialysis 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

The applicant proposes to add two dialysis stations to Wallace Dialysis for a total of 15 dialysis stations upon completion of this project and Project I.D. # O-11086-15.

Capital and Working Capital Costs

In the table in Section F-1, page 23, the applicant states that there are no capital costs associated with the proposed project. In Section F, pages 25-26, the applicant states that there are no working capital needs for the proposed project as Wallace Dialysis is an existing facility.

Availability of Funds

The proposed project does not require financing since there are no capital costs.

In Section F, page 27, the applicant states:

“The financial strength of the company precludes any financial impact upon the operation and performance of the expansion that this application proposes. Therefore, there is no appreciable impact on either this application or from any that has been approved previously or is currently under review.”

See Exhibit F-7 for a copy of the most recent audited financial statements for DaVita HealthCare Partners, Inc. for years ended December 31, 2014 and 2015. As of December 31, 2015, DaVita HealthCare Partners, Inc. had \$1,186,636,000 in cash and cash equivalents, \$14,328,416,000 in total assets and \$4,870,780,000 in total equity.

Financial Feasibility

The applicant projects revenues and expenses and provides assumptions in Section R, Form B, pages 1-2, as summarized below in the table:

WALLACE DIALYSIS		
Revenue and Expenses - Total Facility		
	OPERATING YEAR 1 CY 2018	OPERATING YEAR 2 CY 2019
Gross Patient Revenue	\$ 3, 181,317	\$ 3,304,075
Deductions from Gross Patient Revenue	(\$128,327)	(\$132,935)
Total Revenue	\$ 3,052,989	\$ 3,171,140
Operating Expenses	\$ 2,392,081	\$ 2,459,906
Net Profit	\$ 660,908	\$ 711, 234

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. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

In Section H, page 30, the applicant provides projected staffing and salaries. Form A in Section R, page 1, shows budgeted operating costs adequate to cover the projected staffing. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

Conclusion

In summary, the applicant adequately demonstrates the financial feasibility of the project is based on reasonable projections of revenues and operating costs. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to add two stations to Wallace Dialysis for a total of 15 certified dialysis stations upon completion of this project and Project I.D. #O-11086-15 (relocate three stations to SEDC - Burgaw).

On page 369, the 2015 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Duplin County. Facilities may also serve residents of counties not included in their service area.

Table A in the January 2016 SDR indicates there are three operational facilities in Duplin County, as illustrated below in the table:

DUPLIN COUNTY DIALYSIS FACILITIES	CERTIFIED STATIONS	# PATIENTS	PATIENTS PER STATION	% UTILIZATION
Wallace Dialysis - Wallace	17	59	3.47	86.76%
RAI-West College -- Warsaw	16	25	1.56	39.06%
Southeastern Dialysis Center - Kenansville	17	44	2.58	64.71%

According to the certificate of need database and the most recent SDR, there are currently no pending stations at either of these facilities.

Of the facilities listed above, Fresenius Medical Care owns one (RAI West College in Warsaw) and the applicant owns two. As reported in the January 2016 SDR, one of the three operational facilities (Wallace Dialysis) operated above 80% utilization. RAI-West College had 39% utilization. According to the January 2016 SDR, there is a surplus of four dialysis stations in

Duplin County. However, the applicant is applying to add two additional stations based on the facility need methodology.

At the end of OY1 (2018), the applicant projects an in-center patient census of 66 patients, for a utilization rate of 110% or 4.40 patients per station per week. The projected utilization of 4.40 patients per station per week for OY1 satisfies the 3.2 in-center patients per station per week threshold as required by 10A NCAC 14C .2203(b). At the end of OY2 (2019), the applicant projects an in-center patient census of 68 patients, which is a utilization rate of 113% or 4.53 patients per station per week. The applicant adequately demonstrates that projected utilization is based on growth of in-center patients at the facility.

The applicant adequately demonstrates the need to add two stations to Wallace Dialysis based on the number of in-center patients it proposes to serve. The discussion of analysis of need found in Criterion (3) is incorporated herein by reference. The discussion of competition found in Criterion (18a) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Duplin 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 H-1, page 30, the applicant provides the current staffing for the facility, which includes 13.0 full-time equivalent (FTE) employees, and the proposed staffing for the facility following completion of the project. The applicant does not propose to add any FTE employees for total staffing of 13.0 FTE employees upon project completion. In Section H-3, pages 31-32, the applicant describes its experience and process for recruiting and retaining staff. Exhibit I-3 contains a copy of a letter of support for the project from Brian Donner, M.D., Medical Director for the facility. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed 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 I-1, page 34, the applicant lists the providers of the necessary ancillary and support services to be provided at the existing facility. The applicant discusses coordination with the existing health care system in Section I-3, pages 35-36. Exhibits I-1 and I-3 contain documents from the facility administrator and DaVita Laboratory Services, Inc., respectively, documenting availability of the necessary ancillary and support services. The applicant adequately

demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. The information in Section I and corresponding exhibits is reasonable and supports a finding of conformity 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 L-1, pages 43-45, the applicant states, “*Wallace Dialysis, by policy, makes dialysis services available to all residents in its service area without qualifications. ... Wallace Dialysis helps uninsured/underinsured patients with identifying and applying for financial assistance; 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 addition, on page 45, the applicant discusses its financial policies. In Section L-7, page 47, the applicant states that Medicare/Medicaid represented 95.7 % of all dialysis services provided at Wallace Dialysis in CY2015. The following table illustrates the historical payor sources for Wallace Dialysis:

WALLACE DIALYSIS CY2015			
PAYOR TYPE	% IN-CENTER PATIENTS	% OF PD PATIENTS	PERCENT TOTAL PATIENTS
Commercial Insurance	0.0%	14.4%	2.9%
Medicare	22.8%	21.4%	22.5%
Medicaid	7.0%	7.1%	7.0%
Medicare/Medicaid	26.3%	28.6%	26.8%
VA	0.0%	7.1%	1.4%
Medicare/ Commercial	43.9%	21.4%	39.4%
Total	100.0%	100.0%	100.0%

On page 19, the applicant reports having served no HH patients in CY2015. Regardless, the applicant adequately demonstrates that it has historically served the medically underserved population.

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant’s service area.

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Duplin	16%	51%	48%	28%	11%	26%
Pender	17%	50%	26%	15%	13%	20%
Sampson	16%	51%	48%	29%	14%	24%
Wayne	15%	51%	46%	23%	12%	18%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>. 2014 Estimate as of December 22, 2015.

*Excludes "White alone" who are "not Hispanic or Latino"

**"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

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

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

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

In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older and over 63% were non-Caucasian. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*, page 59).

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

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

C

In Section L-3(d), page 46, the applicant states:

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

In Section L-6, page 46, 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 C-3, page 15, the applicant states:

“By policy, the proposed services will be made available to all residents in its service area without qualifications. ...

Payment will not be required upon admission. 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 L-3(c), page 46, the applicant states:

“Wallace Dialysis makes no effort to categorize patients into groups according to their financial ability to obtain medical care. Physicians identify the patients in need of dialysis services and only then will a financial counselor and/or social worker evaluate their medical insurance and financial status.”

In Section L-1(b), page 44, the applicant reports that it expects 95.7 % of the in-center patients who receive treatments at Wallace Dialysis to have all or part of their services paid for by Medicare and Medicaid, as indicated below in the table.

WALLACE DIALYSIS PROJECTED PAYOR MIX – PROJECT YEAR 2			
PAYOR TYPE	% IN-CENTER PATIENTS	% OF PD PATIENTS	PERCENT TOTAL PATIENTS
Commercial Insurance	0.0%	14.4%	2.9%
Medicare	22.8%	21.4%	22.5%
Medicaid	7.0%	7.1%	7.0%
Medicare/Medicaid	26.3%	28.6%	26.8%
VA	0.0%	7.1%	1.4%
Medicare/ Commercial	43.9%	21.4%	39.4%
Total	100.0%	100.0%	100.0%

On page 44, the applicant states it assumes the projected payor mix for Wallace Dialysis will remain the same as its historical payor mix. The applicant indicates in Section C, page 19, that it did not provide support and training for any HH patients in 2015. Regardless, the applicant adequately projects to serve medically underserved populations.

The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section L-4, page 46, the applicant states:

“Patients with End Stage Renal Disease have access to dialysis services upon referral by a Nephrologist with privileges at Wallace Dialysis. ... Patients from outside the facility catchment area requesting transfer to this facility will be processed in accordance with the facility transfer and transient policies, found at Exhibit L-3. ...”

The applicant adequately demonstrates that it will offer a range of means by which patients will have access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section M-1, page 48, the applicant states that Wallace Dialysis has been offered as a clinical training site for medical assisting students attending James Sprunt Community College in Kenansville.

Exhibit M-2 contains a copy of the student training agreement with James Sprunt Community College. The information provided in Section M and referenced exhibits is reasonable and supports a finding of conformity to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

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

C

The applicant proposes to add two stations to Wallace Dialysis for a total of 15 certified dialysis stations upon completion of this project and Project I.D. #O-11086-15 (relocate three stations to SEDC - Burgaw).

On page 369, the 2015 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Duplin County. Facilities may also serve residents of counties not included in their service area.

Table A in the January 2016 SDR indicates there are three operational facilities in Duplin County, as illustrated below in the table:

DIALYSIS FACILITY	CERTIFIED STATIONS	# PATIENTS	PATIENTS PER STATION	% UTILIZATION
Wallace Dialysis - Wallace	17	59	3.47	86.76%
RAI-West College -- Warsaw	16	25	1.56	39.06%
Southeaster Dialysis Center - Kenansville	17	44	2.58	64.71%

According to the certificate of need database and the most recent SDR, there are currently no pending stations at either of these facilities.

Of the facilities listed above, Fresenius Medical Care owns one (RAI West College in Warsaw) and the applicant owns two. As reported in the January 2016 SDR, one of the three operational facilities (Wallace Dialysis) operated above 80% utilization. RAI-West College had 39% utilization. According to the January 2016 SDR, there is a surplus of four dialysis stations in

Duplin County. However, the applicant is applying to add two additional stations based on the facility need methodology.

In Section N-1, page 49, the applicant discusses how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. The applicant states:

“The expansion of Wallace Dialysis will have no effect on competition in Duplin County. Although the addition of stations at this facility could serve to provide more patients another option ..., this project primarily serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by Total Renal Care of North Carolina, LLC.

The expansion of Wallace Dialysis will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and others involved in the dialysis process to receive services.”

See also Sections B, C, F, G, H and L where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in the Sections referenced above 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 the information in the application, and the following analysis:

- The applicant adequately demonstrates the need for the proposed project and that it is an 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 Wallace Dialysis will continue to provide quality dialysis services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates that Wallace Dialysis will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1), (3) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

See Section B-4(a), pages 9-12, for the applicant’s discussion regarding the methods DVA uses to ensure and maintain quality. In Section O-3, page 53, the applicant states:

“Exhibit O-3 lists facilities located in NC owned by the parent company DaVita HealthCare Partners Inc. that did not operate in compliance with the Medicare conditions of participation during the 18 month look-back period for this application (August 1, 2014 through March 15, 2016). Each facility is currently in compliance.”

In Exhibit O-3, the applicant states that two facilities – Durham West and Dialysis Care of Rowan County were cited for deficiencies that resulted in a finding of Immediate Jeopardy, during the 18 months immediately preceding submittal of the application, as shown in the table below:

DVA Quality Care 18 Month Look Back			
Facility	Survey Date	Back in Compliance	
Durham West	10/7/2015	Yes	9/30/2015
Dialysis Care of Rowan County	9/17/2014	Yes	10/22/2014

Based on a review of the information in the application and publicly available information, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

.2203(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per

station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

-NA- Wallace Dialysis is an existing facility.

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

-C- In Section C-1, pages 13-14, the applicant projects to serve 66 in-center patients by the end of Operating Year 1, which is 4.4 patients per station ($66 / 15 = 4.4$). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C-1, pages 16-18, the applicant provides the assumptions and methodology used to project in-center patient utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.