

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: June 1, 2012

PROJECT ANALYST: Jane Rhoe-Jones
SECTION CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: P-8803-12 / Total Renal Care of North Carolina, LLC. d/b/a Wallace Dialysis Center / Add four dialysis stations for a total of 16 stations upon project completion. / Duplin County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Total Renal Care (TRC) of North Carolina, LLC d/b/a Wallace Dialysis Center, operates a 12-station dialysis facility at 5650 S. North Carolina Highway 41, Wallace, North Carolina. The applicant proposes to add four dialysis stations for a total of 16 stations at Wallace Dialysis Center upon completion of this project. The applicant also proposes constructing additional square feet and the addition of peritoneal dialysis home training and home hemodialysis home training.

The 2012 State Medical Facilities Plan (2012 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the revised January 2012 Semiannual Dialysis Report (SDR), the county need methodology shows there is no need for an additional facility in Duplin County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology, because the utilization rate reported for Wallace Dialysis Center in the January 2012 SDR is 4.25 patients per station. This utilization rate was calculated based on 51 in-center dialysis patients and 12 certified dialysis stations as of June 30, 2011

(51 patients / 12 stations = 4.25 patients per station). Therefore, application of the facility need methodology indicates six additional stations are needed for this facility, as illustrated in the following table. However, the applicant is applying for four additional stations.

APRIL 1 REVIEW --- Wallace Dialysis Center---P-8803-12		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/11__		106.3%
Certified Stations		12
Pending Stations		0
Total Existing and Pending Stations		12
In-Center Patients as of 6/30/11__ (SDR2)		51
In-Center Patients as of 12/31/10_ (SDR1)		45
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 12/31/10	0.2667
(ii)	Divide the result of step (i) by 12	0.0222
(iii)	Multiply the result of step (ii) by the number of months from the most recent month reported in the January[2012] SDR (6/30/11) until the end of calendar year 2012 (6 months)	0.1333
(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	57.8000
(v)	Divide the result of step (iv) by 3.2 patients per station	18.0625
	and subtract the number of certified and pending stations as recorded in SDR2 [12] to determine the number of stations needed	6

- (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 (TRC) of North Carolina, LLC d/b/a Wallace Dialysis Center, proposes to add four dialysis stations for a total of 16 dialysis stations at Wallace Dialysis Center upon

completion of the project. The applicant proposes to add new dialysis stations to an existing facility based on facility need. The applicant also proposes the addition of peritoneal dialysis home training and home hemodialysis home training.

Population to be Served

In Section III.7, page 21, the applicant projects the number of in-center dialysis and home dialysis patients to be served in the first two years of operation following project completion, as illustrated in the following tables:

WALLACE DIALYSIS CENTER				
County	Operating Year 1 Census 2014	Operating Year 2 Census 2015	County Patients as a Percent of TOTAL	
			Year 1	Year 2
	In Center	In Center		
Duplin	48	49	88.8%	89.0%
Pender	6	6	11.1%	10.9%
TOTAL	54	55	100.0%	100.0%

WALLACE DIALYSIS CENTER			
County	Current (patients to transfer) Dec-Jan 2012	Projected Operating Year 1 Census 2015	Projected Operating Year 2 Census 2015
	Home	Home	Home
Duplin	5	8	9
Pender	6	9	10
TOTAL	11	17	19

In Section III, page 21, the applicant states:

“The Wallace Dialysis Center had 51 in-center patients as of June 30, 2011 based on information included on page 12 of the January 2012 Semiannual Dialysis Report (SDR). This is a station utilization rate of 106% based on the 12 certified stations in the facility. Of the 51 in-center patients cited in the SDR, 45 of the patients live in Duplin County. We are applying for a four-station expansion of the Wallace facility.”

The applicant adequately identifies the population to be served.

Need Analysis

In Section III, page 23, the applicant states that the Wallace Dialysis Center is rapidly growing and operating a third shift three days per week.

In-Center Hemodialysis

The following table contains information provided by the applicant in Section III, pages 22-

23 which illustrates the applicant’s assumptions and methodology used to project utilization at the Wallace Dialysis Center. In Section III.7, page 21, the applicant states the in-center projections of Wallace Dialysis Center using the Duplin County 2.5% Average Annual Change Rate for the past five years. The Pender County Average Annual Change Rate for the past five years is .004%. The Average Annual Change Rates for Duplin and Pender Counties are found on pages 18 and 19 of the January 2012 SDR, respectively:

WALLACE DIALYSIS CENTER	
Duplin County	In-Center
January 1, 2012 - December 31, 2012	45 patients x 1.025 = 46.125 patients
January 1, 2013 - December 31, 2013	46.125 x 1.025 = 47.278
January 1, 2014 - December 31, 2014 (Operating Year 1)	47.278 x 1.025 = 48.460
January 1, 2015 - December 31, 2015 (Operating Year 2)	48.460 x 1.025 = 49.672

The applicant projects to serve 54 in-center patients (48 Duplin County + 6 Pender County) by the end of Year One, or 3.4 patients per station [$54 / 16 = 3.37$]; and 55 in-center patients (49 Duplin County + 6 Pender County) by the end of Year Two, or 3.5 patients per station [$55 / 16 = 3.43$]. The projected utilization rate is 84% at the end of Year One [$54 / 64 = 0.844$] and 86% in Year Two [$55 / 64 = 0.859$]. Projected utilization at Wallace Dialysis Center is based on reasonable and supported assumptions.

Home Hemodialysis Training and Peritoneal Dialysis Training

In Section III, page 22, the applicant states:

“The Wallace Dialysis Center is planning to add home hemodialysis training and training in peritoneal dialysis as a part of the expansion of the facility. There are two facilities in Southeastern North Carolina that provide home dialysis training and training in peritoneal dialysis. Both of the facilities are operated by Total Renal Care of North Carolina, LLC. They are the Southeastern Dialysis Center – Jacksonville and Southeastern Dialysis Center – Wilmington.

As of December 31, 2011 the Jacksonville facility had seven home hemodialysis patients and twenty-six peritoneal dialysis patients. We anticipate the two of the peritoneal dialysis patients will consider transfer to the Wallace facility. One of the patients lives in Rose Hill and the other in Chinquapin. In both cases the distance from where these patients live to the Wallace facility is substantially closer than the Jacksonville facility.

As of December 31, 2011 the Wilmington facility had 17 home hemodialysis patients and 53 peritoneal dialysis patients. We anticipate that nine of the peritoneal dialysis patients will consider transfer to the Wallace facility. Two of the patients live in Wallace, three of the patients live in Burgaw, one patient lives in Rose Hill, one patient lives in Willard and two patients live in Watha. In every case the distance from where these patients live to the Wallace facility is substantially closer than the Wilmington facility. We anticipate that one of the home hemodialysis patients will transfer from the Wilmington facility. That patient lives in Pender County and lives

closer to the Wallace facility than to the Wilmington facility.

Five of the home-trained patients live in Duplin County and six of the home-trained patients live in Pender County.

Exhibit 9 (requested by analyst) contains a chart which indicating the mileage and minutes from the town where the patient lives to the dialysis center where they are being followed and to the Wallace Dialysis Center [Applicant emphasis.]

Based on the county growth of the home trained patients in Pender and Duplin Counties over the past five years, it is reasonable to assume that the Wallace Dialysis Center will admit one patient each year from each of the counties. See Exhibit 10 (requested by analyst) for home-trained patient growth data for Duplin and Pender Counties over the past five years. The Duplin County five-year average annual change rate is 15.7% and the Pender County five year average annual change rate is 19.3%. [Applicant emphasis.]

Based on the above assumption, Wallace Dialysis Center is projected to have 17 home-trained patients by the end of Operating Year One and 19 home-trained patients by the end of Operating Year Two.”

WALLACE DIALYSIS CENTER	
Duplin County	Home-Trained Patients
January 1, 2012 - December 31, 2012	11 current home-trained patients + 2 new patients = 13 home-trained patients
January 1, 2013 - December 31, 2013	13 home-trained patients + 2 new patients = 15 home-trained patients
January 1, 2014 - December 31, 2014 (Operating Year 1)	15 home trained patients + 2 new patients = 17 home-trained patients
January 1, 2015 - December 31, 2015 (Operating Year 2)	17 home-trained patients + 2 new patients = 19 home-trained patients

In summary, the applicant adequately identifies the population proposed to be served and demonstrates the need to add four dialysis stations at the Wallace Dialysis Center. 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, pages 23-24, the applicant discusses alternatives considered as the least costly and most effective means to meeting the needs for the project. The alternatives include doing nothing and applying for four stations. The applicant states that applying for four additional stations is the better alternative as it is the least costly and most effective to meet the growing demand for dialysis services. The application is conforming to all other applicable statutory and regulatory review criteria. See Criteria (1), (3), (3a), (5), (6), (7), (8), (13), (14), (18a) (20); and the Criteria and Standards for End Stage Renal Disease Services, promulgated in 10A NCAC 14C .2200. Therefore, the applicant adequately demonstrates that the proposal is its least costly or most effective alternative. 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 its certificate of need application.**
 2. **Total Renal Care of North Carolina, LLC. d/b/a Wallace Dialysis Center shall develop and operate no more than four additional dialysis stations for a total of 16 certified dialysis stations, which shall include any home hemodialysis dialysis training and isolation stations.**
 3. **Total Renal Care of North Carolina, LLC. d/b/a Wallace Dialysis Center shall install plumbing and electrical wiring through the walls no more than four additional dialysis stations for a total of 16 dialysis stations which shall include any isolation stations.**
 4. **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 Certificate of Need Section in writing, prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII, the applicant projects capital costs of \$1,165,767 associated with this project. The applicant states that the project will be financed through cash reserves. This amount includes four new dialysis machines, dialysis chairs and patient televisions, and expanding the current facility by 2,560 square feet. In Section IX, page 45, the applicant projects there will be no start-up costs or initial operating expenses as Wallace Dialysis Center is an existing facility. The breakdown of capital costs is as follows:

WALLACE DIALYSIS CENTER	
Construction Contract	\$935,000
Dialysis Machines	52,680
(RO) Water Treatment Equipment	45,000
Equipment/Furniture (not included above)	44,812
Architect/Engineering Fees	65,000
Dialysis Chairs	3,680
TVs	6,000
Chairside Computers	13,595
TOTAL	\$1,165,767

Exhibit 18 contains a letter from the chief accounting officer of DaVita, Inc. and Total Renal Care of North Carolina, LLC., which confirms the capital costs and financing for the project and states in part:

“... The project calls for a capital expenditure of \$1,165,767. This letter will confirm that DaVita, Inc. has committed cash reserves in the total sum of \$1,165,767 for the project capital expenditure. DaVita, Inc. will make these funds, along with any other funds that are necessary for the development of the project, available to Total Renal Care of North Carolina, LLC.”

In Section X, page 47, the applicant provides the allowable charge per treatment by each payor source for Wallace Dialysis Center, as follows:

WALLACE DIALYSIS CENTER	
Payor	In-Center
Commercial Insurance	\$1313.00
Medicare	\$240.00
Medicare/ Commercial	\$240.00
Medicaid	\$240.00
Medicare/ Medicaid	\$240.00
VA	\$240.00

The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services. In Section X, pages 47 and 52, the applicant projects that revenue will exceed operating expenses in each of the first two operating years.

WALLACE DIALYSIS CENTER		
	Year 1	Year 2
Revenue	\$4,438,766	\$4,632,013
Operating Costs	\$3,269,416	\$3,325,414
Total Revenue	\$1,169,350	\$1,206,599

In Exhibit 19, the applicant provides audited balance sheets for DaVita, Inc. which shows that as of December 31, 2011, DaVita, Inc. had \$8,892,172,000 in total assets, including \$393,752,000 in cash and cash equivalents. The balance sheet also shows that DaVita, Inc. had \$2,268,125,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the financial solvency of the company.

The assumptions used in preparation of the pro formas, including the number of projected treatments are reasonable. See Section X, pages 48-50-51, for the applicant's assumptions. In summary, the applicant adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections regarding 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

TRC proposes to add four dialysis stations at Wallace Dialysis Center, an existing facility, for a total of 16 stations upon project completion. Wallace Dialysis Center is currently serving 51 patients weekly at 4.25 patients per station. Dialysis facilities that operate four shifts per week (2/day on alternate days) have a capacity of four patients per station. The applicant does not propose to establish a new dialysis facility. The applicant discusses projections for the in-center patient population on page 21 of the application. At the end of Operating Year Two, with 16 dialysis stations and 55 dialysis patients after the four-station addition, the Wallace Dialysis Center projects the utilization will be 3.44 in-center patients per station ($55 \text{ patients} / 16 \text{ dialysis stations} = 3.44$). The growth projections are based on Duplin County projected Average Annual Growth Rate in the number of dialysis patients. Wallace Dialysis Center also proposes to establish a home dialysis training program to serve patients who reside in Duplin and Pender Counties. This program will be closer to the patients' homes than the current programs in Jacksonville and Wilmington.

The applicant adequately demonstrates that the proposed project would not result in 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, page 36, the applicant provides projected staffing for Wallace Dialysis Center upon project completion, as illustrated in the following table:

WALLACE DIALYSIS CENTER

Full-Time Equivalent (FTE) Positions	
RN	2.0
HTRN	1.0
PCT	6.0
Bio-Med Tech	.5
Admin	1.0
Dietician	.5
Social Worker	.5
Unit Secretary	1.0
Reuse Tech	1.0
Total FTEs	13.5

The applicant projects a total of 13.5 FTE positions upon project completion and states on page 37 that there is no difficulty expected in recruiting staff. In Section V.4, page 29, the applicant identifies the current Medical Director. Exhibit 13 contains a letter of support from the current Medical Director. The applicant adequately documents the availability of resources, including health manpower and management personnel, for the provision of the services to be provided. 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, pages 27-28, the applicant lists the providers of the necessary ancillary and support services. On pages 28-29, the applicant discusses relationships with other local healthcare and social service providers. The applicant adequately demonstrates that 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.

C

In Section XI, page 60, the applicant proposes an approximately 2560 square foot expansion. Exhibit 21 contains the line drawing of the existing and proposed space. The building requirements table on page 60 indicates the following:

WALLACE DIALYSIS CENTER	
New Addition	2,560 SF
Existing Square Footage	5,131 SF
Total	7,691 SF

In Section XI.6(d), page 58, the applicant describes the energy saving features incorporated into the construction plans. The applicant adequately demonstrates that the cost, design and means of construction are reasonable and that the construction costs will not unduly increase the costs and charges of providing the proposed services. See Criterion (5) for discussion of costs and charges. Therefore, the application is conforming to this criterion.

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

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section VI.1, page 32, the applicant provides the payor mix for services currently provided at the facility. The applicant states:

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

The applicant states that 74.6% of dialysis services were provided to Medicare and/or Medicaid patients in the year prior to submitting this application. An additional 7.8% of services were provided by VA sponsorship. See the following table, from page 32:

WALLACE DIALYSIS CENTER	
PAYOR	% OF TOTAL PATIENTS
Medicare Commercial	37.4%
Medicare/Medicaid	25.5%
Commercial Insurance	17.6%
Medicare	7.8%
VA	7.8%
Medicaid	3.9%
TOTAL	100.0%

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages as of June 2010 and CY 2008-2009, respectively. The data in the table were obtained on May 15, 2012. More current data, particularly with regard to the estimated uninsured percentages, were not available.

	Total # of Medicaid Eligible as % of Total Population	Total # of Medicaid Eligibles Age 21 and older as % of Total Population	% Uninsured CY 2009 (Estimate by Cecil G. Sheps Center)
Duplin County	20.0%	7.6%	24.6%
Statewide	17.0%	6.7%	19.7%

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by Wallace Dialysis Center of Duplin County.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. However, as of May 15, 2012, no population data was available by age, race or gender. Even if the data were available, a direct comparison to the applicants' current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicant demonstrates that medically underserved populations currently have adequate access to the dialysis services provided at Wallace Dialysis Center of Duplin County. 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.6(a), page 35, the applicant states there have been no civil rights access complaints filed against Wallace Dialysis Center within the last five years. Therefore, the application is conforming to this criterion.

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

C

In Section VI.1(c), page 32, the applicant provides the projected payor mix for the proposed dialysis services at the facility. The applicant projects no change from the current payor mix for dialysis visits as stated in Criterion (13a) above. The applicant demonstrates that the elderly and medically underserved populations would have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section VI.5, page 34, the applicant states:

“Patients with End Stage Renal Disease have access to dialysis services upon referral to a Nephrologist with privileges at Wallace Dialysis Center. ... Should a patient contact Wallace Dialysis Center directly or indirectly, the patient is referred to a qualified Nephrologist for evaluation and subsequent admission if medically necessary. ...”

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

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

C

In Section V, page 29, the applicant states:

“Wallace Dialysis anticipates that the facility will eventually establish a working relationship with James Sprunt Community College. The facility would serve as a clinical learning site for nursing students.”

The information provided in Section V3. and Exhibit 12 (requested by analyst) 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

See Sections II, III, V, VI, and VII in the Wallace Dialysis Center application. In particular, see Section V.7, pages 30-31 in which the Wallace Dialysis Center discusses the impact of the project as it relates to promoting cost-effectiveness, quality and access. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition include a positive impact on cost-effectiveness, quality and access to dialysis services in Duplin County. This determination is based on the information in the application, and the following:

- The applicant adequately demonstrates the need to add four dialysis stations and that it is a cost-effective alternative;
- The applicant has and will continue to provide quality services; and
- The applicant has and will continue to provide adequate access to medically underserved populations. The proposed project improves geographic access to patients who wish to transfer their care to a closer facility.

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

According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, Wallace Dialysis Center operated in compliance with all Medicare conditions of participation within the 18 months immediately preceding the date of this decision. Therefore the application is conforming to this criterion.

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

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

C

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

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

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

Utilization rates;

.2202(a)(1)

-C- See Section IV, pages 25-26, and Exhibit 7 (copy of the January 2012 SDR, Tables A and B).

Mortality rates;

.2202(a)(2)

-C- See Section IV, page 25.

The number of patients that are home trained and the number of patients on

.2202(a)(3) home dialysis;

-C- See Section IV, page 25.

The number of transplants performed or referred;

.2202(a)(4)

-C- See Section IV, page 26.

The number of patients currently on the transplant waiting list;

.2202(a)(5)

-C- See Section IV, page 26.

Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;

.2202(a)(6)

-C- See Section IV, page 26.

The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.

.2202(a)(7)

-C- See Section IV, page 26.

(b) An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:

.2202(b)(1)

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

Section 405.2100.

- NA- Wallace Dialysis Center is an existing facility.
.2202(b)(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*
- (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
 - (B) *composition of the assessment/evaluation team at the transplant center,*
 - (C) *method for periodic re-evaluation,*
 - (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and,*
 - (E) *Signatures of the duly authorized persons representing the facilities and the agency providing the services.*
- NA- Wallace Dialysis Center is an existing facility.
.2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- NA- Wallace Dialysis Center is an existing facility.
.2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C- See Exhibit 8.
.2202(b)(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*
- NA- Wallace Dialysis Center is an existing facility.
.2202(b)(6) *Documentation that the services will be provided in conformity to applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*
- C- See Section XI.6(g), pages 58-59; and Exhibits 1, 23 and 24.
.2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C- See Section III.7, pages 21-22.
.2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
- NA- Wallace Dialysis Center is an existing facility.
.2202(b)(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement for such services.*
- C- In Section II, page 12, the applicant states: “*Total Renal Care of North Carolina*

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- Wallace Dialysis Center is an existing facility.

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

-C- In Section II, pages 12-15, and Section III, pages 19, 21-22, the applicant documents the need for the additional stations.

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

-C- In Section II, pages 13-15, and Section III, pages 21-22, the applicant provides the assumptions and methodology used to project utilization of the proposed facility.

10 NCAC 14C .2204 SCOPE OF SERVICES

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

.2204(1) Diagnostic and evaluation services;

- C- See Section V, page 27.
- .2204(2) *Maintenance dialysis;*
- C- See Section V, page 27.
- .2204(3) *Accessible self-care training;*
- C- See Section V, page 27
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
- C- See Section V, page 27
- .2204(5) *X-ray services;*
- C- See Section V, page 27
- .2204(6) *Laboratory services;*
- C- See Section V, page 27
- .2204(7) *Blood bank services;*
- C- See Section V, page 27
- .2204(8) *Emergency care;*
- C- See Section V, page 27
- .2204(9) *Acute dialysis in an acute care setting;*
- C- See Section V, page 27
- .2204(10) *Vascular surgery for dialysis treatment patients*
- C- See Section V, page 28
- .2204(11) *Transplantation services;*
- C- See Section V, page 27
- .2204(12) *Vocational rehabilitation counseling and services; and,*
- C- See Section V, page 28
- .2204(13) *Transportation*
- C- See Section V, page 28

10 NCAC 14C .2205 STAFFING AND STAFF TRAINING

- .2205(a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R. Section 405.2100.*
- C- See Section VII, pages 36-37. Also, in Section VII, page 39, the applicant provides the proposed staffing. The applicant states on page 36 that the facility will comply with all staffing requirements set forth in 42 C.F.R. Section 405.2100. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. See Criterion (7) for discussion.
- .2205(b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*
- C- See Section VII, page 38, and Exhibit 17.