

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: June 27, 2014
PROJECT ANALYST: Bernetta Thorne-Williams
INTERIM CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: L-10269-14/ DVA Healthcare Renal Care, Inc. d/b/a Wilson Dialysis Center/ Add four dialysis stations for a total of 40 certified dialysis stations upon project completion/ Wilson 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.

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DVA Healthcare Renal Care, Inc. d/b/a Wilson Dialysis Center proposes to add four dialysis stations, of which two stations will be used for in-center dialysis patients and two stations will be used for home hemodialysis training, for a total of 40 certified dialysis stations upon completion of the proposed project.

According to the January 2014 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of one dialysis station in Wilson County. However, the applicant is not applying for the additional stations based on the county need methodology. The applicant is eligible to apply for additional stations in its existing facility based on application of the facility need methodology because the utilization rate reported for Wilson Dialysis Center in the January 2014 SDR is 3.66 patients per station. This utilization rate was calculated based on 132 in-center dialysis patients and 36 certified dialysis stations (132 patients / 36 stations = 3.6667 patients per station).

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

Required SDR Utilization		80%
Center Utilization Rate as of 6/30/13		91.67%
Certified Stations		36
Pending Stations		0
Total Existing and Pending Stations		36
In-Center Patients as of 6/30/13 (SDR2)		132
In-Center Patients as of 12/31/12 (SDR1)		123
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	9
	Multiply the difference by 2 for the projected net in-center change	18
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/12	0.1463
(ii)	Divide the result of step (i) by 12	0.0122
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/13 until 12/31/13)	0.0732
(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	141.6585
(v)	Divide the result of step (iv) by 3.2 patients per station	44.2683
	and subtract the number of certified and pending stations as recorded in SDR2 [36] to determine the number of stations needed	8

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is eight 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 four new stations which is half the number of stations that the applicant could apply for based on the facility need methodology. Therefore, the application is consistent with the facility need determination for dialysis stations.

Policy GEN-3: Basic Principles, page 38 of the 2014 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

In Section II.3, pages 17-18, the applicant discusses the quality of services provided at DaVita HealthCare Partners, Inc. owned and operated ESRD facilities. The applicant states that its success in providing quality services stems from a comprehensive Quality Management Program that includes the following components:

- *“Quality Improvement Methodology – utilizing outcome-driven, patient centered management programs to measure, monitor and manage outcomes.*
- *Computerized Information System – integrating clinical and laboratory information for comprehensive outcomes tracking and reporting.*
- *Staff and Patient Education Program – ensuring continuous updates and training to ensure high quality patient care.*
- *Quality Assessment Audit Program – systematically utilizing a comprehensive detailed assessment tool to assure the highest quality standards in every facility.*
- *Quality Management Team – experienced clinical facilitators to implement and maintain ongoing quality improvement programs.*
- *Quality Biomedical Team – experienced specialists in all aspects of Biomedical requirements (i.e., water treatment, reuse, disinfection and machine maintenance).”*

The applicant further states on page 18, that the company’s goal is to have each facility serve as a quality improvement laboratory where successful outcomes can be disseminated throughout DaVita. Exhibit 22 contains DaVita’s Health and Safety Policy & Procedure Manual which includes a section on General Health and Safety Policies. The Health and Safety Policies state, in part:

“The Health and Safety Policy & Procedure Manual is designed to ensure compliance and provide policy and procedure for teammate health and safety issues. Using this manual, each DaVita facility will meet Federal regulations as they relate to Risk and Occupational Safety Health and Administration (OSHA), support the corporate philosophy of consistent practice and operations of facilities within the company ...”

The applicant adequately demonstrates that the proposal will promote safety and quality care at Wilson Dialysis Center.

Promote Equitable Access

In Section VI.1, pages 32-33, the applicant states that Wilson Dialysis Center has and will continue to provide services to all residents of the service area without regard to race, sex, age, gender, handicap, ethnic or socioeconomic groups in need of dialysis service regardless of their ability to pay. The applicant further states on page 32 that 92.7% of its patients had some or all of their services paid for by Medicare or Medicaid.

The applicant adequately demonstrates that the proposal will promote equitable access.

Maximize Healthcare Value

In Section III.9, pages 23-24, the applicant states that Wilson Dialysis Center will maximize healthcare value in several ways which include utilization of a centralized purchasing department to negotiate national contracts with numerous vendors in order to secure the best product available at the best price; utilization of the reuse process that contains costs and the amount of dialyzer waste generated by the facility; the use of an electronic patient charting system that reduces the need for paper in the facility; preventative maintenance on the dialysis machines on a monthly, quarterly and semi-annual schedule to reduce the need for repairs of the dialysis equipment; and inventory control plan that ensures enough supplies are available without having an inordinate amount of supplies on hand.

The applicant adequately demonstrates that the proposal will maximize healthcare value.

The applicant adequately demonstrates the proposal will incorporate the basic principles of Policy GEN 3. The application is also consistent with the facility need determination in the 2014 SMFP and is therefore 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.

The applicant, DVA Healthcare Renal Care, Inc. d/b/a Wilson Dialysis Center, proposes to add four dialysis stations to its existing facility for a total of 40 certified dialysis stations upon completion of the proposed project. Two of the new stations will be used for home hemodialysis training.

Population to be Served

In Section IV.1, page 25, the applicant identifies the population it served, as of June 30, 2013, as illustrated in the table below.

Wilson Dialysis Center Current Patient Origin		
County	In-Center Patients	Home Trained Patients
Wilson	121	23
Wayne	1	4
Edgecombe	1	0
Nash	7	5
Johnston	2	3
Onslow	0	1
Martin	0	1
TOTAL	132	37

In Section III.7, page 21, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, as illustrated in the table below:

Projected Dialysis Patient Origin						
COUNTY	Operating Year 1 2015		Operating Year 2 2016		County In-Center Patients as a Percent of Total	
	In-Center Patients	Home Dialysis Patients	In-Center Patients	Home Dialysis Patients	Year 1	Year 2
Wilson	132	25	139	26	92.3%	92.7%
Edgecombe	1	0	1	0	0.7%	0.7%
Nash	7	5	7	5	4.9%	4.7%
Johnston	2	3	2	3	1.4%	1.3%
Wayne	1	4	1	4	0.7%	0.7%
Martin	0	1	0	1		
Onslow	0	1	0	1		
TOTAL	143	39	150	40	100.0%	100.0%

The applicant adequately identified the population it proposes to serve.

Need Analysis

In Section III.7, page 22, the applicant provides the following assumptions regarding in-center patient utilization for the proposed project:

“We have grown the patient population of Wilson patients beginning January 1, 2014 through the projected operating year 2. The calculations below begin with 121 in-center patients living in Wilson County.

January 1, 2014-December 31, 2014 – 121 patients X 1.048 = 126.808

January 1, 2015-December 31, 2015 – 126.808 patients X 1.048 = 132.894784

January 1, 2016-December 31, 2016 – 132.894784 X 1.048 = 139.2737336

*January 1, 2015 – December 31, 2015 (operating year 1)
January 1, 2016 – December 31, 2016 (operating year 2)”*

The applicant further states on page 22, that at the ending of operating year one, Wilson Dialysis Center is projected to have 143 in-center dialysis patients of which 132 of those patients will be from Wilson County, seven patients will be from Nash County, two patients from Johnston County and one patient each from Edgecombe County and Wayne County. The applicant further states on page 22, that the growth rate for patients residing outside of Wilson County was not calculated.

On page 22, the applicant projects to serve 143 in-center patients dialyzing on 40 stations by the end of operating year 1 for a utilization rate of 85% or 3.4 patients per station. However, it would be 3.5 patients per station [$143/40 = 3.575$] for a utilization rate 89%, not 85%. Either way projected utilization 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).

In operating year 2, the applicant projects serving 150 in-center patients at Wilson Dialysis Center, of which 139 patients are projected to be from Wilson County, seven from Nash County, two from Johnston County and one patient each from Edgecombe County and Wayne County. The applicant states on page 22, that this is a utilization rate of 89% or 3.5 patients per station. However, it would be 3.75 patients per station [$150/40=3.75$] which is a utilization of 93%, and not 89%.

In Section III, page 21, the applicant provides the following support for the projected utilization:

- Wilson Dialysis Center had 132 in-center patients as of 6/30/2013.
- The facility is eligible for an eight-station expansion based on the facility need methodology.
- Wilson County, the location of the facility, had an average annual change rate of 4.8% over the past five years.
- 121 of the 132 patients being served by the Wilson Dialysis Center lived in Wilson County.
- Eleven of those patients receiving in-center services at Wilson Dialysis Center lived in four other counties.
- The home training department experienced growth in the admission of peritoneal dialysis and home hemodialysis modalities.
- 23 of the 37 home trained patients being served by the Wilson Dialysis Center lived in Wilson County.
- Fourteen of those patients receiving home training lived in five other counties.

With regard to home trained patients, the applicant states the following on page 22:

“We have grown the patient population of the home-training patients beginning January 1, 2014 through the projected operating year 2. The calculations below begin with 23 home-trained patients living in Wilson County. The Wilson County five-year average change rate of 4.8% was used in calculating the projected number of patients in operating years one and two:

January 1, 2014-December 31, 2014 – 23 patients X 1.048=24.104

January 1, 2015-December 31, 2015 – 24.104 patients X 1.048 = 25.260992

January 1, 2016-December 31, 2015 (operating year 1)

January 1, 2016-December 31, 2016 (operating year 2)”

The applicant projects to have 39 home-trained patients at the end of operating year 1, with 25 of those patients being Wilson County patients, five patients from Nash County, four patients from Wayne County, three patients from Johnston County, and one patient each from Martin County and Wayne County. At the end of operating year 2, the applicant projects to serve 40 home-trained patients by adding one additional home-trained person in Nash County for a total of five home-trained patients in Nash with the rest of the counties remaining consistent with operating year 1.

Projected utilization is based on reasonable and supported assumptions regarding continued growth in the proposed service area.

Access to Services

In Section VI.1(a), page 32 the applicant states:

“Wilson 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 patients without regard to race, sex, age, handicap, or other ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.

...

Wilson 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. Wilson Dialysis Center works with patients who need transportation, when necessary.”

The applicant projects that 64% of its patients will have all or part of their services covered by Medicare and or Medicaid, 3.3% will be covered by VA and another 28.6% will be covered by Medicare/Commercial. The applicant adequately demonstrates 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.

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 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.

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- (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.

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In Section III.9, pages 23-24, the applicant discusses the two alternatives considered by Wilson Dialysis Center, which include:

- 1) Maintain the Status Quo – the applicant concluded that with the rapid growth of the facility, to do nothing would not be in the best interest of the patients opting to have their dialysis care at Wilson Dialysis Center.
- 2) Adding four stations – the applicant concluded that the proposal of four additional dialysis stations, as proposed in the application, was its best alternative. Thus, the applicant concluded that the project as proposed was its least costly and most effective alternative.

The applicant adequately demonstrates the need for four additional stations based on the continued growth of the ESRD patient population in Wilson County and the facility's projected utilization. See Criterion (3) for discussion on need which is incorporated hereby as if fully set forth herein.

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. Consequently, the application is conforming to this criterion and approved subject to the following conditions:

1. **DVA Healthcare Renal Care, Inc. d/b/a Wilson Dialysis Center shall materially comply with all representations made in the certificate of need application.**
2. **DVA Healthcare Renal Care, Inc. d/b/a Wilson Dialysis Center shall develop and operate no more than four additional stations for a total of no more than 40 certified stations upon project completion, which shall include any home hemodialysis training and isolation stations.**
3. **DVA Healthcare Renal Care, Inc. d/b/a Wilson Dialysis Center shall install plumbing and electrical wiring through the walls for no more than four additional stations for a total of no more than 40 dialysis stations, including any home hemodialysis training and isolation stations.**
4. **DVA Healthcare Renal Care, Inc. d/b/a Wilson 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.

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In Section VIII, page 41, and clarifying supplemental information, the applicant projects the total capital cost of the project is estimated to be \$62,400. The estimated capital cost includes the following:

Dialysis Machine	\$23,712
NxStage	\$14,850
Dialysis Chair	\$ 5,200
Patient TV	\$ 6,000
Chair Side computer	\$ 2,156
Computer Stand	\$ 344
Reverse Osmosis	\$ 8,000
Other Equipment	<u>\$ 2,138</u>
Total	\$ 62,400

The applicant projects no initial start-up costs or initial operating expenses. The applicant states the capital costs for the proposed project will be funded by cash reserves from DaVita Healthcare Partners Inc., the parent company to DVA Healthcare Renal Care, Inc.

In Exhibit 17, the applicant provides a letter dated March 3, 2014 from the Chief Accounting Officer, which states, in part:

“We are submitting a Certificate of Need application to expand our Wilson Center Dialysis Center by four ESRD dialysis stations.

The project calls for a capital expenditure of \$62,400. This letter will confirm that DaVita HealthCare Partners Inc. has committed case reserves in the total sum of \$62,400, for the project capital expenditure. DaVita HealthCare Partners Inc. will make these funds, along with any other funds that are necessary for the development of the project, available to DVA Healthcare Renal Care, Inc....”

In Exhibit 18 the applicant provides the audited financial statements for DaVita Healthcare Partners Inc. for the fiscal years ended December 31, 2013 and 2012. As of December 31, 2013, DaVita HealthCare Partners Inc. had \$946,249,000

in cash and cash equivalents, \$17,098,877,000 in total assets and \$5,302,841,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital needs of the project.

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

Payor	Allowable Charge Per In-center Treatment
Medicare	\$240.00
Medicaid	\$143.00
Medicare/Medicaid	\$240.00
Commercial Insurance	\$1,175.00
VA	\$193.00
Medicare/Commercial	\$240.00

In Sections X.2-X.4, pages 47-51, the applicant projects revenues and operating expenses for Wilson Dialysis Center, as illustrated in the table below:

	Operating Year 1	Operating Year 2
Total Net Revenue	\$6,786,251	\$7,071,696
Total Operating Costs	\$5,686,475	\$5,900,606
Net Profit	\$1,099,776	\$1,171,090

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, credible and adequately supported. See Section X, pages 47-52, for the applicant's assumptions.

The applicant adequately demonstrated that the financial feasibility of the proposal is based on reasonable and supported projections regarding revenues and operating expenses. 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.

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DVA Healthcare Renal Care, Inc. d/b/a Wilson Dialysis Center proposes to add four dialysis stations for a total of 40 certified dialysis stations upon project completion. Wilson Dialysis Center served 132 patients weekly at 3.6667

patients per station, which is 91.67% of its capacity ($132 / (4/36) = 91.66$) as of June 30, 2013.

According to the January 2014 SDR there is one other provider of ESRD services in Wilson County, Forest Hill Dialysis in Forest Hill, which has 21 certified dialysis stations and 10 stations pending certification. The January 2014 SDR reported that Forest Hill Dialysis, which is also owned and operated by DaVita, had 98 in-center patients dialyzing on 21 stations for a utilization rate of 116.67%.

The applicant projects to serve 143 in-center dialysis patients in operating year 1 (2015) dialyzing on 40 stations for a utilization rate of 89% or 3.5 patients per station [$143 / 40 = 3.575 / 4.0 = 0.89375$ or 89%]. The applicant projects 150 in-center patients in operating year 2 for a utilization rate of 93% or 3.7 patients per station [$150 / 40 = 3.75 / 4.0 = 0.9375$ or 93%]. The growth projections are based on Wilson County's projected five-year average annual growth rate in the number of dialysis patients.

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.

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In Section VII.1, page 36, the applicant states that Wilson Dialysis Center currently employs 29.5 full-time equivalent positions (FTEs). The applicant does not propose to hire additional staff as a result of the proposed project. The applicant further states on page 36, *"The facility complies with all staffing requirements as stated in 42 C.F.R. Section 405 .2100"*

In Section VII.10, pages 36-37, the applicant provides the following tables that illustrates the current and projected number of direct care staff per shift:

Current Direct Care Staff per Shift

	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	6am to 11am	9	9	9	9	9	9
Afternoon	11am to 4pm	9	9	9	9	9	9
Evening	N/A	0	0	0	0	0	0

Projected Direct Care Staff per Shift

	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	6am to 11:00am	10	10	10	10	10	10
Afternoon	11am to 4pm	10	10	10	10	10	10
Evening	N/A	0	0	0	0	0	0

The applicant indicates on page 39, that the projected schedule for the morning shift will operate from 6:00 a.m. – 10:30 a.m., however, during subsequent communication with the applicant, the applicant indicated that the information on page 39 was a typographical error and that the projected hours of operation would not differ from the prior hours of operation.

In Section V.4(c), page 30, the applicant states that Dr. Anwar Haidary, of Wilson Nephrology – Internal Medicine, PA, currently serves as the Medical Director of Wilson Dialysis Center and he has expressed his willingness to continue serving in that role. See Exhibit 12 for a letter dated February 28, 2014 from Dr. Haidary expressing his willingness to continue in his current role of Medical Director.

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

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

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In Section V.1, page 27, the applicant provides a list of 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 will be provided by Wilson Medical Center. See Exhibit 9 for a copy of the acute care agreement and Exhibit 10 for a copy of the Transplant Agreement with East Carolina University School of Medicine and Duke University Medical Center. 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

NA

- (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;

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In Section VI.1(a), page 32, the applicant states Wilson Dialysis Center, by policy, will make dialysis services available to all residents in its service area without qualifications.

In Section VI.1(b), page 32, the applicant reports that 92.7% of the patients who received treatments at Wilson Dialysis Center had some or all of their services paid for by Medicare or Medicaid in the past year. The table below illustrates the historical payment source for the existing facility:

WILSON DIALYSIS CENTER PAYOR MIX	
SOURCE OF PAYMENT	PERCENTAGE
Medicare	26.7%
Medicaid	6.7%
Medicare/Medicaid	30.6%
Commercial Insurance	4.0%
VA	3.3%
Medicare/Commercial	28.7%
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 for Wilson County and statewide.

	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Wilson County	22%	8.98%	21.9%
Statewide	17%	6.71%	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 dialysis services offered by Wilson Dialysis Center. In fact, in 2012 only 6.5% of all newly-diagnosed ESRD patients in North Carolina's Network 6 were under the age of 35 (*ESRD Network 6 2012 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 01/01/2012 – 12/21/2012*, page 74).

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

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

*“The December 31, 2011 prevalent population included 430,273 patients on dialysis ...”*¹ (p. 216)

The report also provided the incidence of dialysis patients in 2011, adjusted by age, gender and race, which showed 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 Southeastern Kidney Council (SKC) Network 6 2012 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 76, summarized as follows:

¹ www.usrds.org/adr.aspx

Number and Percent of Dialysis Patients by Age, Race and Gender 2012		
	# of ESRD Patients	% of Dialysis Population
Ages		
0-19	73	0.5%
20-34	751	5.0%
35-44	1,442	9.7%
45-54	2,644	17.7%
55-64	4,013	26.9%
65+	5,995	40.2%
Gender		
Female	6,692	44.9%
Male	8,226	55.1%
Race		
African American	9,346	62.7%
White/Caucasian	5,191	34.8%
Other	380	2.6%

Source: Southeastern Kidney Council (SKC) Network 6.
 Table includes North Carolina statistics only.²

The 2013 United States Renal Data System (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%

*Source: 2013 United States Renal Data System (USRDS) Annual Data Report, page 332.

Wilson Dialysis Center 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;

² www.esrdnetwork6.org/publications/reports.html

C

In Section VI.1(f), page 33, the applicant states,

“Wilson Dialysis Center has no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons except those obligations which are placed upon all medical facilities under Section 504 of the Rehabilitation Act of 1973 and its subsequent amendment in 1993.”

In Section VI.6 (a), page 35, the applicant states, *“There have been no civil rights access complaints filed within the last five years.”*

The application is conforming to this criterion.

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

C

In Section VI.1(c), page 33, the applicant provides the projected payor mix for the proposed services at the existing facility, as follows:

WILSON DIALYSIS CENTER PAYOR MIX	
SOURCE OF PAYMENT	PERCENTAGE
Medicare	26.7%
Medicaid	6.7%
Medicare/Medicaid	30.6%
Commercial Insurance	4.0%
VA	3.3%
Medicare/Commercial	28.7%
Total	100.0%

As illustrated in the table above, the applicant does not project a change in its payor mix.

In Section VI.1(a), page 32, the applicant states,

“Wilson 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.”

The applicant demonstrates that medically underserved populations will continue to 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(a), page 34, the applicant states that:

*“Patients with End Stage Renal Disease have access to dialysis services upon referral by a Nephrologist with privileges at the Wilson Dialysis Center. These referrals most commonly come from primary care physicians or specialty physicians in Wilson County or transfer referrals from other Nephrologists outside of the immediate area. Patients, families and friends can obtain access by contacting a Nephrologist with privileges at the facility. Should a patient contact the Wilson Dialysis Center directly or indirectly, the patient is referred to a qualified Nephrologist for evaluation and subsequent admission if medically necessary. Patients from outside the Wilson Dialysis Center catchment area requesting transfer to this facility are processed in accordance with the Wilson Dialysis Center transfer and transient policies which comprise **Exhibit 13**. The patient, again, is referred to a qualified Nephrologist for evaluation and subsequent admission, if medically necessary.”* [Emphasis in original]

The applicant adequately demonstrates that it provides a range of means by which a person can access services at Wilson Dialysis Center. Therefore, the application is conforming to this criterion.

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

C

In Section V.3(a), page 29, the applicant states,

“Wilson Dialysis Center is utilized as a clinical training site by the Wilson Community College.”

Exhibit 11 includes a copy of an agreement between Gambro Healthcare (now known as Wilson Dialysis Center) and Wilson Technical Community College

for the ESRD facility to be included in its clinical rotation schedule for student nurses. The information provided in Section V.3 is reasonable and credible and supports a finding of conformity with 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 four dialysis stations, two of which will be for the use of in-center patients and two for home hemodialysis training, for a total of 40 certified dialysis stations upon project completion. The January 2014 SDR reported the utilization rate for Wilson Dialysis Center was 3.66 patients per stations. This utilization rate was calculated based on 132 in-center dialysis patients and 36 certified dialysis stations (132 patients / 36 stations = 3.6667 patients per station).

According to the January 2014 SDR there is one other provider of ESRD services in Wilson County, Forest Hill Dialysis in Forest Hill, which has 21 certified dialysis stations and 10 stations pending certification. The January 2014 SDR reported that Forest Hill Dialysis, which is also owned and operated by DaVita Healthcare Partners, Inc. had 98 in-center patients dialyzing on 21 stations for a utilization rate of 116.67%.

In Section V.7, pages 30-31, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states:

“Wilson County is a rural county. The proposed expansion ... of the facility is an effort to provide dialysis services to this rural community and surrounding rural community and is not intended to be a competitive venture. The effect of other facilities in surrounding counties would be difficult to determine since most patients from Wilson County already receive treatment in Wilson.

The effect upon competition is unknown. However, patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs. The Wilson Dialysis Center provides access to all qualified Nephrologists to admit his or her patients.”

See also Sections II, III, V, VI and VII where the applicant discusses cost-effectiveness, quality and access.

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that any enhanced competition in the service area will have a positive impact on the 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 to add four additional stations, two of which will be used for home hemodialysis, to the existing facility based on facility need methodology. The applicant also demonstrates that the proposed project is a cost-effective alternative to meet the need to provide additional access to Wilson Dialysis Center patients;
- 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 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

DVA Healthcare Renal Care, Inc. currently provides dialysis services at Wilson Dialysis Center. According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the Wilson Dialysis Center operated in compliance with the 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.

G.S. 131E-183(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 .2200, are applicable to this review. The proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services. The specific findings 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 10, the applicant states the utilization rate is reported in the January 2014 SDR provided in Exhibit 7. The January 2014 SDR reports a utilization rate of 91.67% which was calculated based on 132 in-center dialysis patients and 36 certified dialysis stations as of June 30, 2013. See Exhibit 1 for the Medicare Certification letter for Wilson Dialysis Center.

(2) *Mortality rates;*

-C- In Section IV.2, page 25, the applicant reports the 2011, 2012 and 2013 facility mortality rates as 11.3%, 13.2% and 13.3%, respectively.

(3) *The number of patients that are home trained and the number of patients on home dialysis;*

-C- In Section IV.3, page 25, the applicant states, “Wilson Dialysis Center had 34 home-trained patients as of June 30, 2013.”

(4) *The number of transplants performed or referred;*

- C- In Section IV.4, page 26, the applicant states, “*Wilson Dialysis Center referred 41 patients for transplant evaluation in 2013. Six Wilson Dialysis Center patients received a transplant in 2013.*”
 - (5) *The number of patients currently on the transplant waiting list;*
- C- In Section IV.5, page 26, the applicant states, “*Wilson Dialysis Center has 31 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 26, the applicant states that Wilson Dialysis Center had 306 hospital admissions in 2013, 125 (40.8%) of which were dialysis related and 181 (59.2%) 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 26, the applicant states that there were two in-center patients dialyzing at Wilson Dialysis Center and one home-trained patient with Hepatitis B, and one home-trained patient with AIDS as of December 31, 2013. The applicant also states that the number of patients treated with infectious disease who have converted to infectious status within the last year is zero.
- (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- Wilson 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- Wilson 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- Wilson 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, where 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- Wilson 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 57, the applicant states, “*Wilson Dialysis Center has and will continue to operate within the applicable laws and regulations pertaining to staffing and fire safety equipment, physical environment, and other relevant health safety requirements.*”

- (7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*

-C- In Section III.7, pages 21-22, the applicant provides the projected patient origin, including all assumptions, the methodology by which the patient origin is projected, as illustrated in the table below.

Projected Dialysis Patient Origin

COUNTY	Operating Year 1 2015		Operating Year 2 2016		County In-Center Patients as a Percent of Total	
	In-Center Patients	Home Dialysis Patients	In-Center Patients	Home Dialysis Patients	Year 1	Year 2
Wilson	132	25	139	26	92.3%	92.7%
Edgecombe	1	0	1	0	0.7%	0.7%
Nash	7	5	7	5	4.9%	4.7%
Johnston	2	3	2	3	1.4%	1.3%
Wayne	1	4	1	4	0.7%	0.7%
Martin	0	1	0	1		
Onslow	0	1	0	1		
TOTAL	143	39	150	40	100.0%	100.0%

See Section III.7, pages 21–23 of the application and the discussion in Criterion (3) with regard to the methodology and assumptions the applicant uses to project patient origin which is incorporated hereby as if set forth fully herein.

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

-NA- Wilson 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 12, the applicant states, “DVA Healthcare Renal Care, Inc. d/b/a Wilson 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.”

.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- Wilson 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- In Section II, pages 12-13, the applicant states that there were 132 in-center patients dialyzing on 36 stations as of December 31, 2013 which resulted in a utilization rate of 91%. The applicant projects to have 143 in-center patients by the end of year one for a utilization rate of 82% or 3.5 patients per station per week [$143 / 40 = 3.575 / 4.0 = 0.89375$ or 89%]. See Criterion (3) for additional discussion which is incorporated hereby as if set forth fully herein.

.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(e), page 27, states patients will be referred to Wilson Medical Center for diagnostic and evaluation services.

(2) *maintenance dialysis;*

-C- The table in Section V.1(c), page 27, states the applicant will provide in-center maintenance dialysis.

(3) *accessible self-care training;*

- C- In Section V.2(d), page 28, the applicant describes the facility's follow-up program.
 - (4) *accessible follow-up program for support of patients dialyzing at home;*
- C- In Section V.1(d), page 27, the applicant proposes to provide support for patients dialyzing at home, which includes two of the four proposed stations being used for home hemodialysis training.
 - (5) *x-ray services;*
- C- The table in Section V.1(g), page 27, states patients will be referred to Wilson Medical Center for x-ray services.
 - (6) *laboratory services;*
- C- The table in Section V.1(h), page 27, 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(i), page 27, states patients will be referred to Wilson Medical Center for blood bank services.
 - (8) *emergency care;*
- C- The table in Section V.1(b), page 27, states patients will be referred to Wilson Medical Center for emergency care.
 - (9) *acute dialysis in an acute care setting;*
- C- The table in Section V.1(a), page 27, states patients will be referred to Wilson Medical for acute dialysis in an acute care setting.
 - (10) *vascular surgery for dialysis treatment patients;*
- C- The table in Section V.1(p), page 27, states dialysis patients will be referred to Wilson Medical Center for vascular surgery.
 - (11) *transplantation services;*
- C- The table in Section V.1(f), page 27, states patients will be referred to East Carolina School of Medicine and Duke

University Medical Center for transplantation services. See Exhibit 10 for documentation of transplantation agreements.

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

-C- The table in Section V.1(o), page 27, states patients will be referred to the NC Division of Vocational Rehabilitation Services for vocational rehabilitation counseling and services.

(13) *transportation.*

-C- The table in Section V.1(q), page 28, states patients will be referred to Tar Heel Medical Transport of Wilson Apple Bus Service transportation.

.2205 STAFFING AND STAFF TRAINING

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

-C- In Section VII, the applicant provides the current and projected staffing for Wilson Dialysis Center. The applicant states, “*The facility complies with all staffing requirements as stated in 42 C.F.R. Section 405.2100 as evidenced below.*” See Criterion (7) for additional discussion which is incorporated hereby as if set forth fully herein.

(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 38, the applicant refers to Exhibit 16 for a copy of the training program description/outline. Exhibit 16 contains a copy of DaVita’s Training Programs for New Patient Care Provider Teammates. Exhibit 23 contains the Wilson Dialysis Center Annual In-Service Calendar.