

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 22, 2017

Findings Date: February 22, 2017

Project Analyst: Jane Rhoe-Jones

Team Leader: Lisa Pittman

Project ID #: L-11250-16

Facility: Wilson Dialysis

FID #: 971340

County: Wilson

Applicant: DVA Renal Healthcare, Inc.

Project: Add one station for a total of 41 stations upon completion of this project, Project ID# L-11132-16 (relocate five stations to Sharpsburg Dialysis) and Project ID# L-11156-16 (add five stations)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

NC

DVA Renal Healthcare, Inc. (DVA) d/b/a Wilson Dialysis (“the applicant”) proposes to add one dialysis station for a total of 41 stations at Wilson Dialysis upon completion of Project ID# L-11132-16 (relocate five stations to Sharpsburg Dialysis) and Project ID# L-11156-16 (add five stations).

Need Determination

The 2016 State Medical Facilities Plan (2016 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2016 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of 11 dialysis stations in Wilson County. Therefore, the July 2016 SDR does not

indicate a need for additional stations in Wilson County based on the county need methodology, which states that the county deficit must be 10 or greater to establish a need for additional stations.

An applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. The utilization rate reported for Wilson Dialysis in the July 2016 SDR is 3.3750 patients per station, or 84.38% (3.3750 / 4 patients per station = 0.8438). This utilization rate was calculated based on 135 in-center dialysis patients and 40 certified dialysis stations (135 patients / 40 stations = 3.3750 patients per station).

However, in applying the facility need methodology the applicant does not include five stations pending at Wilson Dialysis. When the five pending stations are included in the facility need methodology, no stations are needed for this facility, as illustrated in the following table:

WILSON DIALYSIS OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/15		84.4%
Certified Stations		40
Pending Stations		5
Total Existing and Pending Stations		45
In-Center Patients as of 12/31/15 (July 2016 SDR) (SDR2)		135
In-Center Patients as of 6/30/15 (Jan 2016 SDR) (SDR1)		137
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	-2
	Multiply the difference by 2 for the projected net in-center change	-4
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/15	-0.0292
(ii)	Divide the result of Step (i) by 12	-0.0024
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/14 until 12/31/15)	-0.0292
(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	131.0584
(v)	Divide the result of Step (iv) by 3.2 patients per station	40.9557
	and subtract the number of certified and pending stations to determine the number of stations needed	-4.0443

Pending Stations: INCLUDE all previously approved stations to be added to this facility, which includes any stations certified after the cutoff date. Do NOT subtract any stations to be transferred from this facility.

In Section B-2, page 7, the applicant includes the footnote to the table shown above in its application; however, the applicant failed to include the five approved and pending stations.

Furthermore, in Section A-9, page 4, the applicant documents the pending stations as shown below in the table.

WILSON DIALYSIS			
	# of Stations	Description	Project ID#
(iv)	5	# stations previously approved to be added but not yet certified	L-11156-16

On pages 373-374, the 2016 SMFP states the following about facility need,

3. Facility Need

“A dialysis facility located in a county for which the result of the County Need methodology is zero in the current Semiannual Dialysis Report is determined to need additional stations to the extent that:

- a. Its utilization, reported in the current SDR, is 3.2 patients per station or greater.*
- b. Such need calculated as follows, is reported in an application for a certificate of need:*

...

- v. The sum from 3.B.iv is divided by 3.2, and from the quotient is subtracted the facility’s current number of certified stations as recorded in the current SDR and the number of pending new stations for which a certificate of need application has been approved. The remainder is the number of stations needed.*
- c. The facility may apply to expand to meet the need established in 3.B.v, up to a maximum of 10 stations.”*

When the five pending stations are included in the facility need methodology, there is no need determination, therefore, the applicant is not eligible to apply for additional stations.

Policies

There is one policy in the 2016 SMFP which is applicable to this review, Policy GEN-3: Basic Principles. Policy GEN-3, on page 39 of the 2016 SMFP is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

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

meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B-4(a), pages 9-10, Section N-1, page 51 and Section O, page 52, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B-4(b), page 10, Section C-3, page 16, Section L, pages 45-49, Section N-1, page 51, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section B-4(c), page 11, Section F, pages 25-29, and Section N, page 51. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

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

Conclusion

In summary, although the applicant adequately demonstrates that the proposal is consistent with Policy GEN-3: Basic Principles, the applicant does not demonstrate that the proposal is consistent with the facility need methodology in the 2016 SFMP. Therefore, the application is not conforming to this criterion.

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

C

The applicant proposes to add one dialysis station at Wilson Dialysis, an existing facility located at 2833 Wooten Boulevard, SW in Wilson. Upon completion of this project, Project ID# L-11132-16 (relocate five stations to Sharpsburg Dialysis) and Project ID# L-11156-16 (add five stations), Wilson Dialysis will be certified for a total of 41 dialysis stations. Wilson Dialysis provides both hemodialysis and peritoneal dialysis home therapy programs. However, this application is for one additional in-center dialysis station.

Patient Origin

On page 369, the 2016 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Wilson County. Facilities may also serve residents of counties not included in their service area.

In Section C-8, page 20, the applicant identifies the population served as of December 31, 2015, as illustrated below in the table:

WILSON DIALYSIS PATIENT ORIGIN As of December 31, 2015			
County	# In-Center Dialysis Patients	Home Hemo Dialysis Patients	Peritoneal Dialysis Patients
Wilson	117	19	22
Nash	7	0	4
Johnston	5	1	2
Wayne	3	2	1
Edgecombe	2	0	0
Wake	1	0	0
Pitt	0	0	2
Onslow	0	1	0
Total	135	23	31

In Section C-1, page 13, the applicant provides the projected patient origin for Wilson Dialysis for in-center (IC) patients for the first two years of operation following completion of the project as follows:

WILSON DIALYSIS									
PROJECTED IN-CENTER PATIENT ORIGIN by COUNTY									
County	OY1 CY2018			OY1 CY2019			Percent of Total OY1	Percent of Total OY2	
	IC	HH	PD	IC	HH	PD			
Wilson	122	22	24	128	23	25	87.0%	87.6%	
Nash	4	0	4	4	0	4	4.1%	4.0%	
Johnston	5	1	2	5	1	2	4.1%	4.0%	
Wayne	3	2	1	3	2	1	3.1%	3.0%	
Edgecombe	0	0	0	0	0	0	0.0%	0.0%	
Wake	0	0	0	0	0	0	0.0%	0.0%	
Pitt	0	0	2	0	0	2	1.0%	1.0%	
Onslow	0	1	0	0	1	0	0.5%	0.5%	
Total	134	26	33	140	27	34	100.0%	100.0%	

In the table in Section C-1, page 13 and in clarifying information received on December 30, 2016, the applicant states that 18 in-center patients are projected to transfer their care to Sharpsburg Dialysis upon its projected certification date in January 2018. From its projected patient origin at Wilson Dialysis, the applicant deducted three of seven Nash County patients and two of two Edgecombe County patients based on letters of support, plus the sole Wake County patient. Pitt and Onslow counties historically had no in-center dialysis patients, but do have patients utilizing Wilson Dialysis' home dialysis therapies.

The applicant provides the assumptions and methodology used to project in-center patient origin on pages 13-14 and home hemodialysis and peritoneal dialysis on pages 15-16. The applicant adequately identifies the population to be served.

Analysis of Need

In Section B-2, page 6, the applicant states the need for the proposed project is based on the facility need methodology in the 2016 SMFP utilizing data from the July 2016 SDR, and it proposes to add one dialysis station to Wilson Dialysis for a total of 41 stations at that facility. The applicant used the following assumptions in Section C-1, pages 13-14 of the application:

- Based on information in the July 2016 SDR, as of December 31, 2015, the utilization rate for Wilson Dialysis was 84.38% or 3.37 patients per station per week. This utilization was based on 135 in-center patients dialyzing on 40 stations. One hundred seventeen of the 135 patients were residents of Wilson County, and 18 were from Nash, Johnston and Wayne counties.
- The applicant was approved in Project I.D. #L-11132-16 to relocate five stations from Wilson Dialysis to develop Sharpsburg Dialysis, also in Wilson County.
- The applicant projects that upon certification of Sharpsburg Dialysis in January 2018, 18 in-center patients currently receiving care at Wilson Dialysis will transfer their care to Sharpsburg Dialysis.

- To project the growth of Wilson County patients, the applicant uses Wilson County’s Five Year Average Annual Change Rate (AACR) 4.7%, as published in Table B of the July 2016 Semi-Annual Dialysis Report (SDR). The applicant projected no growth rate for patients living outside of Wilson County.
- The applicant projects that by December 31, 2017, Wilson Dialysis will have 146 in-center patients, 128 of whom will be from Wilson County. After subtracting 11 in-center Wilson County patients and six in-center patients from outside of Wilson County who are projected to transfer to Coastal Carolina Dialysis, 76 patients Wilson County patients are projected to dialyze at Wilson Dialysis.
- The applicant projects Wilson Dialysis will have 134 in-center patients by the end of operating year one for a utilization rate of 81.7% or 3.27 patients per station per week and 140 in-center patients by the end of operating year two for a utilization rate of 85.4% or 3.41 patients per station per week.
- OY1 is Calendar Year 2018
- OY2 is Calendar Year 2019

Projected Utilization

The applicant’s methodology is illustrated in the following table.

WILSON DIALYSIS IN-CENTER PATIENT PROJECTIONS					
	Start Date	# SA* Patients x Growth Rate	SA Year End Census + # out of SA existing patients	Total Year End Census	Year End Date
Current Year	1/1/2016	117 x 1.047	122.499 + 18	140.499	12/31/2016
Interim Year	1/1/2017	122.499 x 1.047	128.2565 + 18	146.2565	12/31/2017
OY1	1/1/2018	128-11=117 x 1.047	122.499 + 18-6=12	134.499	12/31/2018
OY2	1/1/2019	122.499 x 1.047	128.2565 + 12	140.2565	12/31/2019

*SA = service area = Wilson County

The applicant projects to serve 134 in-center patients or 3.27 patients per station per week (134/41 = 3.27) by the end of Operating Year 1 and 140 in-center patients or 3.41 patients per station per week (140/41 = 3.41) by the end of Operating Year 2 for the proposed 41-station facility. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C.2203(b). The July 2016 SDR indicates that Wilson Dialysis operated at a utilization rate of 84.38 percent (3.37 patients per station) as of December 31, 2015. Based on data reported in the SDR, during the period from June 30, 2015 to December 31, 2015, the in-center census at Wilson Dialysis decreased from 137 to 135 patients, which is a six month decrease of 1.5 percent. In this application, the applicant assumes a projected five year annual rate of growth of 4.7 percent for the in-center patient census at Wilson Dialysis, which equals the Wilson County Five Year Average Annual Change Rate (AACR) of 4.7 percent. Although the six month growth rate decreased slightly, the applicant did not project an unreasonable growth rate given the AACR in Wilson County.

Projected utilization is based on reasonable and adequately supported assumptions.

Access

In Section L-1(a), pages 45-46, the applicant states that Wilson Dialysis makes its services available to all persons without qualification, including low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons. In Section L-7, page 49, the applicant reports that 90.8% of the in-center patients who received treatments at Wilson Dialysis had some or all of their services paid for by Medicare or Medicaid in CY2015. In Section L-1, page 46, the applicant projects 90.8% of its in-center patients will be Medicare or Medicaid recipients; no change from its current payor mix. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

Conclusion

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

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

NA

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

NC

In Section E-1, page 24, the applicant discusses the alternatives considered prior to submitting this application, which include:

1. Maintain the Status Quo - the applicant states that this option would not support the growth rate at the facility.
2. Apply to add one station – the applicant states the one-station expansion would help to meet the growing demand for dialysis services at Wilson Dialysis.

The applicant states the alternative represented in the application is the most effective alternative to meet the identified need. However, the applicant failed to include approved pending stations

that will be added to Wilson Dialysis, per Project ID# L-11156-16 (add five stations) when applying the facility need methodology. When those stations are included, there is no need determination.

Furthermore, the application is not conforming to all other statutory and regulatory review criteria, and thus, is not approvable. See the discussion in Criterion (1) which is incorporated herein by reference. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant did not adequately demonstrate that this proposal is the least costly or most effective alternative to meet the identified need. Consequently, the application is not conforming to this criterion.

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add one dialysis station to Wilson Dialysis, for a total of 41 dialysis stations at Wilson Dialysis upon completion of this project, Project ID# L-11132- (relocate five stations to Sharpsburg Dialysis) and Project ID# L-11156-16 (add five stations).

Capital and Working Capital Costs

In the table in Section F-1, page 25, the applicant states that there are no capital costs associated with the proposed project. Additionally, in Section F-10, pages 27-28, the applicant states that there are no working capital needs as Wilson Dialysis is an existing facility.

Availability of Funds

In Section F-2, page 26, the applicant states there are no capital costs to finance.

Exhibit F-7 contains the Consolidated Financial Statements for DaVita Healthcare Partners, Inc. which indicates that it had \$965,241 million in cash and cash equivalents as of December 31, 2014, \$17.9 billion in total assets and \$6.1 billion in net assets (total assets less total liabilities). However, the applicant does have 2015 data available and in clarifying information submitted December 15, 2016, states that DaVita Healthcare Partners, Inc. had \$1.5 billion in cash and cash equivalents, \$18.5 billion in total assets and \$5.9 billion in net assets as of December 31, 2015. The applicant adequately demonstrates that sufficient funds would be available if capital needs were required for the project.

Financial Feasibility

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

WILSON DIALYSIS REVENUE AND EXPENSES		
	CY2018	CY2019
Total Treatments	19,488	20,303
Total Charges	\$9,058,936	\$9,411,187
Total Net Revenue	\$8,744,315	\$9,084,079
Total Operating Expenses	\$6,443,978	\$6,683,897
Net Income	\$2,300,337	\$2,400,183

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The assumptions used by the applicant in preparation of the pro forma financial statements including projected utilization, costs and charges are reasonable. See the financial section of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates sufficient funds for the operating needs of the proposal, and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates the financial feasibility of the project is based upon reasonable and adequately supported assumptions regarding revenues (charges) and operating costs. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to add one dialysis station to Wilson Dialysis, for a total of 41 dialysis stations at Wilson Dialysis upon completion of this project, Project ID# L-11132-16 (relocate five stations to Sharpsburg Dialysis) and Project ID# L-11156-16 (add five stations).

On page 369, the 2016 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Wilson County. Facilities may also serve residents of counties not included in their service area.

The July 2016 SDR indicates there are two existing dialysis facilities and one approved new dialysis facility (not yet certified) in Wilson County, as follows:

WILSON COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of DECEMBER 31, 2015						
Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
Wilson Dialysis	DaVita	101	Wilson	40	5*	84.38%
Forest Hills Dialysis	DaVita	111	Wilson	31	0	89.52%
Sharpsburg Dialysis	DaVita	0	Sharpsburg	0	10*	0.00%

*CON issued after cut-off date for July 2016 SDR.

As illustrated above, the two existing facilities are owned and operated by the applicant and have a utilization rate of 84% or above. A new facility owned by the applicant has been approved but is not yet operational.

In Section G.2, page 31, the applicant states,

“... Because this application utilizes the Facility Need Methodology and addresses the specific needs of patients who chose to receive service from DaVita, we will focus on these 3 facilities for the purposes of examining possible duplication of services.

Sharpsburg Dialysis is still under development. The other two facilities are operating at 80% or greater utilization as of December 31, 2015 as reported in the July 2016 SDR. Therefore, each facility has the potential for adding stations, given they can show a need. ... While adding stations at this facility [Wilson Dialysis] does increase the number of stations in Wilson County, it serves to meet the needs of the facility’s growing population of patients referred by the facility’s admitting nephrologists. The addition of stations, therefore, serves to increase capacity rather than duplicate any existing or approved serves in the area.”

The applicant adequately demonstrates the need to add one station to the Wilson Dialysis facility based on the number of in-center patients it proposes to serve.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Wilson County. Consequently, the application is conforming to this criterion.

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

C

In Section H, page 32, the applicant provides a table as illustrated below, with the current and projected staffing in full time equivalents (FTEs) for Wilson Dialysis. The applicant states the Medical Director is not employed by the facility, and thus is not reflected on the staffing chart.

WILSON DIALYSIS			
POSITION	CURRENT # FTES	# FTES TO BE ADDED	PROJECTED # FTES
Registered Nurse	5.0	1.0	6.0
Technician (Patient Care)	15.0	1.0	16.0
Administrator	1.0	1.0	2.0
Dietician	1.0	0.0	1.0
Social Worker	1.0	0.0	1.0
Home Training RN	1.0	0.0	1.0
Administrative Assistant	1.0	0.0	1.0
Bio-med Technician	.5	0.0	0.5
Total	25.5	3.0	28.5

As illustrated in the table above, the applicant projects an increase of 3.0 FTEs in the total number of FTE positions at Wilson Dialysis.

In Section I-3(a), page 37, the applicant identifies Dr. Anwar Al-Haidary as the Medical Director of the facility. Exhibit I-3 contains an August 2016 letter signed by Dr. Al-Haidary of Wilson Nephrology - Internal Medicine, PA, supporting the project to add one dialysis station and confirming his continued commitment to serve as Medical Director. In Section H-3, pages 33-34, the applicant states that vacant staff positions are filled by one or more of the following: the DaVita Teammate Recruiter, Teammate Referral Program and/or Student Internship Program.

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

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

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In Section I-1, page 36, the applicant lists the providers of the necessary ancillary and support services to be provided at the existing facility. The applicant discusses coordination with the existing health care system on pages 37-38. Exhibits I-1 and I-3 contain documents from DaVita, DaVita Laboratory Services, Inc., and Dr. Al-Haidary (Medical Director), respectively, documenting availability of the necessary ancillary and support services. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. The information in Section I and corresponding exhibits is reasonable and supports a finding of conformity to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health

service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

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

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

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

C

In Section L-1, pages 45-46, the applicant states,

“Wilson Dialysis, by policy, makes dialysis services available to all residents in its service area. ... Wilson Dialysis helps uninsured/underinsured patients with identifying and applying for financial assistance; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons.”

In addition, on pages 46-48, the applicant discusses its financial policies to help medically underserved populations. In Section L-7, page 49, the applicant states that Medicare/Medicaid represented 90.8% of in-center dialysis services provided at Wilson Dialysis in calendar year 2015. The following table illustrates the historical payor sources for Wilson Dialysis:

WILSON DIALYSIS HISTORICAL PAYOR MIX CY2015	
PAYOR TYPE	PERCENT OF TOTAL IN-CENTER PATIENTS
Medicare	25.0%
Medicaid	7.9%
Commercial Insurance	7.1%
Medicare/ Commercial	24.3%
Medicare/Medicaid	33.6%
VA	2.1%
Total	100.0%

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

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with Disability	% < Age 65 without Health Insurance**
Wilson	16%	53%	52%	24%	11%	20%
Nash	16%	52%	48%	18%	11%	18%
Johnston	12%	51%	31%	15%	10%	19%
Wayne	15%	51%	46%	23%	12%	18%
Edgecombe	17%	54%	63%	26%	13%	17%
Wake	10%	51%	39%	12%	5%	14%
Pitt	11%	53%	44%	23%	8%	18%
Onslow	8%	45%	33%	14%	11%	16%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>, 2014 Estimate as of December 22, 2015. *Excludes "White alone" who are "not Hispanic or Latino" **"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

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

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

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

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

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

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

C

In Section L-3(d), page 48, the applicant states:

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

In Section L-6, page 48, the applicant states, *“There have been no civil rights equal access complaints filed within the last five years.”*

The application is conforming to this criterion.

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

C

In Section C-3, page 16, the applicant states:

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

Payment will not be required upon admission. Therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons.”

In Section L-3(c), page 48, the applicant states:

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

In Section L-1(b), page 46, the applicant reports that it expects 90.8% of the in-center patients who receive treatments at Wilson Dialysis to have all or part of their services paid for by Medicare and Medicaid, as indicated below in the table.

WILSON DIALYSIS PAYOR MIX - PY2	
PAYOR TYPE	PERCENT OF TOTAL IN-CENTER PATIENTS
Medicare	25.0%
Medicaid	7.9%
Commercial Insurance	7.1%
Medicare/ Commercial	24.3%
Medicare/Medicaid	33.6%
VA	2.1%
Total	100.0%

Also on page 46, the applicant states the projected payor mix for Wilson Dialysis will remain the same as its historical payor mix.

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

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

C

In Section L-4, page 48, the applicant states:

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

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

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

C

In Section M-1, page 50, the applicant states that Wilson Dialysis has been offered as a clinical training site for student nurses attending Wilson Community College. Exhibit M-2 contains a copy of the student training agreement with Wilson Community College. The information provided in Section M and referenced exhibits is reasonable and supports a finding of conformity to this criterion.

- (15) Repealed effective July 1, 1987.
 - (16) Repealed effective July 1, 1987.
 - (17) Repealed effective July 1, 1987.
 - (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to add one dialysis station to Wilson Dialysis, for a total of 41 dialysis stations at Wilson Dialysis upon completion of this project, Project ID# L-11132-16 (relocate five stations to Sharpsburg Dialysis) and Project ID# L-11156-16 (add five stations).

On page 369, the 2016 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Wilson County. Facilities may also serve residents of counties not included in their service area.

The July 2016 SDR indicates there are two existing dialysis facilities and one approved new dialysis facility (not yet certified) in Wilson County, as follows:

WILSON COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of DECEMBER 31, 2015						
Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
Wilson Dialysis	DaVita	101	Wilson	40	*5	84.38%
Forest Hills Dialysis	DaVita	111	Wilson	31	0	89.52%
Sharpsburg Dialysis	DaVita	0	Sharpsburg	0	*10	0.00%

*CON issued after cut-off date for July 2016 SDR.

As illustrated above, the two existing facilities are owned and operated by the applicant and have a utilization rate of 84% or above. A new facility owned by the applicant has been approved but is not yet operational.

In Section N-1, page 51, the applicant discusses how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. The applicant states:

“The expansion of Wilson Dialysis will have no effect on competition in Wilson County. Although the addition of stations at this facility could serve to provide more patients another option to select a provider that gives them the highest quality service and better meets their needs, this project primarily serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by DVA Renal Healthcare, Inc.

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

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

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

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

- ♦ The applicant demonstrates that it will continue to provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1) and (13) is incorporated herein by reference.

The application is conforming to this criterion.

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

C

In Section B-4(a), pages 9-10, the applicant discusses the methods it uses to ensure and maintain quality. In Exhibit O-3, the applicant provides a listing below of four dialysis facilities that were not in compliance with Medicare conditions of participation during the 18 months prior to submission of the application:

DVA Quality Care			
Facility	Survey Date	Back in Compliance	
Southeastern Dialysis Center-Kenansville	3/22/2016	Yes	6/10/2016
Durham Dialysis	3/22/2016	Yes	5/31/2016
Marshville Dialysis	2/29/2016	Yes	4/15/2016
Durham West Dialysis	10/7/2015*	Yes	9/30/2015

*Back in compliance prior to survey on 10/7/2015

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

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

C

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

10 NCAC 14C.2203 PERFORMANCE STANDARDS

- .2203(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*
- NA- This application is to add stations and does not propose a new facility.
- .2203(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- C- In Section C-1, pages 13-16, the applicant adequately documents the need for the project and that it will serve a total of 134 in-center patients on 41 stations at the end of the first operating year, which is 3.27 patients per station per week, or a utilization rate of 81.7%.
- .2203(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section B-2, page 7 and Section C-1, pages 13-16, the applicant provides the assumptions and methodology used to project utilization of the facility.