

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 17, 2016

Findings Date: June 17, 2016

Project Analyst: Bernetta Thorne-Williams

Team Leader: Lisa Pittman

Project ID #: L-11156-16

Facility: Wilson Dialysis

FID #: 971340

County: Wilson

Applicant(s): DVA Renal Healthcare, Inc.

Project: Add five dialysis stations for a total of 40 dialysis stations upon completion of this project and Project I.D. # L-11132-16 (relocate 5 existing stations)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

DVA Renal Healthcare, Inc. (DVA) d/b/a Wilson Dialysis (“the applicant”) proposes to add five dialysis stations for a total of 40 stations at Wilson Dialysis upon completion of Project I.D. # L-11132-16 (relocate five existing stations from Wilson Dialysis and five stations from Forest Hills Dialysis to develop Sharpsburg Dialysis) and this project.

Need Determination

The 2016 State Medical Facilities Plan (2016 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2016 Semiannual Dialysis Report (SDR), the county need methodology shows there is no county need determination in Wilson County. However, an applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the

dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. The applicant is eligible to apply for additional stations because the utilization rate reported for Wilson Dialysis in the January 2016 SDR is 3.4250 patients per station, or 85.63% (3.4250 / 4 patients per station = 0.85625). This utilization rate was calculated based on 137 in-center dialysis patients and 40 certified dialysis stations (137 patients / 40 stations = 3.425 patients per station).

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

Wilson Dialysis April 1 Review-January SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/15		85.63%
Certified Stations		40
Pending Stations		0
Total Existing and Pending Stations		40
In-Center Patients as of 6/30/15 (SDR2)		137
In-Center Patients as of 12/31/14 (SDR1)		125
Step	Description	Result
	Difference (SDR2 - SDR1)	12
(i)	Multiply the difference by 2 for the projected net in-center change	24
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/14	0.1920
(ii)	Divide the result of step (i) by 12	0.0160
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/15 until 12/31/15)	0.0960
(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	150.1520
(v)	Divide the result of step (iv) by 3.2 patients per station	46.9225
	and subtract the number of certified and pending stations to determine the number of stations needed	7

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

Policies

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

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan

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

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B-4(a), pages 9-10, Section O, page 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, page 16, Section L, pages 45-49 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 25-30, 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.

Conclusion

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

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

The applicant proposes to add five new stations at Wilson Dialysis, an existing facility located at 2833 Wooten Boulevard SW in Wilson. Upon completion of Project I.D. # L-11132-16 (relocate five stations from Wilson Dialysis and five stations from Forest Hills Dialysis to develop Sharpsburg Dialysis) and the proposed project, Wilson Dialysis will be certified for a total of 40 dialysis stations.

Population to be Served

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 June 30, 2015, as illustrated below in the table:

WILSON DIALYSIS Patient Origin June 30, 2015			
County	# of In-Center Patients	# of Home Dialysis Patients	# PD Patients
Wilson	119	20	20
Johnston	6	1	1
Nash	6	0	4
Edgecombe	3	0	0
Wake	2	0	0
Wayne	1	3	1
Duplin	0	1	0
Onslow	0	1	0
TOTAL	137	26	26

In Section C-1, page 13, the applicant identifies the patient population it proposes to serve during the first two years of operation following completion of this project and Project I.D. # L-11132-16, as illustrated below in the table:

County	Operating Year 1 2018			Operating Year 2 2019			County Patients as Percent of Total	
	In-Center Patients	Home Hemo Patients	Peritoneal Dialysis Patients	In-Center Patients	Home Hemo Patients	Peritoneal Dialysis Patients	Year 1	Year 2
Wilson	130	24	24	137	25	25	88.0%	88.6%
Johnston	6	1	1	6	1	1	4.0%	3.8%
Nash	3	0	4	3	0	4	3.5%	3.3%
Wake	2	0	0	2	0	0	1.0%	1.0%
Wayne	1	3	1	1	3	1	2.5%	2.4%
Duplin	0	1	0	0	1	0	0.5%	0.5%
Onslow	0	1	0	0	1	0	0.5%	0.5%
TOTAL	142	30	30	149	31	31	100.0%	100.0%

The applicant provides the assumptions and methodology for the projections above on pages 13-16.

The applicant adequately identifies the population it proposes to serve.

Analysis of Need

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

Projected Utilization

The applicant projects to serve 142 in-center dialysis patients dialyzing on 40 stations at the end of the first operating year, which is 3.55 patients per station per week or an 88.8% utilization rate.

In Section C-1, pages 13-15, the applicant provides the assumptions and methodology used to project in-center utilization, which are summarized below.

- Based on information in the January 2016 SDR, Wilson Dialysis had 137 in-center patients which is 3.42 patients per station per week with a station utilization rate of 85.63%. This utilization was based on 137 in-center patients dialyzing on 40 stations. One hundred nineteen of the 137 patients were residents of Wilson County.
- The applicant proposed in Project I.D. # L-11132-16 to relocate five stations from Wilson Dialysis and five stations from Forest Hills Dialysis to develop of a new ten station dialysis facility in Sharpsburg.
- The applicant projects that upon certification of Sharpsburg Dialysis in January 2018 that 17 patients currently receiving care at Wilson Dialysis will transfer their care to Sharpsburg Dialysis.

- The applicant projects that after the growth period beginning July 1, 2015 and ending December 31, 2017 Wilson Dialysis will have 153 in-center patients. After subtracting 17 in-center patients who are projected to transfer to Sharpsburg Dialysis, 136 patients would be dialyzing at Wilson Dialysis. Of the 17 patients projected to transfer their care to Sharpsburg Dialysis 11 will be from Wilson County with the remaining six patients being from outside Wilson County.
- The applicant assumes the in-center patients who are residents of Wilson County will increase at a rate commensurate with Wilson County's Five Year Average Annual Change Rate (AACR) of 5.4%, as published in Table B of the January 2016 Semi-Annual Dialysis Report (SDR), through the second operating year.
- OY1 is Calendar Year 2018
- OY2 is Calendar Year 2019

In Section C.1, page 14, the applicant provides the calculations used to arrive at the projected in-center patient census for Operating Years 1 and 2, as follows:

Wilson Dialysis	In-Center Patients
Census projected forward by using one half (2.7%) of the 5 year AACR from June 1, 2015 to December 31, 2015 for Wilson County.	$119 \times 1.027 = 122.213$
Project census of Wilson County in-center patient population forward by one year using the 5 year AACR for Wilson County of 5.4% to December 31, 2016.	$122.213 \times 1.054 = 128.8125$
The applicant then adds in the 18 patients living outside Wilson County.	$128.8215 + 18 = 146.8125$
Interim Period January 1, 2017 - project the census forward of Wilson County in-center patient population using Wilson County's 5 year AACR of 5.4% to December 31, 2017.	$128.8125 \times 1.054 = 135.7683$
The applicant then adds in the 18 patients living outside Wilson County.	$135.7683 + 18 = 153.7683$
OY1 2018 - beginning census of 124 in-center Wilson County patients [135 Wilson County in-center patients - 11 Wilson County residents projected to transfer to Sharpsburg Dialysis = 124]. The applicant projects the population forward using the 5 year AACR of 5.4%.	$124 \times 1.054 = 130.696$
The applicant projects that six patients who reside outside of Wilson County will transfer their care to Sharpsburg Dialysis, thus the applicant adds in 12 patients [18 - 6 = 12]. This is the projected ending census for OY1.	$130.696 + 12 = 142.696$
OY2 2019 – Wilson County in-center patients are projected forward using the 5 year AACR for Wilson County of 5.4%.	$130.696 \times 1.054 = 137.7535$
The applicant adds in 12 patients who reside outside Wilson County. This is the projected ending census for OY2.	$137.7535 + 12 = 149.7535$

The applicant states, on page 14 that the number of projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY 2018) the facility is projected to serve 142 in-center patients and at the end of OY2 (CY2019) the facility is projected to serve 149 in-center patients.

The projected utilization rates for the first two operating years are as follows:

- OY1: 3.55 patients per station per week, or 88.8% (142 patients / 40 stations = 3.55/4 = 0.8875 or 88.8%).
- OY2: 3.72 patients per station per week, or 93.1% (149 patients / 40 stations = 3.72/4 = 0.9312 or 93.1%).

The projected utilization of 3.5 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

Peritoneal Dialysis

The applicant currently provides peritoneal dialysis (PD) and home hemodialysis (HHD) but this project proposes additional in-center dialysis stations. See Section C, pages 15-16 for the applicant's discussion of its PD and HHD services.

Access

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. The facility will serve patients without regard to race, sex, age, or handicap ... regardless of ethnic or socioeconomic situation.”

In Section L, page 49, the applicant provides its historical payor mix which indicates that Medicare and Medicaid represented 89.4% of all dialysis services in calendar year 2015. The applicant confirms that low income and medically underinsured persons will continue to have access to all services provided by DVA and that the facility will conform to all federal, state and local codes and standards for handicapped access.

The applicant adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services.

Conclusion

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

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

NA

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

CA

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

1. Maintain the Status Quo - the applicant states that this option would not support the growth rate at the facility.
2. Operating a third shift - the applicant considered a third shift but determined a third shift would be inconvenient for patients; and a facility at maximum capacity eliminates patient choice.
3. Apply to add five stations – the applicant states the five-station expansion would help to meet the growing demand for dialysis services at Wilson Dialysis.

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

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

- 1. DVA Renal Healthcare, Inc. d/b/a Wilson Dialysis shall materially comply with all representations made in the certificate of need application.**
 - 2. DVA Renal Healthcare, Inc. d/b/a Wilson Dialysis shall add no more than five dialysis stations at Wilson Dialysis for a total of no more than 40 certified dialysis stations upon completion of Project I.D. # L-11132-16 (relocate 5 stations from Wilson Dialysis to develop Sharpsburg Dialysis) and this project, which shall include any home hemodialysis training or isolation stations.**
 - 3. DVA Renal Healthcare, Inc. d/b/a Wilson Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add five dialysis stations to Wilson Dialysis, for a total of 40 dialysis stations at Wilson Dialysis upon completion of this project and Project I.D. # L-11132-16.

Capital and Working Capital Costs

In the table in Section F-1, page 25, the applicant states 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.

Financial Feasibility

The applicant projects revenues and expenses and provides assumptions in Section R, Form B, pages 3-4, as summarized below in the table:

WILSON DIALYSIS		
Revenue and Expenses - Total Facility		
	OPERATING YEAR 1 CY 2018	OPERATING YEAR 2 CY 2019
Gross Patient Revenue	\$ 9,608,754	\$ 10,009,205
Deductions from Gross Patient Revenue	(\$314,482)	(\$328,352)
Net Patient Revenue	\$ 9,294,272	\$ 9,680,853
Operating Expenses	\$ 5,076,373	\$ 5,247,119
Net Profit	\$ 4,217,899	\$ 4,433,734

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The applicant's projections of treatments and revenues are reasonable based on the number of in-center, PD and HHD patients projected for the first two operating years. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

In Section H, page 32, the applicant provides projected staffing and salaries. Form A in Section R, page 1, shows budgeted operating costs adequate to cover the projected staffing. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

Conclusion

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

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

C

The applicant proposes to add five stations to Wilson Dialysis for a total of 40 certified dialysis stations at Wilson Dialysis upon completion of Project I.D. # L-11132-16 and this project.

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 January 2016 SDR indicates there are two dialysis facilities in Wilson County, as follows:

**Wilson County Dialysis Facilities
June 30, 2015**

Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
Forest Hills Dialysis	DVA	111	Wilson	31	0	89.52%
Wilson Dialysis	DVA	137	Wilson	40	0	85.63%

As illustrated above, both of the existing facilities are owned and operated by the applicant and have a utilization rate over 85.0%. Therefore, all of the operational dialysis facilities in the county are well utilized.

In Section C-1, page 13, the applicant identifies the patient population it proposes to serve during the first two years of operation following completion of this project and Project I.D. # L-11132-16, as illustrated below in the table:

County	Operating Year 1 2018			Operating Year 2 2019			County Patients as Percent of Total	
	In-Center Patients	Home Hemo Patients	Peritoneal Dialysis Patients	In-Center Patients	Home Hemo Patients	Peritoneal Dialysis Patients	Year 1	Year 2
Wilson	130	24	24	137	25	25	88.0%	88.6%
Johnston	6	1	1	6	1	1	4.0%	3.8%
Nash	3	0	4	3	0	4	3.5%	3.3%
Wake	2	0	0	2	0	0	1.0%	1.0%
Wayne	1	3	1	1	3	1	2.5%	2.4%
Duplin	0	1	0	0	1	0	0.5%	0.5%
Onslow	0	1	0	0	1	0	0.5%	0.5%
TOTAL	142	30	30	149	31	31	100.0%	100.0%

As shown in the previous table, at the end of OY1 2018, the applicant is projecting an in-center patient census of 142 patients, for a utilization rate of 88.8% or 3.55 patients per station per week (142 patients / 40 stations = 3.55; 3.55 / 4 = 0.8875 or 88.8%). At the end of OY2 2019, the applicant is projecting an in-center patient census of 149 patients for a utilization rate of 93.1% or 3.72 patients per station per week. The projected utilization of 3.55 patients per station per week for OY1 exceeds the 3.2 in-center patients per station per week threshold as required by 10A NCAC 14C .2203(b).

The applicant adequately demonstrates that projected utilization is based on growth of in-center patients at the facility.

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

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in 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 to illustrate the current and projected staffing in full time equivalents (FTEs) for Wilson Dialysis Center, as illustrated below. The applicant states the Medical Director is not employed by the facility, and thus is not reflected on the staffing chart.

POSITION	CURRENT # FTEs	# FTEs TO BE ADDED	PROJECTED # FTEs
Registered Nurse	5.0	-	5.0
Technician (Patient Care)	15.0	-	15.0
Administrator	1.0	-	1.0
Dietician	1.0	-	1.0
Social Worker	1.0	-	1.0
Home Training RN	2.0	-	2.0
Administrative Assistant	1.0	-	1.0
Bio-med Technician	1.0	-	1.0
Total	27.0	0	27.0

As illustrated in the table above, the applicant does not project an increase in the total number of FTE positions at Wilson Dialysis Center.

In Section H-7, page 35, the applicant provides the projected direct care staff for Wilson Dialysis in Operating Year 2, as shown below in the table:

DIRECT CARE POSITIONS	# FTEs	HOURS PER YEAR PER FTE	TOTAL ANNUAL FTE HOURS	TOTAL ANNUAL HOURS OF OPERATION	# FTE HOURS PER HOUR OF OPERATION
Registered Nurse	5.0	2,080	10,400	3,120	3.3
Patient Care Tech	15.0	2,080	31,200	3,120	10.0
Total	20.0	2,080	41,600	3,120	13.3

In Section I-3(a), page 37, the applicant identifies Dr. Anwar Al-Haidary, as the Medical Director of the facility. In Exhibit I-3, the applicant provides a copy of a February 2016 letter signed by Dr. Al-Haidary of Wilson Nephrology – Internal Medicine, PA, supporting the project and confirming his 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.

C

In Section I-1, page 36, the applicant list 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 the above named classification of persons. In Section L-7, page 49, the applicant states that Medicare/Medicaid represented 89.4% of all dialysis services provided at Wilson Dialysis in calendar year 2015. The following table illustrates the historical payor sources for Wilson Dialysis:

PAYOR TYPE	% IN-CENTER PATIENTS	% OF HHD PATIENTS	% OF PD PATIENTS	TOTAL PERCENT PATIENTS
Medicare	26.1%	13.1%	20.0%	23.8%
Medicaid	6.5%	0.0%	0.0%	4.9%
Commercial Insurance	5.2%	17.4%	23.3%	9.1%
Medicare/ Commercial	28.1%	39.1%	36.7%	30.6%
Medicare/Medicaid	32.1%	30.4%	20.0%	30.1%
VA	2.0%	0.0%	0.0%	1.5%
Total	100.0%	100.0%	100.0%	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 area.

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

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

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

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

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

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

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

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

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

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

C

In Section L-3(d), page 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 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 92.8% 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.

PAYOR TYPE	% IN-CENTER PATIENTS	% OF HHD PATIENTS	% OF PD PATIENTS	TOTAL PERCENT PATIENTS
Medicare	26.1%	13.1%	20.0%	23.8%
Medicaid	6.5%	0.0%	0.0%	4.9%
Commercial Insurance	5.2%	17.4%	23.3%	9.1%
Medicare/ Commercial	28.1%	39.1%	36.7%	30.6%
Medicare/Medicaid	32.1%	30.4%	20.0%	30.1%
VA	2.0%	0.0%	0.0%	1.5%
Total	100.0%	100.0%	100.0%	100.0%

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

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

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

C

In Section L-4, page 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 five dialysis stations to Wilson Dialysis for a total of 40 stations upon completion of Project I.D. # L-11132-16 (relocate 5 stations from Wilson Dialysis to develop Sharpsburg Dialysis) and this project.

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 January 2016 SDR indicates there are two dialysis facilities in Wilson County, as follows:

**Wilson County Dialysis Facilities
June 30, 2015**

Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
Forest Hills Dialysis	DVA	111	Wilson	31	0	89.52%
Wilson Dialysis	DVA	137	Wilson	40	0	85.63%

As illustrated above, both of the existing facilities are owned and operated by the applicant and have a utilization rate over 85.0%. Therefore, all of the operational dialysis facilities in the county are well utilized.

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 Healthcare Renal Care, 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 provided by the applicant in the sections referenced above is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application, and the following analysis:

- The applicant adequately demonstrates the need for the proposed project and that it is an effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that Wilson Dialysis will continue to provide quality dialysis services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates that Wilson Dialysis will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1), (3) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

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

C

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 of two dialysis facilities that were not in compliance with Medicare conditions of participation during the 18 months prior to submission of the application, as shown below:

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

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

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

C

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- 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 13-14, the applicant documents the need for the project and demonstrates that it will serve a total of 142 in-center patients on 40 stations at the end of the first operating year, which is 3.55 patients per station per week, or a utilization rate of 88.8%. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C.1, pages 13-16, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.