

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 21, 2018

Findings Date: December 21, 2018

Project Analyst: Jane Rhoe-Jones

Assistant Chief: Lisa Pittman

Project ID #: L-11591-18

Facility: Wilson Dialysis

FID #: 971340

County: Wilson

Applicant: DVA Renal Healthcare, Inc.

Project: Add two dialysis stations for a total of 37 stations upon completion of this project and Project ID #L-11438-17 (relocate five stations to Kenly Dialysis)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

The applicant, DVA Renal Healthcare Inc. (DVA) d/b/a Wilson Dialysis proposes to add two dialysis stations for a total of 37 stations upon completion of this project and Project ID #L-11438-17 (relocate five stations to Kenly Dialysis).

The applicant also provides home hemodialysis (HHD) and peritoneal dialysis (PD) training and support services; but no changes to HHD or PD are proposed in this project.

Need Determination

The 2018 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2018 Semiannual Dialysis Report (SDR), Wilson County has a surplus of five dialysis stations, therefore, the county need methodology shows there is no county need determination for Wilson County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for Wilson Dialysis in the July 2018 SDR is 3.3750 patients per station per week. This utilization rate was calculated based on 135 in-center dialysis patients and 40 certified dialysis stations as of December 31, 2017 (135 patients / 40 stations = 3.3750 patients per station per week; $3.3750 / 4 = .8438$ or 84.3% facility utilization). Application of the facility need methodology indicates that two additional 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 12/31/17		84.4%
Certified Stations		40
Pending Stations		
Total Existing and Pending Stations		40
In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR2)		135
In-Center Patients as of 6/30/17 (Jan 2018 SDR) (SDR1)		136
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	-1
	Multiply the difference by 2 for the projected net in-center change	-2
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/17	-0.0147
(ii)	Divide the result of Step (i) by 12	-0.0012
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/16 until 12/31/17)	-0.0147
(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	133.0147
(v)	Divide the result of Step (iv) by 3.2 patients per station	41.5671
	and subtract the number of certified and pending stations to determine the number of stations needed	1.5671
<p>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.</p>		

Policies

There is one policy in the 2018 SMFP which is applicable to this review: *Policy GEN-3: Basic Principles. Policy GEN-3*, on page 33, 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.”

In Section B, pages 8-11, the applicant explains why it believes its application is conforming to Policy GEN-3. The applicant *Policy GEN-3* as follows:

Promote Safety and Quality – The applicant describes how it believes the proposed project would promote safety and quality in Section B.3, pages 9-10, Section O, page 53, and Exhibit O. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b), page 10, Section L, pages 46-50, and Exhibit L-3. 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.3(c) and (d), page 11, and Section N, page 52. 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.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the above stated reasons.

- (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

DVA proposes to add two dialysis stations to Wilson Dialysis for a total of 37 stations upon completion of this project and Project ID #L-11438-17 (relocate five stations to Kenly Dialysis).

Patient Origin

On page 365, the 2018 SMFP defines the service area for dialysis stations 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 counties is a separate dialysis station planning area.*” Thus, the service area is Wilson County. Facilities may serve residents of counties not included in their service area.

The following table illustrates the current and projected patient origin for in-center (IC) dialysis.

WILSON DIALYSIS					
Current and Projected In-center Patient Origin*					
County	Current 12/31/2017	OY1 CY2020	OY2 CY2021	County In-center Patients as Percent of In-center Total	
				OY1	OY2
Wilson	124	128	135	92.1%	92.5%
Edgecombe	1	1	1	0.72%	0.68%
Greene	1	1	1	0.72%	0.68%
Johnston	2	2	2	1.44%	1.40%
Nash	6	6	6	4.32%	4.11%
Virginia	1	1	1	0.72%	0.68%
Total	135	139	146	100.00%	100.00%

Source: Section C, pages 13 and 21. *HHD and PD are not included in this table because the applicant proposes no changes in those services (Pitt, Wake and Wayne Counties). This project proposes additional stations for IC dialysis at Wilson Dialysis only. Table does not foot due to rounding.

In Section C, pages 13-15, the applicant provides the assumptions and methodology it used to project patient origin.

The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, page 16, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states,

“Section B-2 clearly outlines the need that the population to [sic] served, the in-center patients of Wilson Dialysis, has for the two-station expansion proposed in this application.

This application does not call for any changes to home hemo or PD services at Wilson Dialysis.”

The project analyst finds it reasonable to conclude that the ESRD Facility Need Methodology table in Section B-2, page 7, supports the applicant’s proposal for two additional in-center dialysis stations at Wilson Dialysis.

Projected Utilization

The applicant’s projected utilization methodology based on its stated assumptions, is provided on pages 13-14 and is summarized in the following table.

WILSON DIALYSIS IC	
The applicant begins with the facility census of Wilson County IC patients as January 1, 2018.	124
The census of Wilson County IC patients is increased by 4.8% to project the census forward one year to December 31, 2018.	$124 \times 1.048 = 129.952$
The applicant adds the 11 patients from outside Wilson County. This is the projected ending census for the current year December 31, 2018	$129 + 11 = 140.952$
The census of Wilson Dialysis IC patients is increased by 4.8% plus 11 patients from outside Wilson County to project the census forward one year to December 31, 2019.	$129 \times 1.048 = 136.1897$ $+ 11 = 147.1897$
The applicant subtracts 13 patients expected to transfer to Kenly Dialysis and subtracts the one patient from outside Wilson County transferring to Kenly Dialysis. This is the projected ending census for OY1 (December 31, 2020).	$136 - 13 = 123 \times 1.048 =$ $128.904 + 11 - 1 = 10 =$ 138.904
The applicant increases the IC patients by 4.8% then adds the 10 patients from outside Wilson County. This is the ending census for OY2 (December 31, 2021).	$128.904 \times 1.048 =$ $135.0914 + 10 =$ 145.0914

Source: Table in Section C.5, page 19.

Projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY 2020) the facility is projected to serve 138 in-center patients, and at the end of OY2 (CY2021) the facility is projected to serve 145 in-center patients.

The projected utilization rate for the first two operating years is as follows:

- **OY1:** 3.73 patients per station per week or 93.2% ($138 \text{ patients} / 37 \text{ stations} = 3.729 / 4 = 0.932$ or 93.2%).
- **OY2:** 3.91 patients per station per week or 97.9% ($145 \text{ patients} / 37 \text{ stations} = 3.9189 / 4 = 0.9797$ or 97.9%).

The projected utilization of 3.729 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).

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant starts with the 124 existing Wilson County patients.
- Wilson County patients are projected to increase 4.8% per year which is the Five Year Average Annual Change Rate census for Wilson County as published in the July 2018 SDR.
- The applicant projects no growth for patient who utilize the facility and live in other counties.

Access

In Section L.1(a), pages 46-47, the applicant states that Wilson Dialysis has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped, elderly, or other underserved persons regardless of their ability to pay. In Section L.1(b), page 47, the applicant provides the projected payor sources for OY2 (2021) for Wilson Dialysis, illustrated as follows.

WILSON DIALYSIS In-center Patients OY2 (2021)	
Payor Source	Percent of In-Center Patients
Medicare	24.4%
Medicaid	8.1%
Commercial Insurance	6.5%
Medicare / Commercial	29.3%
Medicare / Medicaid	29.3%
VA	2.4%
Total	100.0%

As illustrated in the above table, in OY2021, 91.1% of in-center Wilson Dialysis patients are projected Medicare and Medicaid recipients. On page 47, the applicant states that “projected *payor mix is based on the sources of patient payment that have been received by the existing facility in the last full operating year.*”

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

- (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

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (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

The applicant proposes to add two dialysis stations to Wilson Dialysis for a total of 37 certified dialysis stations at Wilson Dialysis upon completion of this project and Project ID #L-11438-17 (relocate five stations to Kenly Dialysis). The applicant also provides home hemodialysis (HHD) and peritoneal dialysis (PD) training and support services; but no changes to HHD or PD are proposed in this project.

In Section E.1, page 25, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo - The applicant states that maintaining the status quo is not an effective alternative because of the growth rate at Wilson Dialysis. Therefore, this alternative was rejected.
- Relocate stations from another DaVita facility - The applicant states that the two other operational DaVita facilities in Wilson County are operating at greater than 80% utilization. Patients utilizing those facilities would be negatively impacted if stations were reduced. Therefore, this alternative was rejected.

On page 25, the applicant states that its proposal to add two stations is the most effective alternative because growth and access issues at the facility have created a need for additional stations. A third shift would be necessary at current levels of utilization and requiring a third shift would be inconvenient for patients and negatively impact patient access.

Conclusion

The Agency reviewed the:

- Application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is 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. Pursuant to the facility need determination in the July 2018 SDR, DVA Renal Healthcare, Inc. shall develop no more than two additional dialysis stations for a total of no more than 37 certified stations at Wilson Dialysis upon completion of this project and Project ID# L-11438-17 (relocate five stations to Kenly Dialysis) which shall include any home hemodialysis training or isolation stations.**
 - 3. DVA Renal Healthcare, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to add two dialysis stations to Wilson Dialysis for a total of 37 certified dialysis stations at Wilson Dialysis upon completion of this project and Project ID #L-11438-17 (relocate five stations to Kenly Dialysis). The applicant also provides home hemodialysis (HHD) and peritoneal dialysis (PD) training and support services; but no changes to HHD or PD are proposed in this project.

Capital and Working Capital Costs

In Section F, page 26, the applicant projects no capital costs, start-up nor initial operating expenses for the project because Wilson Dialysis is an existing facility. Therefore, no working capital is needed.

Financial Feasibility

The applicant provided pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form B, the applicant projects that revenues

will exceed operating expenses in the first two operating years of the project, as shown below in the table.

WILSON DIALYSIS		
	1st Full Calendar Year 2020	2nd Full Calendar Year 2021
Total Treatments (includes HHD and PD patients; adjusted for missed in-center treatments)	29,122	30,307
Total Gross Revenues (Charges)	\$9,741,752	\$10,119,722
Total Net Revenue	\$9,435,379	\$9,800,770
Average Net Revenue per Treatment	\$324	\$323
Total Operating Expenses (Costs)	\$6,714,043	\$6,967,988
Average Operating Expense per Treatment	\$231	\$230
Net Income	\$2,721,336	\$2,832,783

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section R 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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion because 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.

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

C

The applicant proposes to add two dialysis stations to Wilson Dialysis for a total of 37 certified dialysis stations at Wilson Dialysis upon completion of this project and Project ID #L-11438-17 (relocate five stations to Kenly Dialysis). The applicant also provides home hemodialysis (HHD) and peritoneal dialysis (PD) training and support services; but no changes to HHD or PD are proposed in this project.

On page 365, the 2018 SMFP defines the service area for dialysis stations 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 counties is a separate dialysis station planning area.*” Thus, the service area is Wilson County. Facilities may serve residents of counties not included in their service area.

According to the July 2018 SDR, there are four approved and existing dialysis facilities in Wilson County, and all are owned by DaVita, Inc, illustrated as follows.

WILSON COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of June 30, 2018				
Dialysis Facility	Certified Stations 6/30/18	# In-center Patients	Percent Utilization	Patients per Station
Wilson Dialysis	40	135	84.3%	3.3750
Forest Hills Dialysis	36	116	80.56%	3.2222
Sharpsburg Dialysis*	0	0	00.00%	0.0000
Kenly Dialysis *	0	0	00.00%	0.0000

Source: July 2018 SDR. *Approved for 10 stations, but not operational.

In Section G, page 32, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in the Wilson County service area. The applicant states:

“Both of the DaVita facilities in Wilson County that have been operational for more than a year were operating at 80% or greater utilization as reported in the July 2018 SDR. ... In Section B2 and Section C of this application, we demonstrate the need that Wilson Dialysis has for adding stations. While adding stations at this facility does increase the number of stations in Wilson County, it is based on the facility need methodology. It ultimately serves to meet the needs of the facility’s growing population of patients referred by the facility’s nephrologists. The addition of stations, therefore, serves to increase capacity rather than duplicate any existing or approved services in the service area.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The applicant adequately demonstrates the need for the stations based on the facility need methodology.

- The applicant adequately demonstrates that the proposed stations are needed in addition to the existing and/or approved stations in Wilson County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 33, the applicant provides current and projected staffing in full-time equivalents (FTE) for the proposed services at Wilson Dialysis, as illustrated in the following table.

WILSON DIALYSIS		
POSITION	CURRENT # FTES CY2018	PROJECTED # FTES OY2 (CY2021)
Registered Nurse	5.0	5.0
Home Training RN	2.0	2.0
Technician (PCT)	15.0	14.0
Dietician	1.0	1.0
Social Worker	1.0	1.0
Administrator	1.0	1.0
Administrative Assistant	1.0	1.0
Biomed Tech	1.0	1.0
Total	27.0	26.0

The assumptions and methodology used to project staffing are provided in Section H and Section R. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Section H, pages 34-35, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Exhibit I.3, the applicant provides a letter from the medical director indicating his interest in continuing to serve as the medical director of Wilson Dialysis.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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, page 37, the applicant provides a list of the necessary ancillary and support services for the proposed services, as illustrated below.

WILSON DIALYSIS Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	Wilson Dialysis (on site)
Self-care training (in-center)	Wilson Dialysis (on site)
Home training	
HH	Wilson Dialysis (on site)
PD	Wilson Dialysis (on site)
Accessible follow-up program	Wilson Dialysis (on site)
Psychological counseling	Wilson Dialysis (on site)
Isolation – hepatitis	Wilson Dialysis (on site)
Nutritional counseling	Wilson Dialysis (on site)
Social Work services	Wilson Dialysis (on site)
Acute dialysis in an acute care setting	Wilson Medical Center
Emergency care	Wilson Medical Center
Blood bank services	Wilson Medical Center
Diagnostic and evaluation services	Wilson Medical Center
X-ray services	Wilson Medical Center
Laboratory services	DaVita Laboratory Services
Pediatric nephrology	Wilson Medical Center
Vascular surgery	Wilson Medical Center
Transplantation services	Carolinas Medical Center
Vocational rehabilitation & counseling	NC Division of Vocational Rehab.
Transportation	Johnston Ambulance Services

The applicant provides supporting documentation in Exhibit I. regarding DaVita laboratory services, Carolinas Medical Center, Wilson Medical Center and NC Vocational Rehabilitation.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (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

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (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

The applicant does not propose to construct any new space nor renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

- (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, page 50, the applicant provides the historical payor mix during Calendar Year 2017 for the existing services, as shown below in the table.

WILSON DIALYSIS Calendar Year 2017	
Payor Source	In-center Dialysis Services as Percent of Total
Medicare	24.4%
Medicaid	8.1%
Commercial Insurance	6.5%
Medicare Commercial	29.3%
Medicare/Medicaid	29.3%
VA	2.4%
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 area.

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Wilson	18%	53%	53%	22%	11%	14%
Statewide	16%	51%	37%	15%	10%	12%

Source: <http://www.census.gov/quickfacts/table/US/PST045217>

Latest Data 7/1/17 as of 7/17/18

Excludes "White alone, not Hispanic or Latino" "Estimates are not comparable to other geographic levels due to methodology differences that may exist between different data sources. 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., V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states. The 2016 Annual Report does not provide state-specific ESRD patient data, but the aggregate data is likely to be similar to North Carolina’s based on the Network’s recent annual reports which included state-specific data.

The IPRO SA Network 6 2016 Annual Report (pages 25-26¹) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

The Agency reviewed the:

¹ <https://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/07/NW6-2016-Annual-Report-FINAL.pdf>

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency (if applicable)

Based on that review, the Agency concludes that the applicant adequately documents 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. 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

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.D, page 49, 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 49, the applicant states that during the last five years no patient civil rights access complaints have been filed.

The Agency reviewed the application and exhibits to the application. Based on that review, the Agency concludes that 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 L, page 47, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown below in the table.

WILSON DIALYSIS OY2 Projected	
Payor Category	In-center Dialysis Services as Percent of Total
Medicare	24.4%
Medicaid	8.1%
Commercial Insurance	6.5%
Medicare /Commercial	29.3%
Medicare/Medicaid	29.3%
VA	2.4%
Total	100.0%

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 91.1% of in-center services will be provided to Medicare patients and Medicaid patients.

On page 47, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical utilization by payor at Wilson Dialysis.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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, page 49, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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, page 51, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

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

C

The applicant proposes to add two dialysis stations to Wilson Dialysis for a total of 37 certified dialysis stations at Wilson Dialysis upon completion of this project and Project ID #L-11438-17 (relocate five stations to Kenly Dialysis). The applicant also provides home hemodialysis (HHD) and peritoneal dialysis (PD) training and support services; but no changes to HHD or PD are proposed in this project.

On page 365, the 2018 SMFP defines the service area for dialysis stations 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 counties is a separate dialysis station planning area.”* Thus, the service area is Wilson County. Facilities may serve residents of counties not included in their service area.

According to the July 2018 SDR, there are four approved and existing dialysis facilities in Wilson County, and all are owned by DaVita, Inc, illustrated as follows.

WILSON COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of June 30, 2018				
Dialysis Facility	Certified Stations 6/30/18	# In-center Patients	Percent Utilization	Patients per Station
Wilson Dialysis	40	135	84.3%	3.3750
Forest Hills Dialysis	36	116	80.56%	3.2222
Sharpsburg Dialysis*	0	0	00.00%	0.0000
Kenly Dialysis *	0	0	00.00%	0.0000

Source: July 2018 SDR. *Approved for 10 stations, but not operational.

In Section N, page 52, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 52, the applicant states,

“The expansion of Wilson Dialysis will have no effect on competition in Wilson County. ... this project primarily serves to address the needs of a population already served (or projected to be served, based on historical growth rates) ...

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

our patients, family members and others involved in the dialysis process to receive services.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the above stated reasons.

- (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 A.11, page 5, the applicant states that DaVita, Inc. operates over 85 dialysis facilities in North Carolina. In Exhibit A.11, the applicant provides a list of its affiliates.

In Section O.3, pages 53, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were two facilities with incidents related to quality of care occurred. The applicant states that the problems have been corrected as documented in Exhibit O-3. After reviewing and considering information provided by the applicant and considering the quality of care provided at all facilities, including those related or affiliated with the applicant, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

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

C

The Criteria and Standards for End Stage Renal Disease Services 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- Wilson Dialysis is an existing facility.

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

-C- In Section C, pages 13-15, the applicant demonstrates that Wilson Dialysis will serve a total of 139 in-center patients in OY1 for a utilization rate of 93.9% or 3.7 patients per station per week ($139 \text{ patients} / 37 \text{ stations} = 3.7567$ or $3.7 / 4 = 0.9391$ or 93.9%). 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 13-15, the applicant provides the assumptions and methodology used to project in-center utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.