

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 9, 2017

Findings Date: May 9, 2017

Project Analyst: Julie Halatek

Team Leader: Lisa Pittman

Project ID #: L-11319-17

Facility: Forest Hills Dialysis

FID #: 020166

County: Wilson

Applicant(s): DVA Renal Healthcare, Inc.

Project: Add five dialysis stations for a total of 36 dialysis stations upon completion of this project, Project I.D. #L-11132-16 (relocate five stations), and Project I.D. #L-11153-16 (add five stations)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

DVA Renal Healthcare, Inc. (DVA) d/b/a Forest Hills Dialysis (Forest Hills) proposes to add five dialysis stations for a total of 36 certified dialysis stations at the completion of this project, Project I.D. #L-11132-16 (relocate five stations), and Project I.D. #L-11153-16 (add five stations).

Need Determination

The 2017 State Medical Facilities Plan (2017 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2017 Semiannual Dialysis Report (SDR), the county need methodology shows there is a

surplus of seven dialysis stations in Wilson County. However, the 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 percent. 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 Forest Hills in the January 2017 SDR is 3.871 patients per station per week, or 96.77 percent ($3.871 / 4 \text{ patients per station} = 0.9677$). This utilization rate was calculated based on 120 in-center dialysis patients and 31 certified dialysis stations ($120 \text{ patients} / 31 \text{ stations} = 3.8709 \text{ patients per station per week}$).

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

APRIL 1 REVIEW – JANUARY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/16		96.77%
Certified Stations		31
Pending Stations		5
Total Existing and Pending Stations		36
In-Center Patients as of 6/30/16 (January 2017 SDR) (SDR2)		120
In-Center Patients as of 12/31/15 (July 2016 SDR) (SDR1)		111
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	9
	Multiply the difference by 2 for the projected net in-center change	18
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/15	0.1622
(ii)	Divide the result of Step (i) by 12	0.0135
(iii)	Multiply the result of Step (ii) by 6 (the number of months from 6/30/16 until 12/31/16)	0.0811
(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	129.7297
(v)	Divide the result of Step (iv) by 3.2 patients per station	40.5405
	and subtract the number of certified and pending stations to determine the number of stations needed	5

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is five 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

Policy GEN-3: Basic Principles on page 33 of the 2017 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, pages 9-10, Section O, page 50, 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, page 10, Section C, page 15, Section L, pages 43-47, 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, page 11, Section C, pages 13-17, Section N, page 49, and referenced exhibits. 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. Therefore, the application is consistent with Policy GEN-3.

Conclusion

In summary, the applicant adequately demonstrates that the proposal is consistent with the facility need methodology in the January 2017 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.

C

The applicant, DVA, proposes to add five stations to the existing Forest Hills facility for a total of 36 stations upon completion of this project, Project I.D. #L-11132-16 (relocate five stations), and Project I.D. #L-11153-16 (add five stations).

Patient Origin

On page 373, the 2017 SMFP defines the service area for dialysis stations as the “*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.

In Section C.8, page 18, the applicant provides the historical patient origin by county for Forest Hills, as shown in the table below.

Forest Hills Historical Patient Origin as of 6/30/2016	
County	In-Center Patients
Wilson	101
Edgecombe	1
Greene	1
Halifax	1
Johnston	2
Nash	8
Pitt	1
Wayne	3
Other States	2
Total	120

In clarifying information received May 2, 2017, the applicant provides the projected patient origin for Forest Hills for in-center patients for the first two operating years following completion of the project, Calendar Years (CY) 2019 and 2020, as follows:

Forest Hills – Projected Patient Origin – CYs 2019 & 2020				
County	OY 1 – CY 2019	OY 2 – CY 2020	County Patients as % of Total	
	# Patients	# Patients	OY1	OY2
Wilson	114	120	89.1%	89.6%
Greene	1	1	0.8%	0.7%
Johnston	2	2	1.6%	1.5%
Nash	5	5	3.9%	3.7%
Pitt	1	1	0.8%	0.7%
Wayne	3	3	2.3%	2.2%
Other States	2	2	1.6%	1.5%
Total	128	134	100.0%	100.0%

In Section C.1, pages 13-15, the applicant provides the assumptions and data utilized to project patient origin.

The applicant adequately identifies the population to be served.

Analysis of Need

In Section C.2, page 15, the applicant states the need for the proposed project is based on the continued growth of the patient population at Forest Hills. The discussion regarding the need determination found in Criterion (1) is incorporated herein by reference. See also Section B.2, pages 6-7.

Projected Utilization

In clarifying information received May 2, 2017, the applicant provides the projected patient origin for Forest Hills for in-center patients for the first two operating years following completion of the project, Calendar Years (CY) 2019 and 2020, as follows:

Forest Hills – Projected Patient Origin – CYs 2019 & 2020				
County	OY 1 – CY 2019	OY 2 – CY 2020	County Patients as % of Total	
	# Patients	# Patients	OY1	OY2
Wilson	114	120	89.1%	89.6%
Greene	1	1	0.8%	0.7%
Johnston	2	2	1.6%	1.5%
Nash	5	5	3.9%	3.7%
Pitt	1	1	0.8%	0.7%
Wayne	3	3	2.3%	2.2%
Other States	2	2	1.6%	1.5%
Total	128	134	100.0%	100.0%

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

- The Wilson County patient population will grow at a rate of five percent (the Five Year Average Annual Change Rate [AACR] for Wilson County, rounded up to the nearest whole number, as published in the January 2017 SDR) through the end of the second year of operation.
- The applicant assumes no increase for the patients who utilize the facility and live outside of Wilson County, but assumes that those patients will continue to dialyze at Forest Hills and are added to the calculations when appropriate.
- Four patients from Wilson County and five patients from other counties currently dialyzing at Forest Hills will transfer to the new Sharpsburg Dialysis Center upon certification on January 1, 2018.
- The project is scheduled for completion on January 1, 2019. OY1 is CY 2019. OY2 is CY 2020.

In Section C.1, pages 14-15, the applicant provides the calculations used to arrive at the projected in-center patient census for OY1 and OY2 as summarized in the table below.

Forest Hills	
DVA begins with the Wilson County ESRD patient population of Forest Hills as of June 30, 2016.	101
DVA projects the Wilson County population forward six months to December 31, 2016, applying the projected AACR of five percent to a six month period.	$101 \times 1.025 = 103.525$
DVA projects this population forward 12 months to December 31, 2017, applying the projected AACR of five percent.	$103.525 \times 1.05 = 108.7013$
DVA subtracts four Wilson County patients projected to transfer to Sharpsburg Dialysis on January 1, 2018.	$108 - 4 = 104$
DVA projects the Wilson County population forward 12 months to December 31, 2018, applying the projected AACR of five percent.	$104 \times 1.05 = 109.2$
DVA adds the 14 patients from other counties to obtain the starting census for January 1, 2019, the date the stations at Forest Hills are projected to be certified.	$109.2 + 14 = 123.2$
DVA projects the Wilson County population forward 12 months to December 31, 2019, applying the projected AACR of five percent.	$109.2 \times 1.05 = 114.66$
DVA adds the 14 patients from other counties to obtain the ending census for December 31, 2019 (end of OY 1).	$114.66 + 14 = 128.66$
DVA projects the Wilson County population forward 12 months to December 31, 2020, applying the projected five year AACR of five percent.	$114.66 \times 1.05 = 120.393$
DVA adds the 14 patients from other counties to obtain the ending census for December 31, 2020 (end of OY 2).	$120.393 + 14 = 134.393$

The applicant projects to serve 128 in-center patients on 36 stations, which is 3.56 patients per station per week ($128 \text{ patients} / 36 \text{ stations} = 3.56$), by the end of OY 1 and 134 in-center patients on 36 stations, which is 3.72 patients per station per week ($134 \text{ patients} / 36 \text{ stations} = 3.72$), by the end of OY 2. This meets 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).

Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Home Hemodialysis and Peritoneal Dialysis

Forest Hills does not currently provide home hemodialysis or peritoneal dialysis modalities. On page 15, the applicant states that the application does not call for any changes to these modalities of service.

Access

In Section L.1(a), pages 43-44, the applicant states that Forest Hills, by policy, will make services available to all residents of its service area without qualifications and will “...serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability.” On page 44, the applicant projects the payor mix for the second operating year of the project, and it projects that 92.3 percent of projected patients will have some or all of their services paid for by Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents, including underserved groups, will 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 dialysis stations, 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 22, the applicant discusses the alternatives considered prior to submitting this application, which include:

- Maintain the Status Quo - the applicant states that this option was not considered because of the continued growth rate of the population at the facility. Therefore, this is not an effective alternative.
- Relocate Stations From Another DVA Facility – the applicant states that the other operational DVA facility in Wilson County is also operating at greater than 80 percent capacity. Relocating stations from that facility would negatively impact the patients receiving services there. Therefore, this is not an effective alternative.

After considering the above alternatives, the applicant states that given the patient population growth at Forest Hills and the patient population utilizing the other DVA facility in Wilson County, the proposed project is the most effective alternative to meet the identified need.

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 Forest Hills Dialysis shall materially comply with all representations made in the certificate of need application except as modified by the conditions of approval.**
 2. **DVA Renal Healthcare, Inc. d/b/a Forest Hills Dialysis shall develop and operate no more than five additional dialysis stations at Forest Hills Dialysis for a total of no more than 36 certified dialysis stations, which shall include any isolation or home hemodialysis training stations, upon completion of this project, Project I.D. #L-11132-16 (relocate five stations), and Project I.D. #L-11153-16 (add five stations).**
 3. **DVA Renal Healthcare, Inc. d/b/a Forest Hills Dialysis shall not develop a home hemodialysis and peritoneal dialysis training program as part of this project.**
 4. **DVA Renal Healthcare, Inc. d/b/a Forest Hills Dialysis shall install plumbing and electrical wiring through the walls for no more than five additional dialysis stations, which shall include any isolation or home hemodialysis training stations.**
 5. **DVA Renal Healthcare, Inc. d/b/a Forest Hills 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

DVA proposes to add five dialysis stations at Forest Hills for a total of 36 certified dialysis stations at the completion of this project, Project I.D. #L-11132-16 (relocate five stations), and Project I.D. #L-11153-16 (add five stations).

Capital and Working Capital Costs

In Section F, page 23, the applicant projects the capital cost for the proposed project will be \$0. On page 26, the applicant states that there are no start-up expenses or working capital needs for the proposed project since Forest Hills is an existing facility.

Financial Feasibility

The applicant provided pro forma financial statements for the first two years of the project. In the pro forma financial statement (Form B), the applicant projects that revenues will exceed operating expenses in the first two operating years, as shown in the table below.

Projected Revenues and Operating Expenses		
Forest Hills	Operating Year 1 CY 2019	Operating Year 2 CY 2020
Total Treatments	18,599	19,414
Total Gross Revenues (Charges)	\$4,976,338	\$5,194,432
Total Net Revenue	\$4,743,920	\$4,951,831
Total Operating Expenses (Costs)	\$4,429,044	\$4,605,835
Net Income	\$314,876	\$345,997

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. The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based on reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and operating needs of the proposal and that the financial feasibility of the project is based on reasonable projections of costs and charges. 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

DVA proposes to add five dialysis stations at Forest Hills for a total of 36 certified dialysis stations at the completion of this project, Project I.D. #L-11132-16 (relocate five stations), and Project I.D. #L-11153-16 (add five stations).

On page 373, the 2017 SMFP defines the service area for dialysis stations as the “*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 applicant operates two dialysis facilities in Wilson County. Also, DVA has been approved to develop one additional facility in Wilson County – Sharpsburg Dialysis – but the facility was not

yet operational on June 30, 2016. The existing and approved Durham County dialysis facilities are shown below:

Wilson County Dialysis Facilities as of June 30, 2016				
Dialysis Facility	Certified Stations	CON Issued Not Certified	% Utilization	Patients Per Station
Forest Hills Dialysis	31	0	96.77%	3.871
Wilson Dialysis	40	0	87.50%	3.500
Sharpsburg Dialysis	0	10	0.00%	0.000

Source: Table A, January 2017 SDR.

As shown in the table above, both operational facilities in Wilson County were operating at a capacity of greater than 80 percent (3.2 patients per station) as of June 30, 2016.

In Section C, pages 13-15, the applicant demonstrates that Forest Hills will serve a total of 128 patients at the end of OY 1 for a utilization rate of 89 percent or 3.56 patients per station (128 patients / 36 stations = 3.56; 3.56 / 4 = .89 or 89%). The projected utilization of 3.56 patients per station per week for Operating Year One meets the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b). The applicant adequately demonstrates the need to add five additional stations at Forest Hills based on the number of patients it projects to serve.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved dialysis services 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.1, page 30, the applicant provides current and projected staffing for Forest Hills, which includes 24 full-time equivalent (FTE) employee positions, summarized as follows:

Forest Hills Current and Projected Staffing			
Position	Current # FTEs	# FTEs Positions added/deleted	Projected # FTEs
Registered Nurse	4.0	1.0	5.0
Technician (PCT)	12.0	2.0	14.0
Administrator	1.0	0.0	1.0
Dietician	1.0	0.0	1.0
Social Worker	1.0	0.0	1.0
Admin Assistant	1.0	0.0	1.0
Biomed Tech	1.0	0.0	1.0
Total	21.0	3.0	24.0

Note: The Medical Director is a contract position, not an FTE of the facility.

In Section H.3, pages 31-32, along with Exhibit H-3, the applicant describes its experience and process for recruiting and retaining staff.

In Section H.2, the applicant identifies Dr. Will Bynum as the Medical Director of Forest Hills. Exhibit I-3 contains a copy of a letter dated February 15, 2017 from Dr. Will Bynum supporting the proposed expansion of Forest Hills.

The applicant documents the availability of adequate health manpower and management personnel, including a Medical Director, to provide 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, page 34, the applicant includes a list of providers of the necessary ancillary and support services and indicates how they are or will be made available. Exhibit I-3 contains a letter from the medical director of the facility expressing his support for the proposed project. The applicant discusses coordination with the existing health care system on pages 35-36. Exhibit I-1 contains copies of agreements for Gambro Healthcare Wilson, DaVita Laboratory Services, and a letter from the facility administrator describing the additional provisions for ancillary and support services. The information in Section I and Exhibit I-3 is reasonable and adequately supports a finding of conformity with 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 43-44, the applicant lists the ways DVA helps provide access to dialysis services for the underserved populations of North Carolina and states its policy to provide services to all patients including low-income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and any other underserved group. In addition, the applicant describes its admission and financial policies in Section L.3, pages 44-46, and provides a copy of its admission policy in Exhibit L-3.

In Section L.7, page 47, the applicant provides the historical payor mix for Forest Hills, as shown below:

Forest Hills Historical Payor Mix – CY 2016	
Payor Type	% of In-Center Patients
Medicare	27.1%
Medicaid	7.6%
Commercial Insurance	4.3%
Medicare/Commercial	23.7%
Medicare/Medicaid	33.9%
VA	3.4%
Total	100.0%

As illustrated in the tables above, 92.3 percent of Forest Hills patients had some or all of their services paid for by Medicare and/or Medicaid.

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%
Statewide	15%	51%	36%	17%	10%	15%

Source: [http://www.census.gov/quickfacts/table_2014 Estimate as of December 22, 2015](http://www.census.gov/quickfacts/table_2014%20Estimate%20as%20of%20December%22,%202015).

*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%

<http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.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 provide 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 46, the applicant states that it has no obligations under any federal regulations to provide uncompensated care or community service except those federal requirements of the Rehabilitation Act of 1973 and subsequent amendments. The applicant states that the facility has no Hill-Burton obligations.

In Section L.6, page 46, the applicant states there have been no civil rights complaints filed against any DVA facilities in North Carolina within the past five years. Therefore, the application is conforming to this criterion.

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

C

In Section L.1, page 44, the applicant provides the projected payor mix for the proposed project for the second operating year (CY 2020). The applicant states on page 44 that the projected payor mix for Forest Hills is based on the sources of payment received by the existing facility during the last full operating year. The projected payor mix is illustrated as follows:

Forest Hills Projected Payor Mix – CY 2020	
Payor Type	% of In-Center Patients
Medicare	27.1%
Medicaid	7.6%
Commercial Insurance	4.3%
Medicare/Commercial	23.7%
Medicare/Medicaid	33.9%
VA	3.4%
Total	100.0%

As illustrated in the table above, the applicant projects that 92.3 percent of all of the patients receiving dialysis services at Forest Hills in the second year of operation will have some or all of their services paid for by Medicare or Medicaid. The applicant demonstrates that medically underserved groups will have adequate access to the services offered at Forest Hills. 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 46, the applicant describes the range of means by which a person will have access to the dialysis services at Forest Hills. The applicant states that nephrologists with medical staff privileges will admit patients to the facility for dialysis. Referrals to these nephrologists may come from patients themselves, family, or friends. In Exhibit I-3, the applicant provides a letter signed by Dr. Will Bynum, indicating his willingness to serve as Medical Director. Exhibit I-3 also contains letters of support from local nephrologists who state they plan to refer patients to Forest Hills. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to dialysis 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 48, the applicant states it has offered the facility as a clinical learning site to nursing students at Wilson Community College. Exhibit M-2 contains a letter from the applicant to Wilson Community College's president, inviting the school to do clinical rotations for nursing students at its facility. The information provided is reasonable and adequately supports a determination that 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

DVA proposes to add five dialysis stations at Forest Hills for a total of 36 certified dialysis stations at the completion of this project, Project I.D. #L-11132-16 (relocate five stations), and Project I.D. #L-11153-16 (add five stations).

On page 373, the 2017 SMFP defines the service area for dialysis stations as the “*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 applicant operates two dialysis facilities in Wilson County. Also, DVA has been approved to develop one additional facility in Wilson County – Sharpsburg Dialysis – but the facility was not yet operational on June 30, 2016. The existing and approved Durham County dialysis facilities are shown below:

Wilson County Dialysis Facilities as of June 30, 2016				
Dialysis Facility	Certified Stations	CON Issued Not Certified	% Utilization	Patients Per Station
Forest Hills Dialysis	31	0	96.77%	3.871
Wilson Dialysis	40	0	87.50%	3.500
Sharpsburg Dialysis	0	10	0.00%	0.000

Source: Table A, January 2017 SDR.

As shown in the table above, both operational facilities in Wilson County were operating at a capacity of greater than 80 percent (3.2 patients per station) as of June 30, 2016.

In Section N, page 49, the applicant discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. The applicant states:

“The expansion of Forest Hills 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 Forest Hills 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 other [sic] involved in the dialysis process to receive services.”

See also Sections B, C, E, F, G, H, and L 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 the cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application, and the following analysis:

- The applicant adequately demonstrates the need for the proposed dialysis stations 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 Forest Hills 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 Forest Hills will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1) 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 Exhibit O-3, the applicant identifies four of its 70+ North Carolina facilities (Southeastern Dialysis Center – Kenansville, Durham Dialysis, Marshville Dialysis, and Durham West Dialysis) as having been cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. The applicant states that all four facilities are back in full compliance with CMS Guidelines as of the date of submission of this application and provides copies of letters to each facility from the Agency’s Acute and Home Care Licensure and Certification Section that state each facility is back in compliance. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it 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

(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- Forest Hills is an existing facility.

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

-C- In Section C.1, pages 13-15, the applicant adequately demonstrates that Forest Hills will serve at least 128 patients on 36 dialysis stations at the end of the first operating year, which is 3.56 patients per station per week, or a utilization rate of 89 percent ($128 / 36 = 3.56$; $3.56 / 4 = 0.89$ or 89%). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

(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 utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.