

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: December 21, 2012

PROJECT ANALYST: Jane Rhoe-Jones  
SECTION CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: L-10035-12 / DVA Healthcare Renal Care, Inc. dba Forest Hills Dialysis Center / Relocate facility and add ten dialysis stations / Wilson County

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

### C

The applicant, DVA Healthcare Renal Care, Inc. dba Forest Hills Dialysis Center proposes to relocate its 21 station dialysis facility at 2693 Forest Hills Road, Wilson, North Carolina, to 1605 Medical Park West, Wilson, North Carolina, and add 10 dialysis stations for a post project complement of 31 dialysis stations. Because the applicant proposes to add 10 stations, the facility need methodology in the 2012 State Medical Facilities Plan (SMFP) is applicable to this review.

The 2012 State Medical Facilities Plan (2012 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the revised July 2012 Semiannual Dialysis Report (SDR), the county need methodology shows there is no need for an additional facility in 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 Forest Hills Dialysis Center in the July 2012 SDR is 4.57 patients per station. This utilization rate was calculated based on 96 in-center dialysis patients and 21 certified dialysis stations as of December 31, 2011 (96 patients / 21 stations = 4.57 patients per station). Therefore, application of the facility need methodology indicates

eleven additional stations are needed for this facility, as illustrated in the following table. However, the applicant is applying for ten additional stations; the maximum number of stations per the facility need methodology.

<b>ESRD Facility Need Methodology October Review</b>		
<b>L-10035-12 Forest Hills Dialysis Wilson County</b>		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/2011		114.0%
Certified Stations		21
Pending Stations		0
Total Existing and Pending Stations		21
In-Center Patients as of 12/31/2011(SDR2)		96
In-Center Patients as of 6/25/2012(SDR1)		93
Step	Description	
(i)	Difference (SDR2 - SDR1)	3
	Multiply the difference by 2 for the projected net in-center change.	6
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 06/25/12	0.0645
(ii)	Divide the result of Step (i) by 12	0.0054
(iii)	Multiply the result of Step (ii) by the number of months from the most recent month reported in the July 2012 SDR (12/31/11) until the end of calendar year 2012 (12 months).	0.0645
(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	102.1935
(v)	Divide the result of Step (iv) by 3.2 patients per station	31.9355
	and subtract the number of certified and pending stations as recorded in SDR2 [# of stations] to determine the number of stations needed	11

Step (C) of the facility need methodology states, "The facility may apply to add to meet the need established, [...] up to a maximum of ten stations." As shown in the table above, based on the facility need methodology for dialysis stations, the number of stations needed is eleven stations, and the applicant proposes to add ten new stations and, therefore, is consistent with the facility need determination for dialysis stations

Also, SMFP Policy ESRD-2: Relocation of Dialysis Stations is applicable to this review. Policy ESRD-2 states:

*“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties currently served by the facility. Certificate of need applicants proposing to relocate dialysis stations to contiguous counties shall:*

- 1. demonstrate that the proposal shall not result in a deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*

2. *demonstrate that the proposal shall not result in a surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.*”

The applicant is proposing to relocate stations within Wilson County so there will be no change in the overall number of stations in the county. Therefore the application is conforming to this policy.

Policy GEN-3 in the 2012 SMFP is also applicable to this review. Policy GEN-3 states:

*“A CON 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 (SMFP) 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 CON 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 CON applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the SMFP as well as addressing the needs of all residents in the proposed service area.”*

#### Promote Safety and Quality

The applicant discusses its quality index in Section I, pages 7-8. Also, in Section II.3, pages 16-17, the applicant states,

*“DaVita, Inc. is committed to providing quality care to the ESRD population through a comprehensive Quality Management Program. DaVita’s Quality Management Program is facilitated by a dedicated clinical team of RN and Biomedical Quality Management Coordinators working under the direction of our Director of Quality Management and Director of Integrated Quality Development.*

*The program exemplifies DaVita’s total commitment to enhancing the quality of patient care through its willingness to devote the necessary resources to achieve our clinical goals.*

*Dr. William Bynum serves as Medical Director and provides the overall medical supervision of the dialysis unit. The facility unit administrator is the day to day manager of the facility and maintains the company’s Quality Management Program that monitors the overall care of the patients. The Quality Management Program is reviewed by the Quality Assurance Committee consisting of the Nephrologists, Unit Administrator, clinical teammates, social worker and the dietitian. ... Continuous Quality Improvement teams address facility issues with the goal of improving patient care patient outcomes.”*

The applicant also discusses its safety measures in Section XI.6(g), pages 53-54. In Exhibit 4 the applicant provides published articles about its clinical outcomes and a copy of an article

which describes DaVita's quality index. In Exhibit 13, the applicant provides a copy of its isolation policies and procedures, in Exhibit 18, a copy of the training manual for injury prevention and safety, and in Exhibit 19, a copy of its in-service calendar. The applicant adequately demonstrates how its proposal will promote safety and quality in the provision of dialysis services in Wilson County.

### Promote Equitable Access

In Section VI, pages 30-33, the applicant provides information about accessibility to Forest Hills dialysis services. On page 30, the applicant states,

*“Forest Hills Dialysis Center, by policy, has always made dialysis services available to all residents in its service area without qualifications. We have served and will continue to serve without regard to race, sex, age, handicap, or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.*

*Forest Hills Dialysis Center makes every reasonable effort to accommodate all of its patients; especially those with special needs such as the handicapped, patients attending school or patients who work. Forest Hills Dialysis Center provides dialysis six days per week to accommodate patient need. The facility also operates a third shift on Monday, Wednesday and Friday.*

*Forest Hills Dialysis Center does not require payment upon admission to its services; therefore, services are available to all patients including low-income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons. Forest Hills Dialysis works with patients who need transportation when necessary.”*

The applicant adequately demonstrates how its proposal will promote access to medically underserved groups.

### Maximize Healthcare Value

In Section III.9, page 22, the applicant states,

*“The Forest Hills Dialysis Center promotes cost-effective approaches in the facility in the following ways:*

*Forest Hills Dialysis Center purchases all of the products utilized in the facility, from office supplies to drugs to clinical supplies, under a national contract in order to secure the best products at the best price.*

*Forest Hills Dialysis Center utilizes the reuse process that contains costs and the amount of dialyzer waste generated by the facility. The dialyzers are purchased under a national contract in order to get the best quality dialyzer for the best price.*

*Forest Hills Dialysis Center has installed an electronic patient charting system that reduces the need for paper in the facility. Much of the other documentation in the facility is also done on computer which reduces the need for paper.*

*Forest Hills Dialysis Center Bio-Medical Technician assigned to the facility conducts preventative maintenance on the dialysis machines on a monthly, quarterly, and semi-annual schedule that reduces the need for repair maintenance and parts. This extends the life of the dialysis machines.*

*Forest Hills Dialysis Center also has an inventory control plan that ensures enough supplies are available without having an inordinate amount of supplies on hand. Supply orders are done in a timely manner to ensure that the facility does not run out of supplies, thus avoiding emergency ordering, which is costly.”*

The applicant adequately demonstrates how its proposal will maximize healthcare value. Additionally, the applicant demonstrates that projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served. The application is consistent with Policy GEN-3.

In summary, the applicant proposes to relocate 21 existing, certified dialysis stations and add 10 dialysis stations for a total of 31 dialysis stations within the host county of Wilson. The application is conforming to Policy ESRD-2 of the 2012 SMFP and Policy GEN-3 and is consistent with the facility need determination in the July 2012 SDR. 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 Healthcare Renal Care, Inc. dba Forest Hills Dialysis Center proposes to relocate its 21 station dialysis facility at 2693 Forest Hills Road, Wilson, North Carolina, to 1605 Medical Park West, Wilson, North Carolina, and add 10 stations resulting in 31 dialysis stations. The July 2012 SDR indicates a total of 21 certified stations at Forest Hills Dialysis Center, as of June 25, 2012. Based on patient origin information provided in the table in Section III.7, page 20 of the application, the applicant does not propose any home training. In Section IV.3, page 23, the applicant states,

“The Wilson Dialysis Center provides home training for patients living in Mecklenburg County [sic] under an agreement with Forest Hills Dialysis Center.”

Population to be served

In Section IV.1, page 23, the applicant states that the number of in-center patients served at Forest Hills Dialysis Center as of December 31, 2011 is as follows:

<b>Forest Hills Dialysis Center</b>	
<b>County of Residence</b>	<b>Patients Dialyzing In-center</b>
Wilson	77
Johnston	7
Nash	7
Edgecombe	2
Greene	1
Pitt	1
Wayne	1
Total	96

In Section III.7, page 20, the applicant provided the projected patient origin for Forest Hills Dialysis Center for the first two years of operation following completion of the project as follows:

<b>Forest Hills Dialysis Center</b>						
<b>County</b>	<b>Operating Year 1 2014-2015</b>		<b>Operating Year 2 2015-16</b>		<b>County Patients Percent of Total</b>	
	<b>In-center Patients</b>	<b>Home Dialysis Patients</b>	<b>In-center Patients</b>	<b>Home Dialysis Patients</b>	<b>Year 1</b>	<b>Year 2</b>
Wilson	85	0	88	0	81.7%	82.2%
Johnston	7	0	7	0	6.7%	6.6%
Nash	7	0	7	0	6.7%	6.6%
Edgecombe	2	0	2	0	1.9%	1.9%
Greene	1	0	1	0	1.0%	.09%
Pitt	1	0	1	0	1.0%	.09%
Wayne	1	0	1	0	1.0%	.09%
<b>TOTAL</b>	<b>104</b>	<b>0</b>	<b>107</b>	<b>0</b>	<b>100.0%</b>	<b>100.0%</b>

The applicant adequately identified the population Forest Hills Dialysis Center proposes to serve.

Demonstration of Need

In Section II, pages 12-13, and in Section III.7, page 21, the applicant provides the assumptions and methodology it used to project need for ten additional dialysis stations at Forest Hills Dialysis Center. The applicant states,

*“Forest Hills Dialysis Center had 96 in-center patients as of December 31, 2011 based on information included in Table A of the July 2012 Semiannual Dialysis Report (SDR).*

*Of the 96 in-center patients cited in the SDR, 77 of the patients live in Wilson County.*

*The July 2012 SDR indicates in Table B that Wilson County has experienced an average annual change rate of 3.6% for the past five years.*

*The period of growth begins with July 1, 2012 through the projected operating year 2.*

*July 1, 2012-June 30, 2013 - 77 patients X 1.036 = 79.77*

*July 1, 2013-June 30, 2014 - 79.772 patients X 1.036 = 82.64*

*July 1, 2014-June 30, 2015 - 82.64 patients X 1.036 = 85.62 (Operating Year 1)*

*July 1, 2015-June 30, 2016 - 85.62 patients X 1.036 = 88.70 (Operating Year 2)*

*At the end of operating year one the Forest Hills Dialysis Center is projected to have an in-center patient census of 104 patients (85 Wilson County patients, 2 Edgecombe County patients, 7 Johnston County patients, 7 Nash County patients, one Greene County patient, one Pitt County patient and one Wayne County patient = 104 total patients for utilization rate of 83.9% or 3.3 patients per station. At the end of operating year two the Forest Hills Dialysis Center is projected to have an in-center patient census of 107 patients (88 Wilson County patients, 2 Edgecombe County patients, 7 Johnston County patients, 7 Nash County*

*patients, one Greene County patient, one Pitt County patient and one Wayne County patient = 107 total patients for utilization rate of 86.3% or 3.4 patients per station. We did not calculate growth of patients outside Wilson County.”*

Projected utilization at the end of Year One equals 3.3 in-center patients per station per week which exceeds the 3.2 in-center patients per station as required by 10A NCAC 14C .2203(b); and the number of in-center patients projected to be served is based on reasonable and supported assumptions regarding future growth.

### Access

In Section VI, page 31, the applicant projects that greater than 90% of the patients at Forest Hills Dialysis Center will be covered by Medicare and Medicaid. The applicant demonstrates adequate access for the underserved at Forest Hills Dialysis Center.

In summary, the applicant adequately identifies the population to be served and adequately demonstrates the need for ten additional dialysis stations at the Forest Hills Dialysis Center. Consequently, 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.

### C

The applicant proposes to relocate the 21 station Forest Hills Dialysis Center to a new facility (renovated former Wilson Dialysis Center) and add 10 stations resulting in 31 dialysis stations. The new location for Forest Hills Dialysis Center at 1605 Medical Park West, Wilson, North Carolina is approximately 1.1 mile distance from the current location at 2693 Forest Hills Road, Wilson, North Carolina. In clarifying information for Section III.6, page 20, the applicant states,

*“The need of the population presently served will be adequately met at the proposed location at 1605 Medical Park West in Wilson. The facility does not anticipate that the relocation of the facility 1.1 miles from the current location will have any effect on the ability of low income persons, racial and ethnic minorities, women, handicapped persons and other underserved group and the elderly to obtain their dialysis treatments. We do not anticipate that the relocation of the facility will provide any inconvenience to the patients or the transportation service that many patients rely on for their transportation to and from their treatments.”*

In Section IV.1, page 23, the applicant states that Forest Hills Dialysis Center currently has 96 in-center dialysis patients, 77 of whom are from Wilson County. By the end of operating year

one, the projected in-center patients are 104 with 85 from Wilson County; and at the end of operating year two, in-center patients are projected at 107 with 88 from Wilson County. See Criterion (3) for Forest Hills Dialysis Center assumptions and methodology and projected utilization rates. The applicant proposes no change in its service to medically underserved groups.

The applicant further demonstrates that the needs of the population presently served at Forest Hill Dialysis will continue to be adequately met following the relocation of 21 certified dialysis stations to the proposed new facility along with the addition of 10 stations; which is estimated to be 1.1 mile from the current location. Therefore, the application is conforming to this criterion.

- (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.

### C

In Section III.9, page 22, the applicant discusses the alternatives considered prior to the submission of this application, which include:

- 1) Maintain the Status Quo – Forest Hills Dialysis is at 114% utilization and there is no space in which to add capacity at the current location.
- 2) The applicant chooses to apply for 10 station expansion and relocate the facility to a state of the art dialysis facility. The applicant chooses this alternative to meet the growing demand for dialysis services at Forest Hills Dialysis Center. The applicant projects an annual growth rate of 3.6% with an accompanying 83.9% utilization rate by the end of the first operating year.

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 the Forest Hills Dialysis Center proposal is the least costly or most effective alternative to meet the need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

1. **DVA Healthcare Renal Care, Inc. dba Forest Hills Dialysis Center shall materially comply with all representations made in the certificate of need application and supplemental responses. In those instances where representations conflict, DVA Healthcare Renal Care, Inc. dba Forest Hills Dialysis Center shall materially comply with the last-made representation.**

2. **DVA Healthcare Renal Care, Inc. dba Forest Hills Dialysis Center shall develop and operate no more than ten additional dialysis stations for a total of 31 certified stations which shall include any isolation stations.**
  3. **DVA Healthcare Renal Care, Inc. dba Forest Hills Dialysis Center shall install plumbing and electrical wiring through the walls for, develop space for and operate no more a total of 31 certified stations which shall include any isolation stations.**
  4. **DVA Healthcare Renal Care, Inc. dba Forest Hills Dialysis Center shall not offer or develop home hemodialysis or peritoneal dialysis training services as part of this project.**
  5. **DVA Healthcare Renal Care, Inc. dba Forest Hills Dialysis Center shall decertify the former Forest Hills location upon completion of this project.**
  6. **DVA Healthcare Renal Care, Inc. dba Forest Hills Dialysis Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII, the applicant states that the capital cost is projected to be \$1,691,510. In Sections IX.3, page 43, the applicant projects that there will be no start-up expenses associated with the proposed project.

Exhibit 13 includes a letter dated September 14, 2012 from the Chief Accounting Officer of DaVita, Inc., the parent and owner of DVA Healthcare Renal Care, Inc. which states in part:

*“The project calls for a capital expenditure of \$1,691,510. This letter will confirm that DaVita, Inc. has committed cash reserves in the total sum of \$1,691,510 for the project capital expenditure. DaVita Inc. will make these funds, along with any other funds that are necessary for the development of the project, available to DVA Healthcare Renal Care, Inc.”*

In Exhibit 14, the applicant provides the audited financial statements for DaVita, Inc. for the fiscal year ended December 31, 2011. As of December 31, 2011, DaVita had cash and cash equivalents totaling \$393,752 with \$2,281,608 in total assets and \$8,892,172 in net assets (total

assets less total liabilities; dollars in thousands). The applicant adequately demonstrates the availability of funds for the proposed project.

Based on information provided by the applicant in Section X.1, page 44, the dialysis facility’s projected allowable charges per treatment for each payment source are as follows:

<b>Forest Hills Dialysis Center</b>	
Source of Payment	Charge Per treatment
Commercial Insurance	\$800.00
Medicare/Medicaid	\$240.00
Medicare/Commercial	\$240.00
VA	\$240.00
Medicare	\$192.00
Medicaid	\$192.00

The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services. In Section X.2-X.4, pages 44-47, the applicant reported projected revenues and expenses as follows:

<b>Forest Hills Dialysis Center</b>		
	<b>Operating Year 1</b>	<b>Operating Year 2</b>
Total Net Revenue	\$4,068,160	\$4,187,392
Total Operating Costs	\$3,924,606	\$4,047,920
Net Profit	\$143,554	\$139,472

The applicant projects that revenue will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable. See Section X of the application for the applicant’s assumptions.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the operating expenses of this project. The applicant also adequately demonstrates that the financial feasibility of the proposal 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**

DVA Healthcare Renal Care, Inc. dba Forest Hills Dialysis Center proposes to add 10 in-center dialysis stations for a total of 31 dialysis stations upon project completion. Growth in the number of dialysis stations is planned in addition to relocating the facility from 2693 Forest Hills Road, Wilson, North Carolina, to 1605 Medical Park West, Wilson, North Carolina. Forest Hills Dialysis Center is currently serving 96 patients weekly at 4.57 patients per station,

which is 114% of capacity. Dialysis facilities that operate four shifts per week (2 per day on alternate days) have a capacity of four patients per station. The applicant does not propose to establish a new facility. The applicant provides reasonable projections for the in-center patient population it proposes to serve on pages 13 and 21 of the application. The growth projections are based on a projected 3.6% average annual growth rate in the number of dialysis patients in Wilson County. The other dialysis facility in Wilson County is also operating above 100% utilization. At the end of Operating Year Two, the Forest Hills Dialysis Center projects the utilization will be 3.45 in-center patients per station (107 patients / 31 dialysis stations = 3.4).

The applicant adequately demonstrates the need to develop ten additional dialysis stations at the existing facility based on the number of in-center patients it proposes to serve. The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, the applicant 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

The following table illustrates current and projected staffing for Forest Hills Dialysis Center, as provided by the applicant in Section VII.1, page 34:

<b>Forest Hills Dialysis Center</b>			
<b>Position</b>	<b>Current FTEs</b>	<b># of FTE Positions to be Added</b>	<b>Total FTE Positions</b>
RN	3.5	1.5	5.0
PCT	10	4.5	14.5
Bio-Med Tech	.7	.3	1.0
MD	Contract		
Admin	1.0	0	1.0
Dietician	.7	.3	1.0
Social Worker	.7	.3	1.0
Unit Secretary	1.0	0	1.0
Other-Reuse	1.0	.5	1.5
<b>Total</b>	<b>18.6</b>	<b>7.4</b>	<b>26.0</b>

As shown in the above table, the applicant proposes to employ a total of 26.0 full-time equivalent (FTE) positions to staff the Forest Hills Dialysis Center upon completion of the proposed project. In Section VII.1, page 34, the applicant states,

*“The Medical Director is not employed by the facility. There is a signed agreement between the facility and the Medical Director. The fee to be paid is estimated to be \$100,000 annually for the Medical Director responsibilities.”*

In Section V.4(c), page 27 and Section VII.2, page 35, the applicant states that Dr. William Bynum, a Board-Certified Nephrologist will serve as medical director of the facility.

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

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

C

In Section V.1, pages 25-26, the applicant includes a list of providers 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 system. Therefore, the application is conforming to this criterion.

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

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (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:
- would be available under a contract of at least 5 years duration;
  - would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
  - would cost no more than if the services were provided by the HMO; and
  - 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.

C

In Section XI, pages 49-56, the applicant discusses the site for the proposed Forest Hills dialysis facility and states it plans to gut and rebuild space that is currently leased by Wilson Dialysis Center; also a DaVita facility.

The applicant states that the new site is within one mile to the local hospital and key support services. On page 55, the applicant states the facility will be 12,669 square feet with energy saving features as described on page 52. The applicant proposes to lease 12,669 square feet for total capital costs of \$1,691,510; including construction upfit cost of \$1,200,000. See Section VIII.1, pages 38-39 and XI.6(h), page 55. The following table illustrates the square footage breakdown as provided by the applicant in Section XI.6(h), page 55:

<b>Forest Hills Dialysis Center</b>	
<b>Facility Area</b>	<b>Estimated Total Sq. Ft.</b>
<b>Ancillary Areas:</b>	
Administration	989
Public Lobby	381
Mechanical Equipment	491
Housekeeping	39
General Storage/Medical Records	1,016
Exam/Treatment	757
Staff Lounge/Lockers	552
RO	472
Other (Toilets, Circulation /Med. Waste)	635
Sub-Total Support	5,293
<b>Treatment Areas:</b>	
Nurses Station	160
Dialysis Stations	4,672
Isolation Room(s)	158
Other (Patient Bath/corridor/walls)	2,386
Sub-Total Treatment	7,376
<b>Total Square Feet</b>	<b>12,669</b>

The applicant states 12,669 square feet for the proposed facility for a total construction cost of \$1,200,000. Thus the construction cost per square foot is approximately \$95 per square foot.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative and that the construction project would not unduly increase the costs of or charges for providing the proposed health services if the project were approved. Therefore, the application is conforming to this criterion.

- (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 VI.1(b), page 30, the applicant reports that 91.6% of the patients who received treatments at Forest Hills Dialysis Center had some or all of their services paid for by Medicare or Medicaid in the past year. The table below illustrates the historical payment source of the facility:

<b>Forest Hills Dialysis Center</b>	
<b>Source of Payment</b>	<b>Percentage</b>
Medicare/Medicaid	31.6%
Medicare/Commercial	31.6%
Medicare	23.1%
Commercial Insurance	7.4%
Medicaid	5.3%
VA	1.0%
Total	100.0%

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Wilson County and statewide.

	<b>CY 2009 Total # of Medicaid Eligibles as % of Total Population *</b>	<b>CY 2009 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *</b>	<b>CY 2009 % Uninsured (Estimate by Cecil G. Sheps Center)*</b>
Wilson County	17%	6.7%	19.7%
Statewide	22%	9.0%	21.9%

\*More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by the Forest Hills Dialysis Center facility. In fact, only 5.8% of all 2011 ESRD patients in North Carolina’s Network 6 were under the age of 35.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race and gender. However, a direct comparison to the applicants’ current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM’s website does not include information on the number of handicapped persons.

The Centers for Medicare & Medicaid Services (CMS) website states,

*“Although the ESRD population in less than 1% of the entire U.S. population it continues to increase at a rate of 3% per year and includes people of all races, age groups, and socioeconomic standings. ...*

*Almost half (46.6%) of the incident patients in 2004 were between the ages of 60 and 79. These distributions have remained constant over the past five years. While the majority of dialysis patients are White, ESRD rates among Blacks and Native Americans are disproportionately high. While Blacks comprise over 12% of the national population, they make up 36.4% of the total dialysis prevalent population. In 2004 males represented over half of the ESRD incident (52.6%) and prevalent (51.9) populations.”*<sup>[1]</sup>

Additionally, the United States Renal Data System, in its 2012 USRDS Annual Data Report (page 225) provides these national statistics for FY 2010:

*“On December 31, 2010, more than 376,000 ESRD patients were receiving hemodialysis therapy.”*

[1]([www.cms.gov/medicare/end-stage-renal-disease/esrdnetworkorganizations/downloads/esrdnetworkprogrambackgroundpublic.pdf](http://www.cms.gov/medicare/end-stage-renal-disease/esrdnetworkorganizations/downloads/esrdnetworkprogrambackgroundpublic.pdf))

The report validates the statistical constancy reported by CMS above. Of the 376,000 ESRD patients, 38.23% were African American, 55.38% were white, 55.65% were male and 44.65% were 65 and older. The report further states:

*“Nine of ten prevalent hemodialysis patients had some type of Medicare coverage in 2010, with 39 percent covered solely by Medicare, and 32 percent covered by Medicare/Medicaid. ...Coverage by non-Medicare insurers continues to increase in the dialysis population, in 2010 reaching 10.7 and 10.0 percent for hemodialysis and peritoneal dialysis patients, respectively.”*

The report provides 2010 ESRD spending, by payor as follows:

<b>ESRD Spending by Payor</b>		
<b>Payor</b>	<b>Spending in Billions</b>	<b>% of Total Spending</b>
Medicare Paid	\$29.6	62.32%
Medicare Patient Obligation	\$4.7	9.89%
Medicare HMO	\$3.4	7.16%
Non-Medicare	\$9.8	20.63%

Source: 2012 United States Renal Data System (USRDS) Annual Data Report, page 340.

The Southeastern Kidney Council (SKC) provides Network 6 2011 Incident ESRD patient data by age, race and gender demonstrating the following:

<b>Number and Percent of Dialysis Patients by Age, Race and Gender</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Ages</b>		
0-19	89	1.0%
20-34	451	4.8%
35-44	773	8.3%
45-54	1,529	16.4%
55-64	2,370	25.4%
65-74	2,258	24.2%
75+	1,872	20.0%
<b>Gender</b>		
Female	4,237	45.35%
Male	5,105	54.65%
<b>Race</b>		
African American	5,096	54.55%
White/Caucasian	4,027	43.11%
Other	219	2.3%

Source: Southeastern Kidney Council (SKC) Network 6. Includes North Carolina, South Carolina and Georgia

The applicants demonstrate that it 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 VI.6 (a), page 33, the applicant states there have been no civil rights access complaints filed within the last 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 VI.1(c), page 31, the applicant provides the projected payor mix for the proposed services at Forest Hills Dialysis. The applicant projects no change from the current payor mix for dialysis visits as stated in Criterion (13a) above. The applicant demonstrates that medically underserved populations would have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section VI.5, page 32, the applicant states,

*“Patients with End Stage Renal Disease have access to dialysis services upon referral to a Nephrologist with privileges at Forest Hills Dialysis Center. These referrals most commonly come from primary care physicians or specialty physicians in Wilson County or transfer referrals from other Nephrologists outside of the immediate area. Patients, families and friends can obtain access by contacting a Nephrologist with privileges at the facility. Should a patient contact the Wilson Dialysis*

*Center [sic] directly or indirectly, the patient is referred to a qualified Nephrologist for evaluation and subsequent admission if medically necessary. Patients from outside the Forest Hills Dialysis Center catchment area requesting transfer to this facility are processed in accordance with the Forest Hills Dialysis Center transfer and transient policies which comprise Exhibit 9 [Emphasis by applicant.]. The patient, again, is referred to a qualified Nephrologist for final evaluation and subsequent admission if medically necessary.”*

The applicant adequately demonstrates that Forest Hills Dialysis Center will provide a range of means by which a person can access the 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 V.3, page 27 the applicant states,

*“Forest Hills Dialysis Center is utilized as a clinical training site by the Wilson Community College. Both nursing students and dialysis tech students experience clinical rotations at the facility. Forest Hills Dialysis Center is open for any other educational organization to develop an agreement with the facility to be utilized for a health professional training program area.”*

The information provided in Section V.3 is reasonable and credible 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 dialysis facilities in Wilson are owned by DaVita. The applicant states that DaVita is currently building a new facility for the Wilson Dialysis Center. The Wilson Dialysis Center and the Forest Hills Dialysis Centers are located a little more than one mile apart, operate three shifts several days a week and operate greater than 100% capacity.

See Sections II, III, V, VI and VII. In particular, see Section V, pages 28-29, in which Forest Hills Dialysis Center discusses the impact of the project as it relates to promoting cost-effectiveness, quality and access. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition include a positive impact on cost-effectiveness, quality and access to dialysis services in Wilson County. This determination is based on the information in the application, and the following:

The applicant adequately demonstrates the need, based on 'Facility Need,' to increase the number of dialysis stations by 10 stations to 31 certified stations and relocate the dialysis facility, and that it is a cost-effective alternative;

The applicant has and will continue to provide quality services. The information regarding staffing provided in Section VII is reasonable and credible and demonstrates adequate staffing for the provision of quality care services in accordance with 42 C.F.R, Section 494 (formerly 405.2100). The information regarding ancillary and support services and coordination of services with the existing health care system in Sections V.1, V.2, V.4, V.5 and VII is reasonable and credible and demonstrates the provision of quality services; and the applicant has and will continue to provide adequate access to medically underserved populations. In Section VI.1 the applicant states:

*“Forest Hills Dialysis Center, by policy, has always made dialysis services available to all residents in its service area without qualifications. We have served and will continue to serve without regard to race, sex, age, handicap, or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.”*

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

According to the files of the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the Forest Hills Dialysis Center operated in compliance with the Medicare Conditions of Participation within the 18 months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

- (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 and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific findings are discussed below:

**10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT**

*(a) An applicant that proposes to increase stations in an existing certified facility or relocate stations must provide the following information:*

.2202(a)(1) *Utilization rates;*

-C- See Section IV.1, page 23, and Exhibit 7 (copy of the July 2012 SDR, Tables A and B).

.2202(a)(2) *Mortality rates;*

-C- In Section IV.2, page 23, the applicant reports the 2009, 2010 and 2011 facility mortality rates.

.2202(a)(3) *The number of patients that are home trained and the number of patients on home dialysis;*

-NA- In Section IV.3, page 23 and Section V.2(d), page 26, the applicant states that Forest Hills Dialysis Center has an agreement with Wilson Dialysis Center for the provision of home training services. However, the applicant does not propose to have any home hemodialysis patients at the facility.

.2202(a)(4) *The number of transplants performed or referred;*

-C- In Section IV.4, page 24, the applicant stated that Forest Hills Dialysis Center

referred 29 patients for transplant evaluation in 2011. Forest Hills Dialysis Center had one patient to receive a transplant in 2011.

- .2202(a)(5) *The number of patients currently on the transplant waiting list;*  
-C- In Section IV.5, page 24, the applicant states that the Harrisburg Dialysis Center has 12 patients on the transplant waiting list.
- .2202(a)(6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;  
-C- See Section IV.6, page 24, the applicant reports a total of 183 hospital admissions in 2011; 89.1% were non-dialysis related and 10.9% were dialysis-related.
- .2202(a)(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.*  
-C- In Section IV.7, page 24, the applicant reports that in 2011 there was one patient with an infectious disease. No patients converted to infectious status in 2011.
- (b) *An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:*
- .2202(b)(1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100*  
-NA- Forest Hills Dialysis Center is an existing facility moving to a new site.
- .2202(b)(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*
- (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
  - (B) *composition of the assessment/evaluation team at the transplant center,*
  - (C) *method for periodic re-evaluation,*
  - (D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and,*
  - (E) *Signatures of the duly authorized persons representing the facilities and the agency providing the services.*
- NA- Forest Hills Dialysis Center is an existing facility.
- .2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*  
-NA- Forest Hills Dialysis Center is an existing facility.
- .2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*  
-C- Exhibit 8 contains a copy of written policies and procedures for back up for

electrical service in the event of a power outage.

.2202(b)(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*

-NA- Forest Hills Dialysis Center is an existing facility.

.2202(b)(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*

-C- See Sections II.3, pages 16-17; VII.2, pages 34-35 and, XI.6(e), page 53 XI.6(g), pages 53-54.

.2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*

-C- See Section III.7, page 20, Forest Hills Dialysis Center provided projected patient origin based on historical experience using Wilson’s growth rate. The first two years of operation following completion of the project are as follows:

<b>FOREST HILLS DIALYSIS CENTER</b>		
<b>County</b>	<b>Operating Year 1 2014-2015</b>	<b>Operating Year 2 2015-16</b>
	<b>In-center Patients</b>	<b>In-center Patients</b>
Wilson	85	88
Johnston	7	7
Nash	7	7
Edgecombe	2	2
Greene	1	1
Pitt	1	1
Wayne	1	1
<b>TOTAL</b>	<b>104</b>	<b>107</b>

.2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*

-NA- Forest Hills Dialysis Center is an existing facility.

.2202(b)(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement for such services.*

-C- In Section II, page 12, the applicant states, “DVA Healthcare Renal Care, Inc. d/b/a Forest Hills Dialysis Center will admit and provide dialysis services to patients who have no insurance or other source of payment, if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”

## 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- Forest Hills Dialysis Center 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 Sections II, page 12 and III.7, page 21, the applicant projects to serve 104 in-center patients by the end of Year 1, which is 3.3 patients per station ( $104 / 31 = 3.35$ ).
- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section II, pages 13-14 and Section III.7, pages 21, the applicant provides the assumptions and methodology used to project utilization of the proposed facility.

## 10 NCAC 14C .2204 SCOPE OF SERVICES

*To be approved, the applicant must demonstrate that the following services will be available:*

- .2204(1) *Diagnostic and evaluation services;*
- C- See Section V.1, page 25.
- .2204(2) *Maintenance dialysis;*
- C- See Section V.1, page 25.
- .2204(3) *Accessible self-care training;*
- C- See Section V.1, page 25.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
- C- See Section V.1, page 25 and V.1(d), page 26.
- .2204(5) *X-ray services;*
- C- See Section V.1, page 25.
- .2204(6) *Laboratory services;*
- C- See Section V.1, page 25.
- .2204(7) *Blood bank services;*
- C- See Section V.1, page 25.
- .2204(8) *Emergency care;*
- C- See Section V.1, page 25.
- .2204(9) *Acute dialysis in an acute care setting;*
- C- See Section V.1, page 25.

- .2204(10) *Vascular surgery for dialysis treatment patients*
- C- See Section V.1, page 25.
- .2204(11) *Transplantation services;*
- C- See Section V.1, page 25.
- .2204(12) *Vocational rehabilitation counseling and services; and,*
- C- See Section V.1, page 25.
- .2204(13) *Transportation*
- C- See Section V.1, page 26.

#### **10 NCAC 14C .2205 STAFFING AND STAFF TRAINING**

- .2205(a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R. Section 405.2100.*
- C- In Section VII.1, page 34, the applicant provides the proposed staffing. In Section VII.2, pages 34-35, the applicant states the proposed facility will comply with all staffing requirements set forth in 42 C.F.R. Section 405.2100. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. See Criterion (7) for discussion.
- .2205(b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*
- C- See Section VII.5, page 36, and Exhibits 12, 18 and 19.