

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 12, 2016

Findings Date: May 12, 2016

Project Analyst: Bernetta Thorne-Williams

Team Leader: Fatimah Wilson

Project ID #: L-11134-16

Facility: Thomasville Dialysis Center of Wake Forest University

FID #: 020758

County: Davidson

Applicant(s): Wake Forest University Health Sciences

Thomasville Dialysis Center of Wake Forest University

Project: Add four dialysis stations and relocate four existing dialysis stations from High Point Kidney Center for a total of 32 stations upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

The applicants, Wake Forest University Health Sciences (WFUHS) and Thomasville Dialysis Center of Wake Forest University (TVDC) propose to add four dialysis stations and relocate four existing stations from High Point Kidney Center (HPKC) for a total of 32 stations at TVDC upon project completion. WFUHS is the sole owner of TVDC and contracts with Health Systems Management, Inc., (HMS) to operate the facility.

Need Determination

The 2016 State Medical Facilities Plan (2016 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2016 Semiannual Dialysis Report (SDR), the county need methodology shows there is a projected deficit of eight dialysis stations in Davidson County, however, because the projected deficit identified in the SDR is less than ten stations, a new dialysis facility cannot be considered. The applicant is eligible to apply for additional dialysis stations based on the facility need methodology because the utilization rate reported for TVDC in the January 2016 SDR is 3.625 patients per station per week, or 90.63%. This utilization rate was calculated based on 87 in-center dialysis patients and 24 certified dialysis stations as of June 30, 2015 (87 patients / 24 stations = 3.625 patients per station). Application of the facility need methodology indicates additional stations are needed for the facility, as illustrated in the following table.

April 1 Review – January 2016 SDR

Required SDR Utilization		80%
Center Utilization Rate as of 6/30/15		90.63%
Certified Stations		24
Pending Stations		0
Total Existing and Pending Stations		24
In-Center Patients as of 6/30/15 (SDR2)		87
In-Center Patients as of 12/31/14 (SDR1)		84 [85]
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	2
	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 12/31/14	0.0714
(ii)	Divide the result of step (i) by 12	0.0060
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/15 until 12/31/15)	0.0357
(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	90.1071
(v)	Divide the result of step (iv) by 3.2 patients per station	28.1585
	and subtract the number of certified and pending stations to determine the number of stations needed	4

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.*” As shown in the table above, based on the facility need methodology for dialysis stations, TVDC has a need for four additional stations. The applicant proposes to add a total of four new stations and therefore, is consistent with the facility need determination for dialysis stations.

Policies

There are two policies in the 2016 SMFP which are applicable to this review: Policy ESRD-2: Relocation of Dialysis Stations and Policy GEN-3: Basic Principles.

Policy ESRD-2 states:

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

- (1) Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- (2) Demonstrate that the proposal shall not result in a deficit, or increase in existing 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*
- (3) Demonstrate that the proposal shall not result in a surplus, or increase an existing 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 applicants propose to relocate four existing dialysis stations from HPKC in Guilford County, which is contiguous to Davidson County. In Section C, page 28, the applicants report that TVDC was serving one patient from Guilford County as of December 31, 2015. The January 2016 SDR showed a projected surplus of eight dialysis stations in Guilford County and a projected deficit of eight dialysis stations in Davidson County. Additionally, the utilization rate reported for HPKC in the same SDR was 3.64 patients per station per week, or 91.07%. This utilization rate was calculated based on 153 in-center dialysis patients and 42 certified dialysis stations as of June 30, 2015 ($153 \text{ patients} / 42 \text{ stations} = 3.64 \text{ patients per station per week}$). The transfer of four existing dialysis stations from Guilford County to Davidson County will decrease the projected surplus of stations in Guilford County and decrease the projected deficit of stations in Davidson County. Consequently, the application is consistent with Policy ESRD-2.

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 applicants describe how the proposed project would promote safety and quality in Section A-11, pages 5-7, Section B-4(a), page 13-16, Section I-1, page 62, and referenced exhibits. The information provided by the applicants is reasonable and adequately supports the determination that the applicants’ proposal would promote safety and quality.

Promote Equitable Access

The applicants describe how the proposed project would promote equitable access in Section B-4(b), pages 16-21, Section L-1(a), pages 74-75, and referenced exhibits. The information provided by the applicants is reasonable and adequately supports the determination that the applicants’ proposal would promote equitable access.

Maximize Healthcare Value

The applicants describe how the proposed project would maximize healthcare value in Section B-4(a), page 13, Section B-4(c), page 21, Section K, pages 68-69, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicants’ proposal would maximize healthcare value.

The applicants adequately demonstrate how the projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need. Therefore, the application is consistent with Policy GEN-3.

Conclusion

In summary, the applicants adequately demonstrate that the application is consistent with the facility need determination in the January 2016 SDR, Policy ESRD-2 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

TVDC currently operates a 24 station dialysis facility located in Thomasville, in Davidson County. The facility does not provide home hemodialysis or peritoneal dialysis training and support. Those patients that reside in Davidson County and require training and support for home hemodialysis and peritoneal dialysis receive those services from HPKC in Guilford County. HPKC is owned by WFUHS. In this application, the applicants propose to add four dialysis stations and relocate four existing dialysis from HPKC to the existing TVDC facility for a total of 32 certified dialysis stations upon project completion. The applicants do not propose to add home hemodialysis or peritoneal dialysis training and support at TVDC.

Population to be Served

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

In Section C-1, page 26, the applicants identified the historical population served, as of December 31, 2015, as illustrated below.

COUNTY OF RESIDENCE	IN-CENTER PATIENTS	PERCENT
Davidson*	72.00	79.1%
Guilford	1.00	1.1%
Randolph	18.00	19.8%
Total	91.00	100.0%

In Section C-1, page 24, the applicants provide the projected patient origin for TVDC for in-center patients for the first two years of operation following project completion, as illustrated below:

TVDC				
County of Residence	Operating Year 1 CY 2018	Operating Year 2 CY 2019	County In-Center Patients as % of Total	
	In-Center	In-Center	Year 1	Year 2
Davidson	105	112	99.1%	99.1%
Guilford	1	1	0.9%	0.9%
Total	106	113	100.0%	100.0%

The applicants provide the assumptions and methodology used to project patient origin on pages 24-26. The applicants adequately identify the population to be served.

Analysis of Need

In Section B.2, pages 9-10, the applicants state the need for the proposed project is based on the facility need methodology and Policy ESRD-2. Thus, the applicants are proposing to add four new dialysis stations and relocate four existing dialysis stations from HPKC to the existing TVDC facility in Davidson County for a total of 32 certified dialysis stations upon project completion.

In Section C-1, pages 24-26, the applicants provide their assumptions and methodology used to project the number of patients expected to utilize TVDC. The projections are based on the following assumptions:

- The majority of patients projected to utilize TVDC will be Davidson County residents based on the facility's historical experience.
- The January 2016 SDR shows a projected deficit of eight stations in Davidson County and a projected surplus of eight stations in Guilford County, thus the applicants propose to add four new stations and relocate four existing stations. Upon project completion, there will no longer be a deficit of stations in Davidson County and the surplus of stations in Guilford County will be reduced from eight to four.
- The applicants report the beginning patient census for TVDC as of December 31, 2015 was 91 in-center patients with no home hemodialysis or PD patients. Of those 91 patients, 72 patients were residents of Davidson County, one was a resident of Guilford County and 18 were residents of Randolph County.
- The 18 patients from Randolph County are projected to transfer their care to the North Randolph Dialysis Center upon certification of the facility on June 30, 2016. The projected patient population beginning June 30, 2016 and throughout Operating Year 1 (OY 1) and Operating Year 2 (OY 2) does not include the patients from Randolph County.
- The applicants assume that the 14 Davidson County in-center patients currently receiving dialysis services in Guilford County will transfer their care to TVDC upon project completion.
- The Five Year Average Annual Change Rate (AACR), as reported in the January 2016 SDR for Davidson County is 7.0% and was used to project the Davidson County patient population forward.
- The Five Year AACR, as reported in the January 2016 SDR for Guilford County is 3.0% and was used to project the Guilford County patient population forward.

Projected Utilization

As previously stated, the applicants are projecting that 18 in-center patients will transfer their dialysis care to the new North Randolph Dialysis Center upon certification of the facility on June 30, 2016. On page 26, the applicants project a decline in in-center utilization at TVDC from 94.79% (December 31, 2015) to 81.32% (December 31, 2016) as a result of the patient transfer, as shown in the table below.

County of Residence	SDR AACR	# of Patients Year Ending 2014	# of Patients Year Ending 2015	# of Patients Year Ending 2016
Davidson	7.00%	65.00	72.00	77.04
Guilford	3.00%	0.00	1.00	1.03
Randolph	4.80%	19.00	18.00	N/A
Total		84.00	91.00	78.07
# Number of Stations		24	24	24
Utilization		87.50%	94.79%	81.32%

*On page 26, the applicants state that between December 31, 2014 to December 31, 2015, the Davidson County dialysis patients at TVDC increased from 65 to 72 patients at a rate of 10.77%.

As shown in the table above, despite the transfer of 18 in-center patients to another facility, the applicants are still projected to be over 80% utilization by the end of CY2016.

On page 28, the applicants state that even without an increase in stations at the facility, TVDC would potentially have 99.52 in-center patients, or 103.67% utilization by December 31, 2017 because of the projected patient population in the service area (as defined by the applicants) and the transfer of Davidson County patients currently dialyzing in Guilford County to TVDC, as shown in the table below.

County of Residence	SDR AACR	# of Patients Year Ending 2014	# of Patients Year Ending 2015	# of Patients Year Ending 2016	# of Patients Year Ending 2017	# of Patients Year Ending 201
Davidson	7.00%	65.00	72.00	77.04	82.43	88.20
Guilford	3.00%	0.00	1.00	1.03	1.06	1.09
Randolph	4.80%	19.00	18.00	N/A	N/A	N/A
Davidson County Transfers*	7.00%	N/A	N/A	N/A	16.03	17.15
Total		84.00	91.00	78.07	99.52	106.45
# Number of Stations		24	24	24	24	24
Utilization		87.50%	94.79%	81.32%	103.67%	110.88%

*The applicants are not projecting the 14 Davidson County patients currently dialyzing in Guilford County to transfer to TVDC until project completion, December 31, 2017. However, the applicants do project growth of the 14 patients forward using the Davidson County 5-Year AACR.

On page 24, the applicants provide the total projected number of patients by county of residence, as illustrated below.

County of Residence	End of OY 1 12/31/2018	End of OY 2 12/31/2019	County Patients as a % of Total	
			OY 1	OY 2
	In-Center Patients	In-Center Patients		
Davidson	88.20	94.34	82.9%	82.9%
Guilford	1.09	1.13	1.0%	1.0%
Davidson Co. Pts Dialyzing Guilford Co.	17.15	18.35	16.1%	16.1%
Total	106.45	113.85	100.0%	100.0%
Utilization Rate with 32 Stations	83.16%	88.95%		

The applicants states that Operating Year 1 (OY1) is projected to be January 1 – December 31, 2018 [CY 2018] and Operating Year 2 (OY2) is January 1 – December 31, 2019 [CY 2019]. The applicants project to have 105 Davidson County residents dialyzing on 32 in-center dialysis stations at TVDC in OY1. The applicants then add back in the one patient from Guilford County for a projected ending census in OY1 of 106.45 in-center patients for a utilization rate of 83.16% or 3.32 patients per station per week which is based on $(106.45 \text{ patients} / 32 \text{ dialysis stations} = 3.32/4 = 83.16\%)$. The applicants project to have 112 Davidson County residents dialyzing at TVDC in OY2. The applicants then add back in the one patient from Guilford County for a projected ending census in OY2 of 113.85 in-center patients for a utilization rate of 88.95% or 3.55 patients per station per week which is based on $(113.85 \text{ patients} / 32 \text{ dialysis stations} = 3.557/4 = 88.95\%)$.

The applicants project that in-center patient utilization at the end of OY 1 will exceed 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

Home Training

In Section C-1, page 25, the applicants state TVDC does not have a home dialysis training department. The applicants do not project to serve any home hemodialysis or PD patients in OY 1 [CY2018] or OY 2 [CY 2019] (see Section C-1, page 24).

Access

In Section C-3, page 29, the applicants state:

“TVDC accepts patient’s based on medically defined admission criteria. There is not discrimination based on race, sex, national origin nor disability.”

In Section L, page 82, the applicants provide their historical payor mix which indicates that Medicare and Medicaid represented 82% of all dialysis services in calendar year 2015. Additionally, in Section L-1(b), page 75, the applicants report that it expects 82% of the in-center patients who receive treatments at TVDC in CY 2019 (OY 2) to have all or part of their services paid for by Medicare and Medicaid.

In summary, the applicants adequately demonstrate the extent to which all residents of the area service area, including underserved groups, are likely to have access to the proposed services.

Conclusion

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

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

C

The applicants propose to relocate four existing certified dialysis stations from HPKC in Guilford County, based on Policy ESRD-2. The discussion regarding Policy ESRD-2 found in Criterion (1) is incorporated herein by reference.

The January SDR reported HPKC had 153 in-center patients dialyzing on 42 dialysis stations for a utilization rate of 91.07% as of June 30, 2015. The applicants state on page 10 that four dialysis stations are proposed to transfer to TVDC. In Section D-1, pages 35-37, the applicants state:

“HPCK ... as of 12/31/2045, serves [sic] 148 ICH patients with 42 stations at a utilization rate of 94.00%. Randolph County patients and ten (10) dialysis stations are approved to transfer to the new North Randolph County Dialysis Center upon its completion, projected

to be 6/30/16 (see Project I.D. # G-10262-14). *Simultaneously, HPKC is approved to add back eight (8) dialysis stations.*” See Project I.D. # G-11075-15. The resulting utilization rate for 40 ICH stations is projected to be 87.08%.

The applicants project the following utilization for HPKC for OY 1 and OY 2 of the proposed project, as illustrated below.

	Operating Year 1 2018	Operating Year 2 2019
	In-Center	In-Center
# of Stations	36	36
In-Center Patients	133	137
# of Patients per station per week	3.69	3.80
Projected Utilization Rate	92.3%	95.1%

The Guilford County Average Annual Change Rate for the past five years, as reported in the January 2016 SDR, is 3.0%. The same SDR also reports a surplus of eight dialysis stations in Guilford County. The surplus would be reduced to four stations.

The applicants state the medically underserved population will continue to have access to services provided by HPKC as stated in Section C-3, pages 28-29. Therefore, the applicants demonstrate that the needs of the population presently served at HPKC will be adequately met following the relocation of four stations from HPKC to TVDC.

- (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, pages 38-41, the applicants state the following five alternatives were considered:

- **Maintaining the Status Quo** – The applicants concluded that this was not the best option because the patient population of Davidson County continues to grow, as is evident by the County Need Determination which indicates a projected deficit of eight stations in Davidson County, as reported in the January 2016 SDR. Additionally, the applicants anticipate that those Davidson County residents that had previously dialyzed in Guilford County are likely to transfer their care to TVDC once Randolph County patients transfer their care to the new NRDC facility. The utilization for TVDC by 12/31/16 is projected to be 81.32%. With the county growth and the potential for transfer patients, without the addition of new stations, TVDC would be forced to consider a third shift.

- Add Four Stations Based on Facility Need Methodology – The applicants concluded that with the growth in Davidson County and the projected eight station deficit identified in the January 2016 SDR that adding only four stations was not an effective alternative.
- In-County Transfer of Stations – The applicants concluded that transferring stations from Lexington Dialysis Center (LXDC) is not the most effective alternative. As of June 30, 2015, LXDC had a utilization rate of 92.50%. A reduction of stations at the facility would immediately increase the utilization rate for the facility.
- Relocate stations pursuant to Policy ESRD-2 – The applicants reviewed both counties, Forsyth and Guilford, in which the applicants operate dialysis facilities and those that the January 2016 SDR shows a surplus of stations. The applicants concluded that based on the patient population being served by these facilities, the logical county to transfer stations from was Guilford County.
- Develop the Facility as Proposed – The applicants concluded that the development of the project, as proposed, to relocate four existing stations based on Policy ESRD-2 and to add four stations based on the facility need determination was the best alternative to meet the growing need for dialysis services in Davidson County.

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 applicants adequately demonstrate 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. Wake Forest University Health Sciences and Thomasville Dialysis Center of Wake Forest University shall materially comply with all representations made in the certificate of need application.**
- 2. Wake Forest University Health Sciences and Thomasville Dialysis Center of Wake Forest University shall add no more than four additional dialysis stations and relocate no more than four dialysis stations from High Point Kidney Center to Thomasville Dialysis Center of Wake Forest for a total of no more than 32 dialysis stations, which shall include any home hemodialysis training or isolation stations, upon project completion.**
- 3. Wake Forest University Health Sciences and Thomasville Dialysis Center of Wake Forest University shall install plumbing and electrical wiring through the walls for no more than 32 stations, which shall include any home hemodialysis training or isolation stations, upon projection completion.**

4. **After certification of the four stations relocated to Thomasville Dialysis Center of Wake Forest University, Wake Forest University Health Sciences shall take the necessary steps to decertify four stations at High Point Kidney Center for a total of no more than 36 dialysis stations at High Point Kidney Center following completion of Project I.D. # G-10262-14 (relocate 10 stations to North Randolph Dialysis Center to develop a new facility), Project I.D. # G-11075-15 (add eight stations to High Point Kidney Center for a total of 40 stations upon project completion) and this project.**
 5. **Wake Forest University Health Sciences and Thomasville Dialysis Center of Wake Forest University shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicants propose to relocate four existing certified dialysis stations pursuant to Policy ESRD-2 from HPKC in Guilford County and add four dialysis stations, based on the facility need methodology, for a total of 32 stations at TVDC upon project completion.

Capital and Working Capital Costs

In the table in Section F-1, page 45, the applicants provide the capital cost of the proposed project as summarized in the table below:

TVDC Proposed Project Capital Costs	
Construction Contract	\$675,000
Dialysis Machines	\$60,000
Equipment/Furniture	\$74,000
Architect Fees	\$53,000
Total Capital Cost	\$862,000

In Section F, pages 48-49, the applicants state that there are no working capital needs for the proposed project as TVDC is an existing facility.

Availability of Funds

In Section F, page 46, the applicants state that cash reserves/owner's equity is being used to finance the proposed project.

Exhibit F-5 contains a March 15, 2016 letter from the Executive Vice President and Chief Financial Officer of Wake Forest Baptist Medical Center, which states:

“The project has been budgeted to cost approximately \$862,000. Thomasville Dialysis Center is a non-profit subordinate of Wake Forest University Health Sciences. Wake Forest University Health Sciences commits to provide monies to its subordinates in order to fund these costs.”

Exhibit F-7 contains a copy of the most recent audited financial statements for Wake Forest University for the years ended June 30, 2015 and June 30, 2014. As of June 30, 2015, Wake Forest University had \$159,960,000 in cash and cash equivalents, \$1,333,751,000 in total assets and \$458,273,000 in net equity (total assets less total liabilities). The applicants adequately demonstrate the availability of funds for the capital needs of the project.

Financial Feasibility

The applicants project revenues and expenses and provides assumptions in Section R, Form B, pages 1-2, as summarized below in the table:

Thomasville Dialysis Center Revenue and Expenses - Total Facility		
	OPERATING YEAR 1 CY 2017	OPERATING YEAR 2 CY 2018
Gross Patient Revenue	\$30,539,397	\$32,614,890
Deductions from Gross Patient Revenue	\$26,309,997	\$28,098,056
Net Patient Revenue	\$ 4,229,400	\$ 4,516,834
Operating Expenses	\$ 3,596,989	\$ 3,770,569
Net Profit	\$ 632,411	\$ 746,265

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

In Section H, page 54, the applicants provide projected staffing and salaries. Form A in Section R, page 1, shows budgeted operating costs adequate to cover the projected staffing. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

Conclusion

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

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

C

The applicants propose to relocate four existing certified dialysis stations pursuant to Policy ESRD-2 from HPKC in Guilford County and add four dialysis stations, based on the facility need methodology, for a total of 32 stations at TVDC upon project completion.

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

Table A in the January 2016 SDR indicates there are two existing dialysis facilities in Davidson County, as illustrated in the table below:

DIALYSIS FACILITY	CERTIFIED STATIONS 6/30/15	% UTILIZATION	PATIENTS PER STATION
Lexington Dialysis	30	92.50%	3.7
Thomasville Dialysis	24	90.63%	3.6

Source: January 2016 SDR, Table A

As illustrated above, both facilities which are owned by WFUHS, operated above 80% utilization (3.2 patients per station per week).

In Section C-1, page 24, the applicants provide the total projected patients by county of residence for the proposed project, as shown below:

TVDC				
County	Operating Year 1 CY 2018	Operating Year 2 CY 2019	County In-Center Patients as % of Total	
	In-Center	In-Center	Year 1	Year 2
Davidson	88.20	94.38	82.85%	82.89%
Guilford	1.09	1.13	1.02%	1.00%
Davidson Co. Pts Dialyzing in Guilford Co.	17.15	18.35	16.11%	16.09%
Total	106.45	113.85	100.00%	100.00%

As shown above, at the end of OY1 [CY 2018], the applicants are projecting an in-center patient census of 106.45 in-center patients for a utilization rate of 83.16% or 3.32 patients per

station per week which is based on $(106.45 \text{ patients} / 32 \text{ dialysis stations} = 3.32/4 = 83.16\%)$. At the end of OY2 [CY 2019], the applicants are projecting an in-center patient census of 113.85 in-center patients for a utilization rate of 88.95% or 3.55 patients per station per week which is based on $(113.85 \text{ patients} / 32 \text{ dialysis stations} = 3.557/4 = 88.95\%)$. The projected utilization of 3.32 patients per station per week for OY1 exceeds the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b).

The applicants adequately demonstrate the need to add four new stations and to relocate four existing stations to TVDC based on the number of in-center patients TVDC proposes to serve.

The applicants adequately demonstrate that the proposal will not result in the unnecessary duplication of existing or approved dialysis stations or facilities in Davidson County. Therefore, 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 54, the applicants provide the following table to illustrate current and projected staffing in full time equivalents (FTEs) for TVDC. The applicants state the Medical Director is not employed by the facility, and thus is not reflected on the staffing chart.

POSITION	CURRENT # FTES	# FTES TO BE ADDED	PROJECT ED # FTES
Registered Nurse	5.00	2.00	7.00
LPN	1.75	0.00	1.75
Technician (Patient Care)	9.50	1.50	11.00
Clinical Nurse Manger	1.00	0.00	1.00
Dietician	1.00	0.00	1.00
Social Worker	1.00	0.00	1.00
Dialysis Technician	2.00	0.00	2.00
Biomed	1.00	0.00	1.00
Clerical	1.00	0.00	1.00
Total	23.25	3.50	26.75

As illustrated above, the applicants propose the addition of 3.50 new FTE positions for TVDC.

In Section H-7, page 60, the applicants provide the projected direct care staff for TVDC in Operating Year 2, as shown below in the table:

DIRECT CARE POSITIONS	# FTEs	HOURS PER YEAR PER FTE	TOTAL ANNUAL FTE HOURS	TOTAL ANNUAL HOURS OF OPERATION	# FTE HOURS PER HOUR OF OPERATION
DON	1.00	2,080	2,080	3,198	0.65
Registered Nurse	7.00	2,080	14,560	3,198	4.55
LPN	1.75	2,080	3,640	3,198	1.14
Patient Care Tech	11.00	2,080	22,880	3,198	7.15
Total	20.75	2,080	43,160	3,198	13.50

In Section I-3(a), page 64, the applicants identify Dr. Barry Freedman as the Medical Director of the facility. In Exhibit I-3, the applicants provide a copy of a February letter signed by Dr. Freedman of Wake Forest Baptist Health, supporting the project and confirming his commitment to serve as Medical Director. In Section H-3, page 59, the applicants state the means by which vacant staff positions are filled, as follows:

- Online advertising with “Indeed” and “Job Finders”
- Print ad
- Recruitment through local colleges
- Employee referrals
- Through existing training agreements

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

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

C

In Section I-1, page 62, the applicants list the providers of the necessary ancillary and support services to be provided at the existing facility. The applicants discuss coordination with the existing health care system on pages 63-66. Exhibits I-1 to I-3 contain documents from Meridian Laboratory Corporation, Transportation, North Carolina Baptist Hospital, Lexington Dialysis Center, Piedmont Dialysis Center and Dr. Freedman (Medical Director), respectively, as evidence of the necessary ancillary and support services. The applicants adequately demonstrate that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. The information in Section I and corresponding exhibits is reasonable and supports a finding of conformity to this criterion.

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

NA

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

NA

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

C

In Section K-2, page 70, the applicants propose to add 2,296 square feet of new construction to the existing 9,222 square foot facility to accommodate the proposed new and relocated stations for a total of 11,518 square feet upon project completion. The applicants provide the facility's line drawing in Exhibit K-1. In Section F-1, page 45, the applicants have projected costs, including \$675,000 for construction costs. In Section K-1(c), page 68, the applicants describe the methods that will be used by the facility to maintain efficient energy operations and contain the cost of utilities. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicants adequately demonstrate that the cost, design, and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. 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 L-1, pages 74-75, the applicants state, *“TVDC accepts patients based on medically defined admission criteria. There is no discrimination based on race, sex, national origin nor disability. Services are available to all area residents. Further, the facility also accepts the need and the homeless ... WFUHS and TVDC are committed to admitting and providing 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 rate for such services.”*

In addition, on pages 76-79, the applicants discuss their financial policies to help the above named classification of persons. In Section L-7, page 82, the applicants state that Medicare/Medicaid represented 82% of all dialysis services provided at TVDC in calendar year 2015. The following table illustrates the historical payor sources for TVDC:

TVDC Historical Payor Mix

PAYOR TYPE	TOTAL PERCENT PATIENTS
Private Pay	1.0%
Medicare	16.0%
Medicaid	5.0%
Medicare/Medicaid	19.0%
Commercial	7.0%
Medicare/Commercial	17.0%
VA	25.0%
Medicare Advantage	25.0%
Total	100.0%

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

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance*
Davidson	17%	51%	19%	17%	12%	18%
Guilford	14%	53%	48%	17%	7%	18%
Statewide	15%	51%	36%	17%	10%	15%

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

*These statistics are not comparable to other geographic levels of these estimates.

**"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates.

Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable."

"The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

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

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

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

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

The applicants demonstrate that they 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 79, the applicants state:

“The facility has no obligation to provide uncompensated care of community service. The facility will be accessible to minorities and handicapped persons...”

In Section L-6, page 81, the applicants state, *“There have been no civil rights or equal access filed against the existing facility and/or any facilities owned by the parent company in North Carolina in the last five years.”*

The application is conforming to this criterion.

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

C

In Section C-3, page 29, the applicants state:

“There is no discrimination based on race, sex, national origin nor disability. Services are available to all area residents. Further, the facility also accepts the need and the homeless ... WFUHS and TVDC are committed to admitting and providing 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 rate for such services.”

In Section L-3(c), pages 77-79, the applicants describe the facility's definition of medically indigent and the means by which patients are eligible for financial assistance.

In Section L-1(b), page 75, the applicants report that it expects 82% of the in-center patients who receive treatments at TVDC to have all or part of their services paid for by Medicare and Medicaid, as indicated below in the table.

**TVDC Projected Payor Mix
Operating Year 2 CY2019**

PAYOR TYPE	TOTAL PERCENT PATIENTS
Private Pay	1.0%
Medicare	20.0%
Medicaid	4.0%
Medicare/Medicaid	24.0%
Commercial	6.0%
Medicare/Commercial	23.0%
VA	7.0%
Medicare Advantage	15.0%
Total	100.0%

On page 75, the applicants state TVDC used the historical payor mix to project the payor mix for OY 2. Additionally, the applicants state the following on page 75:

“Payor Mix can change daily based on transfers in and out, deaths, re-starts, transplants, and other factors, as patient population changes. Due to the constant fluctuation in payor mix, monthly payor mix snapshots are calculated based upon patient census by payor as of the last day of each month of operation. ... WFUHS maintains a running monthly record of payor trends.”

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

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

C

In Section L-4, page 80, the applicants state:

“Patients desiring treatment at the facility receive consideration for admission by contacting the Nurse Administrator, Medical Director, or facility Social Worker. New patients may be referred by a personal physician. ... Admission to the facility must be by a nephrologist with admitting privileges ...”

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

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

C

In Section M-1, page 84, the applicants state that TVDC provides onsite educational experiences to local training programs in the area which includes third year medical and high school students.

Exhibit M-1 contains a copy of the student training agreement with Lenoir-Rhyne University, NC A&T State University and The University of NC at Greensboro. The information provided in Section M and referenced exhibit is reasonable and supports a finding of conformity to this criterion.

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

C

The applicants propose to relocate four existing certified dialysis stations pursuant to Policy ESRD-2 from HPKC in Guilford County and add four dialysis stations, based on the facility need methodology, for a total of 32 stations at TVDC upon project completion.

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

Table A in the January 2016 SDR indicates there are two existing dialysis facilities in Davidson County, as illustrated in the table below:

DIALYSIS FACILITY	CERTIFIED STATIONS 6/30/15	% UTILIZATION	PATIENTS PER STATION
Lexington Dialysis	30	92.50%	3.7
Thomasville Dialysis	24	90.63%	3.6

Source: January 2016 SDR, Table A

Both facilities are owned by WFUHS.

In Section N-1, page 85, the applicants discuss how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. The applicants state:

“This project shall have not impact on competition in Davidson County. WFUHS is the sole provider of dialysis services. An addition of stations at TVDC is necessary to serve the facility’s existing and projected patients and stave off excessive utilization. By approval of this project ... a third shift can be avoided, patients will be able to keep normal treatment schedules and experience no changes in transportation or other factors that could impact the overall cost-effectiveness, quality, and access to the proposed services.”

See also Sections B, C, E, F, G, H, and L where the applicants discuss the impact of the project on cost-effectiveness, quality and access.

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

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

See Section B-4(a), for a discussion regarding the methods used to ensure and maintain quality. The discussion is found on pages 11-16. In Section O-3, page 52, the applicants

identify the facilities that have been surveyed in the past 18 months prior to submission of the application, as stated below:

- Lake Norman Dialysis Center (LNDC) in Iredell County
- Lexington Dialysis Center (LXDC) in Davidson County
- Miller Street Dialysis Center (MSDC) in Forsyth County
- Northside Dialysis Center (NDC) in Forsyth County
- Piedmont Dialysis Center (PDC) in Forsyth County
- Salem Kidney Center (SKC) in Forsyth County
- Statesville Dialysis Center (SDC) in Iredell County
- Thomasville Dialysis Center (TVDC) in Davidson County

Of those eight facilities listed above, only LNDC and SDC had no deficiencies. In Exhibit O-2, the applicants provide a copy of the CMS Survey and the Plan of Correction that shows all the facilities were back in compliance as of August 10, 2015.

Based on a review of the information in the application and publicly available data, the applicants adequately demonstrate that they 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 proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services in 10A NCAC 14C .2200. The specific findings are discussed below.

10 NCAC 14C .2203 PERFORMANCE STANDARDS

- .2203(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance*

standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

- NA- The applicants do not propose a new facility.

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

- C- In Section C-1, page 24, where the applicants document the need for the project and demonstrates that it will serve a total of 106 in-center patients on 32 stations at the end of the first operating year (CY 2018), which is 3.31 patients per station per week, or a utilization rate of 82.8%. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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

- C- In Section C.1, pages 24-26, where the applicants provide 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.