ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

Decision Date: November 9, 2016
Findings Date: November 9, 2016

Project Analyst: Celia C. Inman
Team Leader: Fatimah Wilson

Project ID #: G-11224-16
Facility: Triad Dialysis Center
FID #: 980262
County: Guilford
Applicants: Wake Forest University Health Sciences, and
Triad Dialysis Center of Wake Forest University
Project: Add 5 dialysis stations for a total of 27 dialysis stations upon project completion

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

Wake Forest University Health Sciences (WFUHS) and Triad Dialysis Center of Wake Forest University, also referred to as "the applicants", propose to add five dialysis stations for a total of 27 dialysis stations at the existing Triad Dialysis Center (TDC) facility upon project completion. TDC is located at 4370 Regency Drive, High Point, Guilford County.

Need Determination

The 2016 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2016 Semiannual Dialysis Report (SDR), the county need

methodology shows there is a deficit of nine dialysis stations in Guilford County. Therefore, the July 2016 SDR does not indicate a need for additional stations in Guilford County based on the county need methodology, which states that the county deficit must be 10 or greater to establish a need for additional stations.

However, the applicants are eligible to apply for additional stations based on the facility need methodology because the utilization rate reported for TDC in the July 2016 SDR is 3.54 patients per station. This utilization rate was calculated based on 78 in-center dialysis patients and 22 certified dialysis stations. (78 patients / 22 stations = 3.5455 patients per station).

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

October 1 REVIEW-July 2016 SDR

Required SDR Utilization		80.00%
Center Utilization Rate as of 12/31/15		88.64%
Certified Stations		22
Pending Stations		0
Total Existing and Pending Stations		**22**
In-Center Patients as of 12/31/15 (SDR2)		78
In-Center Patients as of 6/30/15 (SDR1)		74
Step	Description	
(i)	Difference (SDR2 - SDR1)	4
	Multiply the difference by 2 for the projected net in-center change	8
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/15	0.108108
(ii)	Divide the result of Step (i) by 12	0.009009
(iii)	Multiply the result of Step (ii) by 12	0.108108
(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	86.4324
(v)	Divide the result of Step (iv) by 3.2 patients per station	27.01014
	and subtract the number of certified and pending stations as recorded in SDR2 [# of stations] to determine the number of stations needed	**5.01014**

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is five stations. Step (C) of the facility need methodology states *"The facility may apply to expand to meet the need established ..., up to a maximum of ten stations."* The applicants propose to add five stations. Therefore, the facility need determination for dialysis stations is applicable to this review.

In summary, the applicants are consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2016 SMFP that is applicable to this review, Policy GEN-3: Basic Principles. Policy GEN-3: Basic Principles, page 39 of the 2016 SMFP, 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 they believe the proposed project would promote safety and quality in Section B.4(a), pages 11-16, referencing other application sections with specific details; Section K.1(g), pages 60-61; Section N.1, page 77; 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 they believe the proposed project would promote equitable access in Section B.4(b), pages 16-21, referencing other application sections with specific details; Section N.1, page 77; 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 they believe the proposed project would maximize healthcare value in Section B.4(c), page 21, and referenced exhibits. The information provided by the applicants is reasonable and adequately supports the determination that the applicants' proposal would maximize healthcare value.

The applicants adequately demonstrate how their 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 methodology in the July 2016 SDR and Policy GEN-3 and therefore 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 applicants propose to add five dialysis stations for a total of 27 dialysis stations at the existing TDC facility upon project completion. TDC is located at 4370 Regency Drive, High Point, in Guilford County. The following table, summarized from page 4 of the application, shows TDC has no existing CON projects under development at the facility which impact the number of dialysis stations at TDC.

Stations	Description	Project ID #
22	Total existing certified stations as of the July 2016 SDR	
+5	Stations to be added at TDC as part of this project	G-11224-16
0	Stations previously approved to be relocated from TDC	
0	Stations previously approved to be added at TDC, but not yet certified	
27	Total stations upon completion of above projects	

Patient Origin

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

In Section C.8, page 29, the applicants provide a table showing the historical patient origin for in-center (IC) patients served by TDC.

Historical Patient Origin
TDC
As of June 30, 2016

County	IC	HH	PD
Davidson	1	0	0
Forsyth	6	0	0
Guilford	74	0	0
Rockingham	2	0	0
Total	83	0	0

In Section C.1, page 23, the applicants identify the patient population proposed to be served for the first two years of operation following project completion on June 30, 2017, as summarized in the table below.

Projected TDC Patient Origin
By County of Residence

	Operating Year 1 (OY1) 7/1/17-6/30/18			Operating Year 2 (OY2) 7/1/18-6/30/19			County Patients as % of Total	
County	IC	HH	PD	IC	HH	PD	OY 1	OY2
Davidson	1.14	0.00	0.00	1.21	0.00	0.00	1.27%	1.31%
Forsyth	6.23	0.00	0.00	6.35	0.00	0.00	6.97%	6.84%
Guilford	80.04	0.00	0.00	83.24	0.00	0.00	89.48%	89.64%
Rockingham	2.04	0.00	0.00	2.06	0.00	0.00	2.28%	2.22%
Total	89.45	0.00	0.00	92.86	0.00	0.00	100.00%	100.00%

Totals may not sum due to rounding

The applicants provide the methodology and assumptions for the above projected patient origin on pages 23-24 of the application.

The applicants adequately identify the population to be served.

Analysis of Need

The applicants propose to add five dialysis stations to the existing TDC facility in Guilford County for a total of 27 certified dialysis stations upon project completion. In Section C.1, page 23, the applicants state the need for the proposed project is to:

"... pre-emptively curtail the need for a third shift at TDC."

Projected Utilization

In Section C.2, pages 25-26, the applicants provide the calculations used to arrive at the projected in-center patient census for the first two years of operation following the

completion of the project. The following table illustrates the applicants' projection of in-center dialysis patients at TDC.

TDC Projected In-Center Dialysis Utilization

County	SDR AACR	Beginning Census 6/30/16	Growth until 6/30/2017	End of OY1 6/30/2018	End of OY2 6/30/19
Davidson	6.70%	1.00	1.07	1.14	1.21
Forsyth	1.90%	6.00	6.11	6.23	6.35
Guilford	4.00%	74.00	76.96	80.04	83.24
Rockingham	1.00%	2.00	2.02	2.04	2.06
Total Patients		**83.00**	**86.16**	**89.45**	**92.86**
Patients per Station				3.31	3.43
Utilization Rate				**82.82%**	**85.99% [85.98%]**

Totals may not sum due to rounding

As shown above and on page 26 of the application, at the end of OY1, June 30, 2018, the applicants project serving 89.45 in-center dialysis patients on 27 dialysis stations for a utilization rate of 82.82% (89.45 patients / 27 stations = 3.31 patients per station / 4 = 0.8282). At the end of OY2, the applicants are projecting an in-center patient census of 92.86 for a utilization rate of 85.98% (92.86 / 27 = 3.439 / 4 = .85981). The projected utilization of 3.31 patients per station per week for OY1 satisfies the 3.2 in-center patients per station per week threshold as required by 10A NCAC 14C .2203(b).

In Section C.7, pages 28-29, the applicants summarize the methodology and assumptions used to project utilization at TDC. The project is based upon the facility need methodology. TDC is eligible to add as many as five stations.

The applicants' methodology is summarized below:

- Group the June 30, 2016 patient census by county of origin and modality.
- Apply the July 2016 SDR 5-year Average Annual Change Rate (AACR), by county of patient origin, to the current patient populations to project patient census through the end of Operating Year 2.
- Project utilization based upon service to existing and projected patients at TDC.

The applicants' assumptions are summarized below:

- The 5-year AACR rates, as published in the July 2016, will remain an accurate indicator of patient growth by county through OY2.
- As of December 31, 2017, the existing 22 ICH stations are inadequate to serve the current and projected patient population at TDC.
- Projected completion of the project under review is June 30, 2017; OY1 ends June 30, 2018; OY2 ends June 30, 2019.
- Facility need methodology indicates a need for five additional stations.
- Patient support letters are provided in Exhibit C-7.

The applicants adequately demonstrate that projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Access

In Section C.3, page 27, the applicants state:

> *"TDC 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 with ESRD. Further, the facility also accepts the needy and the homeless, through its referral system, and assists those patients in obtaining the medical care they need."*

Exhibit L-3(a) contains the facility's Referral/Admissions Policy. The applicants project payor mix in Section L.1(b), page 66 as follows:

Projected Payor Mix
Project Year 2 (7/1/18 – 6/30/19)

	Percent of Total Patients	Percent of In-center Patients	Percent of HH Patients	Percent of PD Patients
Private Pay	1%	1%	0%	0%
Medicare	14%	14%	0%	0%
Medicaid	6%	6%	0%	0%
Medicare / Medicaid	25%	25%	0%	0%
Commercial Insurance	7%	7%	0%	0%
Medicare / Commercial	29%	29%	0%	0%
VA	3%	3%	0%	0%
Medicare Advantage	15%	15%	0%	0%
TOTAL	**100%**	**100%**	**NA**	**NA**

Totals may not sum due to rounding.

In Section L.7, page 73, the applicants state that the projected payor mix is:

"... based upon historical data collection and has been found extremely accurate when tested against actual revenue for past years with a less than 0.4% differentiation."

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

Conclusion

In summary, the applicants adequately identify the population to be served; adequately demonstrate the need the population to be served has for the proposed services, based on reasonable and supported utilization projections and assumptions; and demonstrate the extent to which all residents of the area, including underserved groups, are likely to have access to the services. Therefore, the application is conforming to this criterion.

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

NA

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

CA

In Section E.1, pages 33-35, the applicants discuss the alternatives considered prior to submitting this application, which include:

1) Maintain the Status Quo – the applicants state that TDC is currently certified for 22 stations with 83 patients at 94.32% utilization. The applicants further state that the existing and projected in-center patient population at TDC will soon fail to be adequately served by 22 dialysis stations without requiring a third shift. The applicants state that the utilization rate is projected to be 101.64% by June 30, 2018, leaving no margin in patient shift scheduling to accommodate additional needs, which may arise. The applicants further state that maintaining the status quo is not a viable option.

2) Submit an application for an in-county relocation of stations – the applicants state that relocating stations from High Point Kidney Center (HPKC), a WFUHS-owned facility in Guilford County, was considered. As of June 30,

2016, the facility's utilization rate was 91.07%. HPKC has a number of related CON projects under development, and is itself, in need of additional stations to support the remaining patient population at its facility once all of the currently CON-approved projects are complete and certified. Therefore, the applicants state, an in-county relocation of stations is not a viable option.

3) Submit an application for a contiguous county relocation of stations– Policy ESRD-2 allows for relocation of dialysis stations within the host county and to contiguous counties currently served by the facility when a station deficit is not created in the county losing stations and a station surplus is not created in the county gaining stations. Guilford County has a 9-station deficit. WFUHS owns operational dialysis facilities in Davidson and Forsyth counties, both of which are contiguous to Guilford County. Davidson County has a 2-station surplus; therefore the applicants could relocate two stations from its Davidson facility; however, TDC needs five additional stations. Forsyth County has a 7-station surplus; however, Policy ESRD-2 requires the host facility serve patients from the county receiving the stations and WFUHS cannot meet that requirement. Therefore, the applicants state that this option is not viable.

4) Submit an application for additional stations based on the facility need methodology – the applicants state that the facility need methodology demonstrates that up to five additional stations are needed at TDC. The project cost is estimated at $0, since WFUHS already has the needed stations in its inventory and the facility already has the necessary space and available plumbing. Thus, the applicants state that utilizing the facility need methodology is the best option to serve TDC's existing and projected patient population.

After considering the above alternatives, the applicants state that adding stations based on the facility need methodology is the most cost-effective alternative for this project.

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 Triad 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 Triad Dialysis Center of Wake Forest University shall develop and operate no more than five (5) additional dialysis stations for a total of 27 certified stations upon project completion, which shall include any home hemodialysis training or isolation stations.**

3. **Wake Forest University Health Sciences and Triad 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 add five dialysis stations to the existing TDC facility for a total of 27 certified dialysis stations upon project completion.

Capital Costs

In Section F.1, page 36, the applicants project zero capital costs associated with the proposed project. In Section E.2, page 35, the applicants state:

> *"The project cost is estimated at $0, since WFUHS already has the needed stations in its inventory due to bonus machines it received during machine trade-in purchases. Further, when TDC hosted 18 stations from HPKC during the HPKC renovation all plumbing for additional stations was put in place. When those stations went back to HPKC, a panel was placed over the plumbing to conceal it in the wall. Therefore, no additional plumbing expense is required to develop this project, short of removing five panels to reveal the station hookups."*

TDC is an existing dialysis facility with an ongoing operation; therefore the applicants do not project any working capital needs.

Availability of Funds

In Section F.5, page 37, the applicants refer to Exhibit F-5 for a commitment letter of WFUHS funds and Exhibit F-7(a) for a copy of the most recent Wake Forest University consolidated balance sheet, which includes WFUHS. The Corporate Vice President's commitment letter states, *"Wake Forest University Health Sciences commits to provide monies to its subordinates in order to fund project costs."* Per the consolidated balance sheet, as of June 30, 2014, WFUHS had $159,960 cash and cash equivalents, $1,333,751 in total assets and $458,273 in unrestricted net assets (total assets less total liabilities less restricted net assets). The applicants adequately demonstrate the availability of funds for the operating needs of the project.

Financial Feasibility

In Section R, Form C, the applicants provide the allowable charge per treatment for each payment source for in-center dialysis patients. The revenue assumptions are provided in Section R, pages 91-93.

The applicants provide the following assumptions for patient treatments:

- Average annual patients per month calculations (OY1 = 88, OY2 = 91) – pages 91-92
- In-center treatments = patients x 3 treatments per week x 52 weeks (156 treatments per patient), reduced by 6% for missed treatments (147 treatments per patient) – pages 91-92

The applicants project revenues and summarize operating expenses in Section R, Form B, as presented in the table below.

Triad Dialysis Center	Operating Year 1 7/1/17-6/30/18	Operating Year 2 7/1/18-6/30/19
Total Gross Revenue	$ 26,273,016	$ 27,168,687
Deductions from Gross, including Contractual Allowances, Charity Care and Bad Debt	22,833,713	23,582,573
Net Revenue	3,439,303	3,586,114
Total Operating Expenses	3,179,594	3,268,350
Net Profit	**$ 259,709**	**$ 317,764**

Totals may not sum due to rounding

As shown in the table above, the applicants project a positive net income in each of the first two operating years of the project. The assumptions used by the applicants in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section R of the application for the assumptions regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicants adequately demonstrate that sufficient funds will be available for the operating needs of the project. Furthermore, the applicants adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

C

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

The applicants propose to add five dialysis stations to the existing TDC facility in Guilford County. The July 2016 SDR indicates there are eight dialysis facilities in Guilford County, as shown below. Two facilities are WFUHS facilities.

Guilford County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/15	Percent Utilization	Patients Per Station
BMA of Greensboro (BMA)	56	77.68%	3.1071
BMA of South Greensboro (BMA)	59	75.00%	3.0000
BMA of Southwest Greensboro (BMA)	31	89.52%	3.5806
FMC of East Greensboro (BMA)	35	90.00%	3.6000
Fresenius Medical Care High Point (BMA) (10 stations pending)	0	0.00%	0.0000
High Point Kidney Center (WFUHS)	42	94.05%	3.7619
Northwest Greensboro Kidney Center (BMA)	33	74.24%	2.9697
Triad Dialysis Center (WFUHS)	22	88.64%	3.5455

Source: July 2016 SDR, Table A.

As illustrated above, each Guilford County facility is utilized above 70% as of December 31, 2015, with the exception of Fresenius Medical Care High Point (Project ID #G-

11055-15), which is under development. Per the applicants, both WFUHS facilities are operating above the 3.2 patients per station per week or 80% utilization threshold as of June 30, 2016. In Section G, page 43, the applicants' table shows that the June 30, 2016 utilization is 91.07% for HPKC and 94.32% for TDC. On page 44, the applicants further state:

> *"TDC's need is real and immediate. TDC does not project to serve patients currently served at other locations within Guilford County at WFUHS or competitor locations. TDC projects to serve its current patient population plus growth based upon the 5-year AACR projected for its current patient base by county of origin as outlined in the most recent (July 2016) SDR."*

The applicants adequately demonstrate the need for additional stations at TDC based on the number of in-center patients it proposes to serve. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference. The discussion on competition found in Criterion (18a) is incorporated herein by reference.

The applicants adequately demonstrate that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Guilford County. Consequently, the application is conforming to this criterion.

(7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

The following table illustrates the projected salaried staffing for TDC, as provided by the applicants in Section H.1, page 45.

	Current FTE Positions	FTE Positions to be added	Total FTE Positions	Current Annual Salary / FTE	Projected Salary Yr 2 /FTE
RN	5.51	0.00	5.51	$58,926	$64,390
LPN	0.25	0.00	0.25	$39,520	$43,185
Pt Care Technician	10.88	0.00	10.88	$30,077	$32,865
Clinical Nurse Manager	1.00	0.00	1.00	$72,384	$79,097
Dietician	1.00	0.00	1.00	$62,026	$67,778
Social Worker	1.00	0.00	1.00	$55,286	$60,413
Home Training Nurse	0.00	0.00	0.00	$58,926	$64,390
Dialysis Tech	2.00	0.00	2.00	$29,640	$32,388
Biomed	0.50	0.00	0.50	$39,686	$43,366
Clerical	1.00	0.00	1.00	$33,384	$36,481
Total FTE Positions	**23.14**		**23.14**		

The Medical Director, Administration and Medical Records positions are contract positions and are not salaried employees.

The following table reflects the applicants' projected number of direct care staff FTE positions at TDC for Operating Year 2, per page 51 of the application.

Projected Direct Care Staff Hours – Operating Year 2

Direct Care Positions	# FTEs* [a]	Hours / Year / FTE [b]	Total Annual FTE Hours [c] = [a] x [b]	Total Treatment Hours ** [d]	FTE Hours / Total Treatment Hours [e] = [c] ÷ [d]
DON (Clinical Nurse Mgr)	1.00	2,080	2,080	3,198	0.65
RN	5.51	2,080	11,461	3,198	3.84 [3.58]
LPN	0.25	2,080	520	3,198	1.17 [0.16]
Patient Care Tech	10.88	2,080	22,630	3,198	11.19 [7.08]
HT Nurse	0.00	2,080	0	3,198	1.95 [0.00]
Total Direct Care Hours	17.64	2,080	36,691	3,198	11.47

* FTEs should match the direct care Total FTE Positions [a+c] listed in the Facility Staffing table in Section H, Question 1.
** Total annual treatment hours from the Proposed Hours of Operation table in Section H, Question 6.
[The Project Analyst presents the corrected column calculations in brackets in the table above]

In Sections H.2 and H.3, pages 46-50, the applicants describe TDC's staff positions and responsibilities, management's experience, the process for recruiting and retaining staff, and staff training and continuing education. In Section I.3, page 55, the applicants state that James Pirkle, M.D. will serve as the Medical Director for the facility. In Exhibit I-

3(a), the applicants provide a letter signed by Dr. Pirkle confirming his commitment to continue to serve as Medical Director. Exhibit H-2 includes a copy of Dr. Pirkle's curriculum vitae. In Section I.3(b), page 56, the applicants state that medical coverage is provided seven days per week and 24 hours a day by WFUHS physicians on a rotation basis or by local area nephrologists with privileges at the facility. Exhibit I-3(b) contains a list of referral physicians and physician letters of support.

The applicants adequately demonstrate 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, beginning on page 53, the applicants describe the necessary ancillary and support services and indicate how they will be provided. Exhibit I.2(a) contains a copy of the affiliation agreement between the facility and North Carolina Baptist Hospital. Exhibit I.2(b) contains a copy of the transplant agreement. The applicants discuss coordination with the existing health care system on pages 53-57. Exhibit I.3(b) contains a list of referring physicians and physician support letters. 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 referenced Exhibits is reasonable and supports a finding of conformity with this criterion.

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

NA

(10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

(i) would be available under a contract of at least 5 years duration;

(ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
(iii) would cost no more than if the services were provided by the HMO; and
(iv) would be available in a manner which is administratively feasible to the HMO.

NA

(11) Repealed effective July 1, 1987.

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

NA

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L.1, page 65, the applicants state:

> *"TDC 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 with ESRD. Further, the facility also accepts the needy and the homeless, through its referral system, and assists those patients in obtaining the medical care they need.*"

In Section L.3(b), page 68, the applicants further state that the admission of a patient is based upon medical necessity and not the patient's ability to pay. Exhibit L-3(a) contains a copy of HPKC's Referral/Admissions Policy.

In Section L.7, page 73, the applicants report that during the last full operating year, 89% of the patients who were receiving treatments at TDC had some or all of their services paid for by Medicare or Medicaid in the past year. The following table illustrates the facility's historical payment sources.

HISTORICAL PAYOR MIX
7/1/15-6/30/16

	Percent of Total Patients	Percent of In-center Patients	Percent of HH Patients	Percent of PD Patients
Private Pay	1%	1%	0%	0%
Medicare	18%	18%	0%	0%
Medicaid	5%	5%	0%	0%
Medicare / Medicaid	20%	20%	0%	0%
Commercial Insurance	8%	8%	0%	0%
Medicare / Commercial	25%	25%	0%	0%
VA	2%	2%	0%	0%
Medicare Advantage	21%	21%	0%	0%
TOTAL	**100%**	**100%**	**NA**	**NA**

Totals may not sum due to rounding.

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****
2014 Estimate	**2014 Estimate**	**2014 Estimate**	**2014 Estimate**	**2010-2014**	**2010-2014**	**2014 Estimate**
Guilford	14%	53%	48%	17%	7%	18%
Statewide	15%	51%	36%	17%	10%	15%

http://www.census.gov/quickfacts/table Latest Data as of 12/22/15
*Excludes *"White alone"* who are *"not Hispanic or Latino"*
***"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates*
Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable…The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

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, women or handicapped persons utilizing health services.

The *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*[1] 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%

The applicants demonstrate that TDC currently provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

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

[1] http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf

C

In Section L.3(d) page 71, the applicants state:

> *"The facility has no obligation to provide uncompensated care or community service. The facility will be accessible to minorities and handicapped persons as further described in* ***Section B, Section C,*** *and* ***Section L*** *[emphasis in original], and strives to provide services to all patients with End Stage Renal Disease."*

In Section L.6, page 72, the applicants state, *"There have been no civil rights or equal access complaints 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 applicants' proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L.1(b), page 66, the applicants provide the projected payor mix for the proposed services at TDC, combined and by patient category, as shown below.

Projected Payor Mix
Project Year 2 (7/1/18 – 6/30/19)

	Percent of Total Patients	Percent of In-center Patients	Percent of HH Patients	Percent of PD Patients
Private Pay	1%	1%	0%	0%
Medicare	14%	14%	0%	0%
Medicaid	6%	6%	0%	0%
Medicare / Medicaid	25%	25%	0%	0%
Commercial Insurance	7%	7%	0%	0%
Medicare / Commercial	29%	29%	0%	0%
VA	3%	3%	0%	0%
Medicare Advantage	15%	15%	0%	0%
TOTAL	**100%**	**100%**	**NA**	**NA**

Totals may not sum due to rounding.

In Section L.1(a), page 66, the applicants state:

"WFUHS and TDC 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."

On page 66, the applicants report that HPKC expects 89% of the in-center patients who receive treatments at TDC to have all or part of their services paid for by Medicare or Medicaid, as indicated above.

The applicants adequately 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 71, 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 to the facility and the patient must be certified as suffering from chronic, irreversible, End Stage Renal Disease (ESRD)."

The applicants adequately demonstrate that TDC 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, page 76, the applicants state:

"WFUHS dialysis units make every attempt to provide onsite educational experiences to local training programs in the area. ... Therefore, all WFUHS dialysis facilities will provide these experiences to not only health professional training programs in the area, but other applicable training programs as well.

...

The dialysis facilities of WFUHS pursue and participate in encouraging applicable training programs to utilize their facilities."

Exhibit M-1 contains a copies of professional training facility agreements between the Triad Dialysis Center and Forsyth Community Technical College, High Point University, and North Carolina Agricultural and Technical State University/The University of North Carolina at Greensboro. The information provided in Section M and the referenced exhibit is reasonable and supports a finding of conformity with 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

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

The applicants propose to add five dialysis stations to the existing TDC facility in Guilford County. The July 2016 SDR indicates there are eight dialysis facilities in Guilford County, as shown below. Two facilities are WFUHS facilities.

Guilford County Dialysis Facilities

Dialysis Facility	Certified Stations 12/31/15	Percent Utilization	Patients Per Station
BMA of Greensboro (BMA)	56	77.68%	3.1071
BMA of South Greensboro (BMA)	59	75.00%	3.0000
BMA of Southwest Greensboro (BMA)	31	89.52%	3.5806
FMC of East Greensboro (BMA)	35	90.00%	3.6000
Fresenius Medical Care High Point (BMA) (10 stations pending)	0	0.00%	0.0000
Fresenius Medical Care High Point (BMA)	0	0.00%	0.0000
High Point Kidney Center (WFUHS)	42	94.05%	3.7619
Northwest Greensboro Kidney Center (BMA)	33	74.24%	2.9697
Triad Dialysis Center (WFUHS)	22	88.64%	3.5455

Source: July 2016 SDR, Table A.

As illustrated above, each Guilford County facility is utilized above 70% as of December 31, 2015, with the exception of Fresenius Medical Care High Point (Project ID #G-11055-15), which is under development. Per the applicants, both WFUHS facilities are operating above the 3.2 patients per station per week or 80% utilization threshold as of June 30, 2016. In Section G, page 43, the applicants' table shows that the June 30, 2016 utilization is 91.07% for HPKC and 94.32% for TDC.

In Section N.1, page 77, 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 no impact on competition in Guilford County. Patients utilize a facility based upon physician preference, geographical location, or other reasons of convenience. An addition of stations at TDC is necessary to serve the facility's existing and projected patients and stave off excessive utilization. ... However, if TDC's project is not approved and its facility utilization rate is allowed to rise above 100%, cost-effectiveness and access to services could be negatively impacted as patients will have to be scheduled for treatment at times that could reduce their access to transportation availability, which would increase the occurrence of missed treatments and have a detrimental effect on patient outcomes."*

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

The information provided by the applicants in the sections referred to 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 TDC will continue to provide quality services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.

- The applicants demonstrate TDC will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section A.11, pages 5-6, the applicants identify the 17 kidney disease treatment centers located in North Carolina, which are owned and operated by the applicants or an affiliated company.

In Section O, pages 79-81, the applicants refer to Section B.4(a) and Exhibit O-1 for TDC's methods used to insure and maintain quality. In Section O.3(a), the applicants provide a list of the 14 WFUHS dialysis facilities which were surveyed during the last 18 months. In Section O.3(b), pages 80-81, the applicants summarize the deficiencies cited as ten facilities with standard level deficiencies, two with zero substantiated complaint allegations and no deficiencies, and two which had not yet received their survey letter at the time the application was completed. Copies of the surveys, deficiencies and plans of correction were provided by the applicants in Exhibit O-3(b). In Section O.3(c), page 81, the applicants further state: *"All facilities are now in compliance."*

Based on a review of the certificate of need application and publicly available data, the applicants adequately demonstrate that quality care has been provided 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.

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The application is conforming with all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria 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- TDC is an existing facility.

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

-C- In Section C.2, page 26, the applicants propose to serve 89.45 in-center patients on 27 dialysis stations at the end of Operating Year 1, which equates to a utilization rate of 3.31 patients per station per week (89.45 / 27 = 3.31).

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

-C- In Section C.1, pages 23-24, the applicants provide the methodology and assumptions used to project patient origin of the facility. The applicants also summarize the methodology and assumptions for projected utilization on pages 28-29, in response to Question C.7. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.