

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 8, 2020

Findings Date: May 8, 2020

Project Analyst: Celia C. Inman

Co-Signer: Fatimah Wilson

Project ID #: G-11867-20

Facility: Triad Dialysis Center of Wake Forest University

FID #: 980262

County: Guilford

Applicant: Wake Forest University Health Sciences

Triad Dialysis Center of Wake Forest University

Project: Add no more than 8 dialysis stations pursuant to facility need and relocate no more than 2 dialysis stations pursuant to Policy ESRD-2 from High Point Kidney Center for a total of no more than 40 stations upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §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

Wake Forest University Health Sciences (WFUHS) and Triad Dialysis Center of Wake Forest University, collectively referred to as “the applicant”, proposes to add no more than eight dialysis stations pursuant to facility need and relocate no more than two dialysis stations pursuant to Policy ESRD-2 from High Point Kidney Center (HPKC) for a total of no more than 40 dialysis stations upon completion of this project and Project ID #G-11672-19 (relocate five stations from Triad Dialysis Center to HPKC) and Project ID #G-11797-19 (add eight stations for no more than 30 stations).

Need Determination

Chapter 9 of the 2020 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 Table 9D, page 170, the county need methodology shows there is no county need determination for additional dialysis stations in Guilford County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2020 SMFP, if the utilization rate for the dialysis center, as reported in the 2020 SMFP, is at least 75% or 3.0 patients per station per week, as stated in Condition 2.a. The utilization rate reported for Triad Dialysis Center of Wake Forest University (TDC) on page 157 of the 2020 SMFP, is 87.04% or 3.5 patients per station per week, based on 94 in-center dialysis patients and 27 certified dialysis stations [$94 / 27 = 3.48$; $3.48 / 4 = 0.8704$]. Therefore, the applicant exceeds the minimum utilization required in Condition 2.a. and is eligible to apply for additional stations based on the facility need methodology in Condition 2.b.

As shown in Table 9E, page 172 of the 2020 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed at TDC is eight additional stations; thus, the applicant is eligible to apply to add up to eight stations pursuant to the facility need methodology.

The applicant proposes to add no more than eight new stations pursuant to facility need, which is consistent with the 2020 SMFP calculated facility need determination for eight dialysis stations; therefore, the application is consistent with the facility need determination for dialysis stations.

Policies

There are two policies in the 2020 SMFP that are applicable to this review, Policy GEN-3: Basic Principles and Policy ESRD-2: Relocation of Dialysis Stations.

Policy GEN-3: Basic Principles, pages 30-31 of the 2020 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 applicant describes how it believes the proposed project would promote safety and quality in Section B.5, pages 14-19 and 23; Section N, pages 80-81, Section O, page 82; and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access – The applicant describes how it believes the proposed project would promote equitable access in Section B.5(b), pages 19-23; Section L, pages 73-76; Section N, pages 80-81, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value – The applicant describes how it believes the proposed project would maximize healthcare value in Section B.5(c), page 23; and Section N, pages 80-81. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. The application is consistent with Policy GEN-3.

Policy ESRD-2: Relocation of Dialysis Stations, on page 20 of the 2020 SMFP, states:

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicant proposing to relocate dialysis stations to a contiguous county 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 an 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 State Medical Facilities Plan, 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 State Medical Facilities Plan.”*

The applicant proposes to relocate existing dialysis stations within Guilford County, pursuant to Policy ESRD-2. Therefore, the application is consistent with Policy ESRD-2.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

- The applicant adequately demonstrates that the application is consistent with the facility need methodology as applied from the 2020 SMFP.
- The applicant adequately demonstrates how Triad Dialysis Center's projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need.
- The applicant adequately demonstrates that the application is consistent with Policy ESRD-2 because the proposal does not change the dialysis station inventory in Guilford County.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to add no more than eight dialysis stations pursuant to facility need and relocate no more than two dialysis stations pursuant to Policy ESRD-2 from HPKC for a total of no more than 40 stations upon completion of this project and Project ID #G-11672-19 (relocate five stations from TDC to HPKC) and Project ID #G-11797-19 (add eight stations for no more than 30 stations).

The following table, summarized from data on page 8 of the application and page 157 of the 2020 SMFP, shows the projected number of stations at TDC upon completion of this project and the other pending projects, as shown in the SMFP.

TDC		
Stations	Description	Project ID #
27	Total # of existing certified stations in the SMFP in effect on the day the review will begin	
+10	# of stations to be added as part of this project (add eight stations and relocate two stations from HPKC)	G-11867-20
+8	# of stations previously approved to be added but not yet certified	G-11797-19*
-5	# of stations previously approved to be deleted but not yet certified	G-11672-19*
40	Total stations upon completion of proposed project and previously approved projects	

*Both previously approved projects have been completed and the stations certified, as of February 24, 2020. The Agency processed the documentation of certification of the stations and completion of the projects provided by the applicant on March 26, 2020 and marked the projects complete on March 30, 2020.

Patient Origin

On page 113, the 2020 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service area: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.*” Both facilities referred to in this application are located in Guilford County. Thus, the service area for this application is Guilford County. Facilities may serve residents of counties not included in their service area.

In Section C.2, page 26, the applicant provides the historical in-center (IC), home hemodialysis (HH), and peritoneal dialysis (PD) patient origin for TDC during the last full operating year, CY2019, as summarized in the following table:

County	In-Center		Home Hemodialysis		Peritoneal Dialysis	
	IC Patients	% of Total	HH Patients	% of Total	PD Patients	% of Total
Forsyth	13.00	12.50%	0.00	0.00%	0.00	0.00%
Guilford	90.00	86.54%	0.00	0.00%	0.00	0.00%
Randolph	1.00	0.96%	0.00	0.00%	0.00	0.00%
Total	104.00	100.00%	0.00	0.00%	0.00	0.00%

Totals may not sum due to rounding

As shown in the table above and stated on page 26 of the application, TDC does not offer home hemodialysis training and support services.

In Section C.3, page 27, the applicant provides the projected IC, HH, and PD patient origin for TDC for the second full operating year following project completion, January 1, 2022 – December 31, 2022 (CY2022), as summarized in the following table:

County	In-Center		Home Hemodialysis		Peritoneal Dialysis	
	IC Patients	% of Total	HH Patients	% of Total	PD Patients	% of Total
Forsyth	14.84	12.23%	0.00	0.00%	0.00	0.00%
Guilford	105.38	86.91%	0.00	0.00%	0.00	0.00%
Randolph	1.04	0.86%	0.00	0.00%	0.00	0.00%
Total	121.26	100.00%	0.00	0.00%	0.00	0.00%

Totals may not sum due to rounding

In Section C, page 27, the applicant provides the assumptions and methodology used to project TDC’s patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 28-30, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant discusses the need for additional dialysis stations based on TDC’s and Guilford County patient growth rate over the last year. The applicant states:

- TDC’s patient population has increased by 10.63% since December 31, 2018, nearly double that of Guilford County. The applicant states that the patient base is extensive and growing. (page 28)
- TDC is at 86.67% utilization, as of December 31, 2019. (page 29)
- The facility’s existing 30 stations will be utilized at approximately 96%, as of the end of 2021 and at more than 100% by the end of 2022, if no stations are added. (page 30)
- The approval of this project will help to reduce the future county station deficit and ensure that current and future ESRD patients in Guilford and surrounding counties will have needed access to services. (page 30)

In Section C.5, page 30, the applicant explains why two stations need to be relocated from HPKC to TDC, stating that examination of the projected patient census in Section C,

“shows the greatest support for future ICH patient needs that complies with ESRD Performance Standards is realized when 10 total stations are added to TDC. However, current facility need published in the 2020 SMFP shows an 8 station need at TDC based on data from 12/31/18, which is more than a year old at the time this application will be filed. Using more current data as of 12/31/19, TDC has a need for 11 stations, but cannot apply for all 11 at once until 2021.

. . . Given TDC’s growth surge during 2019 and HPKC’s slight decline in utilization and ability to add back stations during 2020, it only makes sense to request to put stations where they can do the most good, now.”

The information is reasonable and adequately supported for the following reasons:

- The applicant demonstrates the need to add stations pursuant to facility need and to relocate stations pursuant to Policy ESRD-2 at TDC, as the facility is currently operating at 87% of capacity.
- The existing operational Guilford County facilities are operating at or above 3.1 patients per station per week or 76% capacity per the 2020 SMFP.
- The applicant provides supporting documentation in Exhibit C-4 and Exhibit H-4.

Projected Utilization

In Section C, pages 27-29, and Section Q, pages 87-88, the applicant describes its need methodology and assumptions for projected utilization for the proposed facility summarized as follows:

- December 31, 2019 facility census was sorted by patient county of residence.
- The 2020 SMFP five-year Annual Average Change Rate (AACR) of 4.5%, 5.4%, and 1.3% was applied to Forsyth, Guilford, and Randolph counties' patient census, respectively, per Section C, page 29.

The Agency's table below summarizes the beginning in-center patient census on December 31, 2019 and its growth through the ending patient census on December 31, 2022.

TDC	Forsyth	Guilford	Randolph
Begin with the respective counties' in-center patients as of December 31, 2019. (page 28 of application)	13	90	1
County AACR per 2020 SMFP	4.5%	5.4%	1.3%
Project the counties' patients forward one year using the respective county's AACR.	$13 \times 1.045 = 13.59$	$90 \times 1.054 = 94.86$	$1 \times 1.013 = 1.01$
Sum the three counties' patients. This is the projected ending census December 31, 2020.	$13.59 + 94.86 + 1.01 = 109.46$		
Project the counties' patients forward one year using the respective county's AACR.	$13.59 \times 1.045 = 14.20$	$94.86 \times 1.054 = 99.98$	$1.01 \times 1.013 = 1.03$
Sum the three counties' patients. This is the projected ending census December 31, 2021 (OY1).	$14.20 + 99.98 + 1.03 = 115.20$		
Project the counties' patients forward one year using the respective county's AACR	$14.20 \times 1.045 = 14.84$	$99.98 \times 1.054 = 105.38$	$1.03 \times 1.013 = 1.04$
Sum the three counties' patients. This is the ending census as of December 31, 2022, (OY2).	$14.84 + 105.38 + 1.04 = 121.26$		

As the table above shows, the methodology used by the applicant achieves a projection of 115.2 in-center patients by the end of the first operating year, OY1 (CY2021), for a utilization rate of 2.9 patients per station per week or 72% ($115 \text{ patients} / 40 \text{ stations} = 2.875 \text{ patients per station} / 4 = 0.7188$). By the end of OY2 (CY2022), following the applicant's methodology and assumptions, TDC will have 121.26 in-center patients

dialyzing at the center for a utilization rate of 3.03 patients per station per week or 75.8% ($121.26 / 40 = 3.025 / 4 = .7579$). The projected utilization of 2.9 patients per station per week for CY2021 satisfies the 2.8 in-center patients per station per week threshold as required by 10A NCAC 14C .2203(b).

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

- The applicant bases the beginning in-center patient census on TDC patients.
- The applicant projects the growth of the Forsyth, Guilford and Randolph county patient census using the Forsyth, Guilford and Randolph county Five-Year AACR of 4.5%, 5.4%, and 1.3%, respectively, as reported in the 2020 SMFP.

Access

In Section C.7, pages 32-34, the applicant discusses access, stating on page 33:

“Admission of a patient is based solely upon medical necessity and not the patient’s ability to pay. Patients may only access the facility’s services via physician referral due to a diagnosis of ESRD. The majority of patients are covered by Medicare, Medicaid, or some other form or combination of healthcare coverage. The facility’s social worker assists patients in seeking out and obtaining coverage for their care when necessary. However, should a circumstance arise in which a patient is ineligible for healthcare coverage, that patient is not turned away due to a lack of ability to pay.”

Exhibits L-4(b) and L-5 contain the facility’s Charity/Reduced Cost Care and Referral/Admissions Policies, respectively. The applicant projects payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table from Section L.3(b), page 73.

**Projected Payor Mix
CY2022**

Payor Source	% of Total Patients	% of IC Patients	% of HH/PD Patients
Private Pay	1.0%	1.0%	0.0%
Medicare	14.0%	14.0%	0.0%
Medicaid	8.0%	8.0%	0.0%
Medicare / Medicaid	22.0%	22.0%	0.0%
Commercial Insurance	8.0%	8.0%	0.0%
Medicare / Commercial	24.0%	24.0%	0.0%
VA	2.0%	2.0%	0.0%
Medicare Advantage	21.0%	21.0%	0.0%
Total	100.0%	100.0%	0.0%

In Section L, page 73, the applicant provides the assumptions for projecting payor mix, stating that the total patients reflects the total average patients per month, as opposed to the total at year end. The monthly payor mix percentage is averaged to obtain the average annual payor mix percentages. The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

- The applicant adequately identifies the population to be served.
 - The applicant adequately explains why the population to be served needs the services proposed in this application.
 - Projected utilization is reasonable and adequately supported.
 - The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.
- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C

The applicant proposes to add no more than eight dialysis stations pursuant to facility need and relocate no more than two dialysis stations pursuant to Policy ESRD-2 from HPKC for a total of no more than 40 stations upon project completion.

In Section D, pages 39-41, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project. On page 40, the applicant provides a table which shows projected HPKC utilization, assuming the relocation of two stations to TDC, and the previously CON-approved stations from Project ID #G-11672-19 (Add no more than 2 dialysis stations and relocate 5 stations from Triad Dialysis Center for a total of no more than 48 stations upon completion of this project), Project ID #G-11587-18 (add 7 stations), Project ID #G-11639-18 (relocate 4 stations) and Project ID #G-11651-19 (relocate 3 stations). The table shows HPKC is projected to have a utilization rate of 3.6 patients per station per week or 90.9% ($167.29 \text{ patients} / 46 \text{ stations} = 3.63 / 4 = .9092$) at the time of the relocation of two stations. However, the 2020 SMFP shows HPKC has a projected facility need of eight stations. The applicant states that HPKC will apply for additional stations when needed by the patients at HPKC. The applicant states that the population presently served at HPKC will continue to have their needs adequately met by the remaining and proposed addition of dialysis stations.

In Section D.3, page 41, the applicant states:

“Patients diagnosed with ESRD and admitted to the facility for dialysis will be treated regardless of their ability to pay, race, sexual orientation, handicap, age, type of insurance coverage, or lack of any insurance coverage.

The two stations to be transferred [relocated] from HPKC to TDC will remain in Guilford County. Many of the patients utilizing HPKC live equally convenient to TDC and have access to both facilities. Patients currently utilizing HPKC will likely see no difference in their availability of care other than an increase in the number of overall patients at HPKC over time as projected, above. There are already plans to add back the two stations that will transfer from HPKC to TDC via the CON process during 2020 to coincide with the certification of this CON.”

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

- The needs of the population currently using the services to be relocated will be adequately met following project completion.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.

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

CA

The applicant proposes to add no more than eight dialysis stations pursuant to facility need and relocate no more than two dialysis stations pursuant to Policy ESRD-2 from HPKC for a total of no more than 40 stations upon project completion.

In Section E, pages 43-44, the applicant describes the alternatives considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the identified need. The alternatives considered were:

- Policy ESRD-2, Contiguous County Station Relocation – the applicant states that WFUHS has dialysis facilities in contiguous counties from which stations might be relocated pursuant to Policy ESRD-2. However, the 2020 SMFP shows Guilford County with a station surplus, which prevents a contiguous county relocation of stations. Thus, this alternative is not an effective alternative.
- Add only eight stations using the Facility Need Methodology – the applicant states that based on the facility utilization, adding only eight stations, while enhancing service availability in Guilford County, is not an effective alternative to meet the projected need at TDC. Thus, this alternative is less effective and more costly.
- The project as proposed – the applicant states that the proposed project to add ten stations (eight through facility need and two through relocation) at TDC, plus the planned “*add-back of stations at HPKC*” will help to prevent a county station shortfall in Guilford County while ensuring patient service needs are well met at both TDC and HPKC.

On page 44, the applicant states that the project, as proposed, is the most effective alternative and the overall net impact on county station demand will be a positive one.

The applicant adequately demonstrates that the alternative proposed in this application is the more effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why they believe the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is 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. Pursuant to the facility need determination in the 2020 SMFP, Wake Forest University Health Sciences and Triad Dialysis Center of Wake Forest University shall develop no more than eight additional in-center dialysis stations pursuant to facility need and relocate no more than two dialysis stations pursuant to Policy ESRD-2 from High Point Kidney Center for a total of no more than 40 in-center stations at Triad Dialysis Center of Wake Forest University upon completion of this project.**
 - 3. Upon completion of this project, Wake Forest University Health Sciences shall take the necessary steps to decertify two stations at High Point Kidney Center for a total of no more than 46 dialysis stations upon completion of this project and Project ID #G-11672-19.**
 - 4. 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 applicant proposes to add no more than eight dialysis stations pursuant to facility need and relocate no more than two dialysis stations pursuant to Policy ESRD-2 from HPKC for a total of no more than 40 stations upon project completion.

Capital and Working Capital Costs

In Section Q Form F.1a Capital Cost, page 92, the applicant projects the total capital cost for the project as summarized below.

Projected Capital Costs	
	Total Costs
Medical Equipment	\$145,000
Non-Medical Equipment/Furniture	\$23,000
Total Capital Costs	\$168,000

The applicant provides the assumptions used to project the capital cost on in Section Q, page 92.

In Section F, page 47, the applicant states that the existing facility will have no start-up or initial operating costs.

Availability of Funds

In Section F, page 45, the applicant states that the capital cost, respectively, will be funded through owner's equity, as shown in the table below.

Sources of Capital Financing	
Type	Wake Forest University Health Sciences
Loans	
Accumulated reserves or OE *	\$168,000
Bonds	
Other (Specify)	
Total Financing	\$168,000

* OE = Owner's Equity

In Exhibit F-2, the applicant provides a letter dated March 15, 2020, from the CEO Wake Forest Baptist Health, authorizing the project and committing to cover the development cost of the project.

Exhibit F-2 also contains pertinent pages from the Consolidated Financial Statements for Wake Forest University for the fiscal year ended June 30, 2019, showing WFUHS with \$19,175,000 in cash and cash equivalents, \$1.37 billion in total assets and \$807,739,000 in net equity.

The applicant adequately demonstrates the availability of funds for the capital needs of the project.

Financial Feasibility

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of this project. In Section Q Form F-2 Income Statement, the applicant project that revenues will exceed operating expenses in the first two operating years of this project, as summarized in the table below.

Thomasville Dialysis Center Revenue and Expenses		
	CY2021	CY2022
In-Center Patients*	112	118
In-Center Treatments	16,800	17,700
Gross Patient Revenue	\$37,625,784	\$39,641,451
Adjustment from Gross**	\$32,279,509	\$34,008,768
Net Patient Revenue	\$5,346,275	\$5,632,683
Average Net Revenue per Treatment	\$318	\$318
Total Operating Expenses	\$4,642,179	\$4,885,035
Average Operating Expense per Treatment	\$264	\$265
Net Income	\$704,096	\$747,648

*Average patients per year = beginning + ending census / 2

**Includes charity care and bad debt

Totals may not sum due to rounding

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

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

C

The applicant proposes to add no more than eight dialysis stations pursuant to facility need and relocate no more than two dialysis stations pursuant to Policy ESRD-2 from HPKC for a total of no more than 40 stations upon project completion.

On page 113, the 2020 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service area: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.*” Both facilities involved in this application are located in Guilford County. Thus, the service area for this application is Guilford County. Facilities may serve residents of counties not included in their service area.

According to Table B of the 2020 SMFP, there are ten existing or approved dialysis facilities in Guilford County, two of which are owned and operated by WFUHS. Information on these dialysis facilities, from Table B of the 2020 SMFP, is provided below:

Guilford County Dialysis Facilities

Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
BMA of Greensboro (FMC)	56	85.27%	3.4
BMA of South Greensboro (FMC)	49	99.49%	4.0
BMA of Southwest Greensboro (FMC)	33	76.52%	3.1
Central Greensboro Dialysis (TRCNC proposed new site)	0	0.00%	0.0
FMC of East Greensboro (FMC)	39	90.38%	3.6
Fresenius Kidney Care Garber-Olin (FMC proposed new site)	0	0.00%	0.0
FMC High Point (FMC)	10	90.00%	3.6
High Point Kidney Center (WFUHS)	41	91.46%	3.7
Northwest Greensboro Kidney Center (FMC)	37	79.05%	3.2
Triad Dialysis Center (WFUHS)	27	87.04%	3.5

Source: 2020 SMFP, Table B.

In Section G, pages 50-51, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Guilford County. The applicant states:

“The application projects the need for the requested stations in line with the Performance Standards, which require 70% utilization by the end of OY1 of the proposed project (12/31/2021).”

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

- The proposal adequately demonstrates the need for the additional eight stations pursuant to facility need.
- The applicant adequately demonstrates that the proposed relocation of the two stations is needed in addition to the existing stations in Guilford County.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information which was publicly available during the review and used by the Agency.

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

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

C

In Section Q Form H Staffing, page 104, the applicant provides the current and projected staffing in full-time equivalent (FTE) positions, as summarized in the following table.

POSITION	CURRENT FTE POSITIONS CY2019	PROJECTED FTE POSITIONS CY2020	PROJECTED FTE POSITIONS CY2021	PROJECTED FTE POSITIONS CY2022
RN	5.50	6.00	6.00	6.00
Patient Care Tech	11.00	11.50	12.00	13.00
Clinical Nurse Manager (DON)	1.00	1.00	1.00	1.00
Dietician	1.00	1.00	1.00	1.00
Social Worker	1.00	1.00	1.00	1.00
Dialysis Tech	2.00	2.00	2.00	2.00
Bio-med Technician	0.50	0.50	0.50	0.50
Clerical	1.00	1.00	1.00	1.00
Total	23.00	24.00	24.50	25.50

Source: Section Q Form H of the application.

The Medical Director and administrative services are contract and regional administration services, respectively, not FTE positions.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in the pro forma financials found in Section Q. In Section H, pages 53-55, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Exhibit H, the applicant provides supporting documentation.

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

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

C

In Section I.1, pages 57-60, the applicant identifies the necessary ancillary and support services and explains how they will be made available. The applicant provides a table on page 57, as summarized below.

**Triad Dialysis Center
 Ancillary and Support Services**

Services	Provider
(a) In-center dialysis/maintenance	On Premises
(b) Self-care training (performed in-center)	On Premises
(c) Home training	
(1) Hemodialysis	HPKC
(2) Peritoneal dialysis	HPKC
(3) Accessible follow-up program	HPKC
(4) Sister-Facility Agreement	HPKC
(d) Psychological counseling	On Premises with appropriate referral after evaluation by MSW
(e) Isolation-hepatitis	On Premises
(f) Nutritional counseling	On Premises
(g) Social work services	On Premises
(h) Acute dialysis in an acute care setting	Wake Forest Baptist Hospital
(i) Emergency care	Wake Forest Baptist Hospital
(j) Blood bank services	Wake Forest Baptist Hospital
(k) Diagnostic and evaluation services	On Premises and WFBH
(l) X-ray services	Wake Forest Baptist Hospital
(m) Laboratory services	Wake Forest Baptist Hospital Meridian Lab Contract/On Premises
(n) Pediatric nephrology	Wake Forest Baptist Hospital
(o) Vascular surgery	Wake Forest Baptist Hospital
(p) Transplantation services	Wake Forest Baptist Hospital
(q) Vocational rehabilitation counseling & services	On Premises with appropriate referral after evaluation by MSW
(r) Transportation	City of High Point DOT/ Guilford County Transportation Services

In Section I, pages 60-61, the applicant describes TDC's proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.

The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

NA

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

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

NA

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

- (11) Repealed effective July 1, 1987.

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

C

In Section K, page 64, the applicant states that the project will involve no new construction, but renovation of 1,500 square feet. The proposed floor plan is provided in Exhibit K-2(b).

On pages 64-65, the applicant adequately explains how the cost, design and means of construction represent a reasonable alternative for the proposal and provides supporting documentation in Exhibit K-2.

On page 65, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On pages 65-66, the applicant discusses and applicable energy saving features that will be incorporated into the renovation plans.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, that energy saving features have been incorporated into the construction plans, 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

The applicant proposes to add no more than eight dialysis stations pursuant to facility need and relocate no more than two dialysis stations pursuant to Policy ESRD-2 from HPKC for a total of no more than 40 stations upon project completion.

In Section L.1, pages 69-70, the applicant provides the HPKC and TDC historical payor mix for CY2019, respectively, as shown in the table below.

Payor Source	HPKC In-center	TDC In-center
Private Pay	1.0%	1.0%
Medicare	17.0%	14.0%
Medicaid	8.0%	8.0%
Medicare / Medicaid	20.0%	22.0%
Commercial Insurance	6.0%	8.0%
Medicare / Commercial	19.0%	24.0%
VA	1.0%	2.0%
Medicare Advantage	28.0%	21.0%
Total	100.0%	100.0%

Totals may not sum due to rounding

In Section L.1(a), page 69, the applicant provides comparison of the demographical information on TDC patients and the service area patients during the last full operating year, as summarized below.

	Percentage of Total TDC Patients Served during the Last Full OY	Percentage of the Population of the Service Area Where the Stations are Located*
Female	45.0%	52.7%
Male	55.0%	47.3%
Unknown	N/A	N/A
64 and Younger	52.0%	84.8%
65 and Older	48.0%	15.2%
American Indian	0.0%	0.8%
Asian	4.0%	5.4%
Black or African-American	60.0%	35.1%
Native Hawaiian or Pacific Islander	1.0%	0.1%
White or Caucasian	26.0%	49.8%
Other Race	6.0%	8.2%
Declined / Unavailable	3.0%	2.4%

* The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.2(a), page 70, the applicant states that while the facility is not required or obligated to provide uncompensated care or community service; but as a Medicare Participating Provider, it is at a minimum subject to Federal laws and regulations regarding equal access and non-discrimination.

On page 72, the applicant states there have been no civil rights access complaints filed against the facility within the last five years.

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

C

In Section L.3 page 73, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

**Projected Payor Mix
CY2022**

Payor Source	Total Patients	IC Patients	PD & HH Patients
Private Pay	1.0%	1.0%	0.0%
Medicare	14.0%	14.0%	0.0%
Medicaid	8.0%	8.0%	0.0%
Medicare / Medicaid	22.0%	22.0%	0.0%
Commercial Insurance	8.0%	8.0%	0.0%
Medicare / Commercial	24.0%	24.0%	0.0%
VA	2.0%	2.0%	0.0%
Medicare Advantage	21.0%	21.0%	0.0%
Total	100.0%	100.0%	0.0%

Source: Application page 73

As shown in the table above, during the second full calendar year of operation, the applicant projects that 1% of the dialysis patients will be private pay patients and 89% will have all or part of their services paid for by Medicare and/or Medicaid.

On page 73, the applicant provides the assumptions and methodology used to project payor mix during the first two fiscal full years of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- the applicant's proposed patient origin is comparable to the historical TDC payor mix, and
- the applicant projects future payor mix based on the last operating year's annual average payor mix.

The Agency reviewed the:

- application, and
- exhibits to the application.

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

- 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.5, pages 76-77, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- application, and
- exhibits to the application.

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

- (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 78, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1.

The Agency reviewed the:

- application, and
- exhibits to the application.

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

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between

providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to add no more than eight dialysis stations pursuant to facility need and relocate no more than two dialysis stations pursuant to Policy ESRD-2 from HPKC for a total of no more than 40 stations upon project completion.

On page 113, the 2020 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service area: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.*” Both facilities involved in this application are located in Guilford County. Thus, the service area for this application is Guilford County. Facilities may serve residents of counties not included in their service area.

According to Table B of the 2020 SMFP, there are ten existing or approved dialysis facilities in Guilford County, two of which are owned and operated by WFUHS. Information on these dialysis facilities, from Table B of the 2020 SMFP, is provided below:

Guilford County Dialysis Facilities

Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
BMA of Greensboro (FMC)	56	85.27%	3.4
BMA of South Greensboro (FMC)	49	99.49%	4.0
BMA of Southwest Greensboro (FMC)	33	76.52%	3.1
Central Greensboro Dialysis (TRCNC proposed new site)	0	0.00%	0.0
FMC of East Greensboro (FMC)	39	90.38%	3.6
Fresenius Kidney Care Garber-Olin (FMC proposed new site)	0	0.00%	0.0
FMC High Point (FMC)	10	90.00%	3.6
High Point Kidney Center (WFUHS)	41	91.46%	3.7
Northwest Greensboro Kidney Center (FMC)	37	79.05%	3.2
Triad Dialysis Center (WFUHS)	27	87.04%	3.5

Source: 2020 SMFP, Table B.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 79, the applicant states that it does not project to serve dialysis patients currently being served by another provider. The applicant further states:

“Additional availability of dialysis services at TDC will not impact competition in the proposed service area, but will enhance the ability of persons suffering from ESRD who will be underserved by at least 12/31/2020 and beyond and who otherwise may be going out of county for their care to receive ESRD care within their home county.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 80, the applicant states:

“As demonstrated in the pro forma the cost of the service is not projected to dramatically increase, while the billable charge per treatment remains constant over all periods. Development of this project is cost-effective.”

Regarding the impact of the proposal on quality, in Section N, page 80, the applicant states:

“Service quality will remain of the highest standard.”

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 80, the applicant states:

“Access to service is based upon a diagnosis of ESRD and appropriate referral. All patients have equal access regardless of their gender, age, race, ethnicity, nor [sic] ability to pay. Expansion of health service resources at TDC will expand access of services to all ESRD patients.”

Considering all the information in the application, the applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would be a positive impact on:

- Cost-effectiveness (see Sections B, C, F, N and Q of the application and any exhibits).
- Quality (see Sections B, C, N and O of the application and any exhibits).
- Access to medically underserved groups (see Sections B, C, D, L and N of the application and any exhibits).

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

- (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 Q Form A, page 86, the applicant identifies the dialysis facilities located in North Carolina and owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 19 WFUHS dialysis facilities located in North Carolina, including North Davidson Dialysis Center, which was not yet operational.

In Section O, pages 82-83, the applicant provides a table showing that 13 of the 18 operational WFUHS dialysis facilities were surveyed within the last 18-month look-back period. During the 18 months immediately preceding the submittal of the application, one or more incidents related to quality of care occurred in 11 of the 13 facilities surveyed. These incidents were issued standard level deficiencies (not resulting in immediate jeopardy) and the list on page 83 shows that the facilities that were back in compliance at the time of application submittal, except for the one on which the report was pending. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 18 operational facilities, the applicant provides sufficient evidence that quality care has been provided in the past.

Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The application is conforming with all applicable Criteria and Standards for End-Stage Renal Disease Services. The specific criteria are discussed below.

**SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL
DISEASE SERVICES**

10A NCAC 14C .2203 PERFORMANCE STANDARDS

- (a) An applicant proposing to establish a new kidney disease treatment center or dialysis facility shall document the need for at least 10 dialysis stations based on utilization of 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the facility. An applicant may document the need for less than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for less than 10 stations.

- (b) -NA- The applicant is not proposing to establish a new ESRD facility.

- (b) An applicant proposing to increase the number of dialysis stations in:
 - (1) an existing dialysis facility; or
 - (2) a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need; shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.

- C- In Section C, pages 27-29, the methodology proposed by the applicant achieves a projection of 115 in-center patients by the end of the first operating year, CY2021, for a utilization rate of 2.9 patients per station per week or 72% ($115 \text{ patients} / 40 \text{ stations} = 2.875 \text{ patients per station} / 4 = 0.7188$). The projected utilization of 2.9 patients per station per week satisfies the 2.8 in-center patients per station per week threshold as required by 10A NCAC 14C .2203(a).

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

- C- In Section C, pages 27-28, the applicant provides the assumptions and methodology used to project utilization of the facility.