

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 25, 2020

Findings Date: November 25, 2020

Project Analyst: Gregory F. Yakaboski

Team Leader: Gloria C. Hale

Project ID #: G-11920-20

Facility: High Point Kidney Center

FID #: 945262

County: Guilford

Applicant(s): Wake Forest University Health Sciences

High Point Kidney Center of Wake Forest University

Project: Add no more than 4 dialysis stations (2 in-center and 2 dedicated home hemodialysis training) pursuant to Condition 2 of the facility need methodology for a total of no more than 50 in-center stations upon completion of this project and Project I.D.#G-11867-20 (relocate 2 stations to Triad Dialysis Center)

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 High Point Kidney Center of Wake Forest University (HPKC), collectively hereinafter referred to as “the applicant”, proposes to add no more than 4 dialysis stations (2 in-center and 2 dedicated home hemodialysis training) to the HPKC dialysis facility pursuant to Condition 2 of the facility need methodology facility need for a total of no more than 50 in-center (IC) stations upon completion of this project and Project I.D.#G-11867-20 (relocate 2 stations to Triad Dialysis Center)

HPKC currently offers both a peritoneal dialysis (PD) program and a home hemodialysis (HH) program.

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 not a 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 percent or 3.0 patients per station per week, as stated in Condition 2.a. The utilization rate reported for HPKC on page 157 of the 2020 SMFP is 91.46 percent or 3.6585 patients per station per week, based on 150 in-center dialysis patients and 41 certified dialysis stations (150 patients / 41 stations = 3.6585; $3.6585 / 4 = 0.9146$ or 91.46%).

As shown in Table 9E on page 171 of the 2020 SMFP, based on the facility need methodology for dialysis stations, the potential number of stations needed at HPKC is up to 8 additional stations; thus, the applicant is eligible to apply to add up to 8 stations during the 2020 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than 4 new stations to HPKC, which is consistent with the 2020 SMFP calculated facility need determination for up to 8 dialysis stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

Policies

There is one policy in the 2020 SMFP that is applicable to this review, Policy GEN-3: Basic Principles.

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.”

In Section B, pages 14-23, the applicant explains why it believes its application is conforming to Policy GEN-3. The applicant states:

“The Medical Director is a Board-Certified Nephrologist. He guides the remainder of the patient care team in the care of the patients and sets protocols, policies, and procedures to ensure that the care provided meets and exceeds industry standards.

The dialysis facilities of WFUHS accept patients on medically-defined admission criteria. There is no discrimination based on race, sex, national origin or 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.

The projection of future need for our facility using the current patient census increased by the 5-year AACR [Average Annual Change Rate] by patient-home-county demonstrates the addition of stations requested via this CON application is needed. Given ESRD providers must prove their need for additional stations in accordance with the Performance Standards ... providers may feel secure in the knowledge their expended resources will be well utilized and do not duplicate existing services, which represents ‘value’ for resources expended.”

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion based on the following reasons:

- 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 HPKC’s projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need.

- (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 4 dialysis stations (2 in-center and 2 dedicated home hemodialysis training) to the HPKC facility for a total of no more than 50 IC stations upon completion of this project and Project I.D.#G-11867-20 (relocate 2 stations to Triad Dialysis Center)

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 areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” HPKC is in Guilford County. Thus, the service area for this facility is Guilford County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates historical patient origin for the last full operating year (OY) 7/1/2019 to 6/30/2020, from page 27.

County	In-Center		Home Hemodialysis		Peritoneal Dialysis	
	# of IC Patients	% of Total	# of HH Patients	% of Total	# of PD Patients	% of Total
Alamance	0.00	0.00%	0.00	0.00%	1.00	2.17%
Davidson	13.00	8.23%	0.00	0.00%	19.00	41.30%
Forsyth	2.00	1.27%	0.00	0.00%	1.00	2.17%
Guilford	137.00	86.71%	0.00	0.00%	24.00	52.17%
Randolph	6.00	3.80%	0.00	0.00%	1.00	2.17%
Total	158.00	100.00%	0.00	100.00%	46.00	100.00%

Totals may not sum due to rounding

The following table illustrates projected patient origin for the second full OY 7/1/2022 to 06/30/2023, from page 28.

County	In-Center		Home Hemodialysis		Peritoneal Dialysis	
	IC Patients	% of Total	HH Patients	% of Total	PD Patients	% of Total
Alamance	0.00	0.00%	0.00	0.00%	1.09	2.03%
Davidson	15.35	8.33%	5.29	62.28%	22.44	41.70%
Forsyth	2.28	1.24%	2.09	24.63%	1.14	2.12%
Guilford	160.41	87.05%	1.11	13.09%	28.10	52.22%
Randolph	6.24	3.38%	0.00	0.00%	1.04	1.93%
Total	184.29	100.00%	8.49	100.00%	53.81	100.00%

Totals may not sum due to rounding

In Section C, pages 28-32, the applicant provides the assumptions and methodology used to project HPKC’s patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed additional dialysis stations. The applicant states:

- Table 9E of the 2020 SMFP, page 171, shows High Point Kidney Center as having a facility need of eight dialysis stations.
- As of December 31, 2018, the utilization rate reported for HPKC, was 91.46 percent or 3.6585 patients per station per week, based on 150 in-center dialysis patients and 41 certified dialysis stations [$150 \text{ patients} / 41 \text{ stations} = 3.6585$; $3.6585 / 4 = 0.9146$ or 91.46%] (See Table 9B of the 2020 SMFP, page 157).
- As of June 30, 2020, HPKC had 48 certified dialysis stations and 158 IC patients for a utilization of 82.29% or 3.2916 patients per station per week, based on 186 in-center dialysis patients and 54 certified dialysis stations [$158 / 48 = 3.2916$; $3.44 / 4 = 0.8229$ or 82.29%]. Pursuant to Project ID# G-11867-20 two dialysis stations are scheduled to be relocated from HPKC to Triad Dialysis Center as of December 31, 2020, which will reduce the number of dialysis stations at HPKC from 48 to 46 and increase utilization above 82.29%
- If no additional stations are added to HPKC upon completion of Project ID# G-11867-20 HPKC will have 46 dialysis stations. The 46 stations will be utilized at approximately 90.00%, as of July 1, 2021, the beginning of OY1 [$166 / 46 = 3.6 / 4 = 0.9$ or 90.00%].

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

- The applicant demonstrates the need to add stations pursuant to facility need as the facility is operating at 81.77% of capacity as of July 1, 2019.
- The applicant bases the future need for services upon the facility's historical patient utilization, applying the 5-year county Average Annual Change Rate (AACR) from Table 9C of the 2020 SMFP of 3.0%, 5.7%, 4.5%, 5.4% and 1.3% for patients from Alamance, Davidson, Forsyth, Guilford, and Randolph counties, respectively, to project growth in patient need at the facility.
- The facility need methodology in the 2020 SMFP shows a need for eight additional dialysis stations at High Point Kidney Center. This application is for four additional dialysis stations and the applicant, to date in CY2020, has not made any other applications to add dialysis stations to HPKC.
- Pursuant to Project ID# G-11867-20 two dialysis stations are scheduled to be relocated from HPKC to Triad Dialysis Center as of December 31, 2020, which will reduce the number of dialysis stations at HPKC from 48 to 46. Based on 158 IC patients at HPKC as of June 30, 2020, even with no growth in the patient census, as of January 1, 2021 utilization at HPKC would be 85.87% or 3.4348 patients per station per week, based on 158 in-center dialysis patients and 46 certified dialysis stations [$158 / 46 = 3.4348$; $3.44 / 4 = 0.8587$ or 85.87%].

Projected Utilization

In-Center Patients

In Section C.4, page 34, the applicant provides 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 provides historical and projected utilization of in-center dialysis patients at HPKC.

High Point Kidney Center In-Center Dialysis Utilization

County	5-Yr AACR	Beginning Census 6/30/2020	Ending Current Year 6/30/2021	End of OY1 6/30/2022	End of OY2 6/30/2023
Alamance	3.0%	0.00	0.00	0.00	0.00
Davidson	5.7%	13.00	13.74	14.52	15.35
Forsyth	4.5%	2.00	2.09	2.18	2.28
Guilford	5.4%	137.00	144.40	152.20	160.41
Randolph	1.3%	6.00	6.08	6.16	6.24
Totals		158.00	166.31	175.06	184.29

Totals may not sum due to rounding

Source: Table on page 34 of the application.

As the table above shows, the methodology used by the applicant shows a projection of 175.06 in-center patients by the end of the first operating year, OY1, for a utilization rate of 3.5 patients per station per week or 87.50% ($175 \text{ patients} / 50 \text{ stations} = 3.5 / 4 = 0.875$ or 87.50%).

By the end of OY2, following the applicant's methodology and assumptions, HPKC will have 184.29 in-center patients dialyzing at the center for a utilization rate of 92.00% ($184 / 50 = 3.68 / 4 = .92$ or 92.00%).

The projected utilization of 3.5 patients per station per week for OY1 satisfies the 2.8 in-center patients per station threshold as required by 10A NCAC 14C .2203(b).

In Section C.3, pages 28-29, and Section Q, pages 89-90, the applicant provides the methodology and assumptions used to project IC utilization at HPKC. Based on the facility need methodology, HPKC is eligible to add eight dialysis stations.

The applicant's methodology and assumptions are summarized below:

- Existing patients are grouped by modality and county of origin, as of June 30, 2020.
- Utilization is based on current patients at HPKC, projected forward by applying the 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.
- OY1 ends June 30, 2022; OY2 ends June 30, 2023.

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

- The applicant bases the future utilization of services upon the facility’s historical patient utilization,
- The applicant bases the future need for services upon the facility’s historical patient utilization, applying the 5-year county Average Annual Change Rate (AACR) from Table 9C of the 2020 SMFP of 3.0%, 5.7%, 4.5%, 5.4% and 1.3% for patients from Alamance, Davidson, Forsyth, Guilford, and Randolph counties, respectively, to project growth in patient need at the facility.
- Based on Table 9E of the 2020 SMFP, page 171, HPKC has a Facility Station Need for eight dialysis stations.

Peritoneal Patients

High Point Kidney Center PD Dialysis: Historical and Projected Utilization

	Last Full Operating Year: 6/30/2020	End of OY2: 6/30/2023
PD Patients	51.00	62.48

Source: Table on page 30 in Section C of the application and Section Q.

The applicant started with the historical number of PD patients as of 6/30/2020 and applied an annual growth rate of 7.0%.

High Point Kidney Center PD Dialysis: Historical and Projected Utilization

Historical number of PD patients at HPKC as of 6/30/2020.	51
Based on a 7.0% growth rate project the number of PD patients forward one year to 6/30/2021.	$1.07 \times 51 = 54.57$
Based on a 7.0% growth rate project the number of PD patients forward one year to 6/30/2022. This is the projected ending PD patient census for Operating Year One.	$1.07 \times 54.57 = 58.39$
Based on a 7.0% growth rate project the number of PD patients forward one year to 6/30/2023. This is the projected ending PD patient census for Operating Year One.	$1.07 \times 58.39 = 62.48$

Home Hemodialysis Patients

High Point Kidney Center HH Dialysis: Historical and Projected Utilization

	Last Full Operating Year: 6/30/2020	End of OY2: 6/30/2023
HH Patients	0.00	12.59

Source: Table on page 32 in Section C of the application and Section Q.

In the last OY ending 6/30/2020 the applicant provided no HH training days of service. The applicant states that this was based on the COVID-19 pandemic, lack of patient interest and other mitigating factors. However, the applicant states that with two dedicated HH training stations available it will be able to comply with the President’s executive order aimed at increasing HH training. The applicant projects to train one patient per month during OY1, therefore the applicant begins its calculations with the projected number of HH patients as of 6/30/2021 and applied an annual growth rate of 7.0%.

High Point Kidney Center HH Dialysis: Historical and Projected Utilization

Historical number of HH patients at HPKC as of 6/30/2020.	0
Projected number of HH patients as of 6/30/2021.	11.00
Based on a 7.0% growth rate project the number of HH patients forward one year to 6/30/2022. This is the projected ending HH patient census for Operating Year One.	$1.07 \times 11.00 = 11.77$
Based on a 7.0% growth rate project the number of HH patients forward one year to 6/30/2023. This is the projected ending HH patient census for Operating Year Two.	$1.07 \times 11.77 = 12.59$

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

- the applicant bases the future utilization of services upon the facility’s historical PD patient utilization, and
- the applicant bases the future need for services upon the facility’s historical PD patient utilization and projected HH patient population, applying a 7% annual growth rate to project utilization.
- Federal focus and emphasis on home dialysis pursuant to the Presidential Executive Order of July 10, 2019.

Access to Medically Underserved Groups

In Section L, page 74 the applicant states:

“The facility fulfills its requirement for non-discrimination by accepting all persons with a diagnosis of ESRD regardless of race, color, national origin, sex, age or disability. ... The facility’s design complies with the ADA standards and was built in accordance with Life Safety Code guidelines.”

In Section L, page 75, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

**High Point Kidney Center Mix
Second Full OY (7/1/2022 to 6/30/2023)**

Payor Source	% of Total Patients
Private Pay	1.0%
Medicare	16.0%
Medicaid	8.0%
Medicare / Medicaid	19.0%
Commercial Insurance	7.0%
Medicare / Commercial	20.0%
Medicare Advantage	29.0%
Total	100.0%

Source: Table on page 75 of the application.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 describes the extent to which all residents, including underserved groups, are likely to have access to the proposed services 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.

NA

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (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 4 dialysis stations to the HPKC facility for a total of no more than 50 IC stations upon completion of this project and Project I.D.#G-11867-20 (relocate 2 stations to Triad Dialysis Center)

In Section E, pages 46-47, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- *Transfer Stations from a Contiguous County per Policy ESRD-2-* The applicant states that WFUHS, the parent of HPKC, has dialysis facilities in the counties of Davidson, Forsyth, Randolph and Stokes which are all contiguous to Guilford County. However, Guilford County has a surplus of 21 stations; therefore, pursuant to Policy ESRD-2, stations cannot be relocated to Guilford County from contiguous counties because the relocation of stations from another county would increase the Guilford County surplus. Therefore, this is not the least costly or most effective alternative.
- *Add Less than 4 Stations-* The Facility Need Methodology identifies a need for 8 additional stations at HPKC. The applicant states that adding less than 4 additional stations will not meet the projected patient needs. Therefore, this is not the least costly or most effective alternative.

In Section B, page 11, Section C, pages 28-29 and Section E, pages 46-47 the applicant states that its proposal is the most effective alternative because there is a facility need for up to 8 dialysis stations at HPKC and projected patient growth supports the development of 4 additional dialysis stations.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on the following reasons:

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes 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 High Point Kidney Center of Wake Forest University (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to Condition 2 of the facility need determination in the 2020 SMFP, the certificate holder shall develop no more than 4 additional in-center dialysis stations for a total of no more than 50 in-center stations at High Point Kidney Center of Wake Forest University upon completion of this project and Project ID# G-11867-20 (relocate 2 stations to Triad Dialysis Center).**
 - 3. The certificate holder 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 4 dialysis stations to the HPKC facility for a total of no more than 50 IC stations upon completion of this project and Project I.D.#G-11867-20 (relocate 2 stations to Triad Dialysis Center)

Capital and Working Capital Costs

In Section Q, Form F.1a, page 93, the applicant projects the total capital cost of the project, as shown in the table below.

Site Costs	\$0
Construction Costs	\$0
Miscellaneous Costs	\$33,600
Total	\$33,600

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F.3, page 50, the applicant states there will be no start-up expenses or initial operating expenses incurred for this project because HPKC is an operational facility.

Availability of Funds

In Section F, page 48, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing		
Type	WFUHS	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$33,600	\$33,600
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$33,600	\$33,600

* OE = Owner's Equity

In Exhibit F-2(c)(ii), the applicant provides a letter dated August 15, 2020, from the Chief Executive Officer of Wake Forest Baptist Health, authorizing the project and committing \$33,600 from WFUHS for the development of the project. Exhibit F-2(c)(iii) contains 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 assets.

Financial Feasibility

The applicant provided pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form F.2, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

	1st Full Fiscal Year	2nd Full Fiscal Year
Total Treatments	33,900	36,000
Total Gross Revenues (Charges)	\$76,696,920	\$81,454,286
Total Net Revenue	\$11,120,516	\$11,833,478
Average Net Revenue per Treatment	\$328	\$329
Total Operating Expenses (Costs)	\$8,877,535	\$9,320,828
Average Operating Expense per Treatment	\$262	\$259
Net Income	\$2,242,981	\$2,512,650

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
- Exhibits to the application

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

- 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 4 dialysis stations to the HPKC facility for a total of no more than 50 IC stations upon completion of this project and Project I.D.#G-11867-20 (relocate 2 stations to Triad Dialysis Center)

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 areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” HPKC is in Guilford County. Thus, the service area for this facility is Guilford County. Facilities may also serve residents of counties not included in their service area.

According to Table 9B: *Inventory of Dialysis Stations and Calculation of Utilization Rates* on pages 156-157 of the 2020 SMFP, there are ten existing or approved dialysis facilities in Guilford County as shown in the following table:

Guilford County Dialysis Facilities: Certified Stations/Utilization as of December 31, 2018			
Dialysis Facility	# of Certified Stations	Percent Utilization	Facility Station Need Determination
BMA of Greensboro	56	85.27%	20
BMA of South Greensboro	49	99.49%	15
BMA of Southwest Greensboro	33	76.52%	3
Central Greensboro Dialysis	0	0.00%	0
FMC of East Greensboro	39	90.38%	12
Fresenius Kidney Care Garber-Olin	0	0.00%	0
Fresenius Medical Care High Point	10	90.00%	9
High Point Kidney Center of Wake Forest University	41	91.46%	8
Northwest Greensboro Kidney Center	37	79.05%	12
Triad Dialysis Center of Wake Forest University	27	87.04%	8

Source: 2020 SMFP, pages 156-157.

In Section G, pages 53-55, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Guilford County. The applicant states on page 54,

“This 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 (6/30/2022.)”

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

- There is a facility need determination in the 2020 SMFP for the proposed dialysis stations.
- The applicant adequately demonstrates that the proposed dialysis stations are needed in addition to the existing or approved dialysis stations.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 based on 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, page 107, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

POSITION	Current FTE Positions as of 12/31/19	PROJECTED FTE POSITIONS OY2 (7/1/2022 TO 6/30/2022)
RN	7.25	8.00
LPN	1.50	1.50
Patient Care Tech	17.50	18.00
Clinical Nurse Manager (DON)	1.00	1.00
Dietician	2.00	2.00
Social Worker	2.00	2.00
Home Training Nurse	3.00	3.00
Dialysis Tech	2.00	2.00
Bio-med Technician	0.25	0.25
Clerical	3.00	3.00
Total	39.50	40.75

Source: Sections Q, Form H, page 107 of the application.

The assumptions and methodology used to project staffing are provided in Section Q, Form H. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4, which is found in Section Q.

In Sections H.2 and H.3, pages 56-58, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 59, the applicant identifies the current medical director. In Exhibit H-4(b), the applicant provides a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services. In Exhibits H-3, H-4(a)(i) and H-4(a)(ii), 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
- Exhibits to the application
- Supplemental information requested by the Agency

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, page 60, the applicant states that the following ancillary and support services are necessary for the proposed services:

HIGH POINT KIDNEY DIALYSIS CENTER Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	On Premises
Self-care training (in-center)	On Premises
Home training Home Hemodialysis Peritoneal Dialysis Accessible follow-up program	On Premises On Premises On Premises
Psychological counseling	On Premises with appropriate referral after evaluation by MSW
Isolation – hepatitis	On Premises
Nutritional counseling	On Premises
Social Work services	On Premises
Acute dialysis in an acute care setting	Wake Forest Baptist Hospital
Emergency care	Wake Forest Baptist Hospital
Blood bank services	Wake Forest Baptist Hospital
Diagnostic and evaluation services	Wake Forest Baptist Hospital/ On Premises
X-ray services	Wake Forest Baptist Hospital
Laboratory services	Wake Forest Baptist Hospital and Meridian Laboratory Corp (Lab Contract)/ On Premises
Pediatric nephrology	Wake Forest Baptist Hospital/ On Premises
Vascular surgery	Wake Forest Baptist Hospital
Transplantation services	Wake Forest Baptist Hospital
Vocational rehabilitation & counseling	On Premises with appropriate referral after evaluation by MSW
Transportation	Social Workers, Department of Social Services, Grant Agencies, Individual Transport Agencies

On pages 60-63, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits I-1(b)(xiii), 1(b)(v), 1(b)(xviii); Exhibits I-2(a), 2(b), 2(c)(i); Exhibits H-4(a)(i) and 4(a)(ii); and Exhibit I-2(b).

In Section I.2, pages 63-64, the applicant describes HPKC’s existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits I-2(a), 2(b), 2(c)(i), 2(c)(ii), 2(c)(iii), 2c(iv). See also Exhibit M-1.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

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.

- (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.

NA

The applicant does not propose any construction with this project and only proposes minor renovation of existing space. Therefore, Criterion (12) is not applicable to this review.

- (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, page 72, the applicant provides the historical payor mix during for the proposed service during the last full operating year (7/1/2019 to 6/30/2020), as shown in the table below.

**High Point Kidney Center Payor Mix
Last Full OY (7/1/2019 to 6/30/2020)**

Payor Source	% of Total Patients
Private Pay	1.0%
Medicare	16.0%
Medicaid	8.0%
Medicare / Medicaid	19.0%
Commercial Insurance	7.0%
Medicare / Commercial	20.0%
Medicare Advantage	29.0%
Total	100.0%

Source: Table on page 72 of the application.

In Section L, page 71, the applicant provides the following comparison.

	Percentage of Total Patients Served (all modalities combined) during the Last Full FY	Guilford County Population
Female	41.77%	52.70%
Male	58.23%	47.30%
Unknown	na	na
64 and Younger	54.00%	84.80%
65 and Older	46.00%	15.20%
American Indian	0.00%	0.80%
Asian	5.06%	5.40%
Black or African-American	70.89%	35.10%
Native Hawaiian or Pacific Islander	0.00%	0.10%
White or Caucasian	18.99%	49.80%
Other Race	4.43%	8.20%
Declined / Unavailable	0.63%	2.40%

The Agency reviewed the:

- Application
- Exhibits to the application

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, pages 72-74, the applicant states:

“The facility is not required nor obligated to provide uncompensated care or community service. ... The facility fulfills its requirement for non-discrimination by accepting all persons with a diagnosis of ESRD regardless of race, color, national origin, sex, age or disability.”

In Section L.2, page 74, the applicant states no patient civil rights access complaints have been filed against High Point Kidney Center within the last five years.

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.

- (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, page 75, 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.

**High Point Kidney Center Payor Mix
Second Full OY (7/1/2022 to 6/30/2023)**

Payor Source	% of Total Patients
Private Pay	1.0%
Medicare	16.0%
Medicaid	8.0%
Medicare / Medicaid	19.0%
Commercial Insurance	7.0%
Medicare / Commercial	20.0%
Medicare Advantage	29.0%
Total	100.0%

Source: Table on page 75 of the application.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that that 1% of the dialysis patients will be private pay patients and 92% will have all or part of their services paid for by Medicare and/or Medicaid.

On page 75, the applicant provides the assumptions and methodology it uses to project payor mix during the second full year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the projected payor mix is based on the historical payor mix of High Point Kidney Center.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 78-79, the applicant adequately describes the range of means by which patients will have access to the proposed services.

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.

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

Conclusion

The Agency reviewed the:

- Application
- 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 4 dialysis stations to the HPKC facility for a total of no more than 50 IC stations upon completion of this project and Project I.D.#G-11867-20 (relocate 2 stations to Triad Dialysis Center)

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 areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” HPKC is in Guilford County. Thus, the service area for this facility is Guilford County. Facilities may also serve residents of counties not included in their service area.

According to Table 9B: *Inventory of Dialysis Stations and Calculation of Utilization Rates* on pages 156-157 of the 2020 SMFP, there are ten existing or approved dialysis facilities in Guilford County as shown in the following table:

Guilford County Dialysis Facilities: Certified Stations/Utilization as of December 31, 2018			
Dialysis Facility	# of Certified Stations	Percent Utilization	Facility Station Need Determination
BMA of Greensboro	56	85.27%	20
BMA of South Greensboro	49	99.49%	15
BMA of Southwest Greensboro	33	76.52%	3
Central Greensboro Dialysis	0	0.00%	0
FMC of East Greensboro	39	90.38%	12
Fresenius Kidney Care Garber-Olin	0	0.00%	0
Fresenius Medical Care High Point	10	90.00%	9
High Point Kidney Center of Wake Forest University	41	91.46%	8
Northwest Greensboro Kidney Center	37	79.05%	12
Triad Dialysis Center of Wake Forest University	27	87.04%	8

Source: 2020 SMFP, pages 156-157.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 81, the applicant states:

“Additional availability of dialysis services at HPKC 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 (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 81, 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 82, 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 82, 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, or ability to pay. Expansion of health service resources at HPKC 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 have a positive impact on:

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 based on 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 88, 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 18 existing WFUHS dialysis facilities located in North Carolina.

In Section O, pages 84-85, the applicant states that during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in eleven of the 18 facilities however, no facilities had any incidents of “immediate jeopardy”. The applicant states that at the time of application submittal, all facilities were in compliance. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 18 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.

- 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- High Point Kidney Center is an existing facility. In Section C, page 34, the applicant projects that the High Point Kidney facility will serve 175 in-center patients on 50 stations, or a rate of 3.5 patients per station per week, as of the end of the first operating year following project completion. This exceeds the minimum performance standard of 2.8 patients per station per week.

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

- C- In Section C, pages 29-32, and in Section Q, pages 89-92, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.