

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 21, 2019

Findings Date: May 21, 2019

Project Analyst: Celia C. Inman

Co-Signer: Lisa Pittman

Project ID #: G-11672-19

Facility: High Point Kidney Center

FID #: 945262

County: Guilford

Applicants: Wake Forest University Health Sciences

High Point Kidney Center of Wake Forest University

Project: 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)

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, the applicants, currently operate High Point Kidney Center (HPKC), a 41-station dialysis facility located in High Point, Guilford County. The applicants propose to add two dialysis stations, pursuant to the facility need methodology and relocate five dialysis stations, pursuant to Policy ESRD-2, to the

existing HPKC facility for a total of 48 certified dialysis stations upon project completion.

Need Determination

The 2019 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 D in the January 2019 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of three dialysis stations in Guilford County. Therefore, there is no county need determination for new dialysis stations for Guilford County.

However, the applicants are eligible to apply for additional stations based on the facility need methodology because the utilization rate reported for HPKC in the January 2019 SDR is 3.68 patients per station per week. This utilization rate was calculated based on 151 in-center dialysis patients and 41 certified dialysis stations. (151 patients / 41 stations = 3.68 patients per station per week). The facility need methodology requires a facility’s utilization rate in the latest SDR to be at least 3.2 patients per station per week to be eligible to apply for additional stations based on facility need.

Application of the facility need methodology indicates that up to a maximum of two additional stations are needed for this facility, as illustrated in the following table.

APRIL 1 REVIEW-JANURARY 2019 SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/18		92.07%
Certified Stations		41
Pending Stations (Project ID #G-11587-18)		7
Total Existing and Pending Stations		48
In-Center Patients as of 6/30/18 (January 2019 SDR) (SDR2)		151
In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR1)		143
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	8
	Multiply the difference by 2 for the projected net in-center change	16
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/17	0.1118
(ii)	Divide the result of Step (i) by 12	0.0093
(iii)	Multiply the result of Step (ii) by 6	0.0559
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	159.4475
(v)	Divide the result of Step (iv) by 3.2 patients per station	49.8273
	and subtract the number of certified and pending stations to determine the number of stations needed	1.8

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to two stations (rounding to the nearest whole number is allowed only in Step (v), where fractions of 0.5 and greater shall be rounded to the next highest whole number.) The applicants propose to add two stations, pursuant to the facility need methodology. Therefore, the facility need determination for dialysis stations is applicable to this review.

In summary, the application is consistent with the facility need determination for dialysis stations.

Policies

There are two policies in the 2019 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, page 31 of the 2019 SMFP, states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Promote Safety and Quality – The applicants describe how they believe the proposed project would promote safety and quality in Section B.4(a), pages 11-16, referencing other application sections and exhibits with specific details. The information provided by the applicants is reasonable and adequately supports the determination that the applicants’ proposal would promote safety and quality.

Promote Equitable Access - The applicants describe how they believe the proposed project would promote equitable access in Section B.4(b), pages 16-21, referencing other application sections and exhibits; and Section N.1, page 81. The information provided by the applicants is reasonable and adequately supports the determination that the applicants’ proposal would promote equitable access.

Maximize Healthcare Value - The applicants describe how they believe the proposed project would maximize healthcare value in Section B.4(c), page 21, referencing Sections F and K; and in Section N.1, page 81. The information provided by the applicants is reasonable and adequately supports the determination that the applicants’ proposal would maximize healthcare value.

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

Policy ESRD-2: Relocation of Dialysis Stations, on page 25 of the 2019 SMFP, states:

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to 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 Semiannual Dialysis Report, and*
- 3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

The applicant proposes to relocate five existing dialysis stations from Triad Dialysis Center (TDC) in Guilford County to HPKC in Guilford County, pursuant to Policy ESRD-2. The total number of dialysis stations in Guilford County will not change due to the proposed relocation of the stations. 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 that the application is conforming to this criterion for the reasons stated above.

- (2) Repealed effective July 1, 1987.

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

C

The applicants propose to add two dialysis stations, pursuant to the facility need methodology, and relocate five stations, pursuant to Policy ESRD-2, for a total of 48 dialysis stations at the existing HPKC facility upon project completion. The following table, summarized from data on page 4 of the application, Table B of the January 2019 SDR, and publicly available data, illustrates the current and projected number of dialysis stations at HPKC.

Stations	Description	Project ID #
41	Total existing certified stations as of the January 2019 SDR	
+7	Stations to be added as part of this project	G-11672-19
+7	Stations previously approved to be added but not yet certified (CA 1/7/19)	G-11587-18
-4	Stations proposed to be deleted in an application still under review	G-11639-18
-3	Stations proposed to be deleted in an application (CA 3/11/19)	G-11651-19
48	Total stations upon completion of proposed project and projects approved or still under review	

Patient Origin

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” HPKC is located in Guilford County; thus, the service area for this facility consists of Guilford County. Facilities may also serve residents of counties not included in their service area.

In Section C.8, page 31, the applicants provide the historical patient origin for the in-center (IC), home hemodialysis (HH) and peritoneal dialysis (PD) services provided at HPKC, as summarized in the following table.

**High Point Kidney Center Historical Patient Origin
 As of February 28, 2019**

County	In-Center	Home Hemodialysis	Peritoneal Dialysis
Catawba	0	0	1
Davidson	15	0	18
Forsyth	6	0	3
Guilford	122	0	34
Randolph	8	0	5
TOTAL	151	0	61

Source: Table on page 31 of the application.

Tables B and C of the January 2019 SDR, show HPKC serving 151 IC patients, 59 PD patients, and 0 HH and, as of June 30, 2018.

In Section C.1, page 24, the applicants provide the projected IC and PD patient origin for HPKC for operating year one (OY1), March 1, 2020 – February 28, 2021, and operating year two (OY2), March 1, 2021 – February 28, 2022, the first two full operating years following project completion, as shown in the following table:

County	End of OY1 Feb 28, 2021		End of OY2 Feb 28, 2022		Percent of Total Patients	
	In-Center	Peritoneal	In-Center	Peritoneal	OY1	OY2
Catawba	0.00	1.19	0.00	1.30	0.54%	0.57%
Davidson	17.21	20.65	18.43	22.11	17.18%	17.73%
Forsyth	6.46	3.23	6.71	3.36	4.40%	4.40%
Guilford	130.44	36.35	134.87	37.59	75.71%	75.41%
Randolph	8.21	5.13	8.32	5.20	6.06%	5.91%
Davidson Transfers Out	(8.57)	0.00	(9.18)	0.00	(3.89%)	(4.01%)
Total	153.75	66.55	159.15	69.55	100.00%	100.00%

Totals may not sum due to rounding

The applicant does not propose to serve HH patients.

In Section C, pages 24-25, the applicants provide the assumptions and methodology used to project HPKC’s patient origin. The methodology includes an erroneous step that assumes the “Davidson Transfers Out” will increase at HPKC after the transfer. However, the result is an immaterial difference.

The applicants’ assumptions are reasonable and adequately supported.

Analysis of Need

The applicants propose to add two dialysis stations, pursuant to the facility need methodology, and relocate five stations, pursuant to Policy ESRD-2, for a total of 48 dialysis stations at the existing HPKC facility upon project completion. In Section C, the applicants explain why they believe the population projected to utilize the proposed services needs the proposed services. In Section C.1, page 24, the applicants state the purpose of the proposed project is to:

“... expand the existing services at HPKC on all patient shifts to meet the current and projected patient needs while accommodating patients at the dialysis facility closes to their home.”

In Section C.2, pages 25-26, the applicants state that HPKC’s facility was serving 151 IC patients, as of February 28, 2019. The applicants discuss that the facility utilization is impacted by the fact that of HPKC’s 151 IC patients, approximately ten patients require isolation, with “*approximately*” four isolation rooms designated for non-medically defined isolation and two stations designated for medically-defined isolation. The applicants state that the restricted use of the isolation stations results in a working utilization rate that approaches 100% of capacity for the existing stations, leaving little capacity for growth.

In Section C.2, page 27, the applicants show that the utilization rate for HPKC, as of February 28, 2019, was 92.07% for 41 stations and is projected to reach 97.04% utilization by February 28, 2022, if no stations are added.

In Section N.1, page 81, the applicants discuss the need for the additional stations at HPKC. The applicants state:

“... An addition of stations at HPKC is necessary to serve the facility’s existing and projected patients and serve Guilford County residents suffering with ESRD. By approval of this project, HPKC will have the ability to continue serving its patient base during current operating hours and expand services during those hours [sic] ensure access of care for those suffering with ESRD. The proposed project will improve the overall cost-effectiveness, quality, and access to ESRD services in Guilford County.”

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

- the facility is currently operating at 92.07% capacity with 41 stations and is expected to reach 97.04% utilization by February 28, 2022, if no stations are added,
- the applicants base the future need for services upon the facility’s current patient utilization, applying the 5-year county average annual change rate (AACR) of 9.1%, 7.1%, 3.8%, 3.4%, and 1.3% for patients from Catawba, Davidson, Forsyth, Guilford, and Randolph counties, respectively, to project growth in patient need at the facility.

Projected Utilization

In-Center Patients

In Section C.2, pages 25-27, the applicants provide the calculations used to arrive at the projected in-center patient census for the first two years of operation following the completion of the project. The following table provides current and projected utilization of in-center dialysis patients at HPKC.

HPKC Current and Projected In-Center Dialysis Utilization

County	January 2019 SDR 5-Yr AACR	Beginning Census 2/28/2019	Growth as of Certification 2/28/2020	End of OY1 2/28/2021	End of OY2 2/28/2022
Catawba	9.1%	0.00	0.00	0.00	0.00
Davidson	7.1%	15.00	16.07	17.21	18.43
Forsyth	3.8%	6.00	6.23	6.46	6.71
Guilford	3.4%	122.00	126.15	130.44	134.87
Randolph	1.3%	8.00	8.10	8.21	8.32
Davidson Transfers Out	7.1%	0.00	(8.00)	(8.57)	(9.18)
Totals		151.00	148.55	153.75	159.15

Totals may not sum due to rounding

As the table above shows, the methodology used by the applicants achieves a projection of 153.75 in-center patients by the end of the first operating year, OY1, for a utilization rate of 3.2 patients per station per week or 80.1% ($153.75 \text{ patients} / 48 \text{ stations} = 3.2031 \text{ patients per station} / 4 = 0.8007$). By the end of OY2, following the applicants' methodology and assumptions, HPKC will have 159.15 in-center patients dialyzing at the center for a utilization rate of 82.9% ($159.15 / 48 = 3.3156 / 4 = 0.8289$). The projected utilization of 3.2 patients per station per week for OY1 satisfies the 3.2 in-center patients per station threshold as required by 10A NCAC 14C .2203(b).

In Section C.7, pages 30-31, the applicants provide the methodology and assumptions used to project utilization at HPKC. Based on the facility need methodology, HPKC is eligible to add as many as two stations. The applicants propose to add two dialysis stations pursuant to the facility need methodology. The applicants also propose to relocate five stations from TDC in Guilford County to HPKC pursuant to Policy ESRD-2. The applicants provide calculations that support the addition of seven stations at HPKC for a total of 48 dialysis stations.

The applicants' methodology and assumptions are summarized below:

- Existing patients are grouped by modality and county of origin.
- Utilization is based on current patients at HPKC, projected forward by applying the January 2019 SDR 5-year AACR, by county of patient origin, to the current patient populations to project patient census through the end of Operating Year 2.
- OY1 ends February 28, 2021; OY2 ends February 28, 2022.
- The 5-year AACR for each county as published in the January 2019 SDR will remain an accurate indicator of patient growth through OY2.

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

- the applicants base the future utilization of services upon the facility’s current patient utilization, and
- the applicants utilize the 5-year county AACR of 9.1%, 7.1%, 3.8%, 3.4%, and 1.3% for patients from Catawba, Davidson, Forsyth, Guilford, and Randolph counties, respectively, to project growth in patient need at the facility.
- the patient utilization is reduced to reflect the eight Davidson County patients willing to transfer their care to TVDC in Davidson County (Project ID #G-11651-19), as of December 31, 2019. The methodology includes an erroneous step that assumes the “Davidson Transfers Out” will increase at HPKC after the transfer. However, the result is an immaterial difference.

Peritoneal Patients

The following table summarized from the table on page 27 shows the current and projected PD utilization following the same methodology and assumptions as outlined above.

HPKC Current and Projected PD Dialysis Utilization

County	January 2019 SDR 5-Yr AACR	Beginning Census 2/28/2019	Growth as of Certification 2/28/2020	End of OY1 2/28/2021	End of OY2 2/28/2022
Catawba	9.1%	1.00	1.09	1.19	1.30
Davidson	7.1%	18.00	19.28	20.65	22.11
Forsyth	3.8%	3.00	3.11	3.23	3.36
Guilford	3.4%	34.00	35.16	36.35	37.59
Randolph	1.3%	5.00	5.07	5.13	5.20
Totals		61.00	63.70	66.55	69.55

Totals may not sum due to rounding

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

- the applicants base the future utilization of services upon the facility’s historical patient utilization, and

- the applicants utilize the 5-year county AACR of 9.1%, 7.1%, 3.8%, 3.4%, and 1.3% for patients from Catawba, Davidson, Forsyth, Guilford, and Randolph counties, respectively, to project growth in patient need at the facility.

Access

In Section C.3, page 28, the applicants state:

“HPKC accepts patients based on medically defined admission criteria [emphasis is original]. There is no discrimination based on race, sex, national origin, ability to pay, nor disability. Services are available to all [emphasis is original] area residents with ESRD. Further, the facility also accepts the needy and the homeless, through its referral system, and assists those patients in obtaining the medical care they need.”

Exhibit L-3(a) contains the facility’s Referral/Admissions Policy. The applicants project payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table from Section L.1(b), page 71.

**Projected Payor Mix
OY2**

Payor Source	Total Patients	In-center Patients	PD Patients
Private Pay	0.0%	0.0%	0.0%
Medicare	15.0%	15.0%	15.0%
Medicaid	4.0%	6.0%	1.0%
Medicare / Medicaid	15.0%	21.0%	9.0%
Commercial Insurance	12.0%	6.0%	19.0%
Medicare / Commercial	22.0%	21.0%	23.0%
VA	6.0%	6.0%	5.0%
Medicare Advantage	26.0%	25.0%	28.0%
Total	100.0%	100.0%	100.0%

In Section L.1(b), page 66, the applicants state that the projected payor mix is based upon the facility’s five-year average annual payor mix, composed of monthly snapshots. 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 applicants adequately identify the population to be served.
 - The applicants adequately explain why the population to be served needs the services proposed in this application.
 - Projected utilization is reasonable and adequately supported.
 - The applicants project 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 applicants propose to relocate five dialysis stations from TDC in Guilford County to HPKC in Guilford County, pursuant to Policy ESRD-2. In Section D, pages 35-36, the applicants explain why they believe the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project. On page 35, the applicants state:

- TDC serves 87 patients on 27 dialysis stations,
- some of the patients at TDC reside closer to HPKC and have expressed an interest in transferring their care to HPKC, and
- a reduction of five stations at TDC would increase the project utilization at the facility to about 92%.

The applicants further state that upon approval of the proposed project, TDC will have 22 dialysis stations. Using the 22 stations, and serving the population presently served, TDC's 92% utilization rate will still be lower than the HPKC rate approaching 100%. The applicant states that the population presently served at TDC will continue to have their needs adequately met by the remaining 22 dialysis stations.

In Section D.2, pages, 35-36, the applicants state:

*“Admission to every WFUHS facility is dependent upon **medically defined admission criteria (a diagnosis of ESRD)** [emphasis is original] and is not based on ability to pay, race, ethnicity, sex, handicap, nor age. . . .*

*. . . A transfer of ICH stations from TDC will better balance the WFUHS facilities’ utilization levels, **improving overall access** [emphasis in original] within the service area.”*

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 applicants propose to add two dialysis stations, pursuant to the facility need methodology, and relocate five stations, pursuant to Policy ESRD-2, for a total of 48 dialysis stations at the existing HPKC facility upon project completion.

In Section E, pages 37-38, the applicants describe the alternatives considered and explain 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:

- Maintain Status Quo – the applicants state that this alternative is not effective because failing to address the facility need at HPKC could have undesirable consequences such as the need for a third shift, patient travel issues, and patient non-compliance.
- Policy ESRD-2, In-County Transfer – HPKC is one of only two WFUHS dialysis centers in Guilford County. The applicants state that TDC, the other WFUHS dialysis facility, is operating at just above 80% utilization, as of February 28, 2019, and though a transfer of any stations will ultimately result in higher utilization at TDC, it will dramatically reduce utilization at HPKC,

improving access to all patients within the service area and balancing utilization between the two facilities.

- Policy ESRD-2, Contiguous County Transfer – the applicants state that WFUHS has dialysis facilities in contiguous counties from which stations might be relocated, pursuant to Policy ESRD-2. However, Guilford County has a surplus of three 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.
- Facility Need Methodology – the applicants state that the facility need methodology indicates that HPKC is eligible to add up to two stations and the patient projections and utilization calculations demonstrate that seven total stations are needed at HPKC.
- Hybrid (Combination Policy ESRD-2 and Facility Need Methodology) – the applicants state that combining Policy ESRD-2 and the facility need methodology meets the projected need at HPKC and will improve overall access to the ESRD patients in the service area.

On page 39, the applicants state that the project as proposed is the most effective alternative because the hybrid model is the only alternative considered that provides a total of seven stations which is the projected need. The applicants state:

“Maintaining the status quo will harm access to services by causing HPKC utilization to continue to rise, requiring a third shift to serve all of its patients. An in-county transfer from TDC of all 7 stations would result in utilization at TDC to rise above 100%. HPKC may add no more than two (2) stations via facility need methodology, which falls far short of the seven (7) it requires. A contiguous county transfer is not possible because Guilford County has a three (3) station surplus. Thus, the only remaining and viable option to reduce the utilization rate at HPKC, enhance access to services, rebalance utilization among the WFUHS Guilford County facilities, and meet the need projected for HPKC is to request additional stations via facility need methodology and in-county transfer from TDC for a total of 7 additional stations at HPKC via this CON application .”

The applicants adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory and regulatory review criteria.
- The applicants provide 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, 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. 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 shall materially comply with all representations made in the certificate of need application.**
 - 2. Wake Forest University Health Sciences and High Point Kidney Center of Wake Forest University shall add no more than two additional dialysis stations and relocate no more than five stations from Triad Dialysis Center for a total of no more than 48 certified dialysis stations at High Point Kidney Center 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), which shall include any home hemodialysis training or isolation stations.**
 - 3. Upon completion of this project, Wake Forest University Health Sciences shall take the necessary steps to decertify five stations at Triad Dialysis Center for a total of no more than 22 dialysis stations.**
 - 4. Wake Forest University Health Sciences and High Point Kidney Center of Wake Forest University shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicants propose to add two dialysis stations, pursuant to the facility need methodology, and relocate five stations, pursuant to Policy ESRD-2, for a total of 48 dialysis stations at the existing HPKC facility upon project completion.

Capital and Working Capital Costs

In Section F.1, page 41 of the application, the capital cost table is not filled in. However, because this is an expedited review, the Agency is able to rely upon the digital second copy which does include the properly filled in table for capital costs, as shown below.

		Total Costs
Dialysis Machines	\$101,500	
Other Equipment/Furniture	\$16,100	
Total Capital Costs		\$117,600

In Section F, pages 44-45, the applicants state that HPKC is an existing operational facility; therefore, there are no start-up or initial operating expenses.

Availability of Funds

In Section F.2, page 42 of the application, the sources of capital table is not filled in. However, because this is an expedited review, the Agency is able to rely upon the digital second copy which does include the properly filled in table, as shown below.

Type	Wake Forest University Health Sciences	High Point Kidney Center	Total
Loans			
Accumulated reserves or OE *	\$117,600		\$117,600
Bonds			
Other (Specify)			
Total Financing	\$117,600		\$117,600

* OE = Owner's Equity

In Exhibit F-5, the applicants provide a letter dated March 15, 2019, from the President of the Wake Forest Baptist Health System, authorizing the project and committing \$117,600 for the development of the project.

Exhibit F-7 contains Consolidated Financial Statements for Wake Forest University for the fiscal year ended June 30, 2018, showing WFUHS with \$16,242,000 in cash and cash equivalents, \$1.37 billion in total assets and \$794,745,000 in net equity.

The applicants adequately demonstrate the availability of funds for the capital needs of the project.

Financial Feasibility

The applicants provide pro forma financial statements for the first two full fiscal years of operation following completion of this project. In Form B, the applicants project

that revenues will exceed operating expenses in the first two operating years of this project, as shown in the table below.

High Point Kidney Center Revenue and Expenses		
	OY1	OY2
In-Center Patients*	151	157
PD Patients*	65	68
In-Center Treatments	22,650	23,550
PD Treatments	21,320	22,304
Gross Patient Revenue (IC and PD)	\$58,430,470	\$ 60,859,807
Adjustment from Gross**	\$48,983,983	\$50,972,878
Net Patient Revenue (IC and PD)	\$9,446,487	\$9,886,929
Average Net Revenue per IC and PD Patient	\$43,734	\$43,942
Total Operating Expenses (IC and PD)	\$6,830,829	\$7,055,634
Average Operating Expense per IC and PD Patient	\$31,624	\$31,358
Net Income	\$2,615,658	\$2,831,295

*Average patients per year calculated per Assumption 2, page 96 of Section R

**Includes charity care and bad debt

Totals may not sum due to rounding

The assumptions used by the applicants in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section R of the application for the assumptions 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 because the applicants adequately demonstrate 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 applicants propose to add two dialysis stations, pursuant to the facility need methodology, and relocate five stations, pursuant to Policy ESRD-2, for a total of 48 dialysis stations at the existing HPKC facility upon project completion.

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.” The facility is located in Guilford County; thus, the service area for this facility consists of Guilford County. Facilities may also serve residents of counties not included in their service area.

According to the January 2019 SDR, there are ten existing and approved dialysis facilities in Guilford County, as follows:

Guilford County Dialysis Facilities

Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
BMA of Greensboro (FMC)	56	81.70%	3.2679
BMA of South Greensboro (FMC)	49	95.92%	3.8367
BMA of Southwest Greensboro (FMC)	33	74.24%	2.9697
FMC of East Greensboro (FMC)	39	87.18%	3.4872
Fresenius Kidney Care Garber-Olin (FMC Proposed new site)	0	0.00%	0.0000
FMC High Point (FMC)	10	75.00%	3.0000
Guilford County Dialysis (TRCNC Proposed Site)*	0	0.00%	0.0000
High Point Kidney Center (WFUHS)	41	92.07%	3.6829
Northwest Greensboro Kidney Center (FMC)	37	76.35%	3.0541
Triad Dialysis Center (WFUHS)	27	79.63%	3.1852

Source: January 2019 SDR, Table B.

* Project ID #G-11439-17 approved the relocation of stations from contiguous counties to establish Guilford County Dialysis. The decision was appealed and the application has been withdrawn.

Fresenius related entities own and operate seven of the ten existing and proposed dialysis facilities in Guilford County. Wake Forest University Health Sciences owns and operates two facilities and Total Renal Care of North Carolina was approved to develop a new facility in Guilford County (Project ID #G-11439-17, currently in appeal). With the exception of the proposed and newly-operational projects, each of the existing dialysis facilities is well-utilized, operating near or above 3.0 patients per station.

In Section G, page 48, the applicants explain why they believe the proposal would not result in the unnecessary duplication of existing or approved dialysis services in

Guilford County. The applicants state that the addition of stations will be accomplished by adding two stations via facility need and relocating five stations within Guilford County pursuant to Policy ESRD-2. The applicants further state:

“The project will essentially move stations from a location of low utilization to a location of high utilization and rebalance the utilization rates at both locations in the process while improving overall access in the services area. The projected end of OY1 utilization rate for HPKC with the addition of stations and patients will exceed the required utilization rate of 80% and will not result in a duplication of existing and approved facilities in the service area.”

The applicants adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is a facility need determination in the 2019 SMFP for the proposed addition of stations.
- The proposal would not result increase the number of stations in Guilford County.
- The applicants adequately demonstrate that the proposed stations are needed in addition to the existing and/or approved stations in Guilford 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 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 H, page 49, the applicant provides the current and projected staffing for the proposed services, as summarized in the following table showing full-time equivalent (FTE) positions.

POSITION	Current FTE Positions as of 12/31/18	PROJECTED FTE POSITIONS OY2
RN	7.75	7.75
LPN	1.75	1.75
Patient Care Tech	15.75	15.75
Clinical Nurse Manager (DON)	1.00	1.00
Dietician	2.00	2.00
Social Worker	2.00	2.00
Home Training Nurse	2.25	2.25
Dialysis Tech	4.00	4.00
Bio-med Technician	1.00	1.00
Clerical	4.25	4.25
Total	41.75	41.75

Source: Sections H and R of the application.

The Medical Director and administrative services, including medical records, are contract services, not FTE positions.

In Section I.2(c), page 59, the applicants state:

“HPKC provides ICH services as well as access to home training and support services such that all modalities of dialysis are available, offering a full range of dialysis options to its patients who qualify for those services.”

The assumptions and methodology used to project staffing are provided in Sections H and R. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in the pro forma financials found in Section R. In Section H, pages 53-54, the applicants describe the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 51, and Section I.3, page 59, the applicants identify the current Medical Director. In Exhibit I.3(a), the applicant provides a letter from Vickie Stovall, M.D., indicating a commitment to continue to serve as Medical Director for the facility. In Exhibit H.2, the applicants provide supporting documentation.

The applicants adequately demonstrate 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 57-58, the applicants identify the necessary ancillary and support services and explains how they will be made available. The applicants provide a table on page 57, as summarized below.

**High Point Kidney 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	On Premises
(2) Peritoneal dialysis	On Premises
(3) Accessible follow-up program	On Premises
(d) Psychological counseling	On Premises
(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
(l) X-ray services	Wake Forest Baptist Hospital
(m) Laboratory services	Wake Forest Baptist Hospital Meridian Lab Contract/On Premises
(n) Pediatric nephrology	On Premises
(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	Assorted transports per Exhibit I-1(q)

In Section I, pages 58-61, the applicants describe HPKC’s existing and proposed relationships with other local health care and social service providers and provide supporting documentation in Exhibits I-1, I-2 (a-c), I-3(a-b), I.4(a), and Exhibit M-1.

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

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 applicants do 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 applicants do 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 applicants are not HMOs. 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 applicants do not propose any new construction or renovations to 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.7, page 78, the applicants provide HPKC's historical payor mix for the last full operating year for the proposed services, as shown in the table below.

Payor Source	Total Patients	In-center Patients	PD Patients
Private Pay	0.0%	0.0%	0.0%
Medicare	13.0%	17.0%	9.0%
Medicaid	3.0%	6.0%	0.0%
Medicare / Medicaid	13.0%	17.0%	9.0%
Commercial Insurance	12.0%	6.0%	18.0%
Medicare / Commercial	24.0%	20.0%	28.0%
VA	4.0%	5.0%	3.0%
Medicare Advantage	31.0%	29.0%	33.0%
Total	100.0%	100.0%	100.0%

Totals may not sum due to rounding

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

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Guilford	15%	53%	50%	18%	7%	11%
Statewide	16%	51%	37%	15%	10%	12%

Source: <http://www.census.gov/quickfacts/table/US/PST045217> Latest Data 7/1/17 as of 7/17/18

* Excludes "White alone, not Hispanic or Latino"

** "Estimates are not comparable to other geographic levels due to methodology differences that may exist between different data sources. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states. The 2016 Annual Report does not provide state-specific ESRD patient data, but the aggregate data is likely to be similar to North Carolina's based on the Network's recent annual reports which included state-specific data.

The IPRO SA Network 6 2016 Annual Report (pages 25-26¹) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

Conclusion

The Agency reviewed the:

¹ <https://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/07/NW6-2016-Annual-Report-FINAL.pdf>

- 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 applicants adequately document the extent to which medically underserved populations currently use the applicants' existing services in comparison to the percentage of the population in the applicants' 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.3(d), pages 75-76, the applicants state:

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

In Section L.6, page 77, the applicants state that there have been no civil rights access complaints filed against the facility or any facilities owned by the parent company in North Carolina 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.1(b), page 71, the applicants project 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 OY2
3/1/2021 - 2/28/2022**

Payor Source	Total Patients	In-center Patients	PD Patients
Private Pay	0.00%	0.00%	0.00%
Medicare	15.00%	15.00%	15.00%
Medicaid	4.00%	6.00%	1.00%
Medicare / Medicaid	15.00%	21.00%	9.00%
Commercial Insurance	12.00%	6.00%	19.00%
Medicare / Commercial	22.00%	21.00%	23.00%
VA	6.00%	6.00%	5.00%
Medicare Advantage	26.00%	25.00%	28.00%
Total	100.0%	100.0%	100.0%

Source: Application page 71

As shown in the table above, during the second full calendar year of operation, the applicants project that 0% of the dialysis patients will be private pay patients and 82% will have all or part of their services paid for by Medicare and/or Medicaid.

On pages 71-72, the applicants provide the assumptions and methodology used to project payor mix during the first and second fiscal full years of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- the applicants' proposed patient origin is comparable to its historical patient origin, and
- the applicants project future payor mix based on the facility's average monthly payor mix by payor type for each of the last five operating 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.

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

C

In Section L.4, pages 76-77, the applicants adequately describe 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 80, the applicants describe the extent to which health professional training programs in the area have access to the facility for training purposes and provide 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 applicants adequately demonstrate 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 applicants propose to add two dialysis stations, pursuant to the facility need methodology, and relocate five stations, pursuant to Policy ESRD-2, for a total of 48 dialysis stations at the existing HPKC facility upon project completion.

On page 369, the 2019 SMFP defines the service area for dialysis stations as “...*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” The facility is located in Guilford County; thus, the service area for this facility consists of Guilford County. Facilities may also serve residents of counties not included in their service area.

According to the January 2019 SDR, there are ten existing and approved dialysis facilities in Guilford County, as follows:

Guilford County Dialysis Facilities

Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
BMA of Greensboro (FMC)	56	81.70%	3.2679
BMA of South Greensboro (FMC)	49	95.92%	3.8367
BMA of Southwest Greensboro (FMC)	33	74.24%	2.9697
FMC of East Greensboro (FMC)	39	87.18%	3.4872
Fresenius Kidney Care Garber-Olin (FMC Proposed new site)	0	0.00%	0.0000
FMC High Point (FMC)	10	75.00%	3.0000
Guilford County Dialysis (TRCNC Proposed Site)*	0	0.00%	0.0000
High Point Kidney Center (WFUHS)	41	92.07%	3.6829
Northwest Greensboro Kidney Center (FMC)	37	76.35%	3.0541
Triad Dialysis Center (WFUHS)	27	79.63%	3.1852

Source: January 2019 SDR, Table B.

* Project ID #G-11439-17 approved the relocation of stations from contiguous counties to establish Guilford County Dialysis. The decision was appealed and the application has been withdrawn.

Fresenius related entities own and operate seven of the ten existing and proposed dialysis facilities in Guilford County. Wake Forest University Health Sciences owns and operates two facilities and Total Renal Care of North Carolina was approved to develop a new facility in Guilford County (Project ID #G-11439-17, currently in appeal). With the exception of the proposed and newly-operational projects, each of the existing dialysis facilities is well-utilized, operating near or above 3.0 patients per station.

In Section N, pages 81-82, the applicants describe the expected effects of the proposed services on competition in the service area and discuss how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 81, the applicants state:

“This project shall have no impact on competition in Guilford County. The proposed project does not assume to capture patients utilizing another provider within the county. It proposes to serve the existing and projected patients anticipated to utilize the services of HPKC, alone. Patients utilize a facility based upon physician preference, geographical location, or other reasons of convenience. An addition of stations at HPKC is necessary to serve the facility’s existing and projected patients and serve Guilford County residents suffering with ESRD. ... The proposed project will improve the overall cost-effectiveness, quality, and access to ESRD services in Guilford County.”

The applicants adequately describe the expected effects of the proposed services on competition in the service area and adequately demonstrate:

- the cost-effectiveness of the proposal (see Sections B, page 21, F, K and R of the application and any referenced exhibits),
- quality services will be provided (see Section B, pages 11-16, and Section O of the application and any referenced exhibits), and
- access will be provided to underserved groups (see Section B, pages 16-21, and Section L of the application and any referenced 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 A.11, pages 5-6, the applicants identify the dialysis facilities located in North Carolina and owned, operated or managed by the applicant or a related entity. The applicants identify a total of 18 WFUHS dialysis facilities located in North Carolina.

In Section O, pages 83-84, the applicant states that during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in five of the 18 facilities. The applicant states that at the time of application submittal, all facilities are 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 End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

-NA- The applicants are not proposing to establish a new ESRD facility.

(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the

review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.

- C- In Section C.2, pages 25-27, the applicants provide the calculations used to arrive at the projected in-center patient census for the first two years of operation following the completion of the project.

As fully discussed in Criterion (3) above, the methodology used by the applicants achieves a projection of 153.65 in-center patients by the end of the first operating year, OY1, for a utilization rate of 3.2 patients per station per week or 80.0% ($153.65 \text{ patients} / 48 \text{ stations} = 3.201 \text{ patients per station} / 4 = 0.8002$). The projected utilization of 3.2 patients per station per week for OY1 satisfies the 3.2 in-center patients per station threshold as required. The discussion on projected utilization in Criterion (3) is incorporated herein by reference.

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

- C- In Sections C.1 and C.7, pages 24-25 and 30-31, respectively, the applicants provide the assumptions and methodology used to project utilization of the facility.