

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 2, 2019

Findings Date: December 2, 2019

Project Analyst: Gregory F. Yakaboski

Team Leader: Gloria C. Hale

Project ID #: G-11795-19

Facility: King Dialysis Center of Wake Forest University

FID #: 020980

County: Stokes

Applicants: Wake Forest University Health Sciences

King Dialysis Center of Wake Forest University

Project: Add no more than 7 dialysis stations for a total of no more than 24 stations upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Wake Forest University Health Sciences (WFUHS) and King Dialysis Center of Wake Forest University (King Dialysis Center), collectively “the applicants”, propose to add no more than 7 dialysis stations to King Dialysis Center for a total of no more than 24 dialysis stations upon project completion. King Dialysis Center currently offers a peritoneal dialysis (PD) program but does not currently offer a home hemodialysis (HH) program.

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 July 2019 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of seven dialysis stations in Stokes County. Therefore, because the deficit is less than 10 stations, there is no county need determination for new dialysis stations for Stokes County.

However, the applicants are eligible to apply for additional stations based on the facility need methodology because the utilization rate reported for King Dialysis Center in Table B of the July 2019 SDR is 3.5882 patients per station per week. This utilization rate was calculated based on 61 in-center dialysis patients and 17 certified dialysis stations. (61 patients / 17 stations = 3.5882 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 seven additional stations is needed for this facility, as illustrated in the following table.

OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/18		89.7%
Certified Stations		17
Pending Stations		0
Total Existing and Pending Stations		17
In-Center Patients as of 12/31/18 (July 2019 SDR) (SDR2)		61
In-Center Patients as of 6/30/18 (Jan 2019 SDR) (SDR1)		54
Step	Description	Result
	Difference (SDR2 - SDR1)	7
(i)	Multiply the difference by 2 for the projected net in-center change	14
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/18	0.2593
(ii)	Divide the result of Step (i) by 12	0.0216
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/17 until 12/31/18)	0.2593
(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	76.8148
(v)	Divide the result of Step (iv) by 3.2 patients per station	24.0046
	and subtract the number of certified and pending stations to determine the number of stations needed	7.0046

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is seven 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 7 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 is one policy in the 2019 SMFP that is applicable to this review, Policy GEN-3: Basic Principles.

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.3(a), pages 10-15, 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.3(b), pages 15-19, referencing other application sections and exhibits; and Section N.2(c), page 70. 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.3(c), page 19, referencing Sections F and K; and in Section N.2(a), page 70. 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 King Dialysis Center’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.

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 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 no more than 7 dialysis stations to King Dialysis Center for a total of no more than 24 dialysis stations upon project completion.

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.*” King Dialysis Center is located in Stokes County. Thus, the service area for this review is Stokes County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin.

	Current (8/1/18 to 7/31/19)				OY2 (8/1/21 to 7/31/22)			
	# of IC Patients	% of Total	# of PD Patients	% of Total	# of IC Patients	% of Total	# of PD Patients	% of Total
Stokes	46.00	83.64%	5.00	41.67%	71.62	80.02%	7.78	50.12%
Forsyth	3.00	5.45%	2.00	16.67%	3.42	3.83%	2.28	14.69%
Surry	2.00	3.64%	1.00	8.33%	2.37	2.65%	1.18	7.62%
Guilford	0.00	0.00%	1.00	8.33%	0.00	0.00%	1.17	7.54%
Rockingham	0.00	0.00%	2.00	16.67%	0.00	0.00%	2.11	13.58%
Henry County, VA	0.00	0.00%	1.00	8.33%	0.00	0.00%	1.00	6.44%
Stokes Transfer In	4.00	7.27%	0.00	0.00%	12.09	13.51%	0.00	0.00%
Total	55.00	100.00%	12.00	100.00%	89.50	100.00%	15.53	100.00%

Source: Section C, Tables on pages 22-23.

In Section C, pages 23-24, the applicants provide the assumptions and methodology used to project its patient origin. The applicants’ assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, the applicants explain why they believe the population projected to utilize the proposed services needs the proposed services. The applicants state:

- The facility need methodology shows a need to add seven dialysis stations to the existing King Dialysis Center facility.
- As of December 31, 2018, based on 17 certified stations, King Dialysis Center was operating at 89.71% utilization (See application page 44).
- In Sections C.3 and C.4, page 24, the applicants state that the facility must request additional stations now to head off excessive utilization in the future. In the table on page 24, based on 17 certified stations, the applicants project utilization of 99.36% at King Dialysis Center as of July 31, 2020 and utilization projected to reach 131.61% by July 31, 2022, if no stations are added.
- In Section C.4, page 25, the applicants state, *“When a patient requires isolation, the 100% utilization rate of a single station decreases from 4 patients per station to 2 patients per station, since isolation stations may only be used once in a 24-hour period.”*
- There is a projected station deficit in Stokes County of seven stations per Table D *ESRD Dialysis Station Need Determinations by Planning Area*, page 63, of the July 2019 SDR.

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

- the facility is currently operating at 89.71% capacity with 17 stations and is expected to reach more than 100% capacity by July 31, 2020, if no stations are added,
- the applicants base the future need for services upon the facility’s historical patient utilization, applying the July 2019 SDR’s 5-year county AACR of 15.9%, 4.5%, 5.4%, 1.8% and 5.8%, for patients from Stokes, Forsyth, Guilford, Rockingham, and Surry counties, respectively, to project growth in patient need at the facility.
- no projected growth is applied to patients residing outside North Carolina

Projected Utilization

In-Center Patients

In Section C.3, page 24, 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 historical and projected utilization of in-center dialysis patients at King Dialysis Center.

King Dialysis Center In-Center Dialysis Utilization

County	July 2019 SDR 5-Yr AACR	Beginning Census 7/31/2019	Growth as of Certification 7/31/2020	End of OY1 7/31/2021	End of OY2 7/31/2022
Stokes	15.9%	46.00	53.31	61.79	71.62
Forsyth	4.5%	3.00	3.14	3.28	3.42
Guilford	5.4%	0.00	0.00	0.00	0.00
Rockingham	1.8%	0.00	0.00	0.00	0.00
Surry	5.8%	2.00	2.12	2.24	2.37
Stokes Transfers In	15.9%	4.00	9.0*	10.43	12.09
Henry County, VA	0.0%	0.00	0.00	0.00	0.00
Totals		55.00	67.57	77.74	89.50

Totals may not sum due to rounding

*Includes 5 existing Stoke County residents currently dialyzing at other WFUHS dialysis facilities projected to transfer their care to King Dialysis Center upon project completion.

As the table above shows, the methodology used by the applicants achieves a projection of 77.74 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% (77 patients / 24 stations = 3.2/ 4 = 0.80 or 80.0%). By the end of OY2, following the applicants’ methodology and assumptions, King Dialysis Center will have 89.5 in-center patients dialyzing at the center for a utilization rate of 92.7% (89 / 24 = 3.708 / 4 = .927 or 92.7%). 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.3, pages 23-24, the applicants provide the methodology and assumptions used to project utilization at King Dialysis Center. Based on the facility need methodology, King Dialysis Center is eligible to add seven dialysis stations.

The applicants' methodology and assumptions are summarized below:

- Existing patients are grouped by modality and county of origin, as of July 31, 2019.
- Utilization is based on current patients at King Dialysis Center, projected forward by applying the July 2019 SDR 5-year Average Annual Change Rate (AACR), by county of patient origin, to the current patient populations to project patient census through the end of Operating Year 2.
- OY1 ends July 31, 2021; OY2 ends July 31, 2022.
- At least 5 IC patients will transfer their care from other WFUHS dialysis facilities.

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,
- The applicants base the future need for services upon the facility's historical patient utilization, applying the July 2019 SDR's 5-year county AACR of 15.9%, 4.5%, 5.4%, 1.8% and 5.8%, for patients from Stokes, Forsyth, Guilford, Rockingham, and Surry counties, respectively, to project growth in patient need at the facility.
- Based on the Facility Need Methodology King Dialysis Center has a need for seven dialysis stations.

Peritoneal Patients

The following table summarized from the table on page 24 shows the historical PD utilization at King Dialysis Center.

King Dialysis Center PD Dialysis Historical Utilization
As of 7/31/2019

County	PD	HH	Total
PD Patients	12	0	12

Following the same assumptions and methodology as above, the applicants project 15 PD patients in OY2, as shown in Section C.3, pages 23 and 24.

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 base the future need for services upon the facility's historical patient utilization, applying the July 2019 SDR's 5-year county AACR of 15.9%, 4.5%, 5.4%,

1.8% and 5.8%, for patients from Stokes, Forsyth, Guilford, Rockingham, and Surry counties, respectively, to project growth in patient need at the facility.

- no projected growth is applied to patients residing outside North Carolina

Access

In Section L.2(b), page 62, the applicants state:

“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. Patients are accepted for care based upon specifically defined admissions criteria- a diagnosis of ESRD and appropriate referral for care. The facility’s design complies with the ADA standards...”

In Section C.7(a), page 28, the applicants state, *“Admission of a patient is based upon medical necessity and not the patient’s ability to pay. Patients may only access the facility’s services via physician referral due to a diagnosis of ESRD.”*

In supplemental information the applicants project the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

Projected Payor Mix OY2

Payor Source	Percent of Total Patients	Percent of In-center Patients	Percent of PD Patients
Private Pay	1.00%	1.00%	0.00%
Medicare	13.00%	13.00%	7.00%
Medicaid	4.00%	4.00%	9.00%
Medicare / Medicaid	14.00%	14.00%	19.00%
Commercial Insurance	9.00%	8.00%	20.00%
Medicare / Commercial	20.00%	20.00%	20.00%
VA	8.00%	8.00%	9.00%
Medicare Advantage	31.00%	32.00%	16.00%
Total	100.0%	100.0%	100.0%

Source: Supplemental Information.

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application,
- Exhibits to the application
- Supplemental information requested by the Agency
- 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 support their 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 applicants do not propose a reduction or elimination of a service, or the relocation of a facility or a 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 applicants propose to add no more than 7 dialysis stations to King Dialysis Center for a total of no more than 24 dialysis stations upon project completion.

In Section E, pages 36-38, 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:

- *Transfer Stations from a Contiguous County per Policy ESRD-2*- The applicants state that WFUHS, the parent of King Dialysis Center, does have dialysis facilities in the counties of Surry, Yadkin, Forsyth and Guilford which are all contiguous to Stokes County. However, the applicants describe in detail on page 36 why transferring stations from any of those dialysis facilities to King Dialysis Center is not feasible. The facilities owned by WFUHS in those counties are either in counties with dialysis station deficits, are already well utilized, or do not currently serve Stokes County residents. Therefore, this is not the least costly or most effective alternative.
- *Add Less than 7 Stations*- The Facility Need Methodology identifies a need for 7 additional stations at King Dialysis Center. The applicants state that adding less than 7 additional

stations will not meet the projected patient needs. Therefore, this is not the least costly or most effective alternative.

On page 36, the applicants state that its proposal is the most effective alternative because the proposed project meets the projected patient population need of 7 dialysis stations using the Facility Need Methodology.

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

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 King Dialysis Center of Wake Forest University shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, Wake Forest University Health Sciences and King Dialysis Center of Wake Forest University shall materially comply with the last made representation.**
 - 2. Pursuant to the facility need determination in the July 2019 SDR, Wake Forest University Health Sciences and King Dialysis Center of Wake Forest University shall develop no more than seven additional dialysis stations for a total of no more than twenty-four certified stations at King Dialysis Center upon completion of this project, which shall include any home hemodialysis training or isolation stations.**
 - 3. Wake Forest University Health Sciences and King Dialysis Center of Wake Forest University shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicants propose to add no more than 7 dialysis stations to King Dialysis Center for a total of no more than 24 dialysis stations upon project completion.

Capital and Working Capital Costs

In Section Q, Form F-1(a), page 80, the applicants project the total capital costs for the project as summarized below.

In Section F, the applicants provide the assumptions used to project the capital cost.

Site Costs	\$0
Construction Costs	\$0
Miscellaneous Costs (Medical Equipment & Furniture)	\$117,600
Total	\$117,600

In Section F, the applicants provide the assumptions used to project the capital cost.

In Section F, page 41, the applicants state that King Dialysis Center is an existing operational facility; therefore, there are no start-up or initial operating expenses.

Availability of Funds

In Section F, page 39, the applicants state that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Wake Forest University Health Sciences	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-2(c)(ii), the applicants provide a letter dated September 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-2(c)(iii) 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 assets.

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 F.2, the applicants project that revenues will exceed operating expenses in the first two operating years of this project, as shown in the table below.

	1st Full Fiscal Year	2nd Full Fiscal Year
Total Treatments	13,050	14,850
Total Gross Revenues (Charges)	\$24,007,172	\$27,318,506
Total Net Revenue	\$4,061,308	\$4,610,645
Average Net Revenue per treatment	\$311	\$310
Total Operating Expenses (Costs)	\$3,410,253	\$3,851,885
Average Operating Expense per treatment	\$261	\$259
Net Income	\$651,056	\$758,759

The assumptions used by the applicants 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 for the following reasons:

- The applicants adequately demonstrate that the capital costs are based on reasonable and adequately supported assumptions.
 - The applicants adequately demonstrate availability of sufficient funds for the capital needs of the proposal.
 - 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 no more than 7 dialysis stations to King Dialysis Center for a total of no more than 24 dialysis stations 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.*” King Dialysis Center is located in Stokes County. Thus, the service area for this review is Stokes County. Facilities may also serve residents of counties not included in their service area.

According to Table B of the July 2019 SDR, King Dialysis Center is the only one existing or approved dialysis facility in Stokes County. Information on King Dialysis Center, from Table B of the July 2019 SDR, is provided below:

Stokes County Dialysis Facilities Certified Stations and Utilization as of December 31, 2018				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
King Dialysis Center	WFUHS	King	17	89.71%

Source: July 2019 SDR, Table B, page 50.

In Section G, page 44, the applicants explain why they believe the proposal would not result in the unnecessary duplication of existing dialysis services in Stokes County. The applicants state:

“KDC is the sole provider of dialysis services in Stokes County. As indicated in the July 2019 SDR, Stokes County is projected to have a 7-station deficit. Coincidentally, KDC has a projected 7-station need using facility need methodology. Given there is no other provider in the county and KDC can prove its need for the additional stations in accordance with the Performance Standards for ESRD services, there are no other ESRD services within Stokes County to duplicate. Therefore, this project will not result in an unnecessary duplication of existing or approved dialysis stations in the service area, which is Stokes County.”

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 seven stations.
- The applicants adequately demonstrate that the proposed stations are needed in addition to the existing stations in Stokes County.

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 for the reasons stated above.

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

C

In Section Q, Form H, page 91, the applicants provide current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

POSITION	Current FTE Positions as of 7/31/19	PROJECTED FTE POSITIONS OY2 (8/1/2021 TO 7/31/2022)
RN	2.0	6.0
LPN	2.0	2.0
Patient Care Tech	6.5	10.0
Clinical Nurse Manager (DON)	1.0	1.0
Dietician	1.0	1.0
Social Worker	1.0	1.0
Home Training Nurse	1.0	1.0
Dialysis Tech	1.0	1.0
Bio-med Technician	1.0	1.0
Clerical	1.0	1.0
Total	17.5	25.0

Source: Section Q, Form H, page 91 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 applicants are budgeted in Form F.2, which is found in Section Q. In Section H.2 and H.3, pages 45-47, the applicants describe the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 48, the applicants identify the current medical director. In Exhibit H-4(b), the applicants provide 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 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
- 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, page 50, the applicants state that the following ancillary and support services are necessary for the proposed services:

KING 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	Piedmont Dialysis Center On Premises King Dialysis Center
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	On Premises
X-ray services	Wake Forest Baptist Hospital
Laboratory services	Meridian Laboratory Corp.
Pediatric nephrology	Wake Forest Baptist Hospital
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 page 50-53, the applicants adequately explain how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits I-1(b)(iii), 1(b)(v), 1(b)(xviii); Exhibits I-2(a), 2(b), 2(c)(i) and Exhibits H-4(a)(i) and 4(a)(ii).

In Section I.2, pages 53-54, the applicants describe King Dialysis Center’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) and 2c(iv).

The applicants adequately demonstrate 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 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 major 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 supplemental information the applicants provide the historical payor mix during the last full OY (8/1/2018 to 7/31/2019) for the proposed services, as shown in the table below.

**Historical Payor Mix
 Last Full OY (8/1/2018 to 7/31/2019)**

Payor Source	Total Patients	In-center Patients	PD Patients
Private Pay	2.00%	2.00%	0.00%
Medicare	13.00%	13.00%	8.00%
Medicaid	7.00%	7.00%	2.00%
Medicare / Medicaid	14.00%	14.00%	21.00%
Commercial Insurance	5.00%	4.00%	20.00%
Medicare / Commercial	23.00%	23.00%	23.00%
VA	7.00%	7.00%	3.00%
Medicare Advantage	30.00%	30.00%	23.00%
Total	100.00%	100.00%	100.00%

Source: Supplemental Information.

In Section L, page 60, the applicants provide the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	36.84%	50.80%
Male	63.16%	49.20%
Unknown	n/a	n/a
64 and Younger	56.14%	78.70%
65 and Older	43.86%	21.30%
American Indian	n/a	0.50%
Asian	n/a	0.40%
Black or African-American	26.32%	4.00%
Native Hawaiian or Pacific Islander	n/a	>0.00%
White or Caucasian	73.68%	93.8%
Other Race	n/a	4.40%
Declined / Unavailable	n/a	n/a

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Information which was publicly available during the review and used by the Agency

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.(a), page 61, the applicants state:

“The facility is not required nor obligated to provide uncompensated care or community service.”

In Section L.2, page 63, the applicants state that there have been no civil rights access complaints filed against the facility in the last five years.

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 supplemental information, 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**

Payor Source	Total Patients	In-center Patients	PD & HH Patients
Private Pay	1.00%	1.00%	0.00%
Medicare	13.00%	13.00%	7.00%
Medicaid	4.00%	4.00%	9.00%
Medicare / Medicaid	14.00%	14.00%	19.00%
Commercial Insurance	9.00%	8.00%	20.00%
Medicare / Commercial	20.00%	20.00%	20.00%
VA	8.00%	8.00%	9.00%
Medicare Advantage	31.00%	32.00%	16.00%
Total	100.00%	100.00%	100.00%

Source: Supplemental Information.

As shown in the table above, during the second full calendar year of operation, the applicants project that 1% of the dialysis patients will be private pay patients and 82% will have all or part of their services paid for by Medicare (includes Medicare/Commercial and Medicare Advantage) and/or Medicaid.

On pages 63-64 and in supplemental information, 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
- Supplemental information requested by the Agency
- Exhibits to the application.

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

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

C

In Section L.5, pages 66-67, the applicants adequately describe the range of means by which patients will have access to the proposed services.

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 69, the applicants describe the extent to which health professional training programs in the area have access to the facility for training purposes.

The Agency reviewed the:

- Application
- 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 no more than 7 dialysis stations to King Dialysis Center for a total of no more than 24 dialysis stations 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.*” King Dialysis Center is located in Stokes County. Thus, the service area for this review is Stokes County. Facilities may also serve residents of counties not included in their service area.

According to Table B of the July 2019 SDR, King Dialysis Center is the only one existing or approved dialysis facility in Stokes County. Information on King Dialysis Center, from Table B of the July 2019 SDR, is provided below:

Stokes County Dialysis Facilities Certified Stations and Utilization as of December 31, 2018				
Dialysis Facility	Owner	Location	# of Certified Stations	Utilization
King Dialysis Center	WFUHS	King	17	89.71%

Source: July 2019 SDR, Table B, page 50.

In Section N, pages 70-71, the applicants describe the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 70, the applicants state:

“Since WFUHS is the sole provider of dialysis services in Stokes County, competition is not a factor, whatsoever.”

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

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)

- Access will be provided to underserved groups (see Section L 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 for the reasons stated above.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section Q, Form A, page 76, the applicants identify the dialysis facilities located in North Carolina and owned, operated or managed by the applicants or a related entity. The applicants identify a total of 18 WFUHS dialysis facilities located in North Carolina.

In Section O, pages 72-73, the applicants state 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, but none of these resulted in a finding of immediate jeopardy. The applicants state that at the time of application submittal, all facilities were in compliance. After reviewing and considering information provided by the applicants and considering the quality of care provided at all 18 facilities, the applicants provide 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.3, page 24, 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 77.74 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% ($77 \text{ patients} / 24 \text{ stations} = 3.2 / 4 = 0.80$ or 80.0%). 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). The discussion related to 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 Section C, pages 22-24, the applicants provide the assumptions and methodology used to project utilization of the facility.