

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 29, 2019

Findings Date: May 29, 2019

Project Analyst: Ena Lightbourne

Team Leader: Fatimah Wilson

Project ID #: G-11676-19

Facility: Salem Kidney Center

FID #: 944758

County: Forsyth

Applicants: Wake Forest University Health Sciences

Salem Kidney Center of Wake Forest University

Project: Add no more than one dialysis station and relocate no more than three dialysis stations from Northside Dialysis Center for a total of 51 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

The applicants, Wake Forest University Health Sciences (WFUHS) and Salem Kidney Center of Wake Forest University (SKC) collectively referred to as “the applicant”, proposes to add no more than one dialysis station and relocate no more than three dialysis stations from Northside Dialysis Center (NDC) in Forsyth County pursuant to Policy ESRD-2, to the existing Salem Kidney Center (SKC) for a total of 51 stations upon project completion.

Need Determination

The 2019 State Medical Facilities Plan (2019 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2019 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of four stations in Forsyth County. Therefore, the January 2019 SDR does not indicate a need for additional stations in Forsyth County based on the county need methodology, which states that the county deficit must be 10 or greater to establish a need for additional stations. However, the applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80 percent. The utilization rate reported for SKC in the January 2019 SDR is 3.7692 patients per station per week, or 94.23 percent, based on 147 in-center dialysis patients and 39 certified dialysis stations [$147 / 39 = 3.7692$; $3.7692 / 4 = 0.9423$ or 94.23%].

Application of the facility need methodology indicates up to one additional station is needed at this facility, as illustrated in the following table.

April 1 Review-January 2019 SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/2018		94.23%
Certified Stations		45
Pending Stations		2
Total Certified and Pending Stations		47
In-Center Patients as of 6/30/2018 (January 2019 SDR) (SDR2)		147
In-Center Patients as of 6/30/2017 (January 2018 SDR) (SDR1)		141
Step	Description	Result
	Difference (SDR2 - SDR1)	6
(i)	Multiply the difference by 2 for the projected net in-center change	12
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/17	0.0851
(ii)	Divide the result of Step (i) by 12	0.0070
(iii)	Multiply the result of Step (ii) by 6	0.0425
(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	153.2553
(v)	Divide the result of Step (iv) by 3.2 patients per station	47.8922
	and subtract the number of certified and pending stations to determine the number of stations needed	0.8922 1

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is one station. Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add no more than one new station based on the facility need; therefore, the facility need determination for one dialysis station is applicable to this review.

Policies

There are two policies in the 2019 SMFP which are applicable to this review. Policy *ESRD-2: Relocation of Dialysis Stations*, on page 25, and Policy *GEN-3: Basic Principles*, on page 31 of the 2019 SMFP.

Policy ESRD-2: Relocation of Dialysis Stations 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 existing dialysis stations within Forsyth County, thus there will be no change to the dialysis station inventory of Forsyth County as a result of the proposed project. Therefore, the application is consistent with Policy ESRD-2.

Policy GEN-3: Basic Principles states:

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

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B.4, pages 11-16; Section K.1 (g), pages 62-63; Section N.1, page 78, and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal would promote safety and quality.

Promote Equitable Access

The applicant describes how they believe the proposed project would promote equitable access in Section B.4, pages 16-24; Section C.3, page 26; Section L, pages 66-71; Section N.1, page 78, and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal would promote equitable access.

Maximize Healthcare Value

The applicant describes how they believe the proposed project would maximize healthcare value in Section B.4(c), page 21; referencing Sections C.1-3 and 7; Section F, pages 38-41; Section K, page 61; Section N.1, page 78, and referenced exhibits. The information provided by the applicant with regard to their efforts to maximize healthcare value is reasonable and supports the determination that the applicant's proposal would maximize healthcare value.

The applicant adequately demonstrates how its proposal incorporates the concepts of quality, equitable access, and maximum value for resources expended in meeting the facility need as identified by the applicant. 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 applicant proposes to add no more than one dialysis station and relocate no more than three dialysis stations from NDC to SKC for a total of 51 stations upon project completion.

The applicant does not currently provide nor proposes in this application to provide home hemodialysis (HHD) or Peritoneal (PD). Patients are referred to NDC and PDC.

The following table, summarized from data on page 4 of the application and Table B of the January 2019 SDR, illustrates the current and projected number of dialysis stations at SKC. However, the applicant's table does not include the three stations proposed to be relocated from NDC. The Project Analyst included this information in the applicant's table, as shown below.

Stations	Description	Project ID #
45	Total existing certified stations as of the January 2019 SDR	
1	Stations to be added as part of this project	G-11676-19
3	Three stations to be relocated from NDC and added as part of this project	G-11676-19
2*	Stations previously approved to be added but not yet certified.	G-11586-18
51	Total stations upon completion of proposed project	

*Two stations were certified pursuant to Project ID# G-11586-18 on April 23, 2019

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.” Thus, the service area for this facility consists of Forsyth County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates historical patient origin as of February 28, 2019 and projected patient origin for the end of Operating Year 1 (OY1) and the end of Operating Year 2 (OY2).

SKC Patients by County – Historical and Operating Years 1 & 2					
County	As of 2/28/2019	End of OY1 CY 2021	End of OY2 CY 2022	County Patients as % of Total	
	IC	IC	IC	OY1	OY2
Davidson	1.00	1.15	1.23	0.68%	0.70%
Forsyth	150.00	161.62	167.76	96.11%	96.09%
Guilford	3.00	3.21	3.32	1.91%	1.90%
Rockingham	1.00	1.05	1.08	0.62%	0.62%
Stokes	1.00	1.13	1.21	0.67%	0.69%
Totals	156.00	168.16	174.59	100.00%	100.0%

Total may not foot due to rounding
 Source: Section C, page 23 and 29

In Section C, pages 23-26, the applicant provides the assumptions and methodology used to project patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 25-26, the applicant explains why they believe the population projected to utilize the proposed services needs the proposed services.

On page 25, the applicant states:

“The current utilization rate for SKC (for 45 stations) is 86.67%. SKC recently received a previously requested CON to add another 2 stations for a total of 47 stations, but those stations are not yet certified. With 47 total stations, the facility’s utilization rate is 82.98%. The utilization rate by 2/28/2020 is projected to be 86.1%, and is projected to reach at least 89.44% utilization by 2/28/2021, if no stations are added.”

On page 26, the applicant states:

“The greatest impact to the SKC utilization rate occurs when four (4) stations are added. Given that facility need methodology returns a one-station need and SKC can show utilization above 80% by the end of OY1 for more than one station, it is clear more than 1 additional station is required to reduce SKC’s utilization rate nearer to 80%. Based on the projections at least 4 new stations are needed to accommodate the existing and projected patient population for a total of 51 stations upon project completion.”

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

- The facility is currently operating at 82.98% capacity with 47 stations. This includes the two stations approved for Project ID# G-11586-18 certified on April 23, 2019. The applicant reasonably projects that the utilization rate of the facility will reach 89.98% (168.16 patients / 47 stations = 3.5778/4 = 0.8944 or 89.44) by the 2/28/2021 if no new stations are added.
- With the addition of one dialysis station and the relocation of three dialysis stations from NDC, the applicant reasonably projects that the utilization rate of the facility will be closer to 80% by February 28, 2021 (168.16 patients / 51 stations = 3.2972/4 = 0.8243 or 82.43%), which exceeds the required minimum operating standard promulgated in 10A NCAC 14C .2203(b), based on the growth of the patient population using the projected AACR by county of patient origin, as published in the January 2019 SDR.

Projected Utilization

In Section C, page 25, the applicant provides historical and projected utilization as illustrated in the following table.

SKC Patient Census						
		Prior Year	Current Year	As of Certification	End of OY1	End of OY2
County	AACR	2/28/2018	2/28/2019	2/29/2020	2/28/2021	2/28/2022
Davidson	7.10%	0.00	1.00	1.07	1.15	1.23
Forsyth	3.80%	144.00	150.00	155.70	161.62	167.76
Guilford	3.40%	1.00	3.00	3.10	3.21	3.32
Rockingham	2.50%	0.00	1.00	1.03	1.05	1.08
Stokes	6.50%	0.00	1.00	1.07	1.13	1.21
Totals		145.00	156.00	161.96	168.16	174.59
			79.47%	79.39%	82.43%	85.58%

In Section C, pages 23-24, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant begins their utilization projections by using the current SKC patient census, by county of origin as of February 28, 2019.
- The two stations approved in Project ID# G-11586-18 are operational and were certified on April 23, 2019. Therefore, the beginning total number of stations is 47.
- The applicant uses the Five-Year Average Annual Change Rate (AACR), as published in the January 2019 SDR for Forsyth County which is 3.8%, to project the Forsyth County patient population forward.

- Operating Year 1 (OY1) = February 28, 2020 – February 27, 2021
Operating Year 2 (OY2) = February 28, 2021 – February 27, 2022

At the end of OY1 (CY2021) the facility is projected to serve 168.16 in-center patients and at the end of OY2 (CY2022) the facility is projected to serve 174.59 in-center patients.

The projected utilization rates for the first two operating years are as follows:

- OY1: 3.2972 patients per station per week or 82.43% (168.16 patients / 51 stations = $3.2972/4 = 0.8243$ or 82.43%)
- OY2: 3.4233 patients per station per week or 85.58% (174.59 patients / 51 stations = $3.4233/4 = 0.8558$ or 85.58%)

The project utilization of 3.2972 patients per station per week at the end of OY1 is equal to or exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- The applicant begins their utilization projections with the existing patient census at SKC.
- The applicant projects a growth rate equal to the Forsyth County Five-Year AACR of 3.8%, as published in January 2019 SDR.
- The applicant projects a growth rate equal to the Davidson, Guilford, Rockingham and Stokes County Five-Year AACR of 7.1%, 3.4%, 2.5% and 6.5%, respectively, as published in the January 2019 SDR.
- The applicant demonstrated that the existing and approved stations are inadequate to serve the current and projected patient population.
- Projected utilization at the end of OY1 exceeds the minimum of 3.2 patients per station per week required by 10A NCAC 14C .2203(b).

Access

In Section C, page 26, the applicant states:

“SKC accepts patients based on medically-defined admission criteria. There is no discrimination based on race, sex, national origin nor disability. Services are available to all area residents with ESRD. Further, the facility also accepts the needy and the

homeless, through its referral system, and assists those patients on obtaining the medical care they need.”

In Section L.1, page 67, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

SKC Projected Payor Mix Year Ending 2/28/2022 (OY2)	
Payment Source	% Total Patients
Medicare	12%
Medicaid	7%
Medicare/Medicaid	26%
Commercial	6%
Medicare Commercial	20%
VA	7%
Medicare Advantage	22%
Total	100%

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately identified the population to be served.
- The applicant adequately explained why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

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

C

The applicant proposes to add no more than one dialysis station and relocate no more than three dialysis stations from NDC to SKC for a total of 51 stations upon project completion.

The following tables show the projected relocation of stations from NDC to SKC.

Salem Kidney Center		
Stations	Description	Project ID #
45	Total existing certified stations as of the January 2019 SDR	
1	Stations to be added as part of this project	G-11676-19
3	Three stations to be relocated from NDC and added as part of this project	G-11676-19
2*	Stations previously approved to be added but not yet certified.	G-11586-18
51	Total stations upon completion of proposed project	

*Two stations were certified pursuant to Project ID# G-11586-18 on April 23, 2019.

Northside Dialysis Center		
Stations	Description	Project ID #
45	Total existing certified stations as of the January 2019 SDR	
3	Stations to be deleted as part of this project	G-11676-19
42	Total stations upon completion of proposed project	

In Section D, page 33, the applicant explains why they believe the needs of the population presently utilizing the services to be reduced, eliminated or relocated will be adequately met following completion of the project. On page 33, the applicant states:

- As the utilization rate continues to rise at SKC, moving three stations from NDC to SKC, allows the current and projected utilization at SKC to be managed effectively.
- As of February 28, 2019, NDC was operating just below 80% utilization with 142 patients on 45 stations which has not changed over several months.
- A reduction of three stations at NDC will continue to meet the needs of the 142 patients on the 42 stations at a utilization rate of approximately 84.5%, leaving room for an additional 26 patients before reaching 100% utilization.

In Section D, page 33, the applicant states:

“WFUHS dialysis facilities accept all patients diagnosed with ESRD without discrimination due to income, race, ethnicity, sex, handicap nor age.”

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 and adequately demonstrates that:

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

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

CA

The applicant proposes to add no more than one dialysis station and relocate no more than three dialysis stations from NDC to SKC for a total of 51 stations upon project completion.

In Section E, pages 34-37, the applicant describes the alternatives they considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo-the applicant states that doing nothing does not address the projected facility growth. The applicant demonstrates a need for an additional station by applying the Five-Year AACR for its current patient census. The applicant projects the utilization rate will be close to 90% by the end of OY1.
- In-County Transfer-The applicant considered taking some number of stations from Miller Street Dialysis Center (MSDC), Piedmont Dialysis Center (PDC) and NDC to in whole or part fulfill the need for stations at SKC. However, the only facility of those three with stations to spare is NDC. A transfer of any stations from MSDC and or PDC in whole or in part is not a viable option.

- Contiguous County Transfer-the applicant states that a surplus of stations in Forsyth County eliminates this alternative from being a viable alternative because transferring stations from a contiguous county would increase the surplus, which would not be consistent with Policy ESRD-2.
- Facility Need Methodology-the applicant states that the facility need methodology indicates that SKC is eligible to add one station; however, the patient projection and utilization calculations demonstrate that four stations are needed at SKC.

On page 36, the applicant states their proposal to add one dialysis station pursuant to the facility need determination and relocate three dialysis stations from NDC pursuant to Policy ESRD-2, is the best alternative to meet the need SKC. A combination of the facility need methodology and Policy ESRD-2 would increase SKC's in-center stations by enough to impact its projected utilization without placing an excess strain on the resources at NDC.

The applicant adequately demonstrates 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 applicant provides credible information to explain why they believe the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

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

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion and is approved subject to the following conditions.

- 1. Wake Forest University Health Sciences and Salem Kidney Center of Wake Forest University shall materially comply with all representations made in the certificate of need application.**
- 2. Pursuant to the facility need determination in the January 2019 SDR, Wake Forest University Health Sciences and Salem Kidney Center of Wake Forest University shall develop no more than one additional dialysis station for a total of no more than 51 certified stations at Salem Kidney Center upon project completion.**

3. Pursuant to Policy ESRD-2, Wake Forest University Health Sciences and Salem Kidney Center of Wake Forest University shall relocate no more than three dialysis stations from Northside Dialysis Center to Salem Kidney Center for a total of no more than 51 certified dialysis stations upon project completion.
 4. Upon completion of this project, Wake Forest University Health shall take the necessary steps to decertify no more than three dialysis stations at Northside Dialysis Center for a total of no more than 42 dialysis stations at Northside Dialysis Center.
 5. Wake Forest University Health Sciences and Salem 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 applicant proposes to add no more than one dialysis station and relocate no more than three dialysis stations from NDC to SKC for a total of 51 stations upon project completion.

Capital and Working Capital Costs

In Section F.1, page 38, the applicant projects the total capital cost of the proposed project as shown in the table below.

Construction Costs	\$149,774
Miscellaneous Costs	\$ 67,200
Total	\$216,974

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

In Section F, pages 41-42, the applicant states that SKC is an existing operational facility; therefore, there are no start-up or initial operating expenses.

Availability of Funds

In Section F.2, page 39, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Wake Forest University Health Sciences	Salem Kidney Center	Total
Loans	\$0	\$0	\$0
Accumulated reserves or OE *	\$216,974	\$0	\$216,974
Bonds	\$0	\$0	\$0
Other (Specify)	\$0	\$0	\$0
Total Financing	\$216,974	\$0	\$216,974

* OE = Owner's Equity

In Section F.2, page 39, the applicant states they will finance the capital costs with accumulated reserves. Exhibit F-5 contains a letter dated March 15, 2019 from the President of the Wake Forest Baptist Health System, authorizing the project and committing \$216,974 for the development of the project.

Exhibit F-7(a) contains Consolidated Financial Statements for Wake Forest University for the fiscal year ended June 30, 2018, showing WFUHS with \$83,542,000 in cash and cash equivalents and \$3,356,046,000 in total assets.

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

Financial Feasibility

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of this project, in Section R, Forms A-C, pages 89-93, respectively. The applicant projects that revenues will exceed operating expenses in the first two operating years of this project, as shown in the table below.

Projected Revenues and Operating Expenses		
SKC	Operating Year 1 2/29/20- 2/28/21	Operating Year 2 2/29/21-2/28/22
In-Center Patients	165	172
Total Treatments	24,750	25,800
Total Gross Revenues (Charges)	\$45,530,843	\$47,462,454
Deductions from Gross Revenue*	\$39,020,66	\$40,628,611
Total Net Revenue	\$6,510,677	\$6,833,843
Average Net Revenue per Treatment	\$263	\$265
Total Operating Expenses (Costs)	\$5,483,747	\$5,663,021
Average Operating Expenses per Treatment	\$222	\$219
Net Income/Profit	\$1,026,930	\$1,170,822

*Includes charity and bad debts

The assumptions used by the applicant 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
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to add no more than one dialysis station and relocate no more than three dialysis stations from NDC to SKC for a total of 51 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.” Thus, the service area is Forsyth County. Facilities may serve residents of counties not included in their service area.

According to Table B of the January 2019 SDR, there are five existing or approved dialysis facilities in Forsyth County. WFUHS is the provider of four of those facilities. NC Baptist Hospital provides dialysis services in an acute unit in the hospital.

Forsyth County Dialysis Facilities Certified Stations and Utilization as of June 30, 2018				
Facility Name	Provider Name	Location	# of Stations	Utilization
Miller Street Dialysis Center	WFUHS	Winston Salem	44	81.25%
Northside Dialysis Center	WFUHS	Winston Salem	45	78.33%
Piedmont Dialysis Center	WFUHS	Winston Salem	58	78.88%
Salem Kidney Center	WFUHS	Winston Salem	45	94.23%
NC Baptist Hospital ESRD	WFBH	Winston Salem	4	12.50%

Source: January 2019 SDR

In Section G, page 45, the applicant explains why they believe their proposal would not result in the unnecessary duplication of existing or approved dialysis services in Forsyth County. The applicant states:

“SKC’s need is real and immediate. SKC does not project to serve patients currently served at other locations within Forsyth County. However, it is likely some may need to temporarily transfer their care there. SKC projects to serve its current patient population plus growth based upon the 5-year AACR projected for its current patient base by county of origin as outline in the most recent (January 2019) SDR. Three of the four stations to be added at SKC are already certified within Forsyth County, but could be better utilized at SKC versus NDC at this time. Approval of this project will not result in duplication of existing and approved service in the proposed service area- Forsyth County. Approval of this project will result in continue access to care for the medically underserved in Forsyth County. ”

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

- There is a facility need determination pursuant to the 2019 SMFP for the proposed addition of one station.

- The proposal would not result in a surplus of stations or increase an existing surplus of stations in Forsyth County.
- The applicant adequately demonstrates that the proposed stations are needed in addition to the existing or approved stations in Forsyth County, as published in the January 2019 SDR.

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 reason 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 47, the applicant provides current and projected staffing in full time equivalents (FTEs) for SKC as demonstrated in the table below. The applicant projects an increase in direct staffing in Operating Year 2. The applicant states the Medical Director is a contracted salaried position and not subject to annual increases or FTE equivalents, and thus is not reflected on the staffing chart.

SKC Current and Projected Staffing		
Position	Current # FTEs	Projected FTEs
	CY 2019	OY2 (CY2022)
Registered Nurse	6.25	7.25
LPN	1.75	1.75
Patient Care Technician	15.00	18.00
DON	1.00	1.00
Dietician	1.00	1.00
Social Worker	1.75	1.75
Dialysis Tech	3.00	3.00
Biomed	1.00	1.00
Clerical	2.75	2.75
Total	33.50	37.50

The assumptions and methodology used to project staffing are provided in Section R. Adequate costs for the health manpower and management positions proposed by the applicant is budgeted in Form A, which is found in Section R. In Section H, page 52, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs and provides supporting documentation in Exhibit H-1. In Section I, page 49, the applicant identifies the current medical director. In Section H, page 52, the applicant describes its physician recruitment plans. In Exhibit H-2, the applicant provides supporting documentation.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

Salem Kidney Center –Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	On site
Self-care training (in-center)	On site
Home training HH PD Accessible follow-up program	NDC/PDC
Psychological counseling	On-site
Isolation – hepatitis	On site
Nutritional counseling	On site
Social Work services	On site
Acute dialysis in an acute care setting	WFBH
Emergency care	WFBH
Blood bank services	WFBH
Diagnostic and evaluation services	On site
X-ray services	WFBH
Laboratory services	Meridian Laboratory Corp.
Pediatric nephrology	On site
Vascular surgery	WFBH
Transplantation services	WFBH
Vocational rehabilitation & counseling	On site
Transportation	Forsyth County Department of Social Services

Source: Section I, page 55

In Section I, pages 55-59, the applicant describes their existing and proposed relationships with other local health care and social service providers and provide supporting documentation in Exhibits I-1 (i and q), I-2 (a-c), I-3 (a-b), and I-4 (a-b).

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health

service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

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

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

NA

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

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

The applicant does not propose to make more than minor renovations to an existing space. Therefore, Criterion (12) is not applicable to this review.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic

minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

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

C

In Section L, page 68, the applicant provides the historical payor mix during year prior to OY1, as of February 28, 2019, for their existing services, as shown in the table below.

SKC Historical Payor Mix Year Ending 2/28/2019	
Payment Source	% Total Patients
Private Pay	1%
Medicare	14%
Medicaid	7%
Medicare/Medicaid	27%
Commercial	4%
Medicare Commercial	20%
VA	6%
Medicare Advantage	21%
Total	100%

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

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Forsyth	16%	53%	43%	18%	7%	12%
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:

- 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 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, page 72, the applicant states:

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

In Section L, page 73, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or related entities and located in North Carolina.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 67, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

SKC Projected Payor Mix Year Ending 2/28/2022 (OY2)	
Payment Source	% Total Patients
Medicare	12%
Medicaid	7%
Medicare/Medicaid	26%
Commercial	6%
Medicare Commercial	20%
VA	7%
Medicare Advantage	22%
Total	100%

As shown in the table above, during the second year of operation, the applicant projects that 80% of total services will be provided to Medicare patients (includes Medicare and Medicare/Commercial), and 7% to Medicaid patients.

On pages 67-68, the applicant provides the assumptions and methodology they use to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- The projected payor mix is based on the historical payor mix.

- Projected utilization is reasonable and adequately supported. 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.

- (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, page 72, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section M.1, page 77, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-1.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to add no more than one dialysis station and relocate no more than three dialysis stations from NDC to SKC for a total of 51 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.*” Thus, the service area for this facility consists of Forsyth County. Facilities may also serve residents of counties not included in their service area.

According to Table B of the January 2019 SDR, there are five existing or approved dialysis facilities in Forsyth County. WFUHS is the provider of four of those facilities. NC Baptist Hospital provides dialysis services in an acute unit in the hospital.

Forsyth County Dialysis Facilities Certified Stations and Utilization as of June 30, 2018				
Facility Name	Provider Name	Location	# of Stations	Utilization
Miller Street Dialysis Center	WFUHS	Winston Salem	44	81.25%
Northside Dialysis Center	WFUHS	Winston Salem	45	78.33%
Piedmont Dialysis Center	WFUHS	Winston Salem	58	78.88%
Salem Kidney Center	WFUHS	Winston Salem	45	94.23%
NC Baptist Hospital ESRD	WFBH	Winston Salem	4	12.50%

Source: January 2019 SDR

In Section N, pages 78-79, the applicant describes 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 78, the applicant states:

“This project shall have no impact on competition in Forsyth County. Patients utilize a facility based upon physician preference, geographical location, or other reasons of convenience. An addition of stations at SKC is necessary to serve the facility’s existing and projected patients and stave off excessive utilization. By approval of this project, SKC will have the ability to continue serving its patient base during current operation hours keeping competition at its current level.”

The applicant adequately describes 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, F and R of the application and any exhibits).
- Quality services will be provided (see Sections B, K, N and O of the application and any exhibits).
- Access will be provided to underserved groups (see Sections B, C, L and N of the application and any exhibits).

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion 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 Exhibit A-11, pages 5-6, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 18 of this type of facility located in North Carolina.

In Section O, pages 80-81, 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 these facilities. The applicant states that all facilities are back in compliance. After reviewing and considering information provided by the applicant and publicly available data 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 to all applicable Criteria and Standards for End Stage Renal Disease Services in 10A NCAC 14C .2200. The specific criteria are discussed below.

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- SKC is an existing 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.1, pages 23-28, the applicant documents the need for the project and demonstrate that they will serve a total of 168.16 in-center patients on 51 stations at the end of the first operating year, which is 3.2972 patients per station per week or a utilization rate of 82.43 percent. The discussion regarding analysis of need found 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, page 28, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.