

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 21, 2018

Findings Date: May 21, 2018

Project Analyst: Celia C. Inman

Team Leader: Gloria Hale

Project ID #: G-11468-18

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 six dialysis stations for a total of no more than 45 stations

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Wake Forest University Health Sciences (WFUHS) and Salem Kidney Center of Wake Forest University (SKC), the applicants, currently operate a 39-station dialysis facility located at 2705 Boulder Park Court, Winston-Salem. The applicants propose to add six dialysis stations, pursuant to the facility need methodology, to the existing SKC facility for a total of 45 certified dialysis stations upon project completion.

Need Determination

The 2018 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table D in the January 2018 Semiannual Dialysis Report (SDR), the county need methodology shows there is no county need determination for new dialysis stations for Forsyth County.

However, the applicants are eligible to apply for additional stations based on the facility need methodology because the utilization rate reported for SKC in the January 2018 SDR is 3.49 patients per station. This utilization rate was calculated based on 136 in-center dialysis patients and 39 certified dialysis stations. (136 patients / 39 stations = 3.487 patients per station). The facility need methodology requires a facility’s utilization rate in the latest SDR to be at least 3.2 patients per station 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 six additional stations are needed for this facility, as illustrated in the following table.

April 1 REVIEW-January 2018 SDR

Required SDR Utilization		80.00%
Center Utilization Rate as of 6/30/16		87.18%
Certified Stations		39
Pending Stations		0
Total Existing and Pending Stations		39
In-Center Patients as of 6/30/17 (SDR2)		136
In-Center Patients as of 12/31/16 (SDR1)		128
Step	Description	
	Difference (SDR2 - SDR1)	8
(i)	Multiply the difference by 2 for the projected net in-center change	16
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/16	0.1250
(ii)	Divide the result of Step (i) by 12	0.0104
(iii)	Multiply the result of Step (ii) by 6	0.0625
(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	144.5000
(v)	Divide the result of Step (iv) by 3.2 patients per station	45.1563
	and subtract the number of certified and pending stations as recorded in SDR2 to determine the number of stations needed	6

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is six stations. The applicants propose to add six stations. 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 2018 SMFP that is applicable to this review, Policy GEN-3: Basic Principles. Policy GEN-3: Basic Principles, page 33 of the 2018 SMFP, states:

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

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

Promote Equitable Access - The applicants describe how they believe the proposed project would promote equitable access in Section B.4(b), pages 16-21; and Section N.1, page 78. The information provided by the applicants is reasonable and adequately supports the determination that the applicants’ proposal would promote equitable access.

Maximize Healthcare Value - The applicants describe how they believe the proposed project would maximize healthcare value in Section B.4(c), page 21, referencing Sections F and K, and in Section N.1, page 78. 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 SKC’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, and
- information publicly available during the review and used by the Agency.

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

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

C

The applicants propose to add six dialysis stations, pursuant to the facility need methodology, for a total of 45 dialysis stations at the existing SKC facility upon project completion. SKC is located at 2705 Boulder Park Court, Winston-Salem in Forsyth County. SKC has no projects currently under development. The following table, summarized from page 4 of the application, illustrates the current and projected number of dialysis stations at SKC.

Stations	Description	Project ID #
39	Total existing certified stations as of the January 2018 SDR	
+6	Stations to be added at SKC as part of this project	G-11468-18
45	Total stations upon completion of proposed project	

Patient Origin

On page 365, the 2018 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.*” SKC is located in Forsyth County; 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 applicants provide in-center dialysis services only and do not propose to provide home hemodialysis or peritoneal services. The applicants provide the current and projected patient origin at SKC on pages 29 and 23, respectively, as summarized in the following table.

County	Current As of 12/31/17		First Full FY OY1 1/1/19-12/31/19		Second Full FY OY2 1/1/20-12/31/20	
	Patients	Percent	Patients	Percent	Patients	Percent
Forsyth	140.00	99.29%	146.23	99.26%	149.44	99.24%
Guilford	1.00	0.71%	1.10	0.74%	1.15	0.76%
Total	141.00	100.00%	147.32	100.00%	150.59	100.00%

Totals may not sum due to rounding

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

Analysis of Need

The applicants propose to add six dialysis stations to the existing SKC facility in Forsyth County for a total of 45 certified dialysis stations upon project completion. In Section C, the applicants explain why they believe the population projected to utilize the proposed services needs the proposed services. In Section C.1, page 23, the applicants state the purpose of the proposed project is to:

“... expand the existing services at SKC on all patient shifts.”

In Section C.2, page 25, the applicants state that the current utilization rate for SKC, as of December 31, 2017, is 90.38%.

In Section N.1, page 78, the applicants discuss the need for the additional stations at SKC. The applicants state,

“... 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 operating hours keeping competition at its current level. Patients will be able to keep normal treatment schedules and experience no changes in transportation or other factors that could impact the overall cost-effectiveness, quality, and access to the proposed services.”

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

- the facility is currently operating at above 90.0% capacity,
- the applicants base the future need for services upon the facility’s historical patient utilization, and
- the applicants utilize the 5-year county average annual change rate (AACR) of 2.20% and 4.70% for Forsyth and Guilford counties, respectively, to project growth in patient need at the facility.

Projected Utilization

In Section C.2, pages 24-26, 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 summarizes the applicants' projection of in-center dialysis patients at SKC.

SKC Projected In-Center Dialysis Utilization

County	January 2018 SDR 5-Yr AACR	Beginning Census 12/31/17	Growth until 12/31/18	End of OY1 12/31/19	End of OY2 12/31/20
Forsyth	2.20%	140.00	143.08	146.23	149.44
Guilford	4.70%	1.00	1.05	1.10	1.15
Totals		141.00	144.13	147.32	150.59

Totals may not sum due to rounding

As the table above shows, the methodology used by the applicants achieves a projection of 147.32 patients by the end of the first operating year, OY1, for a utilization rate of 82% (147.32 patients / 45 stations = 3.27 patients per station / 4 = 0.819). By the end of OY2, following the applicants' methodology and assumptions, SKC will have 150.59 in-center patients dialyzing at the center for a utilization rate of 84% (150.59 / 45 = 3.34 / 4 = 0.837). The projected utilization of 3.27 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 Sections C.1 and C.7, pages 23-24 and 28, respectively, the applicants provide the methodology and assumptions used to project utilization at SKC. The project is based upon the facility need methodology. Based on the facility need methodology, SKC is eligible to add as many as six stations.

The applicants' methodology is summarized below:

- Sort the December 31, 2017 beginning patient census of 141 by county of origin.
- Apply the January 2018 SDR 5-year AACR, by county of patient origin, to the current patient populations to project patient census through the end of Operating Year 2.
- Project utilization based on current patients at SKC, projected forward by the AACR.

The applicants' assumptions are summarized below:

- Projected completion of the project under review is December 31, 2018; OY1 ends December 31, 2019; OY2 ends December 31, 2020.
- The 5-year AACR for each county as published in the January 2018 SDR will remain an accurate indicator of patient growth through OY2.

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

- the applicants base the future utilization of services upon the facility’s historical patient utilization, and
- the applicants utilize the 5-year county AACR of 2.20% and 4.70% for Forsyth and Guilford counties, respectively, to project growth in patient utilization at the facility.

Access

In Section C.3, page 26, the applicants state:

“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 in obtaining the medical care they need.”

Exhibit L-3(a) contains the facility’s Referral/Admissions Policy. The applicants project payor mix in Section L.1(b), pages 67-68, as summarized below:

Payor Source	In-center Patients OY1 and OY2
Private Pay	1.0%
Medicare	12.0%
Medicaid	7.0%
Medicare / Medicaid	26.0%
Commercial Insurance	6.0%
Medicare / Commercial	20.0%
VA	7.0%
Medicare Advantage	21.0%
Total	100.0%

In Section L.7, page 75, the applicants state that the projected payor mix is based upon the facility’s five-year average annual payor mix. The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately identifies the population to be served.

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

NA

The applicants to 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 six dialysis stations, pursuant to the facility need methodology, for a total of 45 dialysis stations at the existing SKC facility upon project completion.

In Section E, pages 32-36, the applicants describe the alternatives considered and explain why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain Status Quo – the applicants state that this alternative is not effective because failing to address the facility need at SKC and the potential for additional non-projected transfer patients from other WFUHS facilities in Forsyth County due to road construction could have undesirable consequences such as the need for a third shift, additional staffing expense, a reduction in the availability of flexible treatment times, and an increase in missed treatments for patients experiencing travel hardships.
- In-County Transfer – the applicants state that this alternative is not effective because the transfer of stations from any of the three other WFUHS facilities could result in an increased need for additional stations at those facilities and/or prove a hardship to patients and staff.

- Contiguous County Transfer – the applicants state that the 9-station surplus 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 applicants state that the facility need methodology indicates that SKC is eligible to add up to six stations and the patient projections and utilization calculations demonstrate that six stations are needed at SKC.

On pages 35-36, the applicants state that the project as proposed is the most effective alternative because the facility need methodology allows SKC to add the six stations which it is projected to need and the proposal meets the requirements for expansion via facility need methodology. The applicants state on page 36:

“Because no other option is compatible with SKC’s need without creating an almost immediate need at the donor facility resulting in additional CON filings at a cost to file of \$5,000 per application, plus attorney’s fees, plus project costs, an increase in stations via facility need methodology is the least costly and the most-effective alternative to meet the current and projected needs at SKC as well as the other WFUHS locations in Forsyth County.”

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

- maintaining the status quo does not address the need for additional stations at the facility,
- transferring stations from other WFUHS Forsyth facilities could result in the need for additional stations at the donor facilities, which would increase costs, and
- the county station inventory does not meet the requirements for a Policy ESRD-2 transfer of stations from a contiguous county.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application 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 2018 SDR, Wake Forest University Health Sciences and Salem Kidney Center of Wake Forest University Dialysis shall develop no more than six additional dialysis stations for a total of no more than 45 certified dialysis stations at Salem Kidney Center upon completion of this project, which shall include any home hemodialysis training or isolation stations.
 3. Wake Forest University Health Sciences and Salem Kidney Center of Wake Forest University Dialysis 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, WFUHS and SKC, currently operate a 39-station dialysis facility located at 2705 Boulder Park Court, Winston-Salem. The applicants propose to add six dialysis stations, pursuant to the facility need methodology, to the existing SKC facility for a total of 45 certified dialysis stations upon project completion.

Capital and Working Capital Costs

In Section F.1, pages 37-38, the applicants state that the capital costs for the project will total \$105,600 and provide a table with the estimated capital costs on page 37, as summarized below.

Projected Capital Costs		Total Costs
Dialysis Machines	\$87,000	
Other Equipment/Furniture	\$18,600	
Total Capital Costs		\$105,600

The project does not involve any construction costs. In Section F, pages 40-41, 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, page 38, 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	Salem Kidney Center	Total
Loans			
Accumulated reserves or OE *	\$105,600		\$105,600
Bonds			
Other (Specify)			
Total Financing	\$105,600		\$105,600

* OE = Owner's Equity

Financial Feasibility

The applicants provide pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Section R, Forms A-C, pages 89-91, the applicants project that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

Salem Kidney Center Revenue and Expenses		
	OY1 (CY2019)	OY2 (CY2020)
In-Center Patient	146	149
In-Center Treatments	21,900	22,350
Gross Patient Revenue	\$ 40,287,897	\$ 41,115,731
Deductions from Gross Revenue*	\$ 34,458,175	\$ 35,125,543
Net Patient Revenue	\$ 5,829,722	\$ 5,990,188
Average Net Revenue per Patient	\$ 39,930	\$ 40,202.60
Total Operating Expenses	\$ 4,966,918	\$ 5,067,761
Average Operating Expenses per Patient	\$ 34,020	\$ 34,011.82
Net Income	\$ 862,804	\$ 922,427

*Includes charity care and bad debt

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

Conclusion

The Agency reviewed the:

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

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

- The applicants adequately 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 six dialysis stations, pursuant to the facility need methodology, to the existing SKC facility for a total of 45 certified dialysis stations upon project completion.

On page 365, the 2018 SMFP defines the service area for dialysis stations as *“the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* The facility is located in Forsyth County; 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 the January 2018 SDR, there are five providers of dialysis services in Forsyth County, as follows:

Forsyth County Dialysis Facilities

Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
Miller Street Dialysis Center (WFUHS)*	36	93.75%	3.7500
NC Baptist Hospital ESRD	4	6.25%	0.2500
Northside Dialysis Center (WFUHS)	45	71.67%	2.8667
Piedmont Dialysis Center (WFUHS)	58	75.00%	3.0000
Salem Kidney Center (WFUHS)	39	87.18%	3.4872

Source: January 2018 SDR, Table B.

* CON Project ID #G-11302-17 approved for eight additional stations, not yet certified on 12/1/17.

In Section G, pages 44-45, the applicants explain why they believe the proposal would not result in the unnecessary duplication of existing or approved dialysis services in Forsyth County. The applicants state:

“Of the 5 existing facilities in Forsyth County, four (4) are WFUHS facilities, while the fifth is the acute unit at WFBH [Wake Forest Baptist Hospital]. As of 12/31/17 all WFUHS facilities are at or nearing 80 % utilization and have shown facility growth since the SDR data date of 6/30/17.

...

SKC projects to serve its current patient population plus growth based upon the 5-year AACR projected for its current patient base by county or origin as outlined in the most recent (January 2018) SDR. Approval of this project will not result in duplication of existing and approved services in the proposed service area – Forsyth 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:

- The applicants demonstrate the need for the stations based on the facility need methodology.
- The applicants adequately demonstrate that the proposed stations are needed in addition to the existing or approved stations in Forsyth County.

Conclusion

The Agency reviewed the:

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

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

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

C

In Sections H and R, the applicants provide current and projected staffing for the proposed services as summarized in the following table.

POSITION	Current FTE Positions as of 12/31/17	PROJECTED FTE POSITIONS OY2
RN	5.50	7.00
DON/Nurse Manager	1.00	1.00
LPN	1.75	1.75
Patient Care Tech	13.50	17.00
Dietician	1.00	1.00
Social Worker	1.75	1.75
Clerical	3.75	3.75
Dialysis Tech	3.00	3.00
Bio-med Technician	1.00	1.00
Total	32.25	37.25*

Source: Sections H and R of the application.

Note: The Medical Director and administrative services, including medical records, are contract services.

*The table on page 46 of the application does not sum the third column, Total FTE Positions [a+b], correctly. The projected facility staff total should be 37.25.

The assumptions and methodology used to project staffing are provided in Sections H and R. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in the pro forma financials found in Section R. In Section H, pages 50-51, 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, and Section I.3, page 56, the applicant identifies the current Medical Director. In Exhibit I.3(a), the applicant provides a letter from Pirouz Daeihagh, M.D., indicating a commitment to continue to serve as Medical Director for the facility. In Exhibit H.2, the applicants provide supporting documentation.

The 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, and
- information publicly available during the review and used by the Agency.

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

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

C

In Section I.1, pages 54-55, the applicants identifies the necessary ancillary and support services and explains how they will be made available. The applicants provide a table on page 54, as summarized below.

**Salem Kidney Center
 Ancillary and Support Services**

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

*PDC – Piedmont Dialysis Center and NDC – Northside Dialysis Center

In Section I, pages 57-58, the applicants describe SKC’s existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits I-I and 2.

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

Conclusion

The Agency reviewed the:

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

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

- (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 proposed project involves no construction. The facility had 72 operational dialysis stations prior to the relocation of 36 stations from SKC to Miller Street Dialysis Center, Project ID#G-7953-07. Therefore, Criterion (12) is not applicable to this review.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L.7, page 74, the applicants provide the SKC historical payor mix during CY2017, as shown in the table below.

Payor Source	In-center Patients
Private Pay	1%
Medicare	12%
Medicaid	7%
Medicare / Medicaid	28%
Commercial Insurance	5%
Medicare / Commercial	21%
VA	7%
Medicare Advantage	19%
Total	100%

As shown in the table above, the applicant reports that 87% of the in-center patients at SKC had some or all of their services paid for by Medicare or Medicaid in CY 2017.

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

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2016 Estimate	2016 Estimate	2016 Estimate	2016 Estimate	2015 Estimate	2011-2015	2015 Estimate
Forsyth	15%	53%	43%	18%	7%	13%
Statewide	16%	51%	37%	16%	10%	13%

Source: <http://www.census.gov/quickfacts/table> Latest Data 7/1/16 as of 8/22/17

*Excludes "White alone" who are "not Hispanic or Latino"

***"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. 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., V2016) refers to the final year of the series (2010 thru 2016). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic (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, and is representative of North Carolina patient profiles.

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

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

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or

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

access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.3(d), page 72, the applicants state:

*“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**, [emphasis in original] and strives to provide services to all patients with End Stage Renal Disease.”*

In Section L.6, page 73, the applicants state that there have been no civil rights access complaints filed against the facility or any facilities owned by the parent company in North Carolina within the last five years.

The Agency reviewed the:

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

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

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

C

In Section L.1(b), pages 67-68, the applicants project the following payor mix for the proposed services during the first and second full calendar year of operation following completion of the project, as shown in the table below.

**Projected Payor Mix OY1 and OY2
 1/1/19-12/31/20**

Payment Source	Percent of Total Patients	Percent of IC Patients	Percent of HH Patients	Percent of PD Patients
Private Pay	1.0%	1.0%	0.0%	0.0%
Medicare	12.0%	12.0%	0.0%	0.0%
Medicaid	7.0%	7.0%	0.0%	0.0%
Medicare/Medicaid	26.0%	26.0%	0.0%	0.0%
Commercial Insurance	6.0%	6.0%	0.0%	0.0%
Medicare/Commercial	20.0%	20.0%	0.0%	0.0%
VA	7.0%	7.0%	0.0%	0.0%
Medicare/Advantage	21.0%	21.0%	0.0%	0.0%
Total	100.0%	100.0%	0.0%	0.0%

Source: Application pages 67-68

As shown in the table above, during both the first and second full calendar years of operation, the applicants project that 86% of the dialysis patients will have all or part of their services paid for by Medicare and/or Medicaid, and 1.0% will be paid through private pay.

On pages 67-68, the applicants provide the assumptions and methodology used to project payor mix during the first and second 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 payor mix by payor type for each of the last five operating years.

The Agency reviewed the:

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

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

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

C

In Section L.4, pages 72-73, 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, and
- information publicly available during the review and used by the Agency.

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

- (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 77, the applicants describe the extent to which health professional training programs in the area have access to the facility for training purposes and provide supporting documentation in Exhibit M-1.

The Agency reviewed the:

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

Based on that review, the Agency concludes that the applicants adequately 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 six dialysis stations, pursuant to the facility need methodology, to the existing SKC facility for a total of 45 certified dialysis stations upon project completion.

On page 365, the 2018 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” The facility is located in Forsyth County; 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 the January 2018 SDR, there are five operational dialysis facilities in Guilford County, as follows:

Forsyth County Dialysis Facilities

Dialysis Facility	Certified Stations	Percent Utilization	Patients Per Station
Miller Street Dialysis Center (WFUHS)*	36	93.75%	3.7500
NC Baptist Hospital ESRD	4	6.25%	0.2500
Northside Dialysis Center (WFUHS)	45	71.67%	2.8667
Piedmont Dialysis Center (WFUHS)	58	75.00%	3.0000
Salem Kidney Center (WFUHS)	39	87.18%	3.4872

Source: January 2018 SDR, Table B.

* CON Project ID #G-11302-17 approved for eight additional stations, not yet certified on 12/1/17.

As the table above shows, WFUHS is the only non-hospital dialysis provider in Forsyth County.

In Section N, pages 78-79, the applicants describe the expected effects of the proposed services on competition in the service area and discuss how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 78, the applicants state:

“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.”

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

- the cost-effectiveness of the proposal (see Sections F and R of the application and any exhibits),
- quality services will be provided (see Section O of the application and any exhibits), and
- 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, and
- information publicly available during the review and used by the Agency.

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

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

C

In Section A.11, pages 5-6, the applicants identify the dialysis facilities located in North Carolina and owned, operated or managed by the applicant or a related entity. The applicants identify a total of 18 WFUHS dialysis facilities located in North Carolina.

In Section O, pages 80-81, the applicants state that seven of the 18 facilities were surveyed during the 18-month look-back period from September 2016 through March 2018 and did not operate in compliance with the Medicare conditions of participation. The applicants state that all facilities are now in compliance. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 18 facilities surveyed, the applicant provided sufficient evidence that quality care has been provided in the past.

The Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the

type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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

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

10A NCAC 14C .2203 PERFORMANCE STANDARDS

(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.

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

(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.

-C- In Section C.2, pages 24-26, 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 summarizes the applicants’ projection of in-center dialysis patients at SKC.

SKC Projected In-Center Dialysis Utilization

County	January 2018 SDR 5-Yr AACR	Beginning Census 12/31/17	Growth until 12/31/18	End of OY1 12/31/19	End of OY2 12/31/20
Forsyth	2.20%	140.00	143.08	146.23	149.44
Guilford	4.70%	1.00	1.05	1.10	1.15
Totals		141.00	144.13	147.32	150.59

Totals may not sum due to rounding

As the table above shows, the methodology used by the applicants achieves a projection of 147.32 patients by the end of the first operating year, OY1, for a utilization rate of 82% ($147.32 \text{ patients} / 45 \text{ stations} = 3.27 \text{ patients per station} / 4 = 0.819$). The projected utilization of 3.27 patients per station per week for OY1 satisfies the 3.2 in-center patients per station threshold as required.

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

-C- In Sections C.1 and C.7, pages 23-24 and 28, respectively, the applicants provide the assumptions and methodology used to project utilization of the facility.