

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: December 6, 2012

PROJECT ANALYST: Kim Randolph
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: G-10030-12/ Wake Forest University Health Sciences and Salem Kidney Center of Wake Forest University/ Add three dialysis stations to the existing facility for a total of 39 certified dialysis stations upon project completion/ Forsyth County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department 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

Co-applicants Wake Forest University Health Sciences (WFUHS) and Salem Kidney Center of Wake Forest University (SKC) currently operate a 36-station dialysis facility located at 2705 Boulder Park Court, Winston-Salem. The applicants propose to add three dialysis stations to the existing SKC facility for a total of 39 certified dialysis stations upon project completion.

The 2012 State Medical Facilities Plan (2012 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2012 Semiannual Dialysis Report (SDR), the county need methodology shows there is no need for an additional facility in Forsyth County. However, the applicants are eligible to apply for additional stations in their existing facility, based on the facility need methodology. The utilization rate reported for SKC in the July 2012 SDR shows 3.4167 patients per station, which is greater than the required 3.2 patients per station. The utilization rate was calculated based on 123 in-center dialysis patients and 36 certified dialysis stations as of December 31, 2011 (123 patients / 36 stations = 3.4167 patients per

station. Therefore, application of the facility need methodology indicates additional stations are needed for this facility, as illustrated under the “Actual” column in the following table.

**ESRD Facility Need Methodology
 2012 October Review – July 2012 SDR**

		<i>Application*</i>	Actual
Required SDR Utilization		80.00%	80.00%
Center Utilization Rate as of 12/31/11		85.42%	85.42%
Certified Stations		36	36
Pending Stations		0	0
Total Existing and Pending Stations		36	36
In-Center Patients as of 12/31/11 (SDR2)		128	123
In-Center Patients as of 06/30/11 (SDR1)		123	120
Step	Description		
	Difference (SDR2 - SDR1)	5	3
(i)	Multiply the difference by 2 for the projected net in-center change.	10	6
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 06/30/11	0.0813	0.05000
(ii)	Divide the result of Step (i) by 12	0.00678	0.00416
(iii)	Multiply the result of Step (ii) by the number of months from the most recent month reported in the July [2012] SDR (12/31/11) until the end of calendar year (12 months)	0.0813	0.04992
(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	138.407	129.14016
(v)	Divide the result of Step (iv) by 3.2 patients per station		40.3563
	and subtract the number of certified and pending stations as recorded in SDR2 [36] to determine the number of stations needed	7.25203	4

* Source: Section III.2, page 20.

In the column titled “*Application*” above, the applicants correctly reflected the utilization rates; however, incorrectly reflected the number of in-center patients for the January 2012 Semiannual Dialysis Report (SDR1) and the July 2012 Semiannual Dialysis Report (SDR2). Since the difference in the number of in-center patients provides the basis for projecting the number of dialysis stations needed, the applicants’ resulting calculations overstated the facility based need. In the column titled “Actual” above, the facility based need was calculated based on the in-center patients reflected in the January and July 2012 SDRs.

In the July 2012 SDR, Step (2)(C) of the facility need methodology states, “*The facility may apply to expand to meet the need established in (2)(B)(v), up to a maximum of 10 stations.*” As shown in Step (v), of the “Actual” column of the table above, the number of dialysis stations needed, based on the facility need methodology, is four. Although the applicants incorrectly calculated a facility based need determination of seven stations in the “Application” column in the table above, the applicants propose to add only three

dialysis stations. Therefore, the applicants' proposal to add three dialysis stations is consistent with the facility need determination of four dialysis stations calculated in the "Actual" column in the table above.

Policy GEN-3: Basic Principles is also applicable to this review. Policy GEN-3 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

In Section II, pages 16-17, the applicants describe the methods used to ensure and maintain quality care, which includes the following:

- Facilities – Provide state of the art facilities with sufficient stations and staffing to offer services to a broad range of patients. See Sections I, VI, VII, XI, and XII.
- Patients – Provide a broad range of services and a high standard of care at convenient times and at reasonable costs. See Sections III, IV, VIII, and X.
- Health Care Coordination – Coordinate with existing healthcare providers to address patient care needs. The applicants state *"WFUHS strives to address its patients' overall state of well-being and undue stressors are alleviated when possible."* See Section V.

In Attachment N, the applicants provide their central Quality Management Plan which explains the key principles of the quality plan and the four parts of the quality program structure designed to ensure patients received high quality, comprehensive care.

The applicants also discuss their safety measures in Section XI.6.(g), page 62. In Attachment U, the applicants provide a copy of the isolation policies and procedures and in Attachment V, provide a copy of the Safety Manual.

The applicants adequately demonstrate how their proposal will promote safety and quality in the provision of dialysis services in Forsyth County.

Promote Equitable Access

In Section VI, pages 32-38, the applicants provide information about accessibility to their services. On page 32, the applicants state that “*SKC accepts patients based on medically defined admission criteria.*” The applicants state they do not discriminate based on race, sex, national origin, disability, or the patient’s ability to pay. See Attachment S for the applicants Referral / Admissions Policy and a list of referring physicians.

In Section IV, page 35, the applicants state the facility is designed and constructed to accommodate handicapped persons with provisions for specified parking areas and accommodations within the facility. The applicants state “*Construction guidelines set forth in the 1978 Edition of the North Carolina Building Code, Life Safety Code, 1991 Edition, and Guidelines for Construction and Equipment of Hospitals and Medical Facilities were utilized in the design of the facility.*”

In Section VI.3, page 36, the applicants state “*The facility does not require payment upon initial treatment for those patients transferring their care to the facility.*” The applicants address the payment policy and conditions for transient patients separately in Attachment S, which indicates the facility does require payment in advance for transient patients not requesting a transfer of care to SKC. As documented in Attachment S, “*New patients, transients and transfers will be accepted into the facility according to stability for outpatient dialysis, availability of an open station, staffing availability, and referral/acceptance by physician with admitting privileges to facility.*” In Section VI.1.(b), page 32, the applicants project the breakdown of patients by payor mix.

The applicants adequately demonstrate medically underserved groups will have equitable access to the proposed services.

Maximize Healthcare Value

In Section II, page 18, the applicants state, “*The facility will maximize healthcare value by providing the proposed services in compliance with all Federal and State rules and regulations to those in need of the services in the proposed service area.*” In order to meet current and future patient needs, the applicants propose to:

- Keep utilization between 80 and 90 percent through cooperation with area sister-facilities;
- Expand the facility when needed; and
- Maintain high levels of efficiency when providing service.

In Section VIII, page 45, the applicants propose to utilize existing space at SKC for the addition of the three dialysis stations, and no renovation is required.

The applicants adequately demonstrate the proposal will maximize healthcare value. Additionally, the applicants demonstrate projected volumes for the proposed services

incorporate the basic principles in meeting the needs of patients to be served. See Criteria (3) and (13c). The application is consistent with Policy GEN-3.

Policy GEN-4: Energy Efficiency and Sustainability for Health Services Facilities in the 2012 SMFP states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.”

The capital cost of this project is less than \$2 million. Therefore, Policy Gen-4 is not applicable to this review.

This application is consistent with the facility need determination in the July 2012 SDR and with Policy GEN-3. Therefore, the application is conforming to this criterion.

- (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

Co-applicants Wake Forest University Health Sciences (WFUHS) and Salem Kidney Center of Wake Forest University (SKC) currently operate a 36-station dialysis facility located at 2705 Boulder Park Court, Winston-Salem. The applicants propose to add three dialysis stations to the existing SKC facility for a total of 39 certified dialysis stations upon project completion. The July 2012 SDR indicates SKC has a total of 36 certified dialysis stations as of December 31, 2011. Based on patient origin information provided in the table in Section III.7, page 22, the applicants do not propose any home training.

Population to be Served

In Section IV.1, page 24, the applicants state that the number of in-center patients served at SKC as of June 30, 2012, as illustrated below.

County of Residence	# of Patients Dialyzing In-Center	Percent of Total
Forsyth	130	99.2%
Rockingham	1	0.8%
Total	131	100.0%

In Section III.7, page 22, the applicants provide the projected patient origin for the first two years of operation following completion of the project, as illustrated in the following table.

County	Year 1 07/01/13 - 06/30/14	Year 2 07/01/14 – 06/30/15	County Patients as a Percent of Total	
	In-Center Patients	In-Center Patients	Year 1	Year 2
Forsyth	133.14	134.74	99.20%	99.18%
Rockingham	1.07	1.11	00.80%	00.82%
TOTAL	134.21	135.85	100.00%	100.00%

The applicants adequately identify the population to be served.

Demonstration of Need

In Section III.7, pages 21-23, the applicants state their application is filed pursuant to the Facility Need Methodology utilizing data from the July 2012 SDR. The applicants propose to add three dialysis stations to the existing SKC facility for a total of 39 certified dialysis stations upon project completion. In the assumptions and methodology used to project need for the three additional dialysis stations at SKC, the applicants provide the following information:

- SKC identified a beginning patient population of 131 in-center patients, as of June 30, 2012.
- The project is scheduled for completion and certification of stations by June 30, 2013. The applicants project July 1, 2013 - June 30, 2014, as operating year 1 (OY1) and July 1, 2014 – June 30, 2015, as operating year 2 (OY2).
- The applicants assume the ESRD patient population of Forsyth and Rockingham counties will increase at the Five Year Average Annual Change Rate (AACR) published in the July 2012 SDR, for at least the period of project development, OY1, and OY2. The AACR for Forsyth County is 1.2 percent and the AACR for Rockingham County is 3.6 percent.
- *“There are no outside indicators to suggest uncalculated growth or deaths shall occur.”*

Therefore, the applicants project in-center utilization starting with a total of 131 in-center patients at of June 30, 2012, (130 Forsyth County patients + 1 Rockingham County patient), as shown below.

	SKC Methodology for Projecting Utilization Using AACR's by County	Projected In-Center Patients
Forsyth County Patient Growth through 06/30/13	130 x 1.012 =	131.560
Rockingham County Patient Growth through 06/30/13	1 x 1.036 =	1.036
Total SKC Projected In-Center Patients through 06/30/13	131.560 + 1.036 =	132.596
Forsyth County Patient Growth through 06/30/14	131.560 x 1.012 =	133.139
Rockingham County Patient Growth through 06/30/14	1.036 x 1.036 =	1.073
Total SKC Projected In-Center Patients through 06/30/14 (Year 1)	133.139 + 1.073 =	134.212
Forsyth County Patient Growth through 06/30/15	133.139 x 1.012 =	134.736
Rockingham County Patient Growth through 06/30/15	1.073 x 1.036 =	1.112
Total SKC Projected In-Center Patients through 06/30/15 (Year 2)	134.736 + 1.112 =	135.848

The applicants project utilization at SKC to be as follows:

Operating Year 1

134 patients dialyzing at 39 stations = 3.44 patients per station (134 / 39 = 3.4359)
 [134 / (39 x 4) = 0.8589] or 86 percent

Operating Year 2

135 patients dialyzing at 39 stations = 3.46 patients per station (135 / 39 = 3.4615)
 [135 / (39 x 4) = 0.8653] or 87 percent

The applicants' projected utilization at the end of Year 1 is equal to or greater than 3.2 in-center patients per station per week as required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and supported assumptions regarding continued growth. The applicants adequately demonstrated the need to add additional dialysis stations to the existing SKC facility.

Access to Services

In Section VI, page 32, 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.”

The applicants project 83 percent of their patients will be covered by Medicare and VA. The applicants demonstrate adequate access for the underserved to their services.

In summary, the applicants adequately identify the population to be served, demonstrate the need the population has for three additional dialysis stations at SKC, and demonstrate

all residents in the area, in particular underserved groups, are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

- (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

- (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.

C

In Section III.9, page 23, the applicants discuss three alternatives considered prior to the submission of this application, which include the following:

- 1) Maintain the Status Quo. This is not an alternative chosen by the applicants because it is not consistent with their goal of quality care stated on page 16, *“maintain sufficient stations and staffing to provide care to the ever-growing ESRD population.”*
- 2) Funnel new and existing patients, who are interested in utilizing WFUHS’ facilities, to one of the four other WFUHS Forsyth County Dialysis facilities operating under 80 percent. This is not an alternative chosen by the applicants because it would create a travel hardship for many patients, since SKC is located further east than the other facilities.
- 3) Add three dialysis stations at SKC for a total of 39 dialysis stations. The applicants propose to add three additional stations to the existing treatment space at SKC to provide adequate access to dialysis services *“...to accommodate patient demand in the eastern-most WFUHS facility.”*

On page 23, the applicants state, *“The project cost is minimal and would not significantly impact SKC’s overhead costs as no new staff would need to be hired nor would costly construction be required to house the new stations.”*

The applicants adequately demonstrate the need for three additional stations based on the continued growth of the ESRD patient population of Forsyth County and the facility’s projected utilization. See Criterion (3) for further discussion on need, which is incorporated hereby as if fully set forth herein.

Furthermore, the application is conforming to all other statutory and regulatory review criteria. Therefore, the application is approvable.

In summary, the applicants adequately demonstrate that their proposal is the least costly or most effective alternative to meet the need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1. Wake Forest University Health Sciences (WFUHS) and Salem Kidney Center of Wake Forest University (SKC) shall materially comply with all representations made in their certificate of need application.**
 - 2. Wake Forest University Health Sciences (WFUHS) and Salem Kidney Center of Wake Forest University (SKC) shall develop no more than 3 additional dialysis stations at Salem Kidney Center of Wake Forest University (SKC) for a total of 39 stations upon completion of this project.**
 - 3. Wake Forest University Health Sciences (WFUHS) and Salem Kidney Center of Wake Forest University (SKC) shall install plumbing and electrical wiring through the walls for no more than 3 additional dialysis stations, for a total of 39 stations, which shall include any isolation stations.**
 - 4. Wake Forest University Health Sciences (WFUHS) and Salem Kidney Center of Wake Forest University (SKC) shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section 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.

CA

In Section VIII.1, pages 45-46, the applicants project a capital cost of \$45,000 for the proposed project, funded through accumulated reserves. In Section IX.3, page 50, the applicants state there will be no start-up or initial operating expenses associated with the proposed project.

In Exhibit D, the applicants provide the audited financial statements for WFUHS and subsidiaries for the years ending June 30, 2011 and 2010. As of June 30, 2011, WFUHS and subsidiaries had cash and cash equivalents totaling \$36,418,000 with \$1,229,067,000 in total assets and \$669,880,000 in net assets (total assets less total liabilities). The applicants adequately demonstrate the availability of funds for the proposed project.

In Section X.1, page 51, the applicants project the following charges per treatment for each payment source as shown below.

Payment Source	In-Center Charge
Commercial Insurance	\$990
Medicare	\$235
Medicaid	\$195
VA	\$252
Private Pay	\$990

The applicants state their revenue is calculated based on a bundled rate. The billable amount of \$1,190 is the same for all payment sources, while the in-center charge varies according to contract term.

The applicants project net revenue in Section X.2, pages 51-52, and operating expenses in Section X.4, page 56, of the application. The applicants project revenues in excess of expenses in each of the first two operating years following completion of the project, as illustrated in the table below.

	Operating Year 1 (OY1) 07/01/2013 - 06/30/2014	Operating Year 2 (OY2) 07/01/2014 - 06/30/2015
Total Projected Net Revenue	4,942,637	5,039,536
Total Projected Operating Costs	4,344,116	4,426,691
Projected Net Profit	598,521	612,845

Source: Application pages 52 and 56.

In Section X.3, pages 53-55, the applicants used the following assumptions to project revenue for OY1 and OY2:

Assumptions

1. Average number of patients for the current year is increased by the county AACR through the first two operating years.
2. Average of three treatments per patient per week is reduced by six percent to allow for missed treatments.
3. Billable amount is increased by three percent per year, except for non-commercial payors, which reflect only the current rates for the first two operating years.
4. Deductions from billable (gross) revenue include:
 - Indigent/Charity care calculated at 0.14 percent of gross revenue;
 - Bad debt calculated at 2.59 percent of gross revenue; and
 - Contractual allowance calculated at 76.64 percent for OY1 and 77.16 percent for OY2 from gross revenue.
5. Average reimbursement per treatment is based on the applicants' historical experience.

In Section X, page 57, the applicants provide projected staffing and salaries. On page 39, the applicants state the facility is in compliance with the requirements of 42 C.F.R. Section 494. Staffing by shift is provided on page 44. The applicants project adequate staffing to provide dialysis treatments for the number of patients projected. See Criterion

(3) for discussion regarding projected utilization which is incorporated hereby as if fully set forth herein.

The applicants adequately demonstrate that the financial feasibility of the proposal is based on reasonable projections of costs and revenues; however, the applicant did not include a commitment of funds letter reflecting financing from accumulated reserves, as stated on page 47 of the application. The application is conforming to Criterion (5) subject to the condition which appears at the end of this criterion.

Therefore, the application is conforming to this criterion subject to the following condition.

Prior to issuance of the Certificate of Need, Wake Forest University Health Sciences (WFUHS) and Salem Kidney Center of Wake Forest University (SKC) shall provide to the Certificate of Need Section a letter from WFUHS indicating a willingness to finance the proposed project.

- (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

Co-applicants Wake Forest University Health Sciences (WFUHS) and Salem Kidney Center of Wake Forest University (SKC) propose to add three dialysis stations to the existing SKC facility for a total of 39 certified dialysis stations upon project completion. The applicants adequately demonstrate the need for three additional stations based on the number of in-center patients it proposes to serve. Per the July 2012 SDR, as of December 31, 2011, the 36 station SKC facility was operating at 85 percent capacity. ($123/36 = 3.4167$; $3.42/4 = 85.5$ percent). The target utilization rate is 80 percent. Therefore, the applicants are eligible to expand their facility and may apply for additional stations. Upon completion of this project, the applicants state on page 22, the facility will have 39 stations serving 134 patients (end of OP1), which is a utilization of 86 percent ($134/39 = 3.4359$; $3.44/4 = 86$ percent). The applicants are conforming to the requirement in 10A NCAC 14C .2203.

WFUHS operates the other three dialysis centers in Forsyth County; Piedmont Dialysis, Northside Dialysis Center, and Miller Street Dialysis Center with utilization rates ranging from 56.85 percent to 75 percent. In Section V, page 31, the applicants state:

“This project will have no impact on competition in Forsyth County. WFUHS is the sole provider of ICH dialysis care within the service area. Expansion of SKC will enhance access to services at that facility in eastern Forsyth County at a minimal cost without resulting in an increase in overhead. The result is greater facility cost-effectiveness as additional patients utilize care in a single plant.”

The applicants adequately demonstrate the proposed project will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Therefore, the application is conforming to this criterion.

- (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 VII.1, page 39, the applicants provide the current and projected number of full-time equivalent (FTE) positions as shown in the table below.

POSITION	CURRENT # OF FTES	PROJECTED # OF NEW FTES	TOTAL # OF FTES
RN	5.5	0	5.5
LPN	3.0	0	3.0
Patient Care Tech (PCT)	14.5	0	14.5
CNM	1.0	0	1.0
Bio-Med Tech	1.0	0	1.0
Dialysis Tech	4.0	0	4.0
Salary – Medical Director	Salary –	Not an FTE	
Admin.	0.1	0	0.1
Clerical	4.0	0	4.0
Dietician	1.0	0	1.0
Social Worker	1.0	0	1.0
Total	35.1	0	35.1

Source: Section VII, page 39.

As shown in the table above, the applicants propose to employ a total of 35.1 full-time equivalent (FTE) positions to staff SKC. In Section V.4, page 29, the applicants state that Dr. Pirouz Daeihagh will continue to serve as medical director of the facility and is a Board Certified Nephrologist. Attachment Q contains resumes of the professional staff. Attachment R contains a letter of support from Dr. Daeihagh.

The applicants adequately demonstrate the availability of sufficient health manpower and management personnel to provide the proposed service. Therefore, the application is conforming to this criterion.

- (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 V.1, page 26, the applicants list the providers of the necessary ancillary and support services. The applicants state the method for providing the services in response to 10 NCAC 14C .2204, beginning on page 15. Ancillary and support services beyond facility capability, excluding transportation, will be provided by Wake Forest Baptist Medical Center. Attachments E, F, J, and K contain documentation on service agreements. Attachment L contains documentation regarding transportation services. The information provided in those sections and exhibits is reasonable and credible and supports a finding of conformity with this criterion.

- (9) An applicant proposes 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

- (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

NA

- (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

- (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

- (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 VI.1.(a), page 32, the applicants discuss SKC's history of providing dialysis services to the underserved populations in North Carolina. 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....” The applicants' referral and admission policy are located in Attachment S.

In Section VI.1.(b), page 32, the applicants report that 91 percent of the patients who received treatments at SKC had some or all of their services paid for by Medicare or Medicaid in the past year. The table below illustrates the current historical payor mix for the facility.

SKC Historical Payor Source	
Payor Source	In-Center
Medicare Advantage	27%
Medicare/Medicaid	26%
Medicare/Commercial	16%
Medicare	12%
Medicaid	10%
Commercial Insurance	7%
VA	2%
Total	100%

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and

estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Forsyth County and statewide.

	June 2010 Total # of Medicaid Eligibles as % of Total Population *	June 2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Forsyth County	16%	5.7%	19.5%
Statewide	17%	6.7%	19.7%

* More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21. This age group would not typically utilize the health services proposed in this application. In fact, only 5.8 percent of all 2011 Incident ESRD patients in North Carolina Network 6 were under the age of 35.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicants' current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The Centers for Medicare and Medicaid Services (CMS) website indicates:

“Although the ESRD population is less than 1% of the entire U.S. population, it continues to increase at a rate of 3% per year and includes people of all races, age groups, and socioeconomic standings.

...

Almost half (46.6%) of the incident patients in 2004 were between the ages of 60 and 79. These distributions have remained constant over the past five years. While the majority of dialysis patients are White, ESRD rates among Blacks and

Native Americans are disproportionately high. While Blacks comprise over 12% of the national population, they make up 36.4% of the total dialysis prevalent population. In 2004 males represented over half of the ESRD incident (52.6%) and prevalent (51.9%) populations.”¹

Additionally, the United States Renal Data System, in its 2012 USRDS Annual Data Report, provides these national statistics for FY 2010:

“On December 31, 2010, more than 376,000 ESRD patients were receiving hemodialysis therapy...”

The report validates the statistics reported by CMS above. Of the 376,000 ESRD patients, 38.23 percent were African American, 55.38 percent were white, 55.65 percent were male and 44.65 percent were 65 and older. The report further states:

“Nine of ten prevalent hemodialysis patients had some type of Medicare coverage in 2010, with 39 percent covered solely by Medicare and 32 percent under Medicare/Medicaid. ... Coverage by non-Medicare insurers continues to increase in the dialysis population, in 2010 reaching 10.7 and 10.0 percent for hemodialysis and peritoneal dialysis patients, respectively.”

The report provides 2010 ESRD spending, by payor as follows:

Payor	Spending in Billions	% of Total ESRD Spending
Medicare Paid	\$29.6	62.32%
Medicare Patient Obligation	\$4.7	9.89%
Medicare HMO	\$3.4	7.16%
Non-Medicare	\$9.8	20.63%

The Southeastern Kidney Council provides 2011 demographic data of Network 6 ESRD Prevalence. Network 6 includes North Carolina, South Carolina, and Georgia, by age, race, and gender as shown on the table below.

¹ www.cms.gov/medicare/end-stage-renal-disease/esrdnetworkorganizations/downloads/esrdnetworkprogrambackgroundpublic.pdf

	# of ESRD Patients	% of Dialysis Population
Age		
0-19	152	0.4%
20-34	2,062	5.2%
35-44	4,056	10.3%
45-54	7,417	18.9%
55-64	10,717	27.2%
65-74	8,751	22.2%
75+	6,225	15.8%
Total	39,380	100.0%
Gender		
Male	21,153	54.0%
Female	18,227	46.0%
Total	39,380	100.0%
Race		
African American	26,693	67.8%
White	11,829	30.0%
Other	858	2.2%
Total	39,380	100.0%

The applicants demonstrate that medically underserved populations currently have adequate access to services available at SKC. 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

In Section VI.1.(f), page 35, the applicants state, *“The facility has no obligation to provide uncompensated care or community service. The facility will be accessible to minorities and handicapped person...”*

In Section VI.6, page 38, the applicants state there have been no civil rights access complaints filed within the last five years. 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 VI.1.(c), page 32, the applicants provide the projected payor mix for the proposed services at the facility. The applicants project no change from the current payor mix for dialysis visits as stated in Criterion (13a) above for OY1 and OY2. The applicant projects 91 percent of all in-center patients will have some or all of their services paid for by Medicare and Medicaid, with VA covering another 2 percent.

In Section VI.2, page 35, the applicants state the facility is designed and constructed to accommodate handicapped persons.

The applicants demonstrate that the elderly and medically underserved populations will have adequate access to the proposed services. Therefore, 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 VI.5, page 36, the applicants state:

“Patients desiring treatment at the facility receive consideration for admission by contacting the Nurse Administrator, Medical Director, or facility Social Worker. New patients may be referred by a personal physician. Once the appropriate medical documentation has been received, it is reviewed and the patient is considered for admission. Admission to the facility must be by a nephrologist with admitting privileges to the facility and the patient must be certified as suffering from chronic, irreversible, End State Renal Disease (ESRD).”

See Attachment E, the Hospital Agreement; Attachment F, the Transplantation Agreement; and Attachment S, the Referral/Admissions Policy.

The applicants adequately demonstrate that they will provide a range of means by which a person can access services. The information provided is reasonable and credible and supports a finding of conformity with 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 V.3, pages 28-29, the applicants state health related education and training programs have the opportunity to visit the facility, receive instruction, and obtain onsite experience. The applicants have a formal agreement with Forsyth Technical Community

College to provide education experiences and clinical internships to their students. See Attachment Y.

The applicants adequately demonstrate that the facility will accommodate the clinical needs of health professional training programs in the proposed service area. The information provided is reasonable and credible and supports a finding of conformity with 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 three dialysis stations to the existing SKC facility for a total of 39 certified dialysis stations upon completion of the proposed project. The July 2012 SDR shows there is a surplus of 23 dialysis stations in Forsyth County; however, the applicants qualify for additional dialysis stations based on the facility need methodology. WFUHS operates Piedmont Dialysis, Northside Dialysis Center, and Miller Street Dialysis Center with utilization rates ranging from 56.85 percent to 75 percent.

In Section V, page 31, the applicants discuss the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality, and access:

“This project will have no impact on competition in Forsyth County. WFUHS is the sole provider of ICH dialysis care within the service area. Expansion of SKC will enhance access to services at that facility in eastern Forsyth County at a minimal cost without resulting in an increase in overhead. The result is greater facility cost-effectiveness as additional patients utilize care in a single plant.”

See also Sections II, III, V, VI and VII where the applicants discuss the impact of the project on cost-effectiveness, quality and access. The information provided by the applicants in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition in the service area include a positive impact on cost-

effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicants adequately demonstrate the need based on “Facility Need”, to add three dialysis stations for a total of 39 certified dialysis stations following completion of this project. The applicants also demonstrate that the proposed project is a cost-effective alternative to meet the need to provide additional access to SKC patients;
- The applicants have and will continue to provide quality services. The information regarding staffing provided in Section VII is reasonable and credible and demonstrates adequate staffing for the provision of quality care services in accordance with 42 C.F.R., Section 494 (formerly 405.2100). The information in Section V regarding ancillary and support services and coordination of services with the existing health care system is reasonable and credible and demonstrates the provision of quality care; and
- The applicants have and will continue to provide adequate access to medically underserved populations. In Section VI.1, page 32, the applicants state that “*SKC accepts patients based on medically defined admission criteria.*” The applicants state they do not discriminate based on race, sex, national origin, disability, or the patient’s ability to pay.

Therefore, the application is conforming to this criterion.

(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

The applicants currently provide dialysis services as Salem Kidney Center of Wake Forest University in Winston-Salem, NC. According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the facility operated in compliance with the Medicare Conditions of Participation and there were no incidents resulting in a determination of immediate jeopardy during the eighteen months immediately preceding the date of this decision. 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 Criteria and Standards for End Stage Renal Disease Services, as promulgated in 10A NCAC 14C Section .2200, are applicable to this review. The proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C Section .2200. The specific findings are discussed below.

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

(a) An applicant that proposes to increase stations in an existing certified facility or relocate stations must provide the following information:

.2202(a)(1) Utilization rates;

-C- In Section III.2, page 20, the applicants provide the utilization rate as reported in the July 2012 SDR of 85.42% with 3.42 (123/36=3.4167) patients per station. Note: In this section the applicants incorrectly report the number of In-Center patients.

.2202(a)(2) Mortality rates;

-C- In Section IV.2, page 24, the applicants report the 2009, 2010, and 2011 facility mortality rates as 19.67%, 17.74%, and 18.70% respectively.

.2202(a)(3) The number of patients that are home trained and the number of patients on home dialysis;

-NA- In Section IV.3, page 24, the applicants state that SKC has a sister-facility agreement with Piedmont Dialysis Center for the provision of home training services. See Attachment J. The applicants do not propose to have any home hemodialysis patients at the facility.

.2202(a)(4) The number of transplants performed or referred;

-C- In Section IV.4, page 24, the applicants state, "From January 2012 – July 2012, there have been three (3) patients at SKC who have received kidney transplants and seven (7) overall in the last twelve months."

.2202(a)(5) The number of patients currently on the transplant waiting list;

-C- In Section IV.5, page 24, the applicants state that the SKC has eight patients on transplant waiting list as of July 2012.

.2202(a)(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*

-C- In Section IV.6, page 25, the applicants report a total of 307 hospital admissions; 105 were dialysis-related admissions and 202 were non-dialysis related admissions.

.2202(a)(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.*

-C- In Section IV.7, page 25, the applicants report that in 2011 there were fourteen patients with an infectious disease. No patients converted to infectious status in 2011.

(b) An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:

.2202(b)(1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100 (Replaced with 42 CFR Part 494).*

-NA- Salem Kidney Center of Wake Forest University is an existing facility.

.2202(b)(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*

(A) *timeframe for initial assessment and evaluation of patients for transplantation,*

(B) *composition of the assessment/evaluation team at the transplant center,*

(C) *method for periodic re-evaluation,*

(D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and,*

(E) *Signatures of the duly authorized persons representing the facilities and the agency providing the services.*

-NA- Salem Kidney Center of Wake Forest University is an existing facility.

.2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*

-NA- Salem Kidney Center of Wake Forest University is an existing facility.

.2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*

-C- See Attachment P for a copy of SKC's Dialysis Planning Guide for Emergency/Disaster Situations which has written policies and procedures for back up of electrical service in the event of a power outage.

- .2202(b)(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*
- NA- Salem Kidney Center of Wake Forest University is an existing facility.
- .2202(b)(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*
- C- See Sections II.1, page 14, and XI.6.(g), page 62, for documentation that SKC's services will be provided in conformity with applicable laws and regulations.
- .2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C- See Section III.7, pages 22-23, for the assumptions and methodology the applicants use to project patient origin. See also discussion in Criterion (3), which is incorporated hereby as if fully set forth herein.
- .2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
- NA- Salem Kidney Center of Wake Forest University is an existing facility.
- .2202(b)(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement for such services.*
- C- In Section II, page 14, the applicants state, "The facility is committed to admitting and providing dialysis services to patients who have no insurance or other source of payment, but for who payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services."

10 NCAC 14C .2203 PERFORMANCE STANDARDS

- .2203(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- Salem Kidney Center of Wake Forest University is an existing facility.

.2203(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 III.7, page 22, the applicants project to serve 134 in-center patients by the end of OY1, which is 3.44 patients per station ($134 / 39 = 3.4359$).

.2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

-C- In Section III.7, pages 22-23, the applicants provide the assumptions and methodology used to project utilization of the proposed facility. The applicants project an annual increase in their current Forsyth and Rockingham County patient utilization by applying the county five year AACR.

10 NCAC 14C .2204 SCOPE OF SERVICES

To be approved, the applicant must demonstrate that the following services will be available:

.2204(1) *Diagnostic and evaluation services;*

-C- See Section V.1, page 26. Applicants will provide diagnostic and evaluation services.

.2204(2) *Maintenance dialysis;*

-C- See Section V.1, page 26. Applicants will provide maintenance dialysis.

.2204(3) *Accessible self-care training;*

-C- See Section V.1, page 26 and Attachment J, which contain a copy of the patient services agreement with Piedmont Dialysis Center.

.2204(4) *Accessible follow-up program for support of patients dialyzing at home;*

-C- See Section V.1, page 26 and Attachment J, which contain a copy of the patient services agreement with Piedmont Dialysis Center.

.2204(5) *X-ray services;*

-C- See Section V.1, page 26 and Attachment E, which contain a copy of the Affiliation Agreement with North Carolina Baptist Hospital.

.2204(6) *Laboratory services;*

-C- See Section V.1, page 26 and Attachments E and K. Attachment E contains a copy of the Affiliation Agreement with North Carolina Baptist Hospital. Attachment K contain a copy of the Contractual Agreement with Meridian Laboratory Corporation and Health Systems Management, Inc.

.2204(7) *Blood bank services;*

-C- See Section V.1, page 26 and Attachment E, which contain a copy of the Affiliation Agreement with North Carolina Baptist Hospital.

- .2204(8) *Emergency care;*
 - C- See Section V.1, page 26 and Attachment E, which contain a copy of the Affiliation Agreement with North Carolina Baptist Hospital.

- .2204(9) *Acute dialysis in an acute care setting;*
 - C- See Section V.1, page 26 and Attachment E, which contain a copy of the Affiliation Agreement with North Carolina Baptist Hospital.

- .2204(10) *Vascular surgery for dialysis treatment patients*
 - C- See Section V.1, page 26 and Attachment E, which contain a copy of the Affiliation Agreement with North Carolina Baptist Hospital.

- .2204(11) *Transplantation services;*
 - C- See Section V.1, page 26 and Attachment F, which contain a copy of the Renal Transplant Facility Agreement with North Carolina Baptist Hospital.

- .2204(12) *Vocational rehabilitation counseling and services; and*
 - C- In Section V.1, page 26, the applicants state they will make an appropriate referral after an initial evaluation is completed by an MSW.

- .2204(13) *Transportation*
 - C- See Section V.1, page 26 and Attachment L, which contain letters of support from transportation services servicing SKC.

10 NCAC 14C .2205 STAFFING AND STAFF TRAINING

- .2205(a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R. Section 405.2100 (Replaced with 42 CFR Part 494).*
 - C- In Section VII, page 39, the applicants state SKC does and will comply with all staffing requirements set forth in 42 C.F.R., Part 494 (formerly 405.2100). See Criterion (7) for further discussion on staffing which is incorporated hereby as if fully set forth herein.

- .2205(b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*
 - C- See Section VII.5, page 42, and Attachment M for information concerning the training/orientation program and continuing education program offered at the facility.