

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: December 19, 2014

PROJECT ANALYST: Kim Randolph

INTERM CHIEF: Martha Frisone

PROJECT I.D. NUMBER: G-10327-14/ Wake Forest University Health Sciences and Davie Kidney Center of Wake Forest University/ Add three dialysis stations for a total of 13 stations/ Davie 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

Wake Forest University Health Sciences (WFUHS) and Davie Kidney Center of Wake Forest University (Davie Kidney Center) propose to add three dialysis stations to the existing facility for a total of 13 certified dialysis stations upon completion of this project. Davie Kidney Center is located at 190 Interstate Drive, Mocksville, NC, Davie County.

#### **Need Determination**

The 2014 State Medical Facilities Plan (2014 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. ESRD dialysis station need determinations are published semiannually, in the January and July North Carolina Semiannual Dialysis Report (SDR), by the State Health Coordinating Council and the Medical Facilities Planning Branch, Division of Health Service Regulation, Department of Health and Human Services, pursuant to Chapter 14 of the 2014 SMFP. The January 2014 SDR is the applicable SDR for applications submitted in 2014 prior to July 1, 2014. The July 2014 SDR is the applicable SDR for applications submitted in 2014 after July 1, 2014.

According to the July 2014 SDR, the county need methodology indicates there is no need for additional stations in Davie County. However, the applicants are eligible to apply for additional stations based on the facility need methodology, because the utilization rate reported for Davie Kidney Center in the July 2014 SDR is 3.50 patients per station. This utilization rate was calculated based on 35 in-center dialysis patients and 10 certified dialysis stations as of December 31, 2013 (35 patients / 10 stations = 3.50 patients per station).

Application of the facility need methodology indicates three additional stations are needed for this facility, as illustrated in the following table.

**October 1 Review - July 2014 SDR**

Required SDR Utilization		80.0%
Center Utilization Rate as of 12/31/13		87.5%
Certified Stations		10
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>10</b>
In-Center Patients as of 12/31/13 (SDR2)		35
In-Center Patients as of 06/30/13 (SDR1)		32
Step	Description	
(i)	Difference (SDR2 - SDR1)	3
	Multiply the difference by 2 for the projected net in-center Change	6
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 06/30/13	0.1875
(ii)	Divide the result of Step (i) by 12	0.0156
(iii)	Multiply the result of Step (ii) by the number of months from 12/31/13 until the end of the current calendar year.	0.1875
(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	41.5625
(v)	Divide the result of Step (iv) by 3.2 patients per station	12.9883
	and subtract the number of certified and pending stations as recorded in SDR2 [10] to determine the number of stations needed	2.9883 = 3 stations

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is three stations. Step (C) of the facility need methodology states *“The facility may apply to expand to meet the need established ..., up to a maximum of*

*ten stations.*” The applicants propose to add three new stations and, therefore, are consistent with the facility need determination for dialysis stations.

### **Policies**

There is one policy in the 2014 SMFP that is applicable to this review, Policy GEN-3: Basic Principles. This policy 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 II, pages 16-17, Section XI.6(g), page 64, and referenced attachments. 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 VI, pages 33-39, and referenced attachments. 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 II, page 18, Section VIII, page 46, and referenced attachments. 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 their 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**

In summary, the applicants adequately demonstrate that the application is consistent with the facility need determination in the July 2014 SDR and 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

Wake Forest University Health Sciences and Davie Kidney Center propose to add three dialysis stations to the existing Davie Kidney Center facility for a total of 13 dialysis stations upon completion of this project.

**Population to be Served**

In Section IV.1, page 25, the applicants state the number of patients served at Davie Kidney Center, as of June 30, 2014, is illustrated below.

<b>County of Residence</b>	<b>Number of ICH Patients*</b>	<b>Number of Home Patients</b>
Alexander	1	0
Burke	1	0
Davie	36	0
Iredell	2	0
<b>Total</b>	<b>40</b>	<b>0</b>

\* In-Center Hemodialysis (ICH)

In Section III.7, page 22, the applicants identify the projected patient origin for Davie Kidney Center’s in-center patients for the first two years of operation following completion of the project, as illustrated below.

County	Operating Year 1 (OY 1) (07/01/15 – 06/30/16)		Operating Year 2 (OY 2) (07/01/16 – 06/30/17)		County Patients as a Percent of Total	
	ICH	Home	ICH	Home	OY 1	OY 2
Davie	38.86	0	40.38	0	89.97%	89.95%
Iredell	2.06	0	2.13	0	4.93%	4.90%
Burke	1.11	0	1.16	0	2.56%	2.59%
Alexander	1.10	0	1.15	0	2.54%	2.56%
<b>Total</b>	<b>43.20</b>	<b>0</b>	<b>44.89</b>	<b>0</b>	<b>100.00%</b>	<b>100.00%</b>

The applicants adequately identify the population Davie Kidney Center proposes to serve.

**Analysis of Need**

In Section III.9, page 23, the applicants state Davie Kidney Center is currently at 100% utilization and needs additional dialysis stations. The applicants propose to add three additional stations. In Section III.7, pages 22-23, the applicants provide the assumptions and methodology used to determine the need for additional stations and to project Davie Kidney Center’s patient utilization as summarized below.

1. The applicants identify a beginning patient population of 40 in-center patients, as of June 30, 2014.
2. The beginning patient population is increased per year by the Five Year Average Annual Change Rate (5-year AACR) published in the July 2014 SDR, by patient county of origin, through the end of OY 2.
3. The 5-year AACR accounts for patient deaths and indicates the net average patient growth.
4. The project is scheduled for completion and certification of stations on June 30, 2015. OY 1 is the period from July 1, 2015 through June 30, 2016, and OY 2 is the period from July 1, 2016 through June 30, 2017.
5. There are no outside indicators to suggest uncalculated growths or deaths.

*Projected Utilization*

Using the beginning patient population and increasing it per year by the published 5-year AACR by patient county of origin, the following table demonstrates the applicants’ calculations used to arrive at the projected in-center patient census for the first two operating years.

County	5-Year AACR	Current ICH 07/01/13 - 06/30/14	Interim ICH 07/01/14 - 06/30/15	OY 1 07/01/15 - 06/30/16	OY 2 07/01/16 - 06/30/17
Davie	0.039	36	37.40	38.86	40.38
Iredell	0.032	2	2.064	2.06	2.13
Burke	0.052	1	1.052	1.11	1.16
Alexander	0.047	1	1.052	1.10	1.15
<b>Total</b>		<b>40</b>	<b>41.57</b>	<b>43.20</b>	<b>44.89</b>

At the end of operating year one, Davie Kidney Center is projecting an in-center patient census of 43 patients for a utilization rate of 83.07% or 3.32 patients per station ( $43 / 13 = 3.32$ ;  $3.32 / 4 = .8307$ ). At the end of operating year two, Davie Kidney Center is projecting an in-center patient census of 44 patients for a utilization rate of 86.32% or 3.45 patients per station ( $44 / 13 = 3.45$ ;  $3.45 / 4 = .8632$ ).

Projected patient in-center utilization at the end of operating year one is 3.3 in-center patients per station per week which satisfies the 3.2 in-center patients per station required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth. The applicants adequately demonstrate the need the population has for the proposed services.

**Access**

In Section VI, page 33, the applicants state

*“The WFUHS dialysis centers accept 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, WFUHS dialysis facilities also accept the needy and the homeless, through its referral system, and assists those patients in obtaining the medical care they need.”*

The applicants project 92% of their patients will be covered by Medicare primary payors (Medicare, Medicare/Medicaid, Medicare/Commercial and Medicare Advantage). The applicants adequately demonstrate the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services.

**Conclusion**

The applicants adequately identify the population to be served, demonstrate the need that population has for the proposed project and demonstrate the extent to which all residents of

the area, including underserved groups, are likely to have access to the services. 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.

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In Section III.9, pages 23-24, the applicants discuss the alternatives considered prior to submission of this application, which include:

- 1) Maintain the status quo – the applicants state Davie Kidney Center could continue to operate with the existing 10 stations and add a third shift, since they are currently at 100% utilization. The applicants state this alternative is not as effective because many patients rely on transportation services. The applicants state travel can be more hazardous in the evening, during the winter. Additionally, WFUHS serves five Davie County residents and five Davie County home patients at other kidney disease treatment centers in neighboring counties. The applicants state if any of these patients want to transfer to Davie Kidney Center or the home patients need ICH services, there would be no daytime treatment slots available.
- 2) Relocate one station from Piedmont Dialysis Center via Policy ESRD-2 - the applicants state this alternative is not as effective because they need more than one additional station based on the facility need methodology. Additionally, Piedmont Dialysis Center is not currently serving any Davie County residents who wish to transfer their care.
- 3) Apply for two additional stations - the applicants state this alternative is not as effective because two additional stations would only temporarily reduce the utilization rate of the facility and is not as cost effective as applying for the number of stations needed.

The applicants state that the chosen alternative, to apply to expand the existing Davie Kidney Center facility by adding three stations for a total of 13 certified dialysis stations, is the most effective or least costly alternative for meeting the needs of the patients projected to receive treatment at Davie Kidney Center based on the following:

- It prevents the need for a third shift;
- It allows patients greater service options during normal business hours;
- It will not create a significant surplus of dialysis stations in Davie County; and
- It will adjust the existing facility utilization rate to a more manageable level.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicants adequately demonstrate that this 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 and Davie Kidney Center of Wake Forest University shall materially comply with all representations made in the certificate of need application and in the supplemental information received on November 18, 2014. In those instances where representations conflict, Wake Forest University Health Sciences and Davie Kidney Center of Wake Forest University shall materially comply with the last made representation.**
  2. **Wake Forest University Health Sciences and Davie Kidney Center of Wake Forest University shall develop and operate no more than three additional dialysis stations for a total of no more than 13 certified dialysis stations upon completion of this project, which shall include any isolation or home hemodialysis stations.**
  3. **Wake Forest University Health Sciences and Davie Kidney Center of Wake Forest University shall install plumbing and electrical wiring through the walls for no more than three additional dialysis stations for a total of no more than 13 dialysis stations, which shall include any isolation or home hemodialysis stations.**
  4. **Wake Forest University Health Sciences and Davie Kidney Center of Wake Forest University 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.

C

In Section VIII, page 46, the applicants project a capital cost of \$50,500 for the project, which includes \$46,500 for dialysis machines, \$3,300 for dialysis chairs and \$700 for plumbing expenses. In Section IX, page 51, the applicants indicate that start-up and initial operating expenses would not apply to this project because Davie Kidney Center is not a new facility.

On page 48, the applicants indicate the project will be funded with accumulated reserves from Wake Forest University Health Sciences. Attachment D contains a letter dated August 13, 2014, from the Chief Financial Officer of Wake Forest University Health Sciences, which states:

*"Davie Kidney Center is a non-profit subordinate of Wake Forest University Health Sciences. Wake Forest University Health Sciences commits to provide monies to its subordinates in order to fund these costs."*

Attachment D also contains the audited financial statements for Wake Forest University Health Sciences and Affiliates for the years ended June 30, 2013 and 2012. As of June 30, 2013, Wake Forest University Health Sciences and Affiliates had \$17,882,000 in cash and cash equivalents, \$1,220,166,000 in total assets and \$662,692,000 in net assets (total assets less total liabilities). The applicants adequately demonstrate the availability of sufficient funds for the capital needs of the project.

In Section X.1, page 52, the applicants state the billable charges are the same for all payors, \$1,467.00 for in-center treatments and \$626.99 for home treatments. The applicants project the allowable in-center charges per treatment for each payment source, based on allowable rates in effect for WFUHS dialysis facilities as of September 15, 2014, as shown below.

<b>Payor</b>	<b>Allowable ICH Charge per Treatment*</b>
Private Pay	\$1,476.00
Medicare	\$245.00
Medicaid	\$180.00
Medicare / Medicaid	\$245.00
Commercial	\$1,057.00
Medicare / Commercial	\$245.00
VA	\$252.00
Medicare / Advantage	\$281.75

\* Davie Kidney Center does not currently have any home dialysis patients and is not projecting revenue from home dialysis treatments.

In supplemental information provided by the applicants in response to questions from the Project Analyst during the expedited review of this project, the applicants state the allowable charge for Medicare treatment shown above is higher than the allowable base rate published by the Centers for Medicare and Medicaid Services (CMS). The applicants state they used the actual facility allowable rates (+/- 3%) from the 16 free-standing dialysis centers operating in North Carolina, for the prior six semi-annual reports, to calculate the Medicare composite rate of \$245.00.

On pages 52-58, the applicants project revenues and expenses for in-center treatments for the first two operating years, as shown below.

**Davie Kidney Center ICH Treatments**

	<b>OY 1</b> <b>07/01/15 - 06/30/16</b>	<b>OY 2</b> <b>07/01/16 - 06/30/17</b>
Projected Gross Revenue*	\$9,510,121	\$10,461,149
Projected Deductions**	\$7,707,104	\$8,575,960
Projected Net Revenue	\$1,803,017	\$1,885,189
Projected Operating Costs	\$1,652,785	\$1,706,170
Projected Net Profit	\$150,232	\$179,019

\* WFUHS dialysis facilities' billable revenue, which is used to calculate gross revenue, is increased by 3% in OY1 and OY2.

\*\* Projected deductions include Indigent/Charity Care, Bad Debt, and Contractual Allowances from page 53 of the application.

As illustrated in the table above, the applicants project revenues will exceed operating expenses in each of the first two operating years following completion of the project. The applicants' projections of treatments and revenues are reasonable based on the number of in-center patients projected for the first two operating years. Operating costs and revenues are based on reasonable assumptions including projected utilization. See Section X.3, pages 54-56, for the applicants' assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

In Section VII.1, page 40, and supplemental information provided by the applicants in response to questions from the Project Analyst during the expedited review of this project, the applicants provide projected staffing and salaries. The financials in Section X.4-5, pages 57-58, budget operating costs adequate to cover the projected staffing.

In summary, the applicants adequately demonstrate the availability of sufficient funds for the capital needs of the project. The applicants also adequately demonstrate that the financial feasibility of the proposal is based on reasonable projections of operating costs and charges. Therefore, the application is conforming with this criterion.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

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Wake Forest University Health Sciences and Davie Kidney Center propose to add three dialysis stations to the existing Davie Kidney Center facility for a total of 13 certified dialysis stations upon completion of this project.

Davie Kidney Center is the only existing and approved kidney disease treatment center located in Davie County as reported in the July 2014 SDR. The applicants are proposing to add three additional stations to their existing facility based on the facility need methodology. The applicants adequately demonstrate the need for three additional stations based on the number of in-center patients they proposed to serve. The discussions regarding analysis of need and competition found in Criteria (3) and (18a), respectively, are incorporated herein by reference.

The applicants adequately demonstrate that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Consequently, 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.

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The following table illustrates the current and projected staffing for Davie Kidney Center, as provided by the applicants in Section VII.1, page 40 and in supplemental information provided by the applicants in response to questions from the Project Analyst during the expedited review of this project.

Position	Current and Projected Full-Time Equivalents (FTEs)
RN	3.00
Patient Care Technician	4.75
Clinical Nurse Manager	1.00
Medical Director	Contract Position
Dietician	1.00
Social Worker	0.50
Home Training RN	0.25
Dialysis Technician**	1.00
Biomedical Technician**	0.50
Clerical	1.00
<b>Total FTEs</b>	<b>13.00 *</b>

\* In supplemental information provided by the applicants in response to questions from the Project Analyst during the expedited review of this project, the applicants explain the total FTEs should be 13.00, not 11.25 as reflected in the application on page 40.

\*\* In supplemental information provided by the applicants in response to questions from the Project Analyst during the expedited review of this project, the applicants explain the Dialysis Technician should be 1.00 FTE and the Biomedical Technician should be 0.50 FTE, instead of the reverse, as reflected in the application on page 40.

As shown in the above table, the applicants propose to employ a total of 13 FTE positions to staff Davie Kidney Center upon completion of the proposed project.

In Section VII.10, pages 44-45, the applicants provide the projected number of direct care staff for each shift offered at Davie Kidney Center, after the addition of the three dialysis stations, as indicated in the table below.

	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	6:30 am – 12:00 pm	4	4	4	4	4	4
Afternoon	12:01 pm – 5:00 pm	4	2	4	2	4	2
Evening	N/A	0	0	0	0	0	0

In Section V.4, page 31, the applicants state that Alexander C. Hadley, M.D. will serve as medical director of the facility. Attachment R contains a letter from Dr. Hadley stating his intention to continue as the medical director for Davie Kidney Center. See Attachment S for a list of Wake Forest physicians with privileges at WFUHS kidney disease treatment centers and a list of local physicians who refer patients to these nephrologists.

The applicants document the availability of adequate health manpower and management personnel, including the medical director, for the provision of the proposed dialysis services. 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.

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In Section V, page 27, the applicants list the providers of the necessary ancillary and support services at Davie Kidney Center. Attachment K contains a copy of a Meridian Laboratory agreement. Attachments E and F respectively, contain copies of an affiliation agreement and a transplant agreement with North Carolina Baptist Hospital. Attachment L and supplemental information provided by the applicants in response to questions from the Project Analyst during the expedited review of this project contain documentation from providers of transportation services. The applicants discuss coordination with the existing health care system in Section V, pages 28-31. The applicants adequately demonstrate that the necessary ancillary and support services will continue to be available and that the proposed services will be coordinated with the existing health care system. Therefore, 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

- (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

(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;

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In Section VI.1(b), page 33, the applicants state that 92% of the in-center patients who received treatment at Davie Kidney Center had some or all of their services paid for by Medicare or Medicaid in the past year. The following table illustrates the historical payment sources for the facility.

#### **Davie Kidney Center ICH Payor Mix**

Sources of Payment	Percentage*
Private Pay	1%
Commercial Insurance	7%
Medicare	18%
Medicaid	0%
Medicare / Medicaid	21%
Medicare / Commercial	42%
Medicare / Advantage	11%
<b>Total</b>	<b>100%</b>

\* Davie Kidney Center does not currently have any home dialysis patients.

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 Davie County and statewide.

	<b>2010 Total # of Medicaid Eligibles as % of Total Population *</b>	<b>2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *</b>	<b>2009 % Uninsured (Estimate by Cecil G. Sheps Center) *</b>
Davie County	13.5%	5.1%	17.3%
Statewide	17.0%	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 does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by dialysis facilities. In fact, in 2013 only 6.6% of all newly-diagnosed ESRD patients in North Carolina were under the age of 35, according to the ESRD Network 6 2013 Annual Report. (*ESRD Network 6 2013 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 1/1/2013 – 12/31/2013, page 99*).<sup>1</sup>

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, as well as data sorted 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 do not include information on the number of elderly, minorities or women utilizing health services.

<sup>1</sup> <http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

Additionally, The United States Renal Data System, in its *2013 USRDS Annual Data Report*, pages 216-223, provides national statistics for FY 2011:

*“The December 31, 2011 prevalent population included 430,273 patients on dialysis ....”*<sup>2</sup> (p. 216)

The report also provided the incidence of dialysis patients in 2011, adjusted by age, gender and race, which showed that 65.4% were white, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian, and 1.2% were Native American (p.218). Moreover, the prevalence of ESRD for the 65-74 year old population grew by 31% since 2000 and by 48% for those aged 75 and older (p. 223). The report further states:

*“In the 2011 prevalent population, 84 percent of hemodialysis patients and 81 percent of those on peritoneal dialysis had some type of primary Medicare coverage, compared to just 53 percent of those with a transplant.”* (p. 216).

The *2013 USRDS Annual Data Report* provides 2011 ESRD spending by payor, as follows:

<b>ESRD Spending by Payor</b>		
<b>Payor</b>	<b>Spending in Billions</b>	<b>% of Total Spending</b>
Medicare Paid	\$30.7	62.4%
Medicare Patient Obligation	\$4.7	9.6%
Medicare HMO	\$3.6	7.3%
Non-Medicare	\$10.2	20.7%
<b>Total</b>	<b>\$49.2</b>	<b>100.0%</b>

The Southeastern Kidney Council (SKC) Network 6 2013 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 101, summarized as follows:

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<sup>2</sup> [www.usrds.org/adr.aspx](http://www.usrds.org/adr.aspx)

<b>Number and Percent of Dialysis Patients by Age, Race, and Gender 2013</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Age</b>		
0-19	65	0.4%
20-34	766	5.0%
35-44	1,498	9.7%
45-54	2,746	17.8%
55-64	4,039	26.2%
65+	6,275	40.8%
<b>Gender</b>		
Female	6,845	44.5%
Male	8,544	55.5%
<b>Race</b>		
African-American	9,559	62.1%
White/Caucasian	5,447	35.4%
Other	383	2.5%

Source: SKC Network 6. Table includes North Carolina statistics only.<sup>3</sup>

The applicants demonstrate that they currently provide adequate access to medically underserved populations. 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, page 36, the applicants state

*“The facility has no obligation to provide uncompensated care or community service. The facility is accessible to minorities and handicapped persons... .”*

In Section VI.6, page 39, the applicants state there have been no patient civil rights or equal access complaints filed within the last five years. Therefore, the application is conforming to this criterion.

<sup>3</sup><http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

- (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, page 33, the applicants provide the projected payor mix for the proposed services at Davie Kidney Center, which is shown below.

**Projected Davie Kidney Center ICH Payor Mix**

Source of Payment	Percentage*
Private Pay	1%
Commercial Insurance	7%
Medicare	18%
Medicaid	0%
Medicare / Medicaid	21%
Medicare / Commercial	42%
Medicare / Advantage	11%
<b>Total</b>	<b>100%</b>

\* Davie Kidney Center does not currently have any home dialysis patients.

The applicants project no change from the current payor mix for in-center dialysis services, which is 92% Medicare and Medicaid. The applicants demonstrate that medically underserved populations would 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, pages 37-38, and Attachment S, the applicants describe the range of means by which patients will have access to the proposed services. The applicants adequately demonstrate that Davie Kidney Center will offer a range of means by which a person can access the services. Therefore, 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 V.3, pages 29-30, the applicants state the Wake Forest Outpatient Dialysis Program participates with community colleges and university systems in North Carolina to provide clinical observation and hands-on learning experiences for students. See Attachment Y for a copy of the Agreement of Affiliation with Lenoir-Rhyne University. The information provided in Section V.3 and the referenced attachment is reasonable 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

Davie Kidney Center proposes to add three dialysis stations to the existing Davie County facility for a total of 13 stations upon completion of this project. According to the July 2014 SDR, Davie Kidney Center is the only existing or approved kidney disease treatment center in Davie County.

In Section V.7, page 32, the applicants discuss how any enhanced competition in the service area will promote the cost effectiveness, quality and access to the proposed services. The applicants state they do not expect this proposal to have an effect on competition in Davie County. The applicants state "*The additional stations will provide greater access to services within Davie County, which will allow DKC to better serve its existing patient base as well [sic] the projected future patient growth.*" 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 in the application is reasonable and credible and adequately demonstrates that any enhanced competition in the service area includes 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 for the proposed project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicants adequately demonstrate that they will continue to provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.
- The applicants demonstrate that they will continue to provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1) and (13) is incorporated herein by reference.

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

According to the records of the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the Davie Kidney Center operated in compliance with the Medicare Conditions of Participation within the 18 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 promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable regulatory review criteria. The specific criteria are discussed below.

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

**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.7, pages 22-23, the applicants state that as of June 30, 2014, Davie Kidney Center had a utilization rate of 100% with 40 in-center patients dialyzing on 10 stations ( $40 / 10 = 4.00$ ;  $4.00 / 4 = 1.00$ ). As of December 31, 2013, the July 2014 SDR indicates Davie Kidney Center had a utilization rate of 87.5% with 35 in-center patients dialyzing on 10 stations ( $35 / 10 = 3.50$ ;  $3.50 / 4 = 0.875$ ).

*.2202(a)(2) Mortality rates;*

- C- In Section IV.2, page 25, the applicants report Davie Kidney Center's 2011, 2012, and 2013 facility mortality rates, as 31.82%, 38.46%, and 15.62% respectively.

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

- C- In Section IV.3, page 25, the applicants state that Davie Kidney Center is certified to provide home dialysis training and support but currently has no home dialysis patients.

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

- C- In Section IV.4, page 25, the applicants indicate that Davie Kidney Center had one patient with a transplant performed or referred in 2013.

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

- C- In Section IV.5, page 26, the applicants state that Davie Kidney Center has four patients on the transplant waiting list.

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

- C- In Section IV.6, page 26, the applicants report that Davie Kidney Center had a total of 89 hospital admissions from July 1, 2013 – June 30, 2014; 36 (40.44%) were dialysis-related admissions and 53 (59.56%) 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 26, the applicants report that in 2013 - 2014, Davie Kidney Center had one patient with AIDS and two patients with Hepatitis C. Zero patients converted to infectious status in 2013 - 2014.

*(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- The applicants do not propose a new facility. Davie Kidney Center is an existing facility. The applicants include a hospital affiliation agreement in Attachment E.

.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- The applicants do not propose a new facility. Davie Kidney Center is an existing facility. The applicants include a transplantation agreement in Attachment F which includes the items listed above.

- .2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*  
 -NA- The applicants do not propose a new or replacement facility. Davie Kidney Center is an existing facility. The applicants include utility documentation in Attachment H.
- .2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*  
 -C- See Attachments H and P which contain copies of written policies and procedures, including back up procedures for 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- The applicants do not propose a new facility. Davie Kidney Center 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; VII.2, page 40; and XI.6, page 64.
- .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- The applicants provide the following projected patient origin in Section III.7, page 22, as shown below.

County	Operating Year 1 (07/01/15 – 06/30/16)		Operating Year 2 (07/01/16 – 06/30/17)		County Patients as a Percent of Total	
	ICH	Home	ICH	Home	OY 1	OY 2
Davie	38.86	0	40.38	0	89.97%	89.95%
Iredell	2.06	0	2.13	0	4.93%	4.90%
Burke	1.11	0	1.16	0	2.56%	2.59%
Alexander	1.10	0	1.15	0	2.54%	2.56%
<b>Total</b>	<b>43.20</b>	<b>0</b>	<b>44.89</b>	<b>0</b>	<b>100.00%</b>	<b>100.00%</b>

In Section III.7, pages 22-24, the applicants provide the assumptions and methodology used to project patient origin. The discussion regarding patient origin found in Criterion (3) is incorporated herein by reference.

- .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- The applicants do not propose a new facility. Davie Kidney Center 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.1, page 14, the applicants state, *“The facility is committed to admitting and providing dialysis services to patients whom 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- The applicants do not propose a new facility. Davie Kidney Center 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 that they will serve 43.20 patients on 13 stations at the end of the first operating year, based on the methodology and assumptions found on pages 22-24 of the application ( $43 / 13 = 3.31$  patients per station per week). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section III.7, pages 22-24, the applicants provide the assumptions and methodology used to project patient utilization. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

#### **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 27. The applicants state they will provide diagnostic and evaluation services.

.2204(2) *Maintenance dialysis;*

-C- See Section V.1, page 27. The applicants state they will provide maintenance dialysis.

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

-C- See Section V.1, page 27. The applicants state they will provide self-care training.

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

-C- See Section V.1, page 27. The applicants state “*DKC is certified to provide ICH services as well as home dialysis training, backup, and support services on site, offering the broadest range of treatment options to our patients.*”

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

-C- See Section V.1, page 27, and Attachment E. The applicants state North Carolina Baptist Hospital will provide X-ray services based on their Affiliation Agreement in Attachment E.

.2204(6) *Laboratory services;*

-C- See Section V.1, page 27, and Attachments E and K. The applicants state North Carolina Baptist Hospital and Meridian Laboratory Corporation will provide laboratory services.

.2204(7) *Blood bank services;*

-C- See Section V.1, page 27, and Attachment E. The applicants state North Carolina Baptist Hospital will provide blood bank services.

.2204(8) *Emergency care;*

-C- See Section V.1, page 27, and Attachment E. The applicants state North Carolina Baptist Hospital will provide emergency care.

.2204(9) *Acute dialysis in an acute care setting;*

-C- See Section V.1, page 27, and Attachment E. The applicants state North Carolina Baptist Hospital will provide acute dialysis in an acute care setting.

.2204(10) *Vascular surgery for dialysis treatment patients;*

-C- See Section V.1, page 27, and Attachment E. The applicants state North Carolina

Baptist Hospital will provide vascular surgery for dialysis treatment patients.

.2204(11) *Transplantation services;*

- C- See Section V.1, page 27, and Attachment F. The applicants state North Carolina Baptist Hospital will provide transplantation services.

.2204(12) *Vocational rehabilitation counseling and services; and*

- C- See Section V.1, page 27. The applicants state they will provide vocational rehabilitation counseling and services.

.2204(13) *Transportation;*

- C- See Section V.1, page 27, Attachment L and supplemental information provided by the applicants in response to questions from the Project Analyst during the expedited review of this project. The applicants state Yadkin Valley Economic Development District Inc. (YVEDDI) Public Transportation will provide transportation services.

## **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 C.F.R. Part 494).*

- C- In Section VII, pages 40-41 and in supplemental information provided by the applicants in response to questions from the Project Analyst during the expedited review of this project, the applicants provide the proposed staffing and state they comply with all staffing requirements set forth in 42 C.F.R. Part 494 (formerly 42 C.F.R., Section 405.2100). The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

.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.3, pages 41-43, and Attachment M.