

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: January 27, 2012

PROJECT ANALYST: Gebrette Miles

SECTION CHIEF: Craig Smith

PROJECT I.D. NUMBER: N-8744-11 / Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Hoke County / Add seven dialysis stations to the existing facility for a total of 27 stations upon completion of this project and Project I.D. #F-8725-11 / Hoke County

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications<sup>0</sup> 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

Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Hoke County currently operates a 30-station dialysis facility located at 403 South Main Street in Raeford, NC. The applicant proposes to add seven dialysis stations to the existing facility for a total of 27 stations upon completion of this project and Project I.D. #F-8725-11 [Establish a new 10-station dialysis facility in Red Springs by relocating ten stations from Dialysis Care of Hoke County (30 - 10 + 7 = 27 stations)]. Project I.D. #F-8725-11 was approved by the CON Section on January 27, 2012.

The 2011 State Medical Facilities Plan (2010 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2011 Semiannual Dialysis Report (SDR), the county need methodology shows there is no need for an additional facility in Hoke County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology. The utilization rate reported for Dialysis Care of Hoke County in the July 2011 SDR is 3.66 patients per station, or 92%. This utilization rate was calculated based on 110 in-center dialysis patients and 30 certified dialysis stations as of

December 31, 2010 (110 patients / 30 stations = 3.66 patients per station; 4.00 patients per station / 3.66 patients per station = 91.5%). Therefore, application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table.

**ESRD Facility Need Methodology  
 October Review**

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/10		92%
Certified Stations		30
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>30</b>
In-Center Patients as of 12/31/10 (SDR2)		110
In-Center Patients as of 6/30/10 (SDR1)		106
Step	Description	
	Difference (SDR2 - SDR1)	4
(i)	Multiply the difference by 2 for the projected net in-center change.	8
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 06/30/10	0.0755
(ii)	Divide the result of Step (i) by 12	0.0063
(iii)	Multiply the result of Step (ii) by the number of months from the most recent month reported in the July [2011] SDR (12/31/10) until the end of calendar year (12 months)	0.0755
(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	118.3019
(v)	Divide the result of Step (iv) by 3.2 patients per station	36.9693
	and subtract the number of certified and pending stations as recorded in SDR2 [30] to determine the number of stations needed	7

[NOTE: "Rounding" to the nearest whole number is allowed only in Step 1(C) and Step 2(B)(v). Fractions of 0.5000 or greater shall be rounded to the next highest whole number.]

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."* As shown in the table above, based on the facility need methodology for dialysis stations, the number of stations needed is seven stations, and the applicant proposes to add seven new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policy GEN-3 in the 2011 SMFP is also applicable to this review. Policy GEN-3 states:

*"A CON 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 (SMFP) 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 CON 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 CON applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the SMFP as well as addressing the needs of all residents in the proposed service area.”*

#### Promote Safety and Quality

The applicant discusses its quality index in Section I, page 7. Also, in Section II.3, pages 16-17, the applicant states,

*“DaVita, Inc. is committed to providing quality care to the ESRD population through a comprehensive Quality Management Program. DaVita’s Quality Management Program is facilitated by a dedicated clinical team of RN and Biomedical Quality Management Coordinators working under the direction of our Director of Quality Management and Director of Integrated Quality Development. ... The program exemplifies DaVita’s total commitment to enhancing the quality of patient care through its willingness to devote the necessary resources to achieve our clinical goals.*

...

*DC of Hoke County is attended by Pinehurst Nephrology Associates, admitting Nephrologists who directly oversees the quality of care of the dialysis facility. In addition, Dr. John Shepherd serves as Medical Director and provides the overall medical supervision of the dialysis unit. The facility unit administrator is the day to day manager of the facility and maintains the company’s Quality Management Program that monitors the overall care of the patients. The Quality Management Program is reviewed by the Quality Assurance Committee consisting of the Nephrologists, Unit Administrator, clinical teammates, social worker and the dietitian. ... Continuous Quality Improvement teams address facility issues with the goal of improving patient care patient outcomes.”*

The applicant also discusses its safety measures in Section XI.6(g), pages 54-55. In Exhibit 4 the applicant provides published articles about its clinical outcomes and a copy of an article which describes DaVita’s quality index. In Exhibit 12, the applicant provides a copy of its isolation policies and procedures and in Exhibit 20, the applicant provides a copy of its safety training outline. The applicant adequately demonstrates how its proposal will promote safety and quality in the provision of dialysis services in Hoke County.

#### Promote Equitable Access

In Section VI, pages 30-33, the applicant provides information about accessibility to its services. On page 30, the applicant states,

*“DC of Hoke County, by policy, has always made dialysis services available to all residents in its service area without qualifications. We have served and will*

*continue to serve without regard to race, sex, age, or handicap or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.*

*DC of Hoke County makes every reasonable effort to accommodate all of its patients; especially those with special needs such as the handicapped, patients attending school or patients who work. DC of Hoke County provides dialysis six days per week with two patient shifts per day to accommodate patient need.*

*DC of Hoke County does not require payment upon admission to its services; therefore, services are available to all patients including low-income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons. DC of Hoke County works with patients who need transportation, when necessary.”*

The applicant adequately demonstrates how its proposal will promote access to medically underserved groups.

#### Maximize Healthcare Value

In Section III.9, pages 21-22, the applicant states,

*“The Dialysis Care of Hoke County promotes cost-effective approaches in the facility in the following ways:*

...

- Dialysis Care of Hoke County purchases all of the products utilized in the facility, from office supplies to drugs to clinical supplies, under a national contract in order to secure the best products at the best price.*
- Dialysis Care of Hoke County utilizes the reuse process that contains costs and the amount of dialyzer waste generated by the facility. The dialyzers are purchased under a national contract in order to get the best quality dialyzer for the best price.*
- Dialysis Care of Hoke County has installed an electronic patient charting system that reduces the need for paper in the facility. Much of the other documentation in the facility is also done on computer which reduces the need for paper.*
- The Dialysis Care of Hoke County Bio-Medical Technician assigned to the facility conducts preventative maintenance on the dialysis machines on a monthly, quarterly, and semi-annual schedule that reduces the need for repair maintenance and parts. This extends the life of the dialysis machines.*
- The Dialysis Care of Hoke County also has an inventory control plan that ensures enough supplies are available without having an inordinate amount of supplies on hand. Supply orders are done in a timely manner to ensure that the facility does not run out of supplies, thus avoiding emergency ordering, which is costly.”*

The applicant adequately demonstrates how its proposal will maximize healthcare value. Additionally, the applicant demonstrates 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.

In addition, Policy Gen-4: *Energy Efficiency and Sustainability for Health Service Facilities* in the 2011 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 costs of this project are less than \$2 million. Therefore, Policy Gen-4 is not applicable to this review.

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

Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Hoke County currently operates a 30-station dialysis facility located at 403 South Main Street in Raeford, NC. The applicant proposes to add seven dialysis stations to the existing facility for a total of 27 stations upon completion of this project and Project I.D. #F-8725-11 [Establish a new 10-station dialysis facility north of Red Springs by relocating ten stations from Dialysis Care of Hoke County (30 – 10 + 7 = 27 stations)]. Project I.D. #F-8725-11 was approved by the CON Section on January 27, 2012. Based on patient origin information provided in the table in Section III.7, page 20 of the application, the applicant does not propose any home training.

#### **Population to be served**

In Section IV.1, page 23, the applicant states that the number of in-center patients served at the Dialysis Care of Hoke County as of December 31, 2010 is as follows:

<i>COUNTY OF RESIDENCE</i>	<i># OF PATIENTS DIALYZING IN-CENTER</i>
<i>Hoke</i>	<i>75</i>
<i>Robeson</i>	<i>29</i>
<i>Cumberland</i>	<i>3</i>
<i>Scotland</i>	<i>3</i>
<i>Total</i>	<i>110</i>

[Note: The information in the chart above differs slightly from information provided by the applicant in the previous application (Project I.D. # N-8725-11), even though the information provided is for the same dialysis center (Dialysis Care of Hoke County) and the same time period. While the total is the same in both applications (110), the previous application stated the following: Hoke (72), Robeson (29), Scotland (4), Cumberland (4), and Moore (1). (See Demonstration of Need Section below for additional discussion.)]

In Section III.7, page 20, the applicant provided the projected patient origin for Dialysis Care of Hoke County for the first two years of operation following completion of the project as follows:

COUNTY	OPERATING YEAR 1 2013/4	OPERATING YEAR 2 2014/5	COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CENTER PATIENTS	IN-CENTER PATIENTS	YEAR 1	YEAR 2
<i>Hoke</i>	100	109	96.2%	96.5%
<i>Cumberland</i>	3	3	2.9%	2.7%
<i>Scotland</i>	1	1	0.9%	0.8%
<b>TOTAL</b>	104	113	100%	100%

The applicant adequately identified the population it proposes to serve.

**Demonstration of Need**

In Section II, pages 13-14, and in Section III.7, pages 20-21, the applicant provides the assumptions and methodology it used to project need for seven additional dialysis stations at Dialysis Care of Hoke County. The applicant states,

- *“DC of Hoke County will transfer 10 dialysis stations and 31 in-center patients to Lumber River Dialysis on July 1, 2013*
- *DC of Hoke County had 110 in-center patients as of December 31, 2010 according to the July 2011 Semiannual Dialysis Report*
- *Taking into consideration that DC of Hoke County will transfer 29 Robeson County patients and 2 Scotland County patients, the facility will have 79 in-center patients (75 Hoke County, 3 Cumberland County and 1 Scotland County) remaining at the facility*
- *DC of Hoke county will grow the Hoke County in-center patient population (75 patients) from January 1, 2011 to June 30, 2013, the projected certification date for Lumbee River Dialysis, which will be the date the 10 stations and 31 in-center patients transfer*

- *DC of Hoke County will then grow the Hoke in-center patient population for the first two operating years in order to determine the number of in-center patients it will be serving in operating years one and two*
- *DC of Hoke County will then add the 3 Cumberland County patients and the one Scotland County patient to the Hoke County patients*
- *DC of Hoke County will submit a Certificate of Need application for additional stations if there is a facility need determination*

*The Dialysis Care of Hoke County had 110 in-center patients as of December 31, 2010 based on information included in Table A of the July 2011 Semiannual Dialysis Report (SDR). This is a station utilization rate of 92% based on the 30 certified stations. Of the 110 in-center patients cited in the SDR, 75 of those in-center patients lived in Hoke County, 29 in-center patients lived in Robeson County, 3 in-center patients lived in Cumberland County and 3 in-center patients lived in Scotland County.*

*On August 15, 2011 Total Renal Care of North Carolina, LLC submitted a Certificate of Need application to develop a 10-station in-center dialysis facility in Hoke County to be known as Lumbee River Dialysis. The Lumbee River Dialysis CON Application indicated that ten stations [sic] Dialysis Care of Hoke County would be transferred to the Lumbee River facility. The CON application indicated and provided supporting documentation that 31 in-center patients would transfer to the Lumbee River facility.*

*This CON application takes into consideration the transfer of patients and stations to the Lumbee River facility. Twenty-nine of the in-center patients anticipated to transfer live in Robeson County and two of the in-center patients live in Scotland County. This leaves Dialysis Care of Hoke County with 20 stations and 79 in-center patients.*

*Based on 79 in-center patients and 20 stations, Dialysis Care of Hoke County is projected to have at least 104 in-center patients at the end of operating year 1, which is calculated to be July 1, 2013 through June 30, 2014 for a utilization rate of 96.3% and 3.85 patients per station. The facility is projected to have at least 113 in-center patients at the end of operating year 2 for a utilization rate of 104.6% and 4.2 patients per station. If Dialysis Care of Hoke County grows at this rate during the first two operating years, the facility will submit a Certificate of Need application for additional station expansion.*

*The period of the growth begins with January 1, 2011 forward to June 30, 2013, which is the date Lumbee River Dialysis is projected to become certified. We continue the period of growth through the first two operating years with the added seven stations.*

*The following are the in-center utilization projections using the 8.8% Average Annual [sic] Change Rate for the Past Five Years as indicated in Table B of the*

*July 2011 Semiannual Dialysis Report for the 75 patients residing in Robeson [sic] County.*

*January 1, 2011-December 31, 2011 – 75 patients X 1.088 = 81.6*

*January 1, 2012-December 31, 2012 – 81.6 patients X 1.088 = 88.7808*

*January 1, 2013-June 30, 2013 – 88.7808 patients X 1.044 = 92.6871552*

*July 1, 2013-June 30, 2014 – 92.6871522 X 1.088 = 100.8436248*

*July 1, 2014-June 30, 2015 – 100.8436248 X 1.088 = 109.7178637*

*Operating Year 1 with the 7 new stations is July 1, 2013-June 30, 2014*

*Operating Year 2 with the 7 new stations is July 1, 2014-June 30, 2015*

*We chose not to grow the out of county in-center patient population (3 in-center patients living in Cumberland County and one in-center patient living in Scotland County)."*

In a previous application (Project I.D. # N-8725-11), the applicant stated that the number of in-center patients from Hoke County at Dialysis Care of Hoke County, as of December 31, 2010, was 72, not 75 as is stated in this application. Therefore, to be consistent with the previous application, the Project Analyst recalculated the projected utilization based on 72 Hoke County patients, as shown below:

January 1, 2011-December 31, 2011 – 72 patients X 1.088 = 78.336

January 1, 2012-December 31, 2012 – 78.336 patients X 1.088 = 85.229568

January 1, 2013-June 30, 2013 – 85.229568 patients X 1.044 = 88.979669

Year 1: July 1, 2013-June 30, 2014 – 88.979669 patients X 1.088 = 96.809879

Year 2: July 1, 2014-June 30, 2015 – 96.809879 patients X 1.088 = 105.332914

As shown in the calculations above, the Project Analyst projects 96 and 105 Hoke County patients in the first two operating years, respectively, versus the applicant's projection of 100 and 109 Hoke County patients. The result is 100 total in-center patients in Year 1 (100 Hoke County + 3 Cumberland County + 1 Scotland County = 100), versus the applicant's projection of 104 total in-center patients. In Year 2, the result is 109 total in-center patients in Year 2 (105 Hoke County + 3 Cumberland County + 1 Scotland County = 109), versus the applicant's projection of 113 total in-center patients. Therefore, the Project Analyst projects the facility will have a utilization rate of 92.5% [ $100 \times (4 \times 27) = 92.5\%$ ] and 3.7 patients per station ( $100 / 27 = 3.7$ ) in Year 1 and 100.9% [ $109 / (4 \times 27) = 100.9\%$ ] and 4.04 patients per station ( $109 / 27 = 4.04$ ) in Year 2, versus the applicant's projection of

96.2% and 3.8 patients per station in Year 1 and 104.6% and 4.2 patients per station in Year 2.

In summary, the applicant adequately identifies the population to be served and adequately demonstrates the need for seven additional dialysis stations at the Dialysis Care of Hoke County. Consequently, 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.

CA

In Section III.9, page 21, the applicant describes the alternatives considered prior to the submission of its application, which were to either maintain the status quo or increase the number of dialysis stations at the facility. The application is conforming or conditionally conforming to all other applicable statutory and regulatory review criteria. See Criteria (1), (3), (5), (6), (7), (8), (12), (13), (14), (18a), (20) and the Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. Consequently, the application is conforming to this criterion subject to the following conditions:

- 1. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Hoke County shall materially comply with all representations made in its certificate of need application.**
- 2. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Hoke County shall develop and operate no more than seven (7) dialysis stations at Dialysis Care of Hoke County for a total of 27 stations upon completion of this project and Project I.D. # N-8725-11, which shall include any isolation stations.**
- 3. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Hoke County shall not offer or develop home hemodialysis training services as part of this project.**
- 4. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Hoke County 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.

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In Section VIII, the applicant projects that there will be no capital costs associated with the proposed project. In Sections IX.3, page 43, the applicant projects that there will be no start-up expenses associated with the proposed project.

Based on information provided by the applicant in Section X.1, page 47, the dialysis facility's projected allowable charges per treatment for each payment source are as follows:

SOURCE OF PAYMENT	CHARGE PER TREATMENT
Medicare	\$136.00
Medicaid	\$136.00
Medicare/Medicaid	\$136.00
Commercial Insurance	\$520.00
Medicare/Commercial	\$136.00

The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services. In Sections X.2-X.4, pages 45-48, the applicant reported projected revenues and expenses as follows:

	OPERATING YEAR 1	OPERATING YEAR 2
Total Net Revenue	\$4,828,844	\$5,239,503
Total Operating Costs	\$4,254,882	\$4,572,050
Net Profit	\$573,962	\$667,453

The applicant projects that revenue will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable. See Section X of the application for the applicant's assumptions.

In summary, the applicant adequately demonstrated the availability of sufficient funds for the operating expenses of this project. The applicant also adequately demonstrated that the financial feasibility of the proposal is based on reasonable projections of revenues and operating costs. Therefore, the application is conforming to 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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Total Renal Care of North Carolina, LLC, d/b/a Dialysis Care of Hoke County proposes to add seven in-center dialysis stations to the existing facility for a total of 27 dialysis stations upon completion of this project and Project I.D. #F-8725-11 [Establish a new 10-station dialysis facility in Red Springs by relocating ten stations from Dialysis Care of Hoke County (30 – 10 + 7 = 27 stations)]. The facility need methodology indicates that seven additional stations are needed. The applicant adequately demonstrates the need to add seven dialysis stations to the existing facility for a total of 27 stations upon completion of this project. See Criteria (1) and (3) for discussion of methodology and need projections. Therefore, the applicant adequately demonstrates that the proposed project will not result in the unnecessary duplication of existing services, and 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

The following table illustrates current and projected staffing for Dialysis Care of Hoke County, as provided by the applicant in Section VII.1, page 34:

POSITION	CURRENT FTEs	# OF FTE POSITIONS TO BE ADDED	TOTAL FTE POSITIONS
RN	4	0	4
PCT	12	-1	11
Bio-Med Tech	1	0	1
MD			
Admin	1	0	1
Dietician	1	0	1
Social Worker	1	0	1
Unit Secretary	1	0	1
Other-Reuse	1	0	1
<b>Total</b>	<b>22</b>	<b>-1</b>	<b>21</b>

As shown in the above table, the applicant proposes to employ a total of 21 full-time equivalent (FTE) positions to staff the Dialysis Care of Hoke County upon completion of the proposed project. In Section VII.1, page 34, the applicant states, “We anticipate the reduction of one patient care technician since the facility will be reducing the number of stations by three. We anticipate that the teammate will transfer to Lumbee River Dialysis.” In Section V.4, page 30, the applicant states that Dr. John Shepherd will serve as medical director of the facility. Exhibit 14 contains a letter signed by Dr. Shepherd, which states that he has agreed to serve as medical director for the Dialysis Care of Hoke County. In Section VII.2, page 35, the applicant states Dr. Shepherd is Board-Certified in Nephrology.

The applicant has documented the availability of adequate health manpower and management personnel, including the medical director, for the provision of 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.1, page 25, the applicant provides a list of providers of the necessary ancillary and support services. The applicant adequately demonstrated that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health 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

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;

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In Section VI.1(b), page 33, the applicant reports that 87.9% of the patients who received treatments at Dialysis Care of Hoke County had some or all of their services paid for by Medicare or Medicaid in the past year. The table below illustrates the historical payment source of the facility:

DIALYSIS CARE OF HOKE COUNTY	
SOURCE OF PAYMENT	PERCENTAGE
Medicare	22.4%
Medicaid	8.6%
Medicare/Medicaid	25.9%
Commercial Insurance	9.5%
VA	2.6%
Medicare/Commercial	31.0%
Total	100.0%

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 as of June 2010 and CY 2009, respectively. The data in the table were obtained on November 15, 2011. More current data, particularly with regard to the estimated uninsured percentages, were not available.

	<b>Total # of Medicaid Eligible as % of Total Population</b>	<b>Total # of Medicaid Eligibles Age 21 and older as % of Total Population</b>	<b>% Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center)</b>
Hoke	19%	6.7%	21.9%
Statewide	17%	6.7%	19.7%

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 Lumbee River Dialysis.

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 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. However, as of November 15, 2011, no population data was available by age, race or gender. Even if the data were available, 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 applicant demonstrates that medically underserved populations currently have adequate access to the dialysis services provided at Dialysis Care of Hoke County. 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.6 (a), page 33, the applicant states there have been no civil rights access complaints filed within the last five years. Therefore, 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 31, the applicant provides the projected payor mix for the proposed services at the facility. The applicant projects no change from the current payor mix for dialysis visits as stated in Criterion (13a) above. The applicant demonstrates 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, page 32, the applicant states that:

*“Patients with End Stage Renal Disease will have access to dialysis services upon referral by a Nephrologist with privileges at DC of Hoke County. These referrals most commonly come from primary care physicians or specialty physicians in Hoke, Moore, Cumberland, Scotland and Robeson Counties. Patients families and friends can obtain access by contacting a Nephrologist with privileges at the facility. Should a patient contact DC of Hoke county directly or indirectly, the patient will be referred to a qualified Nephrologist for evaluation and subsequent admission if it were found to be medically necessary. Patients from outside [sic] DC of Hoke County catchment area requesting transfer to this facility are processed in accordance with the DC of Hoke County transfer and transient policies which compromise **Exhibit 11**. The patient, again, will be referred to a qualified Nephrologist for final evaluation and subsequent admission if medically necessary.”* [Emphasis in original.]

The applicant adequately demonstrated that it will provide a wide 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

Exhibit 9 contains a letter from Mr. William L. Hyland, the applicant's Director of Healthcare Planning, to the President of Fayetteville Technical Community College stating:

*“DaVita, Inc., operating as Total Renal Care of North Carolina, Inc. d/b/a Dialysis Care of Hoke County, is a facility serving patients with End State Renal Disease who require hemodialysis treatments three times a week. ... We want to extend our services as a clinical training site for nursing students of the community college.”*

The information provided in Sections V.3(a)-V.3(c), page 27, and Exhibit 9 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

See Sections II, III, V, VI and VII. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the proposal would have a positive impact on cost-effectiveness, quality and access to the proposed services because:

- a) the applicant adequately demonstrated that the proposal is cost effective [See Criteria (1), (3), (4) and (5)];
- b) the applicant demonstrated that it will provide adequate access to the proposed dialysis services [See Criteria (13) for additional discussion];
- c) the applicant adequately demonstrated that it will provide quality services [See Criteria (7), (8) and (20) for additional discussion].

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 applicant currently provides dialysis services as Dialysis Care of Hoke County facility in Raeford, 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.

G.S. 131E-183(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- See Section IV.1, page 23, and Exhibit 6 (copy of the July 2011 SDR, Tables A and B).

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

-C- In Section IV.2, page 23, the applicant reports the 2008, 2009, and 2010 facility mortality rates.

*.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 23, the applicant states that Dialysis Care of Hoke County has an agreement with DC of Moore County for the provision of home training services. However, the applicant does 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, pages 26-27, the applicant stated that there were no transplants received and 22 patients were referred for transplant evaluation in 2010.

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

-C- In Section IV.5, page 24, the applicant states that the Dialysis Care of Hoke County

has 17 patients on the transplant waiting list.

- .2202(a)(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
- C- See Section IV.6, page 24, the applicant reports a total of 94 hospital admissions in 2010; 90.4% were non-dialysis related and 9.6% were dialysis-related.
- .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 24, the applicant reports that in 2010 there was one patient with an infectious disease. No patients converted to infectious status in 2010.

*(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*
- NA- Dialysis Care of Hoke County 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- Dialysis Care of Hoke County 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- Dialysis Care of Hoke County 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- Exhibit 7 contains a copy of written policies and procedures for back up 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- Dialysis Care of Hoke County 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 9; VII.2, page 34 and, XI.6(e), page 54.
- .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.3, page 19.
- .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- Dialysis Care of Hoke County 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 11, the applicant states, "Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Hoke County will admit and provide dialysis services to patients who have no insurance or other source of payment, if payment for dialysis services is 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- Dialysis Care of Hoke County 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 20, the applicant projects to serve 104 in-center patients by the end of Year 1, which is 3.85 patients per station ( $104 / 27 = 3.85$ ).
- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
  - C- In Section II, pages 11-12 and Section III.7, pages 20-21, the applicant provides the assumptions and methodology used to project utilization of the proposed facility.

#### **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 25.
- .2204(2) *Maintenance dialysis;*
  - C- See Section V.1, page 25.
- .2204(3) *Accessible self-care training;*
  - C- See Section V.1, page 25.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
  - C- See Section V.1, page 25 and V.1(d), page 26.
- .2204(5) *X-ray services;*
  - C- See Section V.1, page 25.
- .2204(6) *Laboratory services;*
  - C- See Section V.1, page 25.
- .2204(7) *Blood bank services;*
  - C- See Section V.1, page 25.
- .2204(8) *Emergency care;*
  - C- See Section V.1, page 25.
- .2204(9) *Acute dialysis in an acute care setting;*
  - C- See Section V.1, page 25.
- .2204(10) *Vascular surgery for dialysis treatment patients*
  - C- See Section V.1, page 25.
- .2204(11) *Transplantation services;*
  - C- See Section V.1, page 25.
- .2204(12) *Vocational rehabilitation counseling and services; and,*
  - C- See Section V.1, page 25.
- .2204(13) *Transportation*
  - C- See Section V.1, page 25.

**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.*
- C- In Section VII.1, page 34, the applicant provides the proposed staffing. In Section VII.2, pages 34-35, the applicant states the proposed facility will comply with all staffing requirements set forth in 42 C.F.R. Section 405.2100. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. See Criterion (7) for discussion.
- .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 36, and Exhibit 9.