

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: October 4, 2016

Findings Date: October 4, 2016

Project Analyst: Gloria C. Hale

Team Leader: Fatimah Wilson

Project ID #: N-11192-16

Facility: East Hoke County Dialysis

FID #: 160286

County: Hoke

Applicant: Total Renal Care of North Carolina, LLC

Project: Develop a new dialysis facility by relocating 10 stations from Dialysis Care of Hoke County and provide a peritoneal dialysis home training program

### 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

The applicant, Total Renal Care of North Carolina, LLC d/b/a East Hoke County Dialysis (East Hoke), proposes to develop a new 10-station dialysis facility in Hoke County by relocating 10 dialysis stations from Dialysis Care of Hoke County (DC of Hoke County). The applicant will also provide a peritoneal dialysis (PD) home training program. Both the existing facility and the proposed facility are located in Hoke County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Upon completion of this project, East Hoke will be certified for 10 dialysis stations and DC of Hoke County will be certified for 14 dialysis stations (28-10 = 18) and Project I.D. #N-11077-15 (18-4 = 14).

### **Need Determination**

The applicant is proposing to relocate existing dialysis stations within Hoke County, therefore there are no need methodologies in the 2016 State Medical Facilities Plan (2016 SMFP) applicable to this review.

### **Policies**

*Policy GEN-3: Basic Principles*, on page 39 of the 2016 SMFP, is not applicable to this review because neither the county nor facility need methodology is applicable to this review.

There is only one policy in the 2016 SMFP that is applicable to this review: *Policy ESRD-2: Relocation of Dialysis Stations*, on page 33.

*Policy ESRD-2: Relocation of Dialysis Stations* states:

*“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to a contiguous county shall:*

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

The applicant proposes to develop a new 10-station dialysis facility, East Hoke, in Hoke County, by relocating existing dialysis stations from DC of Hoke County. The existing facility and the proposed facility are located in Hoke County, therefore there is no change in the dialysis station inventory in Hoke County. Therefore, the application is consistent with Policy ESRD-2.

### **Conclusion**

In summary, the applicant adequately demonstrates that the application is consistent with all applicable policies in the 2016 SMFP.

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

Total Renal Care of North Carolina, LLC d/b/a East Hoke County Dialysis (East Hoke) proposes to develop a new 10-station dialysis facility in Hoke County by relocating 10 dialysis stations from DC of Hoke County. East Hoke will also provide a peritoneal dialysis home training program. Both the existing facility and the proposed facility are located in Hoke County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Upon completion of this project, East Hoke will be certified for 10 dialysis stations and DC of Hoke County will be certified for 14 dialysis stations ( $28-10 = 18$ ) and Project I.D. #N-11077-15 ( $18-4 = 14$ ).

#### **Population to be Served**

On page 369, the 2016 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Hoke County. Facilities may also serve residents of counties not included in their service area.

East Hoke County Dialysis will be a new facility in Hoke County and therefore has no existing patient origin.

In Section C.1, page 14, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, including in-center (IC) patients and home peritoneal dialysis (PD) patients, as illustrated in the following table:

**East Hoke  
 Projected Patient Origin**

County	Operating Year 1 CY 2018		Operating Year 2 CY 2019		County Patients as % of Total	
	IC	PD	IC	PD	OY 1	OY2
Hoke	23	3	24	4	70.3%	71.8%
Cumberland	4	0	4	0	10.8%	10.3%
Robeson	7	0	7	0	18.9%	17.9%
Total	34	3	35	4	100.0%	100.0%

See pages 14-17 for the assumptions and data utilized to project patient origin including a summary of the patient support letters found in Exhibit C-1.

The applicant adequately identifies the population to be served.

**Analysis of Need**

In Section C.2, page 17, the applicant states that it determined a need for a new dialysis facility in eastern Hoke County based on the fact that 34 in-center and two home peritoneal dialysis patients live in or near the eastern part of Hoke County. In Section C.5, page 18, the applicant states that a new dialysis facility located in the eastern part of the county would be more convenient for a greater number of patients receiving dialysis services and that other areas of the county were already being served by existing DaVita, Inc. (DaVita) dialysis facilities or DaVita facilities were under development. DaVita is a subsidiary of the applicant. In Section C.2, page 17, the applicant states,

*“In order to make the travel to dialysis – three times a week for in-patients and monthly for PD patients – more convenient, it was determined that Total Renal Care of North Carolina, LLC needs to provide a dialysis center nearer to their homes and/or that is more convenient for better access to their dialysis services and support.”*

Exhibit C-1 contains 34 patient letters of support. Each of the patients’ letters state that the proposed facility, East Hoke, would be easier to travel to and would save time and money.

In Section C.1, page 15, the applicant states, *“It is assumed that the thirty-four (34) patients who signed letters of support for East Hoke County Dialysis will transfer their care upon certification of the new facility.”*

The information provided by the applicant on the pages referenced above is reasonable and adequately supported.

**Projected Utilization for In-Center Patients**

In Section C.1, pages 14-17, the applicant provides the assumptions and methodology used to determine the need for the proposed dialysis facility in Hoke County and to project utilization. The assumptions and methodology are summarized as follows:

- The applicant states that it received 34 letters of support from in-center patients utilizing DVA dialysis facilities in Hoke and Robeson counties, and who live in either Hoke, Cumberland, or Robeson counties, indicating their willingness to consider transferring their care to the proposed facility. The letters of support are included in Exhibit C-1.
- The applicant assumes that the 23 in-center patients who are residents of Hoke County will increase at a rate commensurate with Hoke County’s Five Year Average Annual Change Rate (AACR) of 4.1%, as published in Table B of the January 2016 Semi-Annual Dialysis Report (SDR), through the second operating year.
- The applicant proposes no growth for the 11 patients who are not residents of Hoke County.

The project is scheduled for occupancy January 1, 2018. Operating Year One (OY1) is Calendar Year 2018 (CY2018), January 1 through December 31, 2018. Operating Year Two (OY2) is Calendar Year 2019 (CY2019), January 1 through December 31, 2019.

In Section C.1, page 16, the applicant provides the calculations used to project in-center patient census for East Hoke for Operating Years One and Two, as follows:

<b>East Hoke</b>	<b>In-Center Patients</b>
January 1, 2018, the beginning of OY1, will begin with 23 in-center patients who have transferred their care from other DVA dialysis facilities.	23
Growth is projected during OY1 by multiplying the beginning census by the Hoke County Five Year AACR of 4.1% to arrive at the end of year census for December 31, 2018 and then adding in the 11 in-center patients living outside Hoke County.	$23 \times 1.041 = 23.943 + 11 = 34.943$
Growth is projected for OY2 by multiplying the beginning census for January 1, 2019 by the Hoke County Five Year AACR of 4.1% to arrive at the end of year census for December 31, 2019 and then adding in the 11 in-center patients living outside Hoke County.	$23.943 \times 1.041 = 24.925 + 11 = 35.925$

The applicant states, on page 16, that the number of projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 (CY2018) the facility is projected to serve 34 in-center patients and at the end of OY2 (CY2019) the facility is projected to serve 35 in-center patients.

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

- OY1: 3.40 patients per station per week, or 85.0% (34 patients/ 10 stations =  $3.40/4 = .850$  or 85.0%).
- OY2: 3.50 patients per station per week, or 87.5% (35 patients/ 10 stations =  $3.50/4 = .875$  or 87.5%).

The projected utilization of 3.4 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Projected utilization of in-center patients is based on reasonable and adequately supported assumptions regarding continued growth.

#### Projected Utilization for Home PD Patients

In Section I.1, page 40, the applicant indicates that a PD home training program will be available at East Hoke. The applicant states, in Section C.1, page 16, that two PD patients who receive home PD support from Dialysis Care of Moore County and who reside in Hoke County will likely transfer their care to East Hoke. The applicant provides two letters of support from these patients, in Exhibit C-1. Each of the patients' letters state that the proposed East Hoke dialysis facility would be closer to their homes, and therefore, would be more convenient. In addition, the patients state in their letters that they would be willing to consider transferring their care to East Hoke.

The applicant provides projected utilization for its PD patients in Section C.1, page 17, as follows:

**East Hoke PD Patient Projections**

	<b>Start Date</b>	<b>Beginning Census</b>	<b>Ending Census</b>	<b>Average # of Patients per year</b>
OY1, CY2018	1/1/2018	2	3	2.5
OY2, CY2019	1/1/2019	3	4	3.5

The applicant provides the assumptions and methodology used to project utilization for PD patients in Section C.1, pages 16-17. Projected utilization of PD patients is based on reasonable and adequately supported assumptions regarding continued growth. The applicant adequately identifies the population to be served and adequately demonstrates the need for a new, 10-station dialysis facility.

### Access to Services

In Section C.3, page 17, the applicant states that by policy, the proposed services will be available to all persons without qualifications, including racial and ethnic minorities, women, low-income persons, persons with disabilities, elderly and “*other underserved persons.*”

In addition, the applicant projects, in Section L.1, page 51, that 87.6% of its patients at East Hoke will be covered by either Medicare or Medicaid. In Section L.1, page 51, the applicant states that its projected payor mix is based on the payor mix for the last full operating year for dialysis facilities owned and operated by DaVita in Hoke County. The applicant adequately demonstrates the extent to which all residents of the area, including the medically underserved, are likely to have access to the proposed services.

### Conclusion

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need that population has for the proposed project and the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed 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.

## C

East Hoke proposes to develop a new 10-station dialysis facility in Hoke County by relocating 10 dialysis stations from DC of Hoke County. The existing facility and the proposed facility are located in Hoke County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Upon completion of this project, East Hoke will be certified for 10 dialysis stations and DC of Hoke County will be certified for 14 dialysis stations ( $28-10 = 18$ ) and Project I.D. #N-11077-15 ( $18-4 = 14$ ).

### DC of Hoke County

In Section D.1, page 25, the applicant states that as of June 30, 2015, as reported in the January 2016 SDR, there were 104 in-center dialysis patients at DC of Hoke County dialyzing on 27 dialysis stations, for a utilization rate of 87.96%. In addition, the applicant states that 77 of the 104 in-center patients lived in Hoke County and that 27 lived outside Hoke County.

The applicant assumes that the number of in-center patients at DC of Hoke County who live in Hoke County will increase at 4.1% per year based on the Five Year AACR for Hoke County, as reported in Table B of the January 2016 SDR. The applicant assumes that no growth will occur for the in-center patients living outside of Hoke County. The applicant states, on page 25,

*“An additional dialysis station was certified on July 28, 2015 for a current total of 28 certified stations...In Project ID #N-11077-15, DaVita is approved to expand Maxton Dialysis in Robeson County via transfer of 4 stations from DC Hoke County. It is projected that 4 in-center patients from DC Hoke County who live outside of Hoke County will transfer to Maxton Dialysis upon certification, which is projected for January 1, 2017.”*

In Section D.1, page 25, the applicant states that at least 27 in-center patients from DC of Hoke County will transfer to East Hoke upon its certification, 23 from Hoke County and four from outside Hoke County. The applicant calculates the in-center patient census for DC of Hoke County starting June 30, 2015 through OY1 (CY2018) and OY2 (CY2019), in Section D.1, page 26, illustrated as follows:

<b>DC of Hoke County</b>	<b>In-Center Patients</b>
Beginning census for June 30, 2015 for Hoke County patients only, increased by half the 4.1% Five Year AACR for Hoke County. Add 27 patients from outside Hoke County to arrive at ending census for December 31, 2015 (six months).	$77 \times 1.0205 = 78.5785 + 27 = 105.5785$
Hoke County patient census for CY2016 increased by 4.1% Five Year AACR for Hoke County. Add 27 patients from outside Hoke County to arrive at ending census for December 31, 2016.	$78.5785 \times 1.041 = 81.80 + 27 = 108.8002$
Hoke County patient census for CY2017 increased by 4.1% Five Year AACR for Hoke County. Add 23 patients from outside Hoke County after subtracting 4 patients transferring to Maxton Dialysis (27-4) to arrive at ending census for December 31, 2017.	$81.80 \times 1.041 = 85.1538 + 23 = 108.1538$
<b>OY1 (CY2018)</b> Twenty-three patients from Hoke County (85 – 23 = 62) and 4 from outside of Hoke County (23-4 = 19) will transfer to East Hoke. The patient census from Hoke County will increase by 4.1% Five Year AACR for Hoke County. Add 19 patients from outside Hoke County to arrive at ending census for December 31, 2018.	$62 \times 1.041 = 64.542 + 19 = 83.542$
<b>OY2 (CY2019)</b> Hoke County patient census for CY2019 increased by 4.1% Five Year AACR for Hoke County. Add 19 patients from outside Hoke County to arrive at ending census for December 31, 2019.	$64.542 \times 1.041 = 67.1882 + 19 = 86.1882$

The applicant rounds down the ending census numbers for OY1 and OY2. (See page 26.) DC of Hoke County is projected to have 83 in-center patients at the end of OY1 for a utilization rate of 148%, or 5.93 patients per station (83 patients/ 14 stations = 5.93/4 = 1.48 or 148.0%). The applicant states, on page 26,

*“Given this projected growth of the in-center patient population, additional Certificate of Need application(s) will be submitted based on facility need as the facility approaches full capacity of stations to ensure that the needs of the facility’s patients will continue to be met.”*

In addition, the applicant states, on page 26, how it will continue to make dialysis services available to all residents in the service area, stating that the relocation of stations will not affect the ability of underserved groups to obtain needed care.

The applicant demonstrates that the needs of the populations presently served at DC of Hoke County will continue to be adequately met following the proposed relocation of 10 dialysis stations from DC of Hoke County to East Hoke and that access for medically underserved groups will not be negatively impacted.

Therefore, the application is conforming to this criterion.

- (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 E.1, page 27, the applicant discusses the alternatives considered prior to submitting this application, summarized as follows:

Maintain the Status Quo – the applicant states that this alternative does not address the growing in-center patient population of DC of Hoke County, in particular those who live in the eastern portion of the county. Therefore, this is not an effective alternative.

Select a Different Location – the applicant states that a different location for the new dialysis center in Hoke County would not address the needs of the patients who live in the eastern portion of the county and who have indicated their willingness to relocate as evidenced in letters provided in Exhibit C-1. Therefore, this is not the most effective alternative to meet the need.

Relocate Dialysis Stations from a Different DaVita Facility – The applicant states that there is one other dialysis facility, Lumbee River Dialysis, in Hoke County, however it is operating at 47.50% and only has 10 dialysis stations as indicated in the January 2016 SDR. The applicant states that relocating stations from Lumbee River Dialysis could negatively impact patients being served there. Therefore, this is not the most effective alternative to meet the need.

After considering the above alternatives, the applicant states that development of the new East Hoke facility would reduce the transportation time and be more convenient. The applicant states, on page 27, that the proposed dialysis facility may improve patients’ quality

of life and their compliance with treatment schedules. The applicant states that developing the new East Hoke facility will be the least costly alternative over time. Therefore, developing the East Hoke facility is the most effective alternative to meet the identified need.

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 applicant adequately demonstrates that this proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1. Total Renal Care of North Carolina, LLC d/b/a East Hoke County Dialysis shall materially comply with all representations made in the certificate of need application.**
  - 2. Total Renal Care of North Carolina, LLC d/b/a East Hoke County Dialysis shall relocate no more than 10 dialysis stations from Dialysis Care of Hoke County.**
  - 3. Total Renal Care of North Carolina, LLC d/b/a East Hoke County Dialysis shall install plumbing and electrical wiring through the walls for no more than 10 dialysis stations, which shall include any isolation or home hemodialysis stations.**
  - 4. Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify 10 dialysis stations at Dialysis Care of Hoke County for a total of no more than 14 dialysis stations at Dialysis Care of Hoke County upon completion of this project and Project I.D. # N-11077-15.**
  - 5. Total Renal Care of North Carolina, LLC d/b/a East Hoke County Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

**Capital Costs and Working Capital Costs**

In Section F.1, page 29, the applicant provides the capital cost of the project as summarized in the following table:

Site Costs	\$44,000
Construction Contract	\$1,204,141
Dialysis Machines	\$152,400
Water Treatment Equipment	\$134,175
Equipment/Furniture	\$277,495
Architect & Engineering Fees	\$92,000
<b>Total Capital Cost</b>	<b>\$1,904,211</b>

In Section F.10, pages 31-32, and Section F.11, page 32, the applicant estimates start-up expenses of \$191,283 and initial operating expenses of \$786,087, respectively. Total working capital needed equals \$977,370.

#### **Availability of Funds**

In Section F.2, page 30, the applicant states that accumulated reserves/owner's equity will be used to finance the project's capital costs. In Section F.13, page 33, the applicant states that the working capital costs will be financed with cash reserves. Exhibit F-5 contains a letter signed by the Director of Healthcare Planning for DaVita HealthCare Partners, Inc. on behalf of James K. Hilger, Chief Accounting Officer of DaVita, dated June 12, 2016, confirming DVA's commitment to funding the project's capital costs and working capital costs with cash reserves.

In Exhibit F-7, the applicant provides a copy of DaVita's United States Securities and Exchange Commission Form 10-K for the fiscal year ended December 31, 2014. DaVita had \$965,241,000 in cash and cash equivalents, \$17,942,715,000 in total assets, and \$6,190,276,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project.

#### **Financial Feasibility**

In Section R, Form C of the pro formas, the applicant provides its allowable charge per treatment for each payment source and provides its operating expense and revenue assumptions in Forms A-C.

The applicant projects revenues in Section R, Form B of the pro formas, and operating expenses in Section R, Form A of the pro formas, summarized in the table below:

<b>East Hoke</b>		
	<b>Operating Year 1 CY2018</b>	<b>Operating Year 2 CY2019</b>
Total Net Revenue	\$1,636,015	\$1,699,455
Total Operating Expenses	\$1,572,175	\$1,618,714
<b>Net Profit</b>	<b>\$63,840</b>	<b>\$80,741</b>

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The assumptions used by the applicant in preparation of the pro formas, including projection utilization, costs and charges, are reasonable and adequately supported. See the pro formas in Section R for the applicant's assumptions regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

In Section H.1, page 36, the applicant provides projected staffing and salaries. Form A in Section R, shows budgeted operating costs adequate to cover the projected staffing. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference. The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project. The applicant also adequately demonstrates that the financial feasibility of the project is based on reasonable projections of costs and charges. 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.

C

East Hoke proposes to develop a new 10-station dialysis facility in Hoke County by relocating 10 dialysis stations from DC of Hoke County. East Hoke will provide a PD home training program. Both the existing facility and the proposed facility are located in Hoke County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations.

On page 369, the 2016 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Hoke County. Facilities may also serve residents of counties not included in their service area.

The January 2016 SDR indicates there are 2 dialysis facilities in Hoke County, as follows:

**Hoke County Dialysis Facilities  
June 30, 2015**

<b>Dialysis Facilities</b>	<b>Owner</b>	<b># of Patients</b>	<b>Location</b>	<b># of Certified Stations</b>	<b># of Approved Stations</b>	<b>Percent Utilization</b>
DC of Hoke County	DVA	95	Raeford	27	0	87.96%
Lumbee River Dialysis	DVA	19	Red Springs	10	0	47.50%

As illustrated above, DC of Hoke County is operating above capacity at 87.96%. Although Lumbee River Dialysis is operating at only 47.50%, it is located in Red Springs in the southern part of the county. The applicant provides 34 letters in Exhibit C-1 from in-center patients at DaVita facilities in both Hoke and Robeson counties, indicating that the proposed facility, in the eastern portion of Hoke County, would be closer to their homes and therefore, more convenient.

The applicant is not increasing the number of dialysis stations in Hoke County, rather it is relocating 10 of them to develop a new facility that is closer to patients living in or near the area where the new facility will be located. Therefore, it is not duplicating services, rather it is proposing to create a new facility to better serve existing patients using existing stations.

In Section C.1, pages 14-16, the applicant demonstrates that East Hoke Dialysis will serve a total of 34 in-center patients on 10 stations at the end of the first operating year, which is 3.4 patients per station per week, or a utilization rate of 85.0% ( $34/10 = 3.4$ ;  $3.4/4 = 0.85$  or 85.0%). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates the need to relocate stations to develop a new dialysis facility in Hoke County. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference. The discussion on the needs of the population presently served at DC of Hoke County, found in Criterion (3a), is incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Hoke County. 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.

C

The applicant provides the projected staffing for East Hoke in Section H.1, page 36, illustrated as follows:

**East Hoke**

<b>Position</b>	<b>Projected Number of FTEs</b>
Medical Director*	
Registered Nurse	2.0
Patient Care Technician	4.0
Administrator	1.0
Dietitian	0.5
Social Worker	0.5
Home Training Nurse	0.5
Administrative Assistant	1.0
Biomedical Technician	0.3
<b>Total</b>	<b>9.8</b>

\*The Medical Director is an independent contractor, not an employee of the facility.

In Section H.3, pages 37-38, the applicant states that it will fill positions by using a DaVita Teammate Recruiter, the Teammate Referral Program, and its Student Internship Program. In addition, the applicant states that it provides a wide range of benefits and competitive salaries to attract candidates for positions.

In Section H.7, page 39, the applicant provides the projected Direct Care Staff Hours for OY2, as follows:

**Projected Direct Care Staff Hours – OY2**

<b>Direct Care Positions</b>	<b># FTEs</b> [a]	<b>Hours / Year / FTE</b> [b]	<b>Total Annual FTE Hours</b> [c] = [a] x [b]	<b>Total Annual Hours of Operation</b> [d]	<b>FTE Hours / Hours of Operation</b> [e] = [c] ÷ [d]
Nurse	2	2,080	4,160	3,120	1.3
Patient Care Technician	4	2,080	8,320	3,120	2.7
<b>Total</b>	<b>6</b>	<b>2,080</b>	<b>12,480</b>	<b>3,120</b>	<b>4.0</b>

In Section H.2, page 37, the applicant states that the Medical Director for East Hoke will be Dr. John Shepherd. In Exhibit I-3, the applicant provides a letter signed by Dr. Shepherd, dated May 16, 2016, confirming his commitment to serve as Medical Director.

The applicant documents 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.

C

In Section I, pages 40-41, the applicant discusses the necessary ancillary and support services to be provided for the proposed facility and provides a list of service providers on page 40. The applicant provides documentation regarding coordination with the existing health care system in Exhibits I-1, I-2(a), I-2(b), and I-3, including letters from several providers such as DaVita Laboratory Services, Inc., the NC Division of Vocational Rehabilitation Services, Pinehurst Surgical Associates, Cape Fear Valley Health, FirstHealth Moore Regional Hospital, and Duke Medicine Transplant Center. The information in Section I and Exhibits I-1, I-2(a), I-2(b) and I-3 is reasonable and adequately supports a finding of conformity with 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.

C

In Section K.2, page 45, the applicant states there will be 3,956 square feet of treatment area, which will include home training and isolation room space. The applicant provides line drawings of the proposed facility in Exhibit K-1(a). In Section F.1, page 29, the applicant lists its project costs, including \$1,248,141 for site work and construction and \$656,070 for miscellaneous costs including dialysis machines, water treatment equipment, furniture, and architect/engineering fees for a total project cost of \$1,904,211. In Section B.5, pages 11-13, the applicant describes its plans to assure improved energy-efficiency and water conservation, including the following:

- The use of full LED lighting packages with a full lighting control system that will provide 28% energy reduction.
- Interior finishes and materials will be used based on sustainable design and *“Indoor Environmental Quality criteria...defined in the US Green Building Council’s LEED Rating system.”*
- The HVAC system will be selected and designed for high performance and energy efficiency.
- The use of Energy Star rated appliances and most information technology equipment, when possible.
- Water optimization protocols will be utilized to reduce the volume of water required to provide patient care, including adjusting the recovery rate for reverse osmosis devices and utilizing water-conserving plumbing fixtures.

Costs and charges are described by the applicant in Section F, pages 29-32, and in the pro forma financial statements in Section R. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, that energy saving features have been incorporated into the construction plans and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of

determining the extent to which the proposed service will be accessible, the applicant shall show:

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

C

In Section L.7, page 54, the applicant provides the historical payor mix for DC of Hoke County for CY2015. DC of Hoke County will relocate 10 dialysis stations to develop the proposed facility and from which at least some patients will transfer (See Exhibit C-1 for patients' letters of support). The historical payor mix is illustrated as follows:

**DC of Hoke County  
Payor Mix CY2015**

<b>Payor Type</b>	<b>Percent of Total Patients</b>
Medicare	39.5%
Medicaid	4.2%
Commercial Insurance	9.3%
Medicare/Commercial	20.6%
Medicare/Medicaid	22.5%
VA	3.9%
Other	0.0%
<b>Total</b>	<b>100.0%</b>

As the table above indicates, 86.8% of DC of Hoke County's patients are covered by Medicare or Medicaid. The applicant provides a copy of DaVita's policy on acceptance of patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability in Exhibit L-3.

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

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Hoke	8%	51%	59%	20%	11%	21%
Robeson	13%	52%	73%	33%	13%	25%
Cumberland	11%	51%	55%	18%	11%	16%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>, 2014 Estimate as of December 22, 2015.

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

\*\*"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

The Southeastern Kidney Council Network 6 Inc. Annual Report provides prevalence data on North Carolina dialysis patients by age, race, and gender on page 59, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014		
	# of ESRD Patients	% of Dialysis Population
<b>Age</b>		
0-19	52	0.3%
20-34	770	4.8%
35-44	1,547	9.7%
45-54	2,853	17.8%
55-64	4,175	26.1%
65+	6,601	41.3%
<b>Gender</b>		
Female	7,064	44.2%
Male	8,934	55.8%
<b>Race</b>		
African-American	9,855	61.6%
White	5,778	36.1%
Other, inc. not specified	365	2.3%

Source: <http://www.esrdnetwork6.org/utis/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older and over 63% were non-Caucasian. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).

The applicant demonstrates that it currently provides 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 applicants;

C

In Section L.3(e) page 53, the applicant states,

*“East Hoke County Dialysis has no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons except those obligations which are placed upon all medical facilities under Section 504 of the Rehabilitation Act of 1973 and its subsequent amendment in 1993. The facility has no obligation under the Hill Burton Act.”*

In Section L.6, page 53, the applicant states, in reference to any facilities owned by DaVita in the state, that there have been no civil rights equal access complaints filed within the last five years.

The application is conforming to this criterion.

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

C

In Section L.1, page 51, the applicant states that the projected payor mix for East Hoke is based on sources of payment for its DaVita-operated facilities in Hoke County for the last full operating year, illustrated as follows:

**East Hoke  
 Projected Payor Mix OY2**

<b>Payor Source</b>	<b>Percent of Total Patients</b>	<b>Percent In-Center Patients</b>	<b>Percent Home PD Patients</b>
Medicare	36.4%	39.5%	23.3%
Medicaid	6.8%	4.2%	16.7%
Commercial Insurance	8.6%	9.3%	6.7%
Medicare/Commercial	22.8%	20.6%	33.3%
Medicare/Medicaid	21.6%	22.5%	16.7%
VA	3.8%	3.9%	3.3%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

The applicant projects that 86.8% of East Hoke’s in-center patients and 90.0% of its home PD patients will be covered by Medicare or Medicaid. For the facility as a whole, 87.6% of the patients will be covered by Medicare or Medicaid.

The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section L.4, page 53, the applicant states that patients will have access to the facility for dialysis services upon referral from a Nephrologist with admitting privileges at the facility. Patients who contact the facility directly or indirectly will be referred to *“a qualified nephrologist for final evaluation and then admission based on the doctor’s orders.”* In Exhibit I-3, the applicant provides letters of support from area Nephrologists

The applicant adequately demonstrates that it will offer a range of means by which patients will have access to the proposed 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 M.1, page 56, the applicant states that it has offered East Hoke as a clinical training site for nursing students from Sandhills Community College. A copy of a letter sent by the applicant to the college, dated May 16, 2016, is included in Exhibit M-2.

The information provided in Section M.1 and Exhibit M-2 is reasonable and adequately 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

East Hoke proposes to develop a new 10-station dialysis facility in Hoke County by relocating 10 dialysis stations from DC of Hoke County. East Hoke will provide a PD home training program. Both the existing facility and the proposed facility are located in Hoke County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations.

On page 369, the 2016 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Hoke County. Facilities may also serve residents of counties not included in their service area.

The January 2016 SDR indicates there are 2 dialysis facilities in Hoke County, as follows:

**Hoke County Dialysis Facilities  
 June 30, 2015**

<b>Dialysis Facilities</b>	<b>Owner</b>	<b># of Patients</b>	<b>Location</b>	<b># of Certified Stations</b>	<b># of Approved Stations</b>	<b>Percent Utilization</b>
DC of Hoke County	DVA	95	Raeford	27	0	87.96%
Lumbee River Dialysis	DVA	19	Red Springs	10	0	47.50%

As illustrated above, DC of Hoke County is operating above capacity at 87.96%. Although Lumbee River Dialysis is operating at only 47.50%, it is located in Red Springs in the southern part of the county. The applicant provides 34 letters in Exhibit C-1 from in-center patients at DaVita facilities in both Hoke and Robeson counties, indicating that the proposed facility, in the eastern portion of Hoke County, would be closer to their homes and therefore, more convenient.

In Section N.1, page 56, the applicant discusses how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. The applicant states that the development of East Hoke will not have any effect on dialysis facilities located in Hoke County nor in any of the contiguous counties. In addition, the applicant states that the proposed facility will not have an adverse effect on competition since it is relocating dialysis stations and transferring care, not developing new dialysis stations. Further, the applicant states,

*“The bottom line is East Hoke County Dialysis will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and other [sic] involved in the dialysis process to receive services. Patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs.”*

See also Sections B, C, D, F, and L where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in the sections referred to above is reasonable 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 applicant adequately demonstrates the need for the proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that DaVita will continue to provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that DaVita will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3), (3a) and (13) are incorporated herein by reference.

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

In Section B.4, pages 8-9, the applicant discusses the methods it uses to insure and maintain quality. In Exhibit O-3, the applicant provides a listing of four dialysis facilities that were not in compliance with Medicare conditions of participation during the 18 months prior to submission of the application. Each facility is back in compliance as of the date of this decision.

Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. 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 criteria, as discussed below.

**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.*

- C- In Section C.1, page 16, the applicant adequately demonstrates that East Hoke will serve at least 34 in-center patients on 10 stations at the end of the first operating year, which is 3.4 patients per station per week, or a utilization rate of 85.0% ( $34/10 = 3.4$ ;  $3.4/4 = 0.85$ ). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

*.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.*

- NA- The applicant is seeking to develop a new 10-station dialysis facility.

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

- C- In Section C.1, pages 14-17, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.