

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming  
CA = Conditional  
NC = Nonconforming  
NA = Not Applicable

DECISION DATE: November 13, 2014  
PROJECT ANALYST: Bernetta Thorne-Williams  
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: J-10319-14 / DVA Healthcare Renal Care, Inc. d/b/a East Durham Dialysis / Develop 10-station dialysis facility, by relocating seven dialysis stations from Durham Dialysis Center and three dialysis stations from Durham West Dialysis Center / Durham County

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

DVA Healthcare Renal Care, Inc. d/b/a East Durham Dialysis, whose parent company is DaVita HealthCare Partners Inc. proposes to relocate seven existing certified dialysis stations from Durham Dialysis Center and three existing certified dialysis stations from Durham West Dialysis Center to develop East Durham Dialysis Center in Durham for a total of ten certified dialysis stations at East Dialysis Center upon project completion.

#### **Need Determination**

The applicant does not propose to add new dialysis stations. Therefore, neither the county or facility need methodologies in the 2014 State Medical Facilities Plan (SMFP) are applicable to this review.

#### **Policies**

Additionally, Policy GEN-3 is not applicable because the applicant is not proposing to develop a facility pursuant to a need determination in the 2014 SMFP. However, Policy ESRD-2: Relocation of Dialysis Stations and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, are both applicable to this review.

Policy ESRD-2 states:

*“Relocations of existing dialysis stations are allowed only within the host county and to contiguous*

*counties currently served by the facility. Certificate of Need applicants proposing to relocate dialysis stations to contiguous counties shall:*

- (A) *Demonstrate that the proposal shall not result in a 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*
- (B) *Demonstrate that the proposal shall not result in a 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 relocate ten existing dialysis stations within Durham County to establish a new facility, East Durham Dialysis. Consequently, there is no change in the dialysis station inventory in Durham County, therefore, the application is consistent with Policy ESRD-2.

Policy GEN-4 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.*

*In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, the Certificate of Need Section shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.*

*Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”*

The applicant projects that the total capital cost for the proposed project will be \$2,287,605 which includes a construction cost of \$1,537,000 for the upfit of the new building. In Section XI.6(d), page 71, the applicant states that the facility will be constructed with energy-efficient glass, cooling and heating system and mechanically operated patient access doors. On page 72, the applicant states how the proposed facility will conserve water and comply with 42 C.F.R. Section 405 .2100.

## **Conclusion**

In summary, the applicant is consistent with Policy ESRD-2 and Policy GEN-4. Therefore, the application is conforming to this criteria.

- (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

DVA Healthcare Renal Care, Inc. (DVA) d/b/a East Durham Dialysis proposes to relocate seven existing certified dialysis stations from Durham Dialysis Center and three existing certified dialysis stations from Durham West Dialysis Center to develop East Durham Dialysis for a total of ten certified dialysis stations at East Durham Dialysis Center, upon completion of the project. The proposed primary site being considered for East Durham Dialysis Center is located at 2945 S. Miami Boulevard in Durham. The applicant does not propose to add new dialysis stations, therefore, the ESRD station inventory of Durham County would not change.

**Population to be Served**

In Section III.7, page 33, the applicant projects the number of in-center patients to be served in the first two years of operation following project completion, as illustrated in the following table:

<b>EAST DURHAM DIALYSIS</b>						
<b>COUNTY</b>	<b>Operating</b>		<b>Operating</b>		<b>County In-Center Patients as % of Total</b>	
	<b>Year 1 2016</b>		<b>Year 2 2017</b>		<b>Year 1</b>	<b>Year 2</b>
	<b>In-Center</b>	<b>Home Dialysis</b>	<b>In-Center</b>	<b>Home Dialysis</b>		
Durham	28	12	29	13	87.0%	87.5%
Wake	5	1	5	1	13.0%	12.5%
<b>Total</b>	<b>33</b>	<b>13</b>	<b>34</b>	<b>14</b>	<b>100.0%</b>	<b>100.0%</b>

The applicant adequately identifies the population it proposes to serve.

**Analysis of Need**

In Section III.7, pages 33-35, the applicant provides the assumptions and methodology used to project the number of patients expected to utilize the East Durham Dialysis Center. It is summarized as follows:

The majority of patients projected to utilize East Durham Dialysis will be Durham County residents. The projections are based on the following assumptions:

- There are thirty (30) in-center patients dialyzing at DVA operated facilities in Durham County who live in the 27703 zip code, which is located in southeastern Durham County.
- 27 in-center patients living in Durham County will transfer their care from the Durham Dialysis Center (17), Durham West Dialysis Center (7) and Southpoint Dialysis Center (3) based on the patient's letters.
- 5 in-center patients living in Wake County will transfer their care from Southpoint Dialysis based on patient letters.
- 12 peritoneal dialysis patients living in Durham County will transfer their care from the Durham West Dialysis Center based on patient letters.
- It is assumed that the number of patients living in Durham County is projected to grow at a rate of 2.4% based on the Durham County Five Year Average Annual Change Rate (AARC) as indicated in Table B of the July 2014 Semiannual Dialysis Report.

In Section III, page 34, the applicant states in-center utilization projections begin with 27 in-center patients living in Durham County and are increased by the Durham County 5 year AARC of 0.024. Then Wake County patients are added, as shown below.

*"January 1, 2014-December 31, 2014 – 27 in-center patients X 1.024 = 27.648*

*January 1, 2015 [sic]-December 31, 2015 – 27.648 in-center patients X 1.024 = 28.311552*

*January 1, 2016-December 31, 2016 – 28.311552 in-center-patients X 1.024 = 28.99102924*

[Add 5 Wake County in-center patients 28.99102924 + 5 = 23.99]

*January 1, 2017-December 31, 2017 – 28.99102824 in-center patients X 1.024 = 29.68681394*

[Add 5 Wake County in-center patients 29.69 + 5 = 34.69]

***January 1, 2016-December 31, 2016 is the first operating year.***

***January 1, 2017-December 31, 2017 is the second operating year."***

Based on the information above, East Durham Dialysis is projected to have 33 in-center patients at the end of operating year one for a utilization rate of 82.5% or 3.3 patients per station. This meets the requirement that at the end of the first operating year the facility shall have at least 32 patients or 3.2 patients per station, which documents the need for at least 10 stations. East Durham Dialysis is projected to have 34 in-center patients at the end of operating year two for utilization rate of 85% or 3.4 patients per station.

On page 34, the applicant states:

*"All of the partial patient numbers in the calculations above have been rounded down to the nearest*

*whole number.*

*The growth of the five patients living in Wake County was not calculated because the calculations would result in a partial patient growth.”*

### **Home-Training**

In Section III.7, pages 34-35, the applicant states that Home training in peritoneal dialysis will be established at East Durham Dialysis. The facility is projected to have twelve peritoneal dialysis patients who live in Cary and Durham transfer their care from the Durham West Dialysis Center.

The applicant projects that the East Durham Dialysis peritoneal dialysis patient population will grow at a conservative rate of one patient per year during the first two years of operation.

In Section III.3, page 25, the applicant states that improved geographic accessibility of in-center hemodialysis and peritoneal dialysis services in the southeastern side of Durham County are key factors for the proposed project. The applicant discusses the number of end stage renal disease patients residing in the southeastern portion of Durham County who are currently receiving services at three other DVA facilities in Durham County; Durham Dialysis Center, located in downtown Durham, Durham West Dialysis Center located on the west side of Durham and Southpoint Dialysis, which is located on the south side of Durham. The applicant provides 42 letters of support from patients currently dialyzing at DVA facilities in Durham County who have expressed a desire to transfer their care to the proposed East Durham Dialysis facility because the facility would be more convenient for their use. The applicant further states on page 25, “[I]t was determined that the existing facilities are serving a total of at least thirty-two patients who live in three zip codes on the eastern side of the county.” The applicant provides letters of support in Exhibit 24 from patients who have expressed an interest in transferring to the proposed facility by zip codes, as illustrated in the table below:

Zip Codes	City/County of Residence	# of In-Center Patients
27519	Cary/ Wake County	3
27560	Morrisville/ Wake County	1
27703	Durham/ Durham County	24
No provided	Durham	14
<b>Total</b>		<b>42</b>

As illustrated in the table above, the applicant provides a total of 42 letters of support from in-center patients currently utilizing DVA facilities for their ESRD needs. Of those letters, 14 letters do not indicate a zip code area in which the patient resides, however, in all 14 letters the patient states they currently live in Durham. Additionally, the applicant states that some ESRD patients residing in Wake County who live in the 27519 and 27560 zip code area are projected to utilize the East Durham Dialysis Center because it is closer to their homes.

Those letters of support state, in part:

*“Having my dialysis treatments in that part of the county would be closer to my home and much more convenient for me. I could travel between my home and that location more easily and quickly, which*

*would save me time and money.”*

Additionally, on page 52, the applicant states that some of the staff from Durham Dialysis Center and Durham West Dialysis Center are projected to transfer to East Durham Dialysis, allowing for consistency in care and services. Further, in Section III.3(c), pages 27-29, the applicant discusses the projected utilization of Durham Dialysis Center, Durham West Dialysis Center and Southpoint Dialysis following the transfer of patients to East Durham Dialysis, as discussed below.

### **Durham Dialysis Center**

The July SDR reported the facility had 91 in-center patients dialyzing on 29 dialysis stations for a utilization rate of 94.79% as of December 31, 2013. The applicant states on page 27 that seven dialysis stations and 17 current in-center patients are projected to transfer to East Durham Dialysis. This would leave 22 dialysis stations and 74 in-center patients at Durham Dialysis Center. The applicant used the Average Annual Change Rate for the past 5 years of 0.024 to project utilization of the facility. The applicant states the following on page 27:

*“[W]e have projected the growth in the patient population from January 1, 2014 to the date East Durham Dialysis is projected to be certified.*

*January 1, 2014-December 31, 2014 – 91 in-center patients X 1.024 = 93.184*

*January 1, 2015-December 31, 2015 – 93.184 in-center patients X 1.024 = 95.420416*

*Using the projections above, the Durham Dialysis Center would have 95 in-center patients at the point when East Durham Dialysis is projected to be certified on January 1, 2016. With 17 patients and 7 dialysis stations transferring from the Durham Dialysis Center to East Durham Dialysis Center, this will leave 78 patients (95 – 17 = 78) and 22 dialysis stations ...”*

Based on the information above, the Durham Dialysis Center is projected to have a utilization rate of 88.6% or 3.54 patients per station once East Durham Dialysis is operational.

### **Durham West Dialysis Center**

The July SDR reported the facility had 98 in-center patients dialyzing on 29 dialysis stations for a utilization rate of 84.48% as of December 31, 2013. The applicant states on page 28 that seven current patients and three dialysis stations are projected to transfer from the facility to East Durham Dialysis. This would leave 26 dialysis stations and 91 in-center patients at Durham Dialysis Center. The applicant used the Average Annual Change Rate for the past 5 years of 0.024 to project utilization of the facility. The applicant states the following on page 28:

*“[W]e have projected the growth in the patient population from January 1, 2014 to the date East Durham Dialysis is projected to be certified.*

*January 1, 2014-December 31, 2014 – 98 in-center patients X 1.024 = 100.352*

*January 1, 2015-December 31, 2015 – 100.352 in-center patients X 1.024 = 102.760448*

*Using the projections above, the Durham West Dialysis Center would have 102 in-center patients at the point when East Durham Dialysis is projected to be certified on January 1, 2016. With 7 patients and three dialysis stations transferring from the Durham West Dialysis Center to East Durham Dialysis Center, this will leave 95 patients (102 – 7 = 95) and 26 dialysis stations ...”*

Based on the information above, the Durham West Dialysis Center is projected to have a utilization rate of 91.3% or 3.65 patients per station once East Durham Dialysis is operational.

### **Southpoint Dialysis Center**

The July SDR reported the facility had 47 in-center patients dialyzing on 12 dialysis stations for a utilization rate of 97.92% as of December 31, 2013. As of June 18, 2014 the facility was licensed for 16 stations. The applicant states on page 28 that eight current patients are projected to transfer from the facility to East Durham Dialysis. This would leave 39 patients and 16 in-center stations at Southpoint Center. The applicant used the Average Annual Change Rate for the past 5 years of 0.024 to project utilization of the facility. The applicant states the following on page 29:

*“[W]e have projected the growth in the patient population from January 1, 2014 to the date East Durham Dialysis is projected to be certified.*

*January 1, 2014-December 31, 2014 – 47 in-center patients X 1.024 = 48.128*

*January 1, 2015-December 31, 2015 – 48.128 in-center patients X 1.024 = 49.283072*

*Using the projections above, the Southpoint Dialysis Center would have 49 in-center patients at the point when East Durham Dialysis is projected to be certified on January 1, 2016. With 8 patients transferring from the Southpoint Dialysis Center to East Durham Dialysis Center, this will leave 41 patients (49 – 8 = 41) and 16 dialysis stations ...”*

Based on the information above, the Southpoint Dialysis Center is projected to have a utilization rate of 64.1% or 2.56 patients per station once East Durham Dialysis is operational.

The applicant projects to serve 33 in-center patients at East Durham Dialysis Center by the end of Year One or 3.3 patients per station [33/10 = 3.3]; and 34 in-center patients by the end of Year Two or 3.4 patients per station [34/10 = 3.4]. The projected utilization rate is 82.5% at the end of Year One [33/(4x10) = 82.5] and 85% in Year Two [34/(4x10) = 85]. Projected in-center utilization at East Durham Dialysis is based on reasonable, credible and supported assumptions. Therefore, projected in-center utilization for East Durham Dialysis Center meets the minimum of 3.2 patients per station per week as of the end of the first operating year required by 10A NCAC 14C .2203(b).

Projected utilization is based on reasonable and supported assumptions regarding continued growth in the proposed service area.

Access

In Section VI.1, pages 46-50, the applicant describes how underserved persons will have access to services provided by East Durham Dialysis. On page 46, the applicant states:

*“East Durham Dialysis, by policy, will make dialysis services available to all residents in its service area without qualifications. The facility will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.”*

## **Conclusion**

In summary, the applicant adequately identified the population to be served, demonstrated the need the population has for the project and the extent to which all residents of the area, in particular underserved groups are likely to have access to the services provided. 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**

The applicant proposes to relocate seven existing certified dialysis stations from Durham Dialysis Center and three existing certified dialysis stations from Durham West Dialysis Center to East Durham Dialysis in Durham for a total of ten certified dialysis stations at East Dialysis Center upon completion of the project. In Section III.3(c), pages 27-28, the applicant discusses how the needs of dialysis patients at Durham Dialysis Center and Durham West Dialysis Center will continue to be met after the transfer of those stations to the proposed East Durham Dialysis Center.

## **Durham Dialysis Center**

The July SDR reported the facility had 91 in-center patients dialyzing on 29 dialysis stations for a utilization rate of 94.79% as of December 31, 2013. The applicant states on page 27 that seven dialysis stations and 17 current in-center patients are projected to transfer to East Durham Dialysis. This would leave 22 dialysis stations and 74 in-center patients at Durham Dialysis Center. The applicant used the Average Annual Change Rate for the past 5 years of 0.024 to project utilization of the facility. The applicant states the following on page 27:

*“[W]e have projected the growth in the patient population from January 1, 2014 to the date East Durham Dialysis is projected to be certified.*

*January 1, 2014-December 31, 2014 – 91 in-center patients X 1.024 = 93.184*

*January 1, 2015-December 31, 2015 – 93.184 in-center patients X 1.024 = 95.420416*

*Using the projections above, the Durham Dialysis Center would have 95 in-center patients at the point when East Durham Dialysis is projected to be certified on January 1, 2016. With 17 patients*

*and 7 dialysis stations transferring from the Durham Dialysis Center to East Durham Dialysis Center, this will leave 78 patients ( $95 - 17 = 78$ ) and 22 dialysis stations ...”*

Based on the information above, the Durham Dialysis Center is projected to have a utilization rate of 88.6% or 3.54 patients per station once East Durham Dialysis is operational.

### **Durham West Dialysis Center**

The July SDR reported the facility had 98 in-center patients dialyzing on 29 dialysis stations for a utilization rate of 84.48% as of December 31, 2013. The applicant states on page 28 that seven current patients and three dialysis stations are projected to transfer from the facility to East Durham Dialysis. This would leave 26 dialysis stations and 91 in-center patients at Durham Dialysis Center. The applicant used the Average Annual Change Rate for the past 5 years of 0.024 to project utilization of the facility. The applicant states the following on page 28:

*“[W]e have projected the growth in the patient population from January 1, 2014 to the date East Durham Dialysis is projected to be certified.*

*January 1, 2014-December 31, 2014 – 98 in-center patients X 1.024 = 100.352*

*January 1, 2015-December 31, 2015 – 100.352 in-center patients X 1.024 = 102.760448*

*Using the projections above, the Durham West Dialysis Center would have 102 in-center patients at the point when East Durham Dialysis is projected to be certified on January 1, 2016. With 7 patients and three dialysis stations transferring from the Durham West Dialysis Center to East Durham Dialysis Center, this will leave 95 patients ( $102 - 7 = 95$ ) and 26 dialysis stations ...”*

Based on the information above, the Durham West Dialysis Center is projected to have a utilization rate of 91.3% or 3.65 patients per station once East Durham Dialysis is operational. The proposed project does not reduce the total number of stations in Durham County; it merely separates them into another facility owned and operated by DVA Healthcare Renal Care, Inc.

The applicant states the medically underserved population will continue to have access to services provided by DVA. as stated in Section VI.1, pages 46-50. Therefore, the applicant demonstrates that the needs of the population presently served at Durham Dialysis Center and Durham West Dialysis Center will be adequately met following the relocation of seven stations from Durham Dialysis and three stations from Durham West Dialysis Center to East Durham Dialysis. Additional discussion relating to promoting equitable access in Criterion (13) is incorporated herein by reference.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

### **C**

In Section III.9, pages 36-37, the applicant discusses the analysis that DVA engaged in to determine the need for the proposed ESRD facility. The applicant states on page 36, “DVA Healthcare Renal Care studied appropriate alternatives to this application and concluded that developing a new facility in the

*southeastern Durham County area is the best option.*” The applicant states the following other alternatives were considered:

- Maintaining the Status Quo – The applicant concluded that this was not the best option for the patients residing in the 27703 zip code area and those patients residing Wake County.
- Locating a the Facility in Another Area of the County – The applicant concluded that with the other three existing DVA owned and operated ESRD facilities which are located in downtown, to the west and in the south portions of Durham, that based on their existing patients there is a need for a more convenient option for those residents that reside in eastern Durham and Wake County. Therefore, to locate the proposed facility in another area within the county would not be in the best interest of the patients.
- Develop the Facility as Proposed – The applicant concluded that the development of the project, as proposed, would provide a more convenient option for the patients who reside in the 27519, 27560 and 27703 zip code areas and currently receive dialysis services at Durham Dialysis, Durham West Dialysis and Southpoint Dialysis.

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 the East Durham Dialysis proposal is the least costly or most effective alternative to meet the need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1. DVA Healthcare Renal Care, Inc. d/b/a East Durham Dialysis shall materially comply with all representations made in the certificate of need application.**
- 2. DVA Healthcare Renal Care, Inc. d/b/a East Durham Dialysis shall develop and operate no more than ten dialysis stations at East Durham Dialysis which shall include any home hemodialysis or isolation stations.**
- 3. DVA Healthcare Renal Care, Inc. d/b/a East Durham Dialysis shall install plumbing and electrical wiring through the walls for no more than ten dialysis stations which shall include any home hemodialysis or isolation stations.**
- 4. DVA Healthcare Renal Care, Inc. shall take the necessary steps to decertify seven stations at Durham Dialysis Center for a total of no more than twenty-two certified dialysis stations at Durham Dialysis Center upon project completion.**
- 5. DVA Healthcare Renal Care, Inc. shall take the necessary steps to decertify three stations at Durham West Dialysis Center for a total of no more than twenty-six certified dialysis stations at Durham West Dialysis Center upon project completion.**
- 7. DVA Healthcare Renal Care, Inc. d/b/a East Durham Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII.1, page 56, the applicant states that the total capital cost of the project will be \$2,287,605 which includes \$1,537,000 in construction contract cost, \$140,000 for dialysis machines, \$95,000 for water treatment equipment, \$274,560 in equipment/furniture, \$145,000 in architect/engineering fees, \$19,560 for dialysis chairs, \$7,835 for scale cost, \$33,000 for television system cost, and \$35,650 for a patient computer system.

In Section IX.2 page 59, the applicant projects that the initial operating expenses associated with the proposed project will equal \$949,715. On page 59, Section IX.1(b), the applicant states the estimated start-up expenses will be \$177,537. Therefore, the projected total working capital (start-up and initial operating expenses) associated with the proposed project will be \$1,127,252, as illustrated below.

• Start-up Expenses	\$177,537
• Initial Operating Expenses	<u>\$949,715</u>
<b>Total Working Capital</b>	<b>\$1,127,252</b>

In Section VIII.3, page 57, the applicant states that the project will be funded with cash reserves of DaVita Healthcare Partners Inc., the parent company of DVA Healthcare Renal Care, Inc. Exhibit 29 contains a letter dated April 13, 2014 from the Chief Accounting Officer of DaVita Healthcare Partners, which states in part:

*“We are submitting a Certificate of Need application to develop a ten-station End Stage Renal Disease hemodialysis facility in Durham in Durham County. I am writing this letter ... to confirm DaVita’s commitment of \$2,287,605, for the capital expenditures associated with this project; a commitment of \$177,537, for its start up expenses; and a further commitment of \$949,715 in working capital. ...*

*DaVita HealthCare Partners has committed cash reserves in the total sum of \$3,414,857, for the capital costs, start-up costs and working capital for this project.”*

Exhibit 30 of the application contains the audited financial statements for DaVita HealthCare Partners Inc. for the fiscal year ended December 31, 2013. As of December 31, 2013, DaVita HealthCare Partners Inc. had \$946,249,000 in cash and cash equivalents, \$17,098,877,000 in total assets and \$5,302,841,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital and working capital needs of the project.

In Section X.1, page 61, the applicant provides the allowable charges, per treatment, for each payment source for East Durham Dialysis Center, as illustrated in the table below:

Payor Source	Charge per Treatment
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Medicare	\$239.02
Medicaid	\$143.00
Medicare/Medicaid	\$239.02
Commercial Insurance	\$1,275.00
VA	\$193.00
Medicare/Commercial	\$239.02

The applicant projects revenues in Section X.2, page 62 and operating expenses in Section X.4, page 65, of the application. In Section X.2-X.4, pages 62-65, the applicant reports projected revenues and expenses for East Durham Dialysis, as illustrated in the table below:

<b>East Durham Dialysis</b>		
	<b>Operating Year 1</b>	<b>Operating Year 2</b>
Total Net Revenue	\$2,100,448	\$2,169,811
Total Operating Costs	\$1,899,429	\$1,954,068
<b>Net Profit</b>	<b>\$201,019</b>	<b>\$215,743</b>

The applicant projects that revenues 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, credible and supported. See Section X of the application for the applicant's assumptions.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of this project. The applicant also adequately demonstrates that the financial feasibility of the proposal 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

DVA Healthcare Renal Care, Inc. d/b/a East Durham Dialysis proposes to relocate seven existing certified dialysis stations from Durham Dialysis Center and three existing certified dialysis stations from Durham West Dialysis Center to East Durham Dialysis to establish a ten-station ESRD facility at 2945 South Miami Boulevard in Durham, upon completion of the proposed project. The July 2014 SDR reports that the following eight ESRD facilities are currently located in Durham County.

Name of Facility	Own/Operated By	# of Certified Stations	% of Utilization	Address	Distance to Proposed Facility <sup>1</sup>
Duke Hospital Dialysis	Duke University Hospital	16	79.69%	1306 Moreen Rd - Durham	10.87 miles

<sup>1</sup> <http://www.mapquest.com>

Durham Dialysis	DaVita HealthCare Partners, Inc.	24	94.79%	201 Hood St - Durham	6.38 miles
Durham West Dialysis	DaVita HealthCare Partners, Inc.	29	84.48%	4307 Western Park Place - Durham	11.73 miles
FMC Dialysis Services of Briggs Avenue	Fresenius Medical Care Holdings, Inc.	29	68.97%	1209 South Briggs Ave - Durham	5.16 miles
FMC Dialysis Services West Pettigrew	Fresenius Medical Care Holdings, Inc.	20	76.25%	1507 West Pettigrew St - Durham	8.36 miles
FMC South Durham Dialysis	Fresenius Medical Care Holdings, Inc.	12	97.92%	211 East Cornwallis Rd - Durham	5.60 miles
Freedom Lake Dialysis	BMA of North Carolina, Inc.	22	81.82%	4016 Freedom Lake Drive - Durham	11.44 miles
Southpoint Dialysis	DaVita Healthcare Partners, Inc.	12	97.92%	415 West Highway 54 - Durham	7.12 miles

Source: July 2014 SDR

Of those facilities listed above, Duke University Hospital owns one of the facilities, the applicant owns three and BMA owns four. Five of those facilities are located less than 10 miles from the proposed East Durham Dialysis Center with the FMC Dialysis Services of Briggs Avenue being 5.16 miles away. As reported in the July 2014 SDR, the FMC Dialysis Services of Briggs Avenue facility operated with 29 certified stations and had a utilization rate of 68.97% as of December 31, 2013. The relocation of the existing stations from Durham Dialysis and Durham West Dialysis would not change the inventory of certified ESRD stations within Durham County.

Consequently, the applicant adequately demonstrates the proposal would not result in the unnecessary duplication of existing health service capabilities or facilities. Therefore, the application is conforming to this criterion.

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

C

In Section VII.1, page 51, the applicant provides projected staffing for East Durham Dialysis upon project completion, as illustrated in the following table:

<b>East Durham Dialysis</b> Full-Time Equivalent (FTE) Positions	
RN	1.50
HTRN	1.00
PCT	4.50
Bio-Med Tech	.30

Admin.	1.00
Dietician	.50
Social Worker	.50
Reuse Tech	1.00
Unit Secretary	1.00
<b>Total FTEs</b>	<b>11.30</b>

The applicant projects a total of 11.30 FTE positions upon project completion and states on page 52 that some teammates from Durham Dialysis Center and Durham West Dialysis Center are projected to transfer to the proposed East Durham Dialysis Center. On pages 52-53, the applicant discusses DaVita HealthCare Partners' recruitment policy and states that they do not anticipate difficulty in recruiting and retaining qualified staff because of their aggressive recruiting practice and their competitive salary structure. In Section V.4, page 43, the applicant identifies the Medical Director for East Durham Dialysis as Dr. Stephen Smith. In Exhibit 23 the applicant provides a letter from Dr. Smith indicating his willingness to serve as Medical Director of the facility. Additionally, in Section VII.10, page 54, the applicant states East Durham Dialysis will operate two shifts, six days a week from 6:00 a.m. to 4:00 p.m.

The applicant adequately documents the availability of resources, including health manpower and management personnel, for 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 V.1, pages 41-42, the applicant lists the proposed providers of the necessary ancillary and support services. Exhibits 8-10 contain documentation of service agreements. The applicant adequately demonstrates that necessary ancillary and support services are available and that the proposed services will be coordinated with the existing healthcare system. Therefore, the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the

basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

- (i) would be available under a contract of at least 5 years duration;
- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

In Section XI, pages 68-69, the applicant discusses the primary and secondary sites being considered for the proposed East Durham Dialysis Center. The applicant states that DVA Healthcare Renal Care, Inc. plans to lease space for the proposed new facility. The applicant states there are two sites being considered for the proposed facility. The primary site consists of 11,500 square feet in an existing building and is located at 2945 S. Miami Boulevard, in Durham and is currently zoned for dialysis facility use. The secondary site is located at 4024 Stirrup Creek Drive, in Durham and consists of 11,500 square feet and is currently zoned for dialysis facility use. See Exhibits 12 and 13 for documentation on the availability of both sites for leasing. Also, see Exhibits 12 and 13 for documentation on the availability of water, sewer, and electric services for the proposed sites. Maps for the proposed sites can also be found in Exhibits 12 and 13. The applicant further states on pages 69-70, that both sites are located on major highways that are easily accessible by patients and transportation agencies.

In Section XI.6, page 71, the applicant states that each dialysis station will be 274 square feet with energy saving features. The applicant projects the construction cost will be \$1,537,000 and architect and engineering fees will be \$145,000, which is a total of \$1,682,000. Thus, the per square feet cost is projected to be \$146.26 ( $\$1,682,000/11,500 = \$146.26$ ). See Section VIII.1, page 56 and Section XI.6(h), page 74. The following table illustrates the square footage breakdown as provided by the applicant in Section XI.6(h), page 74:

<b>East Durham Dialysis</b>	
<b>Facility Area</b>	<b>Estimated Total Sq. Ft.</b>
Ancillary Areas:	
Administration/Offices/Receptions/Elevator & Lobby	441
Public Lobby	739
Mechanical Equipment	66
Biomedical	121
General Storage/Medical Records	822
Exam/Treatment/ PD Training & Medical Offices	1,446

Staff Lounge & Lockers	499
RO	640
Other: Handicap baths, dock and walkways	417
<b>Sub-Total Support</b>	<b>5,191</b>
Treatment Areas:	
Nurses Station	717
Dialysis Stations	2,745
Isolation Room(s)	120
Other: Walkways, Lab, Storage	165
<b>Sub-Total Treatment</b>	<b>3,747</b>
<b>Miscellaneous (Corridors/Walls)</b>	<b>2,542</b>
<b>Total Square Feet</b>	<b>11,480</b>

The applicant includes a note on page 75, which states:

*“There is a 20 square foot discrepancy between the letter from the real estate firm indicating the amount of square footage to be leased and the line drawing in Exhibit 28 and the chart above. It is the intent of DVA Healthcare Renal Care to lease 11,500 square feet of space.”*

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative and that the construction project would not unduly increase the costs of or charges for providing the proposed dialysis 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 VI.1(b), page 46, the applicant reports that 91.2% of the patients who received treatments at Durham Dialysis Center and 89.6% of patients who received treatments at Durham West Dialysis Center had some or all of their services paid for by Medicare or Medicaid in the past year. The tables below illustrate the historical payment source for these two existing facilities:

<b>2013 DURHAM DIALYSIS CENTER PAYOR MIX</b>	
<b>SOURCE OF PAYMENT</b>	<b>PERCENTAGE</b>
Medicare	31.8%
Medicaid	15.4%
Medicare/Medicaid	26.4%
Commercial Insurance	6.6%
VA	2.2%
Medicare/Commercial	17.6%
<b>Total</b>	<b>100.0%</b>

<b>2013 DURHAM WEST DIALYSIS CENTER PAYOR MIX</b>	
<b>SOURCE OF PAYMENT</b>	<b>PERCENTAGE</b>
Medicare	27.1%
Medicaid	6.3%
Medicare/Medicaid	13.5%
Commercial Insurance	8.3%
VA	2.1%
Medicare/Commercial	42.7%
<b>Total</b>	<b>100.0%</b>

The Division of Medical Assistance (DMA) maintains a website which provides the number of persons eligible for Medicaid in North Carolina, and estimates the percentage of uninsured people for each county. The following table illustrates those percentages for Durham County and statewide.

	<b>2010 Total # of Medicaid Eligibles as % of Total Population *</b>	<b>2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *</b>	<b>2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *</b>
Durham County	16%	5.74%	20.1%
Statewide	17%	6.7%	19.7%

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

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by dialysis facilities. In fact, in 2013 only 6.6% of all newly-diagnosed ESRD patients in North Carolina were under the age of 35, according to the ESRD Network 6 2013 Annual Report. (*ESRD Network 6 2013 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 1/1/2013 – 12/21/2013, page 99*).<sup>2</sup>

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, as well as data sorted by age, race or gender. However, a direct comparison to the applicant's current payor mix

<sup>2</sup> <http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

would be of little value. The population data by age, race or gender do not include information on the number of elderly, handicapped, minorities or women utilizing health services.

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

*“The December 31, 2011 prevalent population included 430,273 patients on dialysis ...”*<sup>3</sup> (p. 216)

The report also provides the incidence of dialysis patients in 2011, adjusted by age, gender and race, which show that 65.4% were white, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian, and 1.2% were Native American (p.218). Moreover, the prevalence of ESRD for the 65-74 year old population grew by 31% since 2000 and by 48% for those aged 75 and older (p. 216). The report further states:

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

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

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

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

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<sup>3</sup> [www.usrds.org/adr.aspx](http://www.usrds.org/adr.aspx)

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

Source: SKC Network 6. Table includes North Carolina statistics only.<sup>4</sup>

Durham Dialysis and Durham West Dialysis Center demonstrate that each 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 applicant;

C

In Section VI.1(f), page 48, the applicant states,

*“East Durham Dialysis will have 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. East Durham Dialysis will have no obligation under the Hill Burton Act.”*

In Section VI.6(a), page 50, 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.

<sup>4</sup><http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

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

C

In Section VI.1(c), page 47, the applicant provides the projected payor mix for in-center patients for the proposed East Durham Dialysis Center, as shown in the table below.

Source of Payment	As a % of Total
Medicare	29.0%
Medicaid	10.7%
Medicare/Medicaid	19.7%
Commercial Insurance	9.4%
VA	1.7%
Medicare/Commercial	29.5%
<b>Total</b>	<b>100.0%</b>

As shown in the table above, the applicant projects 88.9% of all patients will have their care paid for by Medicare and Medicaid. The applicant states on page 47, that the payment source for East Durham Dialysis Center is based on the consolidated in-center patient payor mix for DVA Healthcare Renal Care facilities located in Durham County for 2013.

The applicant demonstrates that medically underserved populations would have adequate access to the proposed services at East Durham Dialysis. 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(a), page 49, the applicant states,

*“Patients with End Stage Renal Disease will have access to dialysis services upon referral by a Nephrologist with privileges at East Durham Dialysis. East Durham Dialysis will grant privileges to all qualified nephrologists. Referrals to nephrologists most commonly come from primary care physicians or specialty physicians in Durham and surrounding counties or transfer referrals from other Nephrologists outside of the immediate area. Patients, families and friends can obtain access by contacting a Nephrologist with privileges at the facility. ... Patients from outside the facility catchment area requesting transfer to this facility will be processed in accordance with the facility transfer and transient policies which comprise Exhibit 25.”* [Emphasis in original]

The applicant adequately demonstrates that East Durham Dialysis will offer a range of means by which a person can access its services. Therefore, the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section V.3, page 43, the applicant states that East Durham Dialysis will be offered as a training site for nursing students. Exhibit 22 includes a letter dated April 7, 2014 from DaVita HealthCare Partners Inc. to the President of Durham Technical Community College offering the use of East Durham Dialysis Center as a clinical training site.

The information provided in Section V.3 is reasonable and credible for a new facility and supports a finding of conformity to this criterion.

- (15) Repealed effective July 1, 1987.  
(16) Repealed effective July 1, 1987.  
(17) Repealed effective July 1, 1987.  
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to relocate seven existing certified dialysis stations from Durham Dialysis Center and three existing certified dialysis stations from Durham West Dialysis Center in Durham to East Durham Dialysis in Durham for a total of ten certified dialysis stations at East Durham Dialysis upon completion of the project. According to the July 2014 SDR there are currently eight ESRD facilities and a surplus of 19 dialysis stations located in Durham County. Of those existing ESRD facilities, one operated below 70% utilization (FMC Dialysis Services of Briggs Avenue) and seven facilities operated above 79% utilization. The applicant projects that 88.9% of all patients who receive services at East Durham Dialysis will have their care paid for by Medicare and Medicaid.

In Section V.7, page 44-45, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost effectiveness, quality and access. The applicant states in part:

*“The development of DVA Healthcare Renal Care, Inc. d/b/a East Durham Dialysis will have no effect on any dialysis facilities located in Durham County or in counties contiguous to Durham County. Fresenius Medical Care operates four dialysis facilities and Duke Hospital operates one dialysis facility in Durham County. Each provider has their own source of referrals from Nephrologists. The Nephrologists associated with the DVA Healthcare Renal Care refer patients to the Durham Dialysis Center, East Durham Dialysis Center and Southpoint Dialysis.*

...

*The proposed East Durham Dialysis will not have an adverse effect on competition since the patients already being served by DVA Healthcare Renal Care will be transferring their care from one DVA facility to another DVA facility, which will be more convenient for the patients who have indicated this in the letters they signed. ...*

*The Southeastern Durham County communities do not have a dialysis facility available for patients associated with DVA Healthcare Renal Care. ...*

*Bottom line, East Durham 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 involved in the dialysis process to receive services.”*

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that any enhanced competition in the service area would have a positive impact on quality and access to the proposed services. This determination is based on the following analysis:

- The applicant adequately demonstrates the need to relocate seven existing dialysis stations from Durham Dialysis Center and three existing dialysis stations from Durham West Dialysis Center to develop East Durham Dialysis Center, a new ten-station ESRD facility that will offer home training in peritoneal dialysis. The applicant also demonstrates that the proposed project is a cost-effective alternative to meet the need to provide additional access to Durham County dialysis patients;
- The applicant will provide quality services; and
- The applicant will provide adequate access to medically underserved populations.

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

According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, Durham Dialysis and Durham West Dialysis operated in compliance with the Medicare Conditions of Participation within the 18 months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The Criteria and Standards for End Stage Renal Disease Services, as promulgated in 10A NCAC 14C .2200, are applicable to this review. The application is conforming to all applicable criteria which 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, page 38, and Exhibit 7 (copy of the July 2014 SDR, Tables A and B). As of December 31, 2013, the utilization rate for Durham Dialysis Center was 94.79% and the utilization rate at Durham West Dialysis was 84.48%.

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

- C- In Section IV.2, page 39, the applicant states mortality rates for Durham Dialysis Center were 11.5% in 2011, 12.7% in 2012, and 14.4% in 2013. The mortality rates for Durham West Dialysis Center for the same timeframe were 10.2%, 6.0% and 15.0%, respectively.

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

- C- In Section IV.3, page 39, the applicant states, “*Durham Dialysis Center has an agreement with the Durham West Dialysis Center to provide home training.*” On page 39, the applicant reports that 16 patients were home trained at Durham West Dialysis Center as of December 31, 2013.

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

- C- In Section IV.4, page 39, the applicant states Durham Dialysis Center referred 13 patients for transplant evaluation and two transplants were performed in 2013. Durham West Dialysis Center referred 15 patients for transplant evaluation and five patients received a transplant in 2013.

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

-C- In Section IV.5, page 40, the applicant states there are currently five patients on the transplant waiting list at Durham Dialysis Center and 23 patients on the transplant waiting list at Durham West Dialysis Center.

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

-C- In Section IV.6, page 40, the applicant provides the hospital admissions rates, by admission diagnosis, as illustrated in the tables below.

*Durham Dialysis Center Hospital Admissions*

<b>01/13-12/13 Hospital Admissions</b>	<b>Total</b>
<i>Number dialysis related</i>	42
<i>Percent Dialysis related</i>	26.4%
<i>Number non-dialysis related</i>	117
<i>Percent non-dialysis related</i>	73.6%
<b>Total number Admissions</b>	<b>159</b>

*Durham West Dialysis Center Hospital Admissions*

<b>01/13-12/13 Hospital Admissions</b>	<b>Total</b>
<i>Number dialysis related</i>	28
<i>Percent Dialysis related</i>	12.6%
<i>Number non-dialysis related</i>	194
<i>Percent non-dialysis related</i>	87.4%
<b>Total number Admissions</b>	<b>222</b>

.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 40, the applicant reported as of June 30, 2014 there were no patients dialyzing at Durham Dialysis Center or Durham West Dialysis Center with an infectious disease (Hepatitis B or AIDS). Additionally, the applicant reports that none of the patients dialyzing at either facility converted to infectious disease status.

(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.*

- C- See Exhibit 8 for an acute care hospital agreement with Duke University Hospital.
- .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.*
- C- In Section V.1(f), page 41, the applicant indicates that transplantation services will be provided by Carolinas Medical Center (CMC). The applicant references Exhibit 9 which contains a transplantation agreement with Carolinas HealthCare System.
- .2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- C- In Section XI.6(e), page 72, the applicant states that the facility will be located in an area that is supplied by portable city water and sewer. In Section XI.6(f), page 72, the applicant further states that the facility will be served by standing power service. See Exhibit 10 for a copy of a letter dated April 1, 2014 to the Regional Operations Director for DaVita requesting that Durham Dialysis Center serve as the primary back-up for East Durham Dialysis. Additionally, Exhibit 10 contains copies of the applicant's policies, procedures and guidelines which include policies on, *Termination of Dialysis in an Emergency, Using Hand Crank During Power Failure and Back Up Generator Operational Checks*. See also Exhibit 15 for copies of the applicant's policies, procedures and guidelines which include policies on, *Water Culture Policy and General Water Quality Policy*.
- .2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C- See Exhibit 10 for copies of the applicant's policies, procedures and guidelines; which includes a section on power failure.
- .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.*

- C- See Exhibits 12 and 13 for documentation from BPG Management Company – NC, LLC that the primary site is located at 2945 S. Miami Boulevard, in Durham and the secondary site is located at 4024 Stirrup Creek Drive, in Durham. Both site are approximately 11,500 square feet.
  
- .2202(b)(6) *Documentation that the services will be provided in conformity to applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*
  
- C- See Section VII.2, pages 51-52 and Section XI.6, pages 71-74. In Section XI.6(g), page 72, the applicant states, “*East Durham Dialysis will operate within the applicable laws and regulations pertaining to staffing, and fire safety equipment, physical environment and other relevant health safety requirements.*”
  
- .2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
  
- C- See Section III.7, pages 33-34, for all assumptions, including the methodology by which patient origin is projected. The applicant provides projected patient origin which is based on the historical experience of DVA Healthcare Renal Care facilities operated in Durham County and letters of support from current patients at DVA Healthcare Renal Care, Inc. owned and operated facilities who have expressed an interest in considering transferring their care to the proposed East Durham Dialysis facility, as shown in the below table.

<b>EAST DURHAM DIALYSIS</b>						
<b>COUNTY</b>	<b>Operating</b>		<b>Operating</b>		<b>County In-Center Patients as % of Total</b>	
	<b>Year 1 2016</b>		<b>Year 2 2017</b>		<b>Year 1</b>	<b>Year 2</b>
	<b>In-Center</b>	<b>Home Dialysis</b>	<b>In-Center</b>	<b>Home Dialysis</b>		
<b>Durham</b>	<b>28</b>	<b>12</b>	<b>29</b>	<b>13</b>	<b>87.0%</b>	<b>87.5%</b>
<b>Wake</b>	<b>5</b>	<b>1</b>	<b>5</b>	<b>1</b>	<b>13.0%</b>	<b>12.5%</b>

<b>Total</b>	<b>33</b>	<b>13</b>	<b>34</b>	<b>14</b>	<b>100.0%</b>	<b>100.0%</b>
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- .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.*
- C- In Section III.8, page 35, the applicant states that 100% of its patients will reside within 30 miles of the proposed East Durham Dialysis Center.
- .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 16, the applicant states, “DVA Healthcare Renal Care, Inc. d/b/a East Durham Dialysis 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.*
- C- In Section II, pages 16-19, the applicant states East Durham Dialysis Center is projected to have 33 patients by the end of operating year 1. Therefore, the applicant projects to have 3.3 patients  $[33/10 = 3.3]$  per station per week as of the end of the first operating year of East Durham Dialysis. See discussion regarding projected utilization in Criterion (3) 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- East Durham Dialysis is a new ESRD facility.
- .2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

- C- In Section II, pages 18-20 and Section III.7, pages 33-35, 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- In Section V.1(e), page 41, the applicant states that diagnostic and evaluation services will be provided by Duke University Medical Center.

.2204(2) *Maintenance dialysis;*

- C- In Section V.1(c), page 41, the applicant states that maintenance dialysis will be provided at East Durham Dialysis.

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

- C- In Section V.1(d), page 41, the applicant states that accessible self-care training will be provided by Durham West Dialysis Center. See Exhibit 16 for a copy of a service agreement between Durham West Dialysis and East Dialysis facility for Durham West Dialysis to provide home training in home hemodialysis.

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

- C- In Section V.1, page 41, the applicant states that an accessible follow-up program for support of peritoneal patients dialyzing at home will be provided by East Durham Dialysis Center. On page 43, the applicant states that the same services will be provided to home hemodialysis patients by Durham West Dialysis.

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

- C- In Section V.1(g), page 41, the applicant states that X-ray services will be provided by Duke University Medical Center.

.2204(6) *Laboratory services;*

- C- In Section V.1(h), page 41, the applicant states that routine, special and immunological laboratory services will be provided by Dialysis Laboratories.

.2204(7) *Blood bank services;*

- C- In Section V.1(i), page 41, the applicant states that blood bank services will be provided by Duke University Medical Center.

.2204(8) *Emergency care;*

- C- In Section V.1(b), page 41, the applicant states emergency care will be provided by Duke University Medical Center.
- .2204(9) *Acute dialysis in an acute care setting;*
- C- In Section V.1(a), page 41, the applicant states that acute dialysis in an acute care setting will be provided by Duke University Medical Center.
- .2204(10) *Vascular surgery for dialysis treatment patients*
- C- See Section V.1(p), page 41, the applicant states vascular surgery for dialysis treatment patients will be provided by Duke University Medical Center.
- .2204(11) *Transplantation services;*
- C- In Section V.1(F), page 41, the applicant indicates that transplantation services will be provided by Carolinas Medical Center. The applicant provides a copy of a transplantation agreement with Carolinas Healthcare System in Exhibit 9.
- .2204(12) *Vocational rehabilitation counseling and services; and,*
- C- In Section V.1(o), page 41, the applicant states that referrals will be made to NC Department of Vocational Rehabilitation for vocational rehabilitation counseling and services.
- .2204(13) *Transportation*
- C- In Section V.1(q), page 42, the applicant states that transportation will be provided by DSS and First Transit.

#### **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, page 51, the applicant provides the proposed staffing for East Durham Dialysis. The applicant projects to have 11.30 full time equivalent staff (FTEs), 4.5 of which are projected to be patient care technicians (PCT). The applicant states on page 51 that the facility will comply with all staffing requirements set forth in the Code of Federal Regulations. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. See discussion of staffing in Criterion (7) incorporated herein by reference.

- .2205(b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*
- C- In Section VII.4, pages 52-53 the applicant describes the training for new employees, ongoing in-service training and continuing education programs. Exhibit 20 contains the training outline.