

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

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

DECISION DATE: July 11, 2014
PROJECT ANALYST: Bernetta Thorne-Williams
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: J-10282-14 / 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 Durham Dialysis Center upon project completion. 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. 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 IX.6(d), page 62, 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 63, the applicant states how the proposed facility will conserve water and comply with 42 C.F.R. Section 405 .2100.

The applicant adequately demonstrates that the proposed facility will be designed and operated to assure improved energy efficiency and water conservation.

In summary, the applicant is consistent with Policy ESRD-2 and Policy GEN-4 and is therefore 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.

NC

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 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 26, 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:

COUNTY	EAST DURHAM DIALYSIS					
	Operating Year 1 2016		Operating Year 2 2017		County In-Center Patients as % of Total	
	In-Center	Home Dialysis	In-Center	Home Dialysis	Year 1	Year 2
Durham	32	1	33	2	94.3%	94.6%
Wake	0	2	0	2	5.7%	5.4%
Total	32	3	33	4	100.0%	100.0%

In Section III.7, pages 26-28, the applicant provides the assumptions and methodology used to project the number of patients expected to utilize the East Durham Dialysis Center, as follows:

“The majority of patients who are projected to utilize East Durham Dialysis will be Durham County residents. ... [T]hese projections are based on the following assumptions:

- *The letters from in-center dialysis patients residing in Durham indicate that all of the patients live in Durham County.*
- *All the patients who signed letters of support indicating that they would consider transferring to East Durham Dialysis live closer to the proposed site of the new facility.*

- *The number of patients is projected to grow at a rate of 0.7% based on the Durham County January 2014 Semiannual Dialysis Report.*

Thirty-two patients who currently receive their dialysis treatments at the Durham Dialysis Center, the Durham West Dialysis Center and Southpoint Dialysis in Durham County have signed letters of support or indicated verbal support for the proposed East Durham Dialysis. All of the patients who signed letters or indicated verbal support have indicated in their letters that they live closer to the proposed East Durham Dialysis and that the facility will be more convenient for them.

Based on these letters, East Durham Dialysis will have at least 32 in-center ESRD patients dialyzing in the facility January 1, 2016, which is projected to be the beginning of the first year of operation. Those 32 patients are projected to transfer from the Durham Dialysis Center, Durham West Dialysis Center and Southpoint Dialysis. The facility is projected to have 32 in-center patients by the end of operating year one based on the current Average Annual Change Rate for the Past Five Years that is cited in the January 2014 Semiannual Dialysis Report in Table B: ... 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.

...

In-Center Utilization Projections using the average annual change rate for the past five years of 0.7% and starting with 32 in-center patients dialyzing at the Durham Dialysis Center, Durham West Dialysis Center and Southpoint Dialysis who will transfer their treatments to East Durham Dialysis as of January 1, 2016.

January 1, 2016-December 31, 2016 – 32 in-center patients $X 1.007 = 32.224$

January 1, 2017-December 31, 2017 – 32.224 in-center patients $X 1.007 = 32.449568$

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

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

Home-Training

Home training in peritoneal dialysis will be established at East Durham Dialysis. The facility is projected to have two peritoneal dialysis patients transfer their care from the Durham West Dialysis Center when East Durham Dialysis is certified, which is projected to be on January 1, 2016. These two patient live in Cary and Raleigh. They travel two times monthly to the western side of Durham to the Durham West Dialysis Center for support and follow-up.

It is projected 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. It is projected that Durham East Dialysis [sic] will have 3 peritoneal dialysis patients at the end of operating year one for an average of 2.5 peritoneal dialysis patients. It is projected that Durham East Dialysis [sic] will have 4 peritoneal dialysis patients at the end of operating year two for an average of 3.5 peritoneal

dialysis patients.” [Emphasis in origin]

The applicant adequately identifies the population it proposes to serve. See discussion of the need analysis below regarding the reasonableness of the projections.

Need Analysis

In Section III.3, page 20, the applicant states that improved geographic accessibility of services in the eastern side of Durham County is a key factor for the proposed project. The applicant further states on page 20, “[I]t was determined that the existing facilities are serving a total of thirty-two patients who live in three zip codes on the eastern side of the county.” However, the applicant did not provide a list of the zip codes currently served by Durham Dialysis Center, Durham West Dialysis Center or Southpoint Dialysis. Nor did the applicant provide a list of those zip codes that would be better served by the proposed East Durham Dialysis Center.

In Section III.3, page 21 and Section III.7, page 27, the applicant states, “*Thirty-two patients who currently receive their dialysis treatments at the Durham Dialysis Center, the Durham West Dialysis Center and Southpoint Dialysis in Durham County have signed letters of support or indicated verbal support for the proposed East Durham Dialysis.*” The applicant further states on page 27, “**Based on these letters, East Durham Dialysis will have at least 32 in-center ESRD patients dialyzing in the facility January 1, 2016, which is projected to be the beginning of the first year of operation. ... 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.** [Emphasis added] Additionally, in Section III.3, page 21 the applicant states, “*Based on these letters and the comments from patients who preferred not to sign letters ... East Durham Dialysis will have at least 32 in-center dialysis patients.*”

In Exhibit 16 the applicant provides letters of support from 23 patients currently dialyzing at other dialysis centers (Durham Dialysis Center with 15 letters, the Durham West Dialysis Center with 5 letters and Southpoint Dialysis with 3 letters) in Durham. In those 23 letters, patients indicate a willingness to consider transferring their dialysis care to East Durham Dialysis because of the convenience and closer proximity to their individual residence. The letters provided by the applicant are generic form letters that do not provide the address nor the zip code for those patients who state they would consider transferring their care to the proposed East Durham Dialysis Center. While letters are not expressly required by the statutory or regulatory review criteria, in lieu of other supported assumptions by the applicant they would help support the applicant’s projections.

Therefore, based on the number of letters of support (23) from existing patients expressing a willingness to consider transferring to the proposed East Durham Dialysis Center, the applicant is projected to have 2.3 patients per station per week [$23 / 10 = 2.3$] or 57.5% utilization [$23/(4 \times 10) = 57.5\%$] by the end of Operating Year One (2016). Even if the applicant grows the 23 patients at the Durham County Average Annual Growth Rate of .007, the number of patients would not reach 32 to start Operating Year 1 [$23 \text{ in-center patients} \times 1.007 = 23.16$ as of January 1, 2015]. Operating Year 2 [$23.16 \text{ in-center patients} \times 1.007 = 23.32$ as of January 1, 2016].

In Section III.3(c), page 22, the applicant states that 17 patients will transfer from Durham Dialysis Center and on page 23, the applicant states 9 patients will transfer from Durham West Dialysis for a

total of 26 [17 + 9 = 26], patients that the applicant projects will transfer from the existing facilities in Durham County. Even with adding in the three letters of support from patients at Southpoint, this would only total 29 patients (26+3=29) and thus leave the facility short of 3 patients needed to reach 32 patients. Therefore, based on the number of patients the applicant states on pages 22-23, would considering transferring from Durham Dialysis Center, Durham West Dialysis Center and the 3 Southpoint patients who signed a letter, the applicant would be projected to have 2.9 patients per station per week [$29 / 10 = 2.9$] or 72.5% utilization [$29/(4 \times 1000) = 72.5\%$].

Consequently, the applicant does not adequately demonstrate that projected utilization is based on reasonable, credible and supported assumptions. The applicant must demonstrate that the proposed new facility would serve 32 patients for a total of 3.2 patients per station, per week. Thus, projected in-center utilization for East Durham Dialysis Center does not meet 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).

In Section III.7, page 27, the applicant also proposes to offer home training in peritoneal dialysis at the East Durham Dialysis Center. The applicant states that two peritoneal dialysis patients who are currently receiving home training in peritoneal dialysis will transfer from Durham West Dialysis Center to East Durham Dialysis Center. The applicant further states that those two patients live in Cary and Raleigh. None of the letters of support found in Exhibit 16, are from patients who receive training for peritoneal dialysis. However, prior to the end of the public comment period, five letters of support from patients currently receiving support services for home hemodialysis and peritoneal dialysis training at Durham West Dialysis were submitted for the proposed East Durham Dialysis Center's proposal.

Access

In Section VI.1, pages 38-40, the applicant describes how underserved persons will have access to services provided by East Durham Dialysis. The applicant states:

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

In summary, the applicant adequately identifies the population to be served, but did not demonstrate the need the population has for the proposed project. Therefore, the application is not 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 22-23, 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 January 2014 SDR reports that Durham Dialysis Center had 93 in-center patients dialyzing on 24 certified stations with a utilization rate of 96.88% as of June 30, 2013 when the data was compiled. The applicant reports on page 22, that an additional five stations were certified in April 2014 which gives the facility a total of 29 certified stations for a utilization rate of 80%. In Section III.3(c), page 22, the applicant states:

“Taking into consideration that the Durham Dialysis Center had 93 in-center patients as of June 30, 2013 and that Durham County had an Average Annual Change Rate for the Past Five Years of .007%, we have projected the growth in the patient population from July 1, 2013 to the date East Durham Dialysis is projected to be certified.

July 1, 2013-December 31, 2013 – 93 in-center patients X 1.0035 = 93.3255

January 1, 2014-December 31, 2014 – 93.3255 in-center patients X 1.007 = 93.9787785

January 1, 2015-December 31, 2015 – 93.9787785 in-center patients X 1.007 = 94.63662994

Using the projections above, the Durham Dialysis Center would have 94 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 Durham Dialysis Center to East Durham Center, this will leave 77 patients (94 – 17 = 77) and 22 dialysis stations at the Durham Dialysis Center. ... Durham Dialysis Center utilization rate would be 87.5%.”

Durham West Dialysis Center

The January 2014 SDR reports that Durham West Dialysis Center had 95 in-center patients dialyzing on 29 certified stations with a utilization rate of 81.90% as of June 30, 2013 when the data was compiled. In Section III.3(c), page 23, the applicant states:

“Taking into consideration that the Durham West Dialysis Center had 95 in-center patients as of June 30, 2013 and that Durham County had an Average Annual Change Rate for the Past Five Years of .007%, we have projected the growth in the patient population from July 1, 2013 to the date East Durham Dialysis is projected to be certified.

July 1, 2013-December 31, 2013 – 95 in-center patients X 1.0035 = 95.3325

January 1, 2014-December 31, 2014 – 95.3325 in-center patients X 1.007 = 95.9998275

January 1, 2015-December 31, 2015 – 95.9998275 in-center patients X 1.007 = 96.67182629

Using the projections above, the Durham West Dialysis Center would have 96 in-center patients at the point when East Durham Dialysis is projected to be certified on January 1, 2016. With 9 patients

and three dialysis stations transferring from Durham West Dialysis Center to East Durham Center, this will leave 87 patients (96 – 9 =87) and 26 dialysis stations at the Durham West Dialysis Center. ... Durham West Dialysis Center utilization rate would be 83%.”

Thus, the applicant projects to serve 77 in-center patients at Durham Dialysis Center and 87 in-center patients at Durham West Dialysis Center by January 1, 2016. This is a utilization rate of 3.5 patients per station [$77/22= 3.5$] at Durham Dialysis Center and 3.3 [$87/26=3.346$] at Durham West Dialysis Center. 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 Healthcare Renal Care, Inc. as stated in Section VI.1, pages 38-40. 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. See Criterion (13) for additional discussion relating to promoting equitable access which is hereby incorporated by reference as if fully set forth herein.

- (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.

NC

In Section III.9, pages 28-29, the applicant mentions the analysis that DVA Healthcare Renal Care, Inc. engaged in to determine the need for the proposed ESRD facility. The applicant states on page 28, “*We have analyzed other areas in Durham County and have determined that the area in Eastern Durham County has more need for a dialysis center than any other area of the county at this time*” The applicant states on page 29, that DVA Healthcare Renal Care, Inc. studied other alternatives, however the applicant does not discuss the other alternatives considered.

The applicant did not adequately demonstrate the need to relocate stations from existing facilities in Durham County to establish a new facility in East Durham, nor did the applicant demonstrate that the projected utilization for the proposed project was based on reasonable, credible and supported assumptions. See Criterion (3) for discussion on need which is incorporated hereby as if fully set forth herein. Furthermore, the applicant did not adequately demonstrate the proposed project is its least costly or most effective alternative, therefore, the application is not conforming with this criteria.

- (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.

NC

In Section VIII.1, page 47, 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.3, page 50, the applicant projects that the total working capital (start-up and initial operating expenses) associated with the proposed project will be \$929,352, as illustrated below.

• Start-up Expenses	\$156,067
• Initial Operating Expenses	<u>\$773,285</u>
Total Working Capital	\$929,352

In Section VIII.3, page 48, the applicant states that the project will be funded by means of DaVita Healthcare Partners Inc., the parent company of DVA Healthcare Renal Care, Inc. cash reserves. Exhibit 21 contains a letter dated April 11, 2014 from the Vice President of Tax 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 \$2,287,604, for the capital expenditures associated with this project; a commitment of \$156,067, for its start up [sic] expenses; and a further \$773,285 in working capital. ...

DaVita HealthCare Partners has committed cash reserves in the total sum of \$3,216,956, for the capital costs, start-up costs and working capital for this project.”

Exhibit 22 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 52, 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
Medicare	\$240.00
Medicaid	\$143.00
Medicare/Medicaid	\$240.00
Commercial Insurance	\$1,275.00
VA	\$193.00
Medicare/Commercial	\$240.00

The applicant projects revenues in Section X.2, page 53 and operating expenses in Section X.4, page 56, of the application. In Section X.2-X.4, pages 53-56, the applicant reports projected revenues and expenses for East Durham Dialysis, as illustrated in the table below:

East Durham Dialysis		
	Operating Year 1	Operating Year 2
Total Net Revenue	\$1,596,623	\$1,665,015

Total Operating Costs	\$1,579,202	\$1,636,072
Net Profit	\$17,421	\$28,943

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. However, the assumptions used in preparation of the pro formas, including the number of projected treatments, are unreasonable and not supported based on the number of patients the applicant projects to serve at East Durham Dialysis Center. See Section X, pages 52-58, 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. However, the applicant does not adequately demonstrate that the financial feasibility of the proposal is based on reasonable, credible and supported assumptions regarding projections of costs and charges. Therefore, the application is not 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 January 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 Facility¹
Duke Hospital Dialysis	Duke University Hospital	16	75.00%	1306 Moreen Rd - Durham	10.87 miles
Durham Dialysis	DaVita Healthcare Partners, Inc.	24	96.88%	201 Hood St - Durham	6.38 miles
Durham West Dialysis	DaVita Healthcare Partners, Inc.	29	81.90%	4307 Western Park Place - Durham	11.73 miles
FMC Dialysis Services of Briggs Avenue	Fresenius Medical Care Holdings, Inc.	29	63.79%	1209 South Briggs Ave - Durham	5.16 miles
FMC Dialysis Services West Pettigrew	Fresenius Medical Care Holdings, Inc.	20	83.75%	1507 West Pettigrew St - Durham	8.36 miles
FMC South Durham Dialysis	Fresenius Medical Care Holdings, Inc.	12	83.33%	211 East Cornwallis Rd - Durham	5.60 miles
Freedom Lake Dialysis Unit	BMA of North Carolina, Inc.	22	87.80%	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: January 2014 SDR

As illustrated in the table above, there are currently eight ESRD facilities in Durham. Of those existing ESRD facilities, five 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 January 2014 SDR, the FMC Dialysis Services of Briggs Avenue facility operates with 29 certified stations and had a utilization rate of 63.79% as of June 30, 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

¹ <http://www.mapquest.com>

In Section VII.1, page 43, the applicant provides projected staffing for East Durham Dialysis upon project completion, as illustrated in the following table:

East Durham Dialysis Full-Time Equivalent (FTE) Positions	
RN	1.50
HTRN	.50
PCT	4.50
Bio-Med Tech	.30
Admin.	1.00
Dietician	.50
Social Worker	.50
Unit Secretary	1.00
Total FTEs	9.80

The applicant projects a total of 9.80 FTE positions upon project completion and states on page 44 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 44-45, 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 35, the applicant identifies the Medical Director for East Durham Dialysis as Dr. Stephen Smith. In Exhibit 15 the applicant provides a letter from Dr. Smith indicating his willingness to serve as Medical Director of the facility. Additionally, in Section VII.9, page 45, 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 33-34, the applicant lists the providers of the necessary ancillary and support services. Exhibits 8-11 and 13 contain documentation on 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 59-61, 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 25 and 26 for documentation on the availability of both sites for leasing. Also, see Exhibits 25 and 26 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 25 and 26. The applicant further states on pages 60-61, that both sites are located on major highways that are easily accessible by patients and transportation agencies.

In Section XI.6, page 62, 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 foot cost is projected to be \$146.26 ($\$1,682,000/11,500 = \146.26). See Section VIII.1, pages 46-47 and Section XI.6(h), page 65. The following table illustrates the square footage breakdown as provided by the applicant in Section XI.6(h), page 65:

Facility Area	Estimated Total Sq. Ft.
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
Sub-Total Support	5,191
Treatment Areas:	
Nurses Station	717
Dialysis Stations	2,745
Isolation Room(s)	120
Other: Walkways, Lab, Storage	165
Sub-Total Treatment	3,747
Miscellaneous (Corridors/Walls)	2,542
Total Square Feet	11,480

The applicant includes a note on page 66, 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(a), page 38, the applicant states East Durham Center, by policy, will make dialysis services available to all residents in its service area without qualifications.

In Section VI.1(b), pages 38-39, 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:

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

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

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

	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Durham County	16%	5.74%	20.1%
Statewide	17%	6.71%	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 dialysis services to be offered by East Durham Dialysis Center. In fact, in 2012 only 6.5% of all newly-diagnosed ESRD patients in North Carolina's Network 6 were under the age of 35 (*ESRD Network 6 2012 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 01/01/2012 – 12/21/2012*, page 74).

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

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

*"The December 31, 2011 prevalent population included 430,273 patients on dialysis ..."*² (p. 216)

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

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

The Southeastern Kidney Council (SKC) Network 6 2012 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 76, summarized as follows:

² www.usrds.org/adr.aspx

Number and Percent of Dialysis Patients by Age, Race and Gender 2012		
	# of ESRD Patients	% of Dialysis Population
Ages		
0-19	73	0.5%
20-34	751	5.0%
35-44	1,442	9.7%
45-54	2,644	17.7%
55-64	4,013	26.9%
65+	5,995	40.2%
Gender		
Female	6,692	44.9%
Male	8,226	55.1%
Race		
African American	9,346	62.7%
White/Caucasian	5,191	34.8%
Other	380	2.6%

Source: Southeastern Kidney Council (SKC) Network 6. Table includes North Carolina statistics only.³

The 2013 United States Renal Data System (USRDS) Annual Data Report provides 2011 ESRD spending by payor, as follows:

ESRD SPENDING BY PAYOR*		
PAYOR	SPENDING IN BILLIONS	% OF TOTAL SPENDING
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%
TOTAL	\$49.2	100.0%

*Source: 2013 United States Renal Data System (USRDS) Annual Data Report, page 332.

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

³ www.esrdnetwork6.org/publications/reports.html

In Section VI.1(f), pages 40-41, the applicant states,

“East Durham Dialysis Center 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 42, the applicant states there have been no civil rights access complaints filed within the last five years. Therefore, the application is conforming to this criterion.

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

C

In Section VI.1(c), page 39, the applicant provides the projected payor mix for the proposed services at East Durham Dialysis, 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%
Total	100.0%

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 39, that the payment source for East Durham Dialysis Center is based on the consolidated in-center patient payor mix for Durham Dialysis, Durham West Dialysis and Southpoint Dialysis 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 41, 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 referral 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 17.**”* [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 35, the applicant states that East Durham Dialysis will be offered as a training site for nursing students. Exhibit 14 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.

NC

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 January 2014 SDR there are currently eight ESRD facilities located in Durham County. Of those existing ESRD facilities, two operated below 80% utilization (Duke Hospital Dialysis and FMC Dialysis Services of Briggs Avenue) and six facilities operated above 80% 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 36-37, 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 Center 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 Eastern Durham County communities do not have a dialysis facility available for patients associated with DVA Healthcare Renal Care Center. ...

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.”

According to the January 2014 SDR there is a surplus of 22 dialysis stations in Durham County.

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 it will continue to provide quality services; and
- The applicant demonstrates it will continue to provide adequate access to medically underserved populations.

However, the applicant did not adequately demonstrate that any enhanced competition includes a positive impact on the cost-effectiveness of the proposed services based on the following analysis.

- The applicant did not adequately demonstrated that projected utilization is based on reasonable, credible and supported assumptions. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein.

- The applicant did not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of revenues and costs because the projected revenues and costs are based on unreasonable and unsupported assumptions projected utilization. See Criterion (5) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein.
- The development of a facility that is not needed is not cost effective.

Therefore, the application is nonconforming 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.

NC

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 not 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 30, and Exhibit 7 (copy of the January 2014 SDR, Tables A and B). As of June 30, 2013, the utilization rate for Durham Dialysis Center was 96.88% and the utilization rate at Durham West Dialysis was 81.90%.

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

-C- In Section IV.2, page 31, the applicant states mortality rates for Durham Dialysis Center were 11.5% in 2011, 12.7% in 2012, and 14.2% in 2013. The mortality rates for Durham West Dialysis Center for the same timeframe were 10.2%, 6.0% and 14.3%, 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 31, the applicant states, “Durham Dialysis Center has an agreement with the Durham West Dialysis Center to provide home training.” On page 31, the applicant reports that 30 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 31, 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 32, 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 32, the applicant provides the hospital admissions rates, by admission diagnosis, as illustrated in the tables below.

Durham Dialysis Center Hospital Admissions

01/13-12/13 Hospital Admissions	Total
<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%
Total number Admissions	159

Durham West Dialysis Center Hospital Admissions

01/13-12/13 Hospital Admissions	Total
<i>Number dialysis related</i>	28
<i>Percent Dialysis related</i>	23.6%
<i>Number non-dialysis related</i>	194

<i>Percent non-dialysis related</i>	<i>87.4%</i>
Total number Admissions	222

.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 32, the applicant reported as of December 31, 2013 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.*

-NC- In Section II, page 12, the applicant refers to Exhibit 8 for an acute care hospital agreement. However, the applicant failed to provide a copy of an acute care agreement with an acute care provider.

.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 33, the applicant indicates that transplantation services will be provided by Duke University Medical Center and 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 63, 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 63, 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 11 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 Exhibit 25 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 43-44, Section XI.6, pages 62-64, and Exhibits 11 and 12. In Section XI.6(g), page 63, 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 26-28, 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 Durham Dialysis Center and Durham West Dialysis Center and letters of support from current patients at DVA Healthcare Renal Care, Inc. owned and operated facilities, as shown in the below table.

EAST DURHAM DIALYSIS						
COUNTY	Operating		Operating		County In-Center Patients as % of Total	
	Year 1 2016		Year 2 2017		Year 1	Year 2
	In-Center	Home Dialysis	In-Center	Home Dialysis		
Durham	32	1	33	2	94.3%	94.6%
Wake	0	2	0	2	5.7%	5.4%
Total	32	3	33	4	100.0%	100.0%

.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 28, 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 13, 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.*

-NC- In Section II, pages 14, the applicant states East Durham Dialysis Center is projected to have 32 patients by the end of operating year 1. Therefore, the applicant projects to have 3.2 patients [32/10 = 3.2] per station per week as of the end of the first operating year of East Durham Dialysis. However, the applicant does not adequately demonstrate that projected utilization is based on reasonable, credible and supported assumptions. The applicant must demonstrate that the

proposed new facility would serve 32 patients for a total of 3.2 patients per station, per week. Thus, projected in-center utilization for East Durham Dialysis Center does not meet 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). See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein.

.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 13-14 and Section III.7, pages 26-27, 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 33, 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 33, 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 33, the applicant states that accessible self-care training will be provided by Durham West Dialysis Center. See Exhibit 13 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 33, the applicant states that an accessible follow-up program for support of patients dialyzing at home will be provided by East Durham Dialysis Center.
- .2204(5) *X-ray services;*
- C- In Section V.1(g), page 33, 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 33, the applicant states that routine and special laboratory services will be provided by Dialysis Laboratories.
- .2204(7) *Blood bank services;*
- C- In Section V.1(i), page 33, 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 33, 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 33, 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 33, the applicant states vascular surgery for dialysis treatment patients will be provided by Duke University Medical Center.
- .2204(11) *Transplantation services;*
- CA- In Section V.1(F), page 33, the applicant indicates that transplantation services will be provided by Duke University Medical Center and Carolinas Medical Center. The applicant provides a copy of a transplantation agreement with Carolinas Healthcare System in Exhibit 13, however, the applicant did not provide a copy of a transplantation agreement with Duke University Medical Center.
- .2204(12) *Vocational rehabilitation counseling and services; and,*

-C- In Section V.1(o), page 33, 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 34, 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 43, the applicant provides the proposed staffing for East Durham Dialysis. The applicant projects to have 9.8 full time equivalent staff (FTEs), 4.5 of which are projected to be patient care technicians (PCT). The applicant states on page 43 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 Criterion (7) for discussion which is incorporated hereby as if set forth fully herein.

.2205(b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*

-C- In Section VII, pages 44-45 the applicant describes the training for new employees, ongoing in-service training and continuing education programs. Exhibit 20 contains the training outline.