

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: July 15, 2014  
PROJECT ANALYST: Gene De Porter  
INTERIM CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: F-10270-14/ DVA Healthcare Renal Care, Inc. d/b/a Charlotte East Dialysis Center/ Add two dialysis stations for a total of 26 stations/ Mecklenburg

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.

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The applicant, DVA Healthcare Renal Care, Inc. d/b/a Charlotte East Dialysis Center (CEDC), operates 24 certified dialysis stations at 5627 Albemarle Road, Charlotte. This application [Project ID # F-10270-14] is a request for two additional dialysis stations for a total of 26 stations upon completion of the project.

The 2014 State Medical Facilities Plan (2014 SMFP) provides a county need methodology and a facility need methodology for determining the need for additional dialysis stations. According to the January 2014 Semiannual Dialysis Report (SDR), the county need methodology shows there is no need for an additional facility in Mecklenburg County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for CEDC in the January 2014 SDR is 4.8125 patients per station. This utilization rate was calculated based on 77 in-center dialysis patients and 16 certified dialysis stations as of June 30, 2013 [77 patients / 16 stations = 4.8125 patients per station; 4.8125 patients per station / 4 patients per station = 120.31%]. Therefore, application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table.

**Charlotte East Dialysis Center  
 ESRD Facility Need Methodology**

Required SDR Utilization		80%
Center Utilization Rate as of 6/30/13		80.21%
Certified Stations		24
Pending Stations		0
Total Existing and Pending Stations		24
In-Center Patients as of 6/30/13 (SDR2)		77
In-Center Patients as of 12/31/12 (SDR1)		70
Step	Description	Result
(i)	Difference (SDR2 – SDR1)	7
	Multiply the difference by 2 for the projected net in-center change	14
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/12	0.2000
(ii)	Divide the result of step (i) by 12	0.0167
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/13 to 12/31/13)	0.1000
(iv)	Multiply the result of step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR1	84.7000
(v)	Divide the result of step (iv) by 3.2 patients per station	26.4688
	and subtract the number of certified and pending stations as recorded in SDR2 [24] to determine the number of stations needed	2

As shown in the above table, based on the facility need methodology for dialysis stations the potential number of stations needed is two stations. Step (v) of the facility need methodology, page 364 of the 2014 SMFP, states; *“The facility may apply to expand to meet the need established... up to a maximum of 10 stations.”* The applicant proposes to add two dialysis stations and therefore is consistent with the facility need determination for additional dialysis stations.

Policy GEN-3: Basic Principles, on page 40 in the 2014 SMFP is applicable to this review. Policy GEN-3 states:

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and*

*quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

### Promote Safety and Quality

In Section II.3, page 16, the applicant states how the proposed plan will insure quality care. The applicant states:

*“DaVita HealthCare Partners Inc. is committed to providing quality care to the ESRD population through a comprehensive Quality Management Program. DaVita’s Quality Management Program is facilitated by a dedicated clinical team of Registered Nurses who make up our clinical support services and Biomedical Quality Management Coordinators working under the direction of our Director of Clinical Support Services and Area Biomedical Administrator. These efforts receive the full support and guidance of the clinical executive leadership team of DaVita. ...*

*Our Quality Management Program includes the following Quality Programs:*

- *Quality Improvement Methodology - utilizing outcome-driven, patient-centered management programs to measure, monitor and manage outcomes.*
- *Computerized Information System-integrating clinical and laboratory information for comprehensive outcomes tracking and reporting.*
- *Teammate and Patient Education Program ensuring continuous updates and training to ensure high quality patient care.*
- *Quality Assessment Audit Program systematically utilizing a comprehensive detailed assessment tool to assure the highest quality standards in every facility.*
- *Quality Management Team experienced clinical facilitators to implement and maintain ongoing quality improvement programs.*
- *Quality Biomedical Team - experienced specialists in all aspects of biomedical requirements (i.e. water treatment, reuse, disinfection and machine maintenance)*

*DaVita’s Quality Management team works closely with each facility’s Quality Improvement team to:*

- *Improve patient outcomes*
- *Provide patient and staff training*
- *Develop Quality Improvement Programs*
- *Facilitate the Quality Improvement Process*
- *Continuously improve care delivered*
- *Assure facilities meet high quality standards*
- *Experienced specialists in all aspects of*
- *Biomedical requirements (i.e., water treatment, reuse, disinfection and machine maintenance)."*

The applicant adequately demonstrates the proposal will promote quality and safety.

#### Promote Equitable Access

In Section VI.1(c), page 31, the applicant projects 90.0% of its patients will be Medicaid or Medicare patients. On page 30, the applicant states:

*"Charlotte East Dialysis Center, by policy, has always made dialysis services available to all residents in its service area without qualifications. We have served and will continue to serve without regard to race, sex, age, handicap, or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay."*

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

#### Maximize Healthcare Value

In Section III.9, pages 22-23, the applicant states how the addition of two certified stations will allow Charlotte East Dialysis Center to maximize healthcare value. The applicant states:

*"The Charlotte East Dialysis Center promotes cost-effective approaches in the facility in the following ways:*

- *The parent corporation, DaVita HealthCare Partners Inc., operates over 2,074 dialysis facilities nationwide. The corporation has a centralized purchasing department that negotiates national contracts with numerous vendors in order to secure the best product available at the best price. ...*
- *Charlotte East Dialysis Center purchases all of the products utilized in the facility, from office supplies to drugs to clinical supplies, under a national contract in order to secure the best products at the best price. ...*

- *Charlotte East Dialysis Center utilizes electronic patient charting system that reduces the need for paper in the facility. Much of the other documentation in the facility are done on computer which reduces the need for paper.*
- *Charlotte East Dialysis Center has an inventory control plan that ensures enough supplies are available without having an inordinate amount of supplies on hand. Supply orders are done in a timely manner to ensure that the facility does not run out of supplies, thus avoiding emergency ordering, which is costly.”*

The applicant adequately demonstrates the proposal will maximize healthcare value. Consequently, the applicant demonstrates that the projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served.

The application is consistent with the facility need determination in the 2014 SMFP and Policy GEN 3. Consequently, the application is conforming to this criterion.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

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The applicant, DVA Healthcare Renal Care, Inc. d/b/a Charlotte East Dialysis Center, proposes to add two dialysis stations for a total of 26 stations upon completion of the project.

Population to be Served

In Section IV.1, page 24, the applicant identifies the population served as of June 30, 2013.

**Charlotte East Dialysis Center  
Current In-Center Patient Population**

<b>County of Residence</b>	<b># of Patients Dialyzing In-Center</b>	<b>Percentage</b>
Mecklenburg	77	100.0%
<b>Total</b>	<b>77</b>	<b>100.0%</b>

In Section III.7, page 21, the applicant identifies the patient population proposed to be served during the first two operating years following project completion, as shown in the table below.

**Charlotte East Dialysis Center  
 Projected Utilization**

County	Operating Year 1 2015		Operating Year 2 2016		County Patients as a Percent of Total	
	In-Center Patients	Home Dialysis	In-Center Patients	Home Dialysis	Year 1	Year 2
Mecklenburg	87	55	93	60	90.5%	91.0%
Gaston	0	1	0	1	0.6%	0.6%
Union	0	6	0	6	3.8%	3.6%
Cabarrus	0	1	0	1	0.6%	0.6%
South Carolina	0	7	0	7	4.5%	4.2%
<b>Total</b>	<b>87</b>	<b>70</b>	<b>93</b>	<b>75</b>	<b>100.0%</b>	<b>100.0%</b>

The applicant adequately identified the population to be served.

Need Analysis

In Section III.7, page 21, the applicant provides the assumptions and methodology it used to project need for two additional stations at CEDC. The applicant states:

*“The Charlotte East Dialysis Center had 77 in-center patients as of June 30, 2013, based on information included in Table A of the January 2014 Semiannual Dialysis Report (SDR). This is a station utilization of 80% based on 24 certified stations in the facility. All of the patients dialyzing at the Charlotte East Dialysis Center live in Mecklenburg County. We are applying for a two-station expansion of the Charlotte East Facility.*

*Based on the patients and stations above, Charlotte East Dialysis Center is projected to have at least 87 in-center patients by the end of operating year 1 for a utilization rate of 83% or 3.3 patients per station and at least 93 in-center patients by the end of operating year 2 for a utilization rate of 89% or 3.5 patients per station. This information is based upon the calculations below.*

*The period of the growth begins with January 1, 2014 forward to December 31, 2016. The following are the in-center patient projections using the 6.6% Average Annual Change Rate for the Past Five Years as indicated in Table B of the January 2014 SDR.*

*January 1, 2014-December 31, 2014 - 77 patients X 1.066 = 82.082*

*January 1, 2015-December 31, 2015 - 82.082 patients X 1.066 = 87.499412*

*January 2016-December 31, 2016 - 87.499412 patients X 1.066 = 93.27437319*

*Operating Year 1 is projected to begin January 1, 2015 and end December 31, 2015*

*Operating Year 2 is projected to begin January 1, 2016 and end December 31, 2016”*

CEDC is projected to serve 87 in-center patients at the end of operating year 1 which is a utilization rate of 3.35 patients per station or 83.65% of capacity [87 patients / 26 stations = 3.35 patients per station;  $3.35 / 4.0 = 0.8365$ ]. This exceeds the minimum of 3.2 patients per station per week at the end of the first operating year as required by 10A NCAC 14C .2203(b).

CEDC is projected to serve 93 in-center patients at the end of operating year 2 which is a utilization rate of 3.57 patients per station or 89.42% of capacity [93 patients / 26 stations = 3.57 patients per station; or  $3.57/4.0 = 0.8942$ ].

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

The number of home trained patients is determined in the same manner. See page 22 of the application. Projected utilization by home trained patients is also based on reasonable and adequately supported assumptions.

#### Access

In Section VI.1, page 49, the applicant projects that 84.3% of the patients at CEDC during operating year 2 will have their services reimbursed by Medicare or Medicaid. The applicant adequately demonstrates 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 proposed services.

In summary, the applicant adequately identified the population to be served and demonstrated the need for the additional two stations based on the population it proposes to serve. Therefore, the application is conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

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

CA

In Section III.9, page 22, the applicant discusses the one alternative it considered prior to submitting this application for two additional stations, which was to do nothing. The applicant states the alternative to add two stations was chosen because of the growing demand for services at CEDE. The applicant adequately demonstrates the need for two additional stations based on the number of in-center patients it projects to serve. See Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.

The application is conforming to all other applicable statutory and regulatory review criteria and is thus approvable. An application that cannot be approved cannot be an effective alternative.

The applicant adequately demonstrated that the proposal to add two dialysis stations is its 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. **DaVita Healthcare Renal Care, Inc. d/b/a Charlotte East Dialysis Center shall materially comply with all representations made in the certificate of need application.**
2. **DaVita Healthcare Renal Care, Inc. d/b/a Charlotte East Dialysis Center shall develop no more than 2 additional stations for a total of no more than 26 stations upon completion of this project, which shall include any home hemodialysis training or isolation stations.**
3. **DVA Healthcare Renal Care, Inc. d/b/a Charlotte East Dialysis Center shall install plumbing and electrical wiring through the walls for no more than a total of 26 dialysis stations, including any home hemodialysis training or isolation stations.**
4. **DVA Healthcare Renal Care, Inc. d/b/a Charlotte East Dialysis Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to insurance of the certificate of need.**

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

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In Section VIII.1, pages 37-38, the applicant projects the total capital cost of the project to be \$35,638, as shown in the following table. The applicant projects no initial start-up costs or initial operating expenses. The applicant states the capital costs for the proposed project will be funded by cash reserves from DaVita Healthcare Partners, Inc. the parent company of DVA Healthcare Renal Care, Inc.

	Cost
Dialysis Machines	\$27,000
Furniture	\$ 2,610
Dialysis Chairs	\$ 1,950
Televisions	\$ 3,000
Computer Terminal	\$ 1,078
Total Capital Cost	\$35,638

Exhibit 17 includes a letter dated March 3, 2014 from the Chief Accounting Officer of DaVita Healthcare Partners, Inc., which states:

*"I am the Chief Accounting Officer of DaVita Healthcare Partners Inc., the parent and 100% owner of DVA Healthcare Renal Care, Inc.*

*We are submitting a Certificate of Need application to expand our Charlotte East Dialysis Center by two ESRD dialysis stations. The project calls for a capital expenditure of \$35,638. This letter will confirm that DaVita Healthcare Partners Inc. has committed cash reserves in the total sum of \$35,638. [sic] for the project capital expenditure. DaVita HealthCare Partners, Inc. will make these funds, along with any other funds that are necessary for the development of the project, available to DVA Healthcare Renal Care."*

Exhibit 18, page F-6, contains an audited balance sheet for DaVita Healthcare Partners, Inc. 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 \$4,605,541,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

The following table illustrates the projected charges as reported by the applicant in Section X.1, page 44.

Source of Payment	Charge per Treatment
Medicare	\$240
Medicaid	\$143
Medicare/Medicaid	\$240
Commercial Insurance	\$1,442
VA	\$193
Medicare/Commercial	\$240

In Section X.2 the applicant projected revenues in excess of expenses in each of the first two operating years following completion of the project, as illustrated in the table below.

**Net Revenue and Operating Expenses**

	Operating Year 1 2015	Operating Year 2 2016
Net Revenue	\$7,628,040	\$8,128,022
Operating Expenses	\$5,898,652	\$6,226,174
Net Income	\$1,729,388	\$1,901,848

The assumptions used in preparation of the pro forma financial statements, including the number of projected treatments, are reasonable and adequately supported.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project. The applicant also adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of revenues (charges) and operating costs. Therefore, the application is conforming to this criterion.

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

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The following table identifies the existing and approved kidney disease treatment centers located in Mecklenburg County as reported in the January 2014 SDR.

Facility	# of Certified Stations as of 6/30/13	# of In-Center Patients as of 6/30/13	Utilization Rate
Charlotte East Dialysis Center (DaVita)	16	77	120.31%
North Charlotte Dialysis Center (DaVita)	25	120	120.00%
BMA of North Charlotte	27	119	110.19%
FMC Matthews	21	90	107.14%
BMA Nations Ford	24	102	106.25%
BMA Beatties Ford	32	120	93.75%
Charlotte Dialysis Center (DaVita)	34	120	88.24%
BMA of East Charlotte	24	83	86.46%
FMC Charlotte	40	130	81.25%
Mint Hill Dialysis Center (DaVita)	10	32	80.00%
South Charlotte Dialysis Center (DaVita)	20	63	78.75%
BMA of West Charlotte	29	83	71.55%
DSI Glenwater Dialysis	42	116	69.05%
DSI Charlotte Latrobe Dialysis	24	60	62.50%
Carolinas Medical Center	9	13	36.11%
FMC of Southwest Charlotte (approved)	0	NA	NA
Huntersville Dialysis (approved) (DaVita)	0	NA	NA

As shown in the table above, the only existing facility operating at less than 60% of capacity as of June 30, 2013, was Carolinas Medical Center. These stations are part of a hospital. Hospital based in-center dialysis stations do not typically operate at a high occupancy rate. This may be due to the types of patients that would choose to use a hospital based facility for their dialysis rather than a freestanding facility with easier physical access.

The applicant proposes to add two dialysis stations to the existing facility for a total of 26 stations upon completion of the proposed project. The applicant adequately demonstrated the need for two additional stations based on the number of in-center patients it proposes to serve. See Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.

In summary, the applicant adequately demonstrated that the proposal would not result in the unnecessary duplication of existing or approved 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.

The following table illustrates current and projected staffing for CEDC, as provided by the applicant in Section VII, page 35:

<b>Charlotte East Dialysis Center</b>			
<b>Position</b>	<b>Current # of FTEs</b>	<b># of FTE Positions to be Added</b>	<b>Total FTE Positions</b>
Registered Nurse	4.0	0.0	4.0
HTRN	0.0	4.0	4.0
PCT	10.0	0.0	10.0
Bio-Med Tech	0.7	0.0	0.7
Administrator	1.0	0.0	1.0
Dietician	0.7	0.3	1.0
Social Worker	0.7	0.3	1.0
Unit Secretary	1.0	1.0	2.0
Total	18.1	5.6	23.7

As shown in the above table, the applicant plans to employ a total of 23.7 full-time equivalent (FTE) positions to staff the Charlotte East Dialysis Center upon completion of the proposed project. In Section VII.2, page 35, the applicant states that the Medical Director is Joel Bruce, M.D., a board-certified nephrologist. Exhibit 12 contains a letter from Dr. Bruce.

The applicant adequately documents the availability of sufficient health manpower and management personnel, including the medical director, for the provision of dialysis services. Therefore, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

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In Section V.1, page 26, the applicant includes a list of providers of the necessary ancillary and support services. Exhibit 12 contains a letter from the medical director of the facility expressing his support for the proposed project. The applicant adequately demonstrates that the necessary ancillary and support services will be available and the proposed services will be coordinated with the existing health system. Therefore, the application is conforming to this criterion.

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

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers: (i) would be available under a contract of at least 5 years duration; (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO; (iii) would cost no more than if the services were provided by the HMO; and (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

NA

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section VI.1(b), page 30, the applicant reports that 84.3% of patients who received treatments at CEDC had some or all of their services paid for by Medicare or Medicaid.

**Current Payer Mix**

<b>Payer Source</b>	<b>Percentage</b>
Medicare	24.3%
Medicaid	8.6%
Medicare/Medicaid	27.1%
Commercial Insurance	10.0%
VA	5.7%
Medicare/Commercial	24.3%
<b>Total</b>	<b>100.0%</b>

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 Mecklenburg County and statewide.

<b>County/ State</b>	<b>2010 Total # of Medicaid Eligible as % of Total Population *</b>	<b>2010 Total # of Medicaid Eligible Age 21 and older as % of Total Population *</b>	<b>2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *</b>
Mecklenburg	14.7%	5.1%	20.1%
Statewide	16.5%	6.7%	19.7%

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

The majority of Medicaid eligible 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 offered by Charlotte East 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 ...*”<sup>1</sup> (p. 216)

The report also provided the incidence of dialysis patients in 2011, adjusted by age, gender and race, which showed that 65.4% were White, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian, and 1.2% were Native American (p. 218). Moreover, the prevalence of ESRD for the 65-74 year old population grew by 31% since 2000 and by 48% for those aged 75 and older (p. 223). The report further states: “*In the 2011 prevalent population, 84 percent of hemodialysis patients and 81 percent of those on peritoneal dialysis had some type of primary Medicare coverage, compared to just 53 percent of those with a transplant.*”(p. 216)

The 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:

<b>Number and Percent of Dialysis Patients by Age, Race and Gender 2012</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Ages</b>		
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%
<b>Gender</b>		
Female	6,692	44.9%
Male	8,226	55.1%
<b>Race</b>		
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.<sup>2</sup>

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

<sup>1</sup> [www.usrds.org/adr.aspx](http://www.usrds.org/adr.aspx)

<sup>2</sup> [www.esrdnetwork6.org/publications/reports.html](http://www.esrdnetwork6.org/publications/reports.html)

<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>

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

The applicant demonstrates that it 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;

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Section VI.1(f), page 31, the applicant states, *“Charlotte East Dialysis Center has no obligation under any applicable federal regulation to provide uncompensated care, community service or access by minorities and handicapped persons except those obligations which are placed upon all medical facilities under Section 504 of the Rehabilitation Act of 1973 and its subsequent amendments in 1993.”* In Section VI.6(a), page 33, the applicant states, *“There have been no civil rights complaints filed against the existing facility and/or any facilities owned by the parent company in North Carolina in the last five years.”* The application is conforming to this criterion.

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

C

In Section VI.1(c), page 31, the applicant provides the projected payor mix, as shown in the table below.

**Projected Payor Mix**

<b>Payor Source</b>	<b>Projected Percent of Total</b>
Commercial Insurance	10.0%
Medicare	24.3%
Medicaid	8.6%
Medicare/Commercial	24.3%
Medicare/Medicaid	27.1%
VA	5.7%
Total	100.0%

The applicant projects that 84.3% of the patients will have some or all of their services paid by Medicare or Medicaid, which is the same as the current payor mix. The applicant demonstrates that medically underserved populations will continue to have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section VI.5 (a), page 32, the applicant states,

*“Patients with End Stage Renal Disease have access to dialysis services upon referral to a Nephrologist with privileges at Charlotte East Dialysis Center. These referrals most commonly come from primary care physicians or specialty physicians in Mecklenburg County or transfer referrals from other Nephrologists outside the immediate area. ... Patients from outside the Charlotte East Dialysis Center catchment area requesting transfer to this facility are processed in accordance with the Charlotte East Dialysis Center transfer and transient policies which comprise Exhibit 13.”*

The applicant adequately demonstrates that Charlotte East Dialysis Center offers a range of means by which a person can access services. Therefore, the application is conforming to this criterion.

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

C

Exhibit 11 contains a copy of an executed agreement with King's College in Charlotte for the use of DaVita Healthcare Partners' facilities as training sites for the school's students. The applicant adequately demonstrates that the facility will accommodate the clinical needs of area health professional training programs. Therefore, the application is conforming 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 add two stations to CEDC for a total of 26 stations upon project completion. CEDC is one of six facilities owned by the same parent, DaVita Healthcare Partners, Inc. (DaVita). The following table identifies the existing and approved kidney disease treatment centers located in Mecklenburg County as reported in the January 2014 SDR.

Facility	# of Certified Stations as of 6/30/13	# of In-Center Patients as of 6/30/13	Utilization Rate
Charlotte East Dialysis Center (DaVita)	16	77	120.31%
North Charlotte Dialysis Center (DaVita)	25	120	120.00%
BMA of North Charlotte	27	119	110.19%
FMC Matthews	21	90	107.14%
BMA Nations Ford	24	102	106.25%
BMA Beatties Ford	32	120	93.75%
Charlotte Dialysis Center (DaVita)	34	120	88.24%
BMA of East Charlotte	24	83	86.46%
FMC Charlotte	40	130	81.25%
Mint Hill Dialysis Center (DaVita)	10	32	80.00%
South Charlotte Dialysis Center (DaVita)	20	63	78.75%
BMA of West Charlotte	29	83	71.55%
DSI Glenwater Dialysis	42	116	69.05%
DSI Charlotte Latrobe Dialysis	24	60	62.50%
Carolinas Medical Center	9	13	36.11%
FMC of Southwest Charlotte (approved)	0	NA	NA
Huntersville Dialysis (approved) (DaVita)	0	NA	NA

As shown in the table above, the only existing facility operating at less than 60% of capacity as of June 30, 2013, was Carolinas Medical Center. These stations are part of a hospital. Hospital based in-center dialysis stations do not typically operate at a high occupancy rate. This may be due to the types of patients that would choose to use a hospital based facility for their dialysis rather than a freestanding facility with easier physical access.

In Section V.7, page 29, the applicant discusses how any enhanced competition in the service area will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states:

*“Mecklenburg County is an urban county. The proposed expansion of the facility is not intended to be a competitive venture. The effect of other facilities in Mecklenburg County and surrounding counties would be difficult to determine since most patients from Mecklenburg County already receive treatment in established facilities operated by several different providers.*

*The effect upon competition is unknown. However, patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs. The Charlotte East Dialysis Center provides access to all qualified Nephrologists to admit his or her patients.”*

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

- The applicant adequately demonstrates the need to add two dialysis stations and that its proposal is a cost-effective alternative to meet the need.
- The applicant adequately demonstrates that it will continue to provide quality services.
- The applicant demonstrates that it will continue to provide adequate access to medically underserved populations.

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 files in the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, Charlotte East Dialysis Center operated in compliance with all Medicare Conditions of Participation within the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable regulatory review criteria. The specific criteria are discussed below.

## **.2202 INFORMATION REQUIRED OF APPLICANTS**

*(a) An applicant that proposes to increase stations in an existing certified facility or relocated stations must provide the following information:*

- .2202(a)(1) Utilization Rates;*  
-C- See Exhibit 7 (copy of the January 2014 SDR) which indicates the utilization rate was 102.31% as of June 30, 2013.
- .2202(a)(2) Mortality rates;*  
-C- In Section IV.2, page 24 the applicant states the mortality rate was 13.1% in 2011, 17.1% in 2012 and 13.2% in 2013.
- .2202(a)(3) The number of patients that are home trained and the number of patients on home dialysis;*  
-C- See Section IV.3, page 24. CEDC does not currently offer home dialysis but will shortly.
- .2202(a)(4) The number of transplants performed or referred;*  
-C- See Section IV.4, page 24. In 2013, one transplant was performed and 11 patients were referred for evaluation.
- .2202(a)(5) The number of patients currently on the transplant waiting list;*  
-C- See Section IV.5, page 25. CEDC reports it has five patients on the waiting list.
- .2202(a)(6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*  
-C- See Section IV.6, page 25. CEDC reports that 120 patients were admitted to a hospital in 2013. Of those, 19.2% were dialysis related.
- .2202(a)(7) The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.*  
-C- See Section IV.7, page 25. CEDC reports that, as of December 31, 2013, there was one patient with Hepatitis B and four with AIDS. No patients converted to infectious 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.*

*-NA- Charlotte East Dialysis Center is an existing facility.*

*.2202(b)(2) For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*

*(A) timeframe for initial assessment and evaluation of patients for transplantation,*

*(B) composition of the assessment/evaluation team at the transplant center,*

*(C) method for periodic re-evaluation,*

*(D) criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and*

*(E) signatures of the duly authorized persons representing the facilities and the agency providing the services.*

*-NA- Charlotte East Dialysis Center is an existing facility.*

*.2202(b)(3) For new or replacement facilities, documentation that power and water will be available at the proposed site.*

*-NA- Charlotte East Dialysis Center is an existing facility.*

*.2202(b)(4) Copies of written policies and procedures for back up for electrical service in the event of a power outage.*

*-C- See Section XI.6 (f), page 52, and Exhibit 8 which includes the policy and procedures in the event of a power shortage.*

- .2202(b)(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*
- NA- Charlotte East Dialysis Center is an existing facility.
- .2202(b)(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, and other relevant health and safety requirements.*
- C- See Section II, pages 10-18, Section VII, pages 34-36, and Exhibits 1, 18, and 19.
- .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- In Section III.7, pages 21-22. CEDC provides projected patient origin and the assumptions and methodology used. See Criterion (3) for discussion which is incorporated herein as if set fully herein.
- .2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
- NA- Charlotte East Dialysis Center is an existing facility.
- .2202(b)(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*
- C- In Section II, page 12, CEDC states it “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.”

### **.2203 PERFORMANCE STANDARDS**

.2203(a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

-NA- Charlotte East Dialysis Center is an existing facility.

.2203(b) *An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*

-C- In Section III.7, pages 21-22, the applicant projects to serve 87 in-center patients or 3.3 patients per station [ $87 / 26 = 3.34$ ] by the end of Year 1. See Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.

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

-C- In Section III.7, pages 21-23, the applicant provided the assumptions and methodology used to project utilization. See Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.

### **.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- Provided by Novant Health Presbyterian Medical Center. See Section V.1, page 26.

.2204(2) *Maintenance dialysis;*

-C- Provided by CEDC. See Section V.1, page 26.

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

-C- Will be provided by CEDC. See Section V.1, page 26.

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

-C- Will be provided by CEDC. See Section V.2, page 27.

- .2204(5) *X-ray services;*
  - C- Provided by Novant Health Presbyterian Medical Center. See Section V.1, page 26.
- .2204(6) *Laboratory services;*
  - C- Provided by Dialysis Laboratories. See Section V.1, page 26.
- .2204(7) *Blood bank services;*
  - C- Provided by Novant Health Presbyterian Medical Center. See Section V.1, page 26.
- .2204(8) *Emergency care;*
  - C- See Section V.1, page 26. Provided by Novant Health Presbyterian Medical Center.
- .2204(9) *Acute dialysis in an acute care setting;*
  - C- See Section V.1, page 26. Provided by Novant Health Presbyterian Medical Center.
- .2204(10) *Vascular surgery for dialysis treatment patients;*
  - C- See Section V.1, page 26. Provided by Novant Health Presbyterian Medical Center.
- .2204(11) *Transplantation services;*
  - C- See Exhibit 10. Provided by Carolinas Medical Center.
- .2204(12) *Vocational rehabilitation counseling and services;*
  - C- See Section V.1, page 26. NC Division of Vocational Rehabilitation Services.
- .2204(13) *Transportation*
  - C- See Section V.1, page 26. Provided by the Department of Social Services and others.

**.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- See Section VII, pages 34-36 and discussion in Criterion (7) 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- See Section VII.5, page 36, and Exhibit 16, which includes a copy of the training program outline.