

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 29, 2016

Findings Date: January 29, 2016

Project Analyst: Julie Halatek

Team Leader: Lisa Pittman

Project ID #: F-11079-15

Facility: Charlotte East Dialysis Center

FID #: 001554

County: Mecklenburg

Applicant: DVA Healthcare Renal Care, Inc.

Project: Add eight dialysis stations for a total of 34 stations upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Agency 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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DVA Healthcare Renal Care, Inc. d/b/a Charlotte East Dialysis Center (Charlotte East) proposes to add eight dialysis stations for a total of 34 certified dialysis stations upon project completion.

Need Determination

The 2015 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2015 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of seven dialysis stations in Mecklenburg County; therefore, based on the county need methodology, there is no need for additional stations 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 Charlotte East in the July 2015

SDR is 3.69 patients per station, which is at least 3.2 patients per week. This utilization rate was calculated based on 96 in-center dialysis patients and 26 certified dialysis stations as of December 31, 2014 (96 patients / 26 stations = 3.69 patients per station).

October 1 Review – July 2015 SDR		
Required SDR Utilization		80.0%
Center Utilization Rate as of 12/31/14		92.3%
Certified Stations		26
Pending Stations		0
Total Existing and Pending Stations		26
In-Center Patients as of 12/31/14 (July 2015 SDR) (SDR2)		96
In-Center Patients as of 6/30/14 (January 2015 SDR) (SDR1)		81
Step	Description	Result
	Difference (SDR2 - SDR1)	15
(i)	Multiply the difference by 2 for the projected net in-center change	30
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/14	0.3704
(ii)	Divide the result of Step (i) by 12	0.0309
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/14 until 12/31/15)	0.3704
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	131.5556
(v)	Divide the result of Step (iv) by 3.2 patients per station	41.1111
	and subtract the number of certified and pending stations to determine the number of stations needed	15

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is 15 stations. Step (C) of the facility need methodology states “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add eight new stations and, therefore, is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2015 SMFP which is applicable to this review. **Policy GEN-3: Basic Principles** on page 38 of the 2015 SMFP is applicable to this review because the facility need methodology 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

The applicant describes how it believes the proposed project would promote safety and quality in Section B.4(a) on pages 9-10. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal will promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B.4(b), page 10; Section C.3, page 16; Section I, pages 37-40; Section L, pages 47-51; and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal will promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4(c), page 11, and Section N, page 53. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal will maximize healthcare value.

The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access, and maximum value for resources expended in meeting the facility need as identified by the applicant. Therefore, the application is consistent with Policy GEN-3.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with the facility need methodology in the July 2015 SDR and Policy GEN-3. Therefore, the application is conforming to this criterion.

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

DVA Healthcare Renal Care, Inc. d/b/a Charlotte East Dialysis Center (Charlotte East) proposes to add eight dialysis stations for a total of 34 certified dialysis stations upon project completion.

Population to be Served

On page 361, the 2015 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

In Section C.8, page 19, the applicant provides the historical patient origin for Charlotte East patients as of December 31, 2014, which is summarized in the following table:

Charlotte East Dialysis Patients by County/State 12/31/2014			
County/State	# In-Center	# Home Hemo*	# PD**
Mecklenburg	94	10	30
South Carolina	1	2	2
Moore	1	0	0
Gaston	0	0	2
Union	0	3	4
Total	96	15	38

*Home Hemo or HH = home hemodialysis.

** PD = peritoneal dialysis.

In Section C.1, page 13, the applicant provides the projected patient origin for Charlotte East for in-center patients for the first two operating years (OY) following completion of the project, as shown below.

Charlotte East Dialysis Patients by County/State – OYs 1 & 2								
County	OY1 – CY 2017			OY2 – CY 2018			Patients as % of Total	
	In-Center	Home Hemo	PD	In-Center	Home Hemo	PD	OY1	OY2
Mecklenburg	110	13	33	116	14	34	91.2%	91.6%
South Carolina	1	2	2	1	2	2	2.9%	2.8%
Moore	1	0	0	1	0	0	0.6%	0.6%
Gaston	0	0	2	0	0	2	1.2%	1.1%
Union	0	3	4	0	3	4	4.1%	3.9%
Total	112	18	41	118	19	42	100.0%	100.0%

The applicant provides the assumptions and methodology used to project patient origin on pages 13-15. The applicant adequately identifies the population to be served.

Analysis of Need

Charlotte East proposes to add eight dialysis stations for a total of 34 certified dialysis stations upon project completion. In Section C, pages 13-15, the applicant states the need for the proposed project is based on the following factors:

- The first two full OYs of the project are expected to be CY 2017 and CY 2018.
- On December 31, 2014, Charlotte East was providing dialysis treatment for:
 - 96 in-center patients, including 94 patients who reside in Mecklenburg County, one patient who resides in Moore County, and one patient who resides in South Carolina;
 - 15 home hemodialysis patients, including 10 patients who reside in Mecklenburg County, three patients who reside in Union County, and two patients who reside in South Carolina; and
 - 38 home peritoneal dialysis patients, including 30 patients who reside in Mecklenburg County, four patients who reside in Union County, two patients who reside in Gaston County, and two patients who reside in South Carolina.
- The applicant assumes the Mecklenburg County ESRD patient population utilizing the facility will increase at the rate of 5.8 percent per year, the Five Year Average Annual Change Rate (AACR) for Mecklenburg County as published in the July 2015 SDR. The applicant states that no growth was calculated for the two patients residing outside of Mecklenburg County.
- The applicant states that Charlotte East has a need for the eight additional stations due to current utilization of the existing stations and because the facility need methodology showed the potential need for 15 additional stations (a maximum of 10 may be developed using the facility need methodology).

Projected Utilization

In Section C.1, pages 13-15, the applicant provides the assumptions and methodology it uses to determine the need for additional dialysis stations at the facility. The applicant's assumptions and methodology are summarized below:

- The Mecklenburg County patient population will grow at a rate of 5.8 percent (the Five Year AACR for Mecklenburg County as published in the July 2015 SDR) through the end of the second year of operation.
- The applicant assumes no increase for residents of other counties and states who utilize the facility but assumes those patients will continue to dialyze at Charlotte East and are added to the calculations when appropriate.
- The project is scheduled for completion on January 1, 2017. OY1 is CY 2017. OY2 is CY 2018.

In Section C.1, pages 13-15, the applicant provides the calculations used to arrive at the projected in-center patient census for OY1 and OY2 as summarized in the table below.

Charlotte East	In-Center Dialysis
Starting point of calculations is Mecklenburg County patients dialyzing at Charlotte East on January 1, 2015.	94
Mecklenburg County patient population is projected forward by one year to December 31, 2015. Projection is based on the AACR for Mecklenburg County (5.8%).	$94 \times 1.058 = 99.452$
Mecklenburg County patient population is projected forward by one year to December 31, 2016, using the Five Year AACR (5.8%).	$99 \times 1.058 = 104.742$
The two patients from other counties and states are added. This is the projected census on December 31, 2016.	$104.742 + 2 = 106.742$ (106)
Mecklenburg County patient population is projected forward by one year to December 31, 2017, using the Five Year AACR (5.8%).	$104 \times 1.058 = 110.032$
The two patients from other counties and states are added. This is the projected census on December 31, 2017 (OY1).	$110.032 + 2 = 112.032$ (112)
Mecklenburg County patient population is projected forward by one year to December 31, 2018, using the Five Year AACR (5.8%).	$110.032 \times 1.058 =$ 116.4139
The two patients from other counties and states are added. This is the projected census on December 31, 2018 (OY2).	$116.4139 + 2 = 118.4139$ (118)

The applicant projects to serve 112 in-center patients on 34 stations, which is 3.29 patients per station ($112 \text{ patients} / 34 \text{ stations} = 3.29$), by the end of OY1 and 118 in-center patients on 34 stations, which is 3.47 patients per station ($118 \text{ patients} / 34 \text{ stations} = 3.47$), by the end of OY2 for the proposed 34-station facility. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b). The July 2015 SDR indicates that Charlotte East's utilization rate was 92.3 percent (3.69 patients per station) as of December 31, 2014. In this application, the applicant projects the Mecklenburg County in-center patient census will increase annually by 5.8 percent, which is consistent with the Mecklenburg County AACR (2010-2014). Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Home Hemodialysis and Peritoneal Dialysis

The applicant currently provides home hemodialysis (HH) and peritoneal dialysis (PD) services, but this project proposes only additional in-center dialysis stations. See Section C.1, pages 14-15, for the applicant's discussion of its HH and PD services.

Access

In Section L.1, pages 47-48, the applicant states that Charlotte East provides dialysis services to all residents in its service area without qualifications and serves patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability. The applicant also states that it makes every reasonable effort to accommodate those with special needs and helps uninsured and underinsured patients with applying for assistance so it can serve low-income

persons, racial and ethnic minorities, women, handicapped persons, elderly persons, and other underserved persons. The applicant projects 79.8 percent of its patients will have some or all of their services paid for by Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for eight additional stations at Charlotte East, and demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the services proposed. 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 E.1, page 23, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo –The applicant states that this alternative was dismissed due to the growth rate of the patient population at Charlotte East.
- Apply for the Eight Station Expansion – The applicant states the eight additional stations will help meet the growing demand for services at Charlotte East. The applicant further states that maintaining the status quo could force the patients projected to be served at Charlotte East to utilize a third shift or into a different facility if there is no capacity to provide services.

After considering those alternatives, the applicant states the alternative represented in the application is the most effective alternative to meet the identified need.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

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

1. **DVA 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. **DVA Healthcare Renal Care, Inc. d/b/a Charlotte East Dialysis Center shall develop and operate no more than eight additional dialysis stations for a total of no more than 34 certified stations which shall include any isolation or home hemodialysis stations.**
 3. **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 Healthcare Planning and Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

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The applicant proposes to add eight dialysis stations for a total of 34 certified dialysis stations upon project completion.

Capital and Working Capital Costs

In the table in Section F.1, page 25, the applicant states that the projected capital cost is \$134,032, which includes \$104,000 for dialysis machines and \$30,032 for other equipment.

Charlotte East is an existing dialysis facility with an ongoing operation; therefore, in Sections F.10-12, pages 27-28, the applicant does not project any working capital needs.

Availability of Funds

In Section F.2, page 26, the applicant states that cash reserves/owner's equity is being used to finance the proposed project.

Exhibit F-5 contains a September 10, 2015 letter from the Vice President of Tax of DaVita HealthCare Partners, stating that the company is submitting a certificate of need application to add eight stations to Charlotte East. The letter states that DaVita HealthCare Partners has committed cash reserves in the amount of \$134,032 for the project's capital expenditure.

In Section F.8(b), page 27, the applicant states:

“The financial strength of the company precludes any financial impact upon the operation and performance of the expansion that this application proposes. Therefore, there is no appreciable impact on either this application or from any that has been approved previously or is currently under review.”

In Section F.7(a), page 27, the applicant refers to Exhibit F-7 for a copy of the most recent audited financial statements for DaVita HealthCare Partners, Inc. for years ended December 31, 2013 and 2014. As of December 31, 2014, DaVita HealthCare Partners, Inc. had \$965,241,000 in cash and cash equivalents, \$17,942,715,000 in total assets and \$5,360,311,000 in net equity (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital needs of the project.

Financial Feasibility

The applicant provides pro forma financial statements for the first two years of the project. In the pro forma financial statement (Form B), the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

Projected Revenues and Operating Expenses		
Charlotte East	Operating Year 1 CY 2017	Operating Year 2 CY 2018
Gross Patient Revenue	\$11,010,598	\$11,522,771
Deductions from Gross Patient Revenue	(\$181,392)	(\$190,060)
Net Patient Revenue	\$10,829,205	\$11,332,711
Total Operating Expenses	\$4,133,624	\$4,285,026
Net Income/Profit	\$6,695,581	\$7,047,686

The applicant’s projections of treatments and revenues are reasonable based on the number of patients projected for the first two operating years. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

In Section H.1, page 33, the applicant provides projected staffing and salaries. Form A in Section R, page 62, shows budgeted operating costs adequate to cover the projected staffing. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

Conclusion

In summary, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

DVA Healthcare Renal Care, Inc. d/b/a Charlotte East Dialysis Center (Charlotte East) proposes to add eight dialysis stations for a total of 34 certified dialysis stations upon project completion.

On page 361, the 2015 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

According to the July 2015 SDR, there are 14 operational dialysis facilities, 1 dialysis facility not in operation, and 3 dialysis facilities under development in Mecklenburg County. The applicant and its parent company (DaVita) operate six of the 18 facilities in Mecklenburg County. Bio-Medical Applications of North Carolina, Inc. (BMA) operates nine facilities, DSI Renal, Inc. (DSI) operates two facilities, and Carolinas Medical Center (CMC) operates one facility, as shown in the table below.

Mecklenburg County Dialysis Facilities – July 2015 SDR				
Facility	Owner	Location	Number of Existing/ Approved Stations	Utilization as of December 31, 2014
BMA Beatties Ford	BMA	Charlotte	43	88.28%
BMA Nations Ford	BMA	Charlotte	28	114.58%
BMA of East Charlotte	BMA	Charlotte	21	84.00%
BMA of North Charlotte	BMA	Charlotte	36	104.46%
BMA West Charlotte	BMA	Charlotte	29	78.45%
Carolinas Medical Center*	CMC	Charlotte	9	0.00%
Charlotte Dialysis	DaVita	Charlotte	36	78.47%
Charlotte East Dialysis	DaVita	Charlotte	26	92.31%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	66.67%
DSI Glenwater Dialysis	DSI	Charlotte	42	77.38%
FMC Charlotte	BMA	Charlotte	43	82.50%
FMC Matthews	BMA	Matthews	21	114.29%
FMC of Southwest Charlotte**	BMA	Charlotte	10	0.00%
FMC Regal Oaks**	BMA	(none listed)	12	0.00%
Huntersville Dialysis**	DaVita	Huntersville	10	0.00%
Mint Hill Dialysis	DaVita	Mint Hill	11	100.00%
North Charlotte Dialysis Center	DaVita	Charlotte	31	99.29%
South Charlotte Dialysis	DaVita	Charlotte	23	82.50%

*Facility is not currently in operation.

**Facility under development.

As shown in the table above, 10 of the 14 operational Mecklenburg County dialysis facilities are operating above 80 percent utilization (3.2 patients per station), and 13 of the 14 facilities are operating at or above 75 percent utilization (3.0 patients per station).

Charlotte East proposes to add eight dialysis stations for a total of 34 dialysis stations upon project completion. Charlotte East was serving 96 patients weekly on 26 stations, which is 3.69 patients per station or 92.3 percent of capacity, as of December 31, 2014. Dialysis facilities

that operate four shifts per week (two per day on alternate days) have a capacity of four patients per station per week. The applicant does not propose to establish a new facility. The applicant provides reasonable projections for the in-center patient population it proposes to serve on pages 13-15 of the application. The growth projections of the number of Mecklenburg County dialysis patients at Charlotte East are based on the 5.8 percent AACR for Mecklenburg County as published in the July 2015 SDR. At the end of Operating Year Two, Charlotte East projects the utilization will be 3.47 in-center patients per station (118 patients / 34 dialysis stations = 3.47), which is 86.8 percent of capacity. The applicant adequately demonstrates the need to develop eight additional dialysis stations at the existing facility based on the number of in-center patients it proposes to serve.

The applicant adequately demonstrates the proposed project would not result in the unnecessary duplication of existing or approved dialysis services or facilities in Mecklenburg County. Consequently, the application is conforming to this criterion.

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

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In Section H.1, page 33, the applicant provides the current and proposed staffing for the facility, which includes 25 full-time equivalent (FTE) employees in OY2. The applicant plans to add four FTE positions (one registered nurse and three patient care technicians) as a result of this project. In Section H.3, pages 34-35, the applicant describes its experience and process for recruiting and retaining staff. Exhibit I-3 contains a copy of a letter from Thomas Smarz, Jr., M.D., the Medical Director for Charlotte East, expressing his support for the proposed eight station expansion. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed 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 I.1, pages 37-38, and Exhibit I-3, the applicant includes a list of providers of the necessary ancillary and support services. Exhibit I-3 also 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 that the proposed services will be coordinated with the existing health system. Therefore, the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health

service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

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

NA

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

NA

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

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In Section L.7, page 51, the applicant reports that 79.8 percent of the patients who received treatments at Charlotte East had some or all of their services paid for by Medicare or Medicaid in CY 2014. The historical payor mix for patients dialyzing at Charlotte East are shown in the table below, taken from Section L.7, page 51.

Charlotte East Historical Payor Mix – CY 2014				
Payment Source	% Total Patients	% In-Center Patients	% HH Patients	% PD Patients
Medicare	15.4%	15.6%	13.3%	15.8%
Medicaid	11.4%	15.6%	0.0%	5.3%
Commercial Insurance	16.8%	10.4%	26.7%	28.9%
Medicare/Commercial	30.2%	22.9%	53.3%	39.5%
Medicare/Medicaid	22.8%	31.3%	6.7%	7.9%
VA	3.4%	4.2%	0.0%	2.6%
Total	100.0%	100.0%	100.0%	100.0%

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

Although the majority of Medicaid eligibles are children under the age of 21, they represent a very small percentage of those who utilize the services offered by dialysis facilities. In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).¹

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, as well as data sorted by age, race, or gender. But it does not include information on the number of elderly, handicapped, minorities, or women utilizing health services.

However, the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report* provides prevalence data on North Carolina dialysis patients by age, race, and gender on page 59, summarized as follows:

¹<http://www.esrdnetwork6.org/utlils/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

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

Source: Southeastern Kidney Council Network 6 Inc. 2014 Annual Report.²

The applicant demonstrates that it provides adequate access to medically underserved groups. 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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In Section L.3(d), page 50, the applicant states:

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

In Section L.6, pages 50-51, 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.

²<http://www.esrdnetwork6.org/utlils/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

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

C

In Section L.1(b), page 48, the applicant projects that 79.8 percent of the patients who will receive treatments at Charlotte East in the second operating year (CY 2018) will have some or all of their services paid for by Medicare or Medicaid. The table below shows the projected OY 2 payor mix for the facility.

Charlotte East Projected Payor Mix – CY 2018				
Payment Source	% Total Patients	% In-Center Patients	% HH Patients	% PD Patients
Medicare	15.4%	15.6%	13.3%	15.8%
Medicaid	11.4%	15.6%	0.0%	5.3%
Commercial Insurance	16.8%	10.4%	26.7%	28.9%
Medicare/Commercial	30.2%	22.9%	53.3%	39.5%
Medicare/Medicaid	22.8%	31.3%	6.7%	7.9%
VA	3.4%	4.2%	0.0%	2.6%
Total	100.0%	100.0%	100.0%	100.0%

On page 48, the applicant states that the projected payor mix is based on the patient payor mix received during the last full operating year. The applicant demonstrates that medically underserved groups will have adequate access to the services offered at Charlotte East. Therefore, the application is conforming to this criterion.

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

C

In Section L.4, page 50, the applicant describes the range of means by which a person will have access to the dialysis services at Charlotte East, including referrals from other providers, family, and friends, which will result in a referral to a qualified nephrologist for evaluation as to medical necessity. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to dialysis services. Therefore, the application is conforming to this criterion.

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

C

In Section M.1, page 52, the applicant states that Charlotte East has established an agreement with King's College to serve as a clinical learning site for nursing students. Exhibit M-2 contains a copy of the existing Student Training Agreement between Charlotte East and King's

College. The information provided is reasonable and adequately supports a determination that 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

DVA Healthcare Renal Care, Inc. d/b/a Charlotte East Dialysis Center (Charlotte East) proposes to add eight dialysis stations for a total of 34 certified dialysis stations upon project completion.

On page 361, the 2015 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

According to the July 2015 SDR, there are 14 operational dialysis facilities, 1 dialysis facility not in operation, and 3 dialysis facilities under development in Mecklenburg County. The applicant and its parent company (DaVita) operate six of the 18 facilities in Mecklenburg County. Bio-Medical Applications of North Carolina, Inc. (BMA) operates nine facilities, DSI Renal, Inc. (DSI) operates two facilities, and Carolinas Medical Center (CMC) operates one facility, as shown in the table below.

Mecklenburg County Dialysis Facilities – July 2015 SDR				
Facility	Owner	Location	Number of Existing/ Approved Stations	Utilization as of December 31, 2014
BMA Beatties Ford	BMA	Charlotte	43	88.28%
BMA Nations Ford	BMA	Charlotte	28	114.58%
BMA of East Charlotte	BMA	Charlotte	21	84.00%
BMA of North Charlotte	BMA	Charlotte	36	104.46%
BMA West Charlotte	BMA	Charlotte	29	78.45%
Carolinas Medical Center*	CMC	Charlotte	9	0.00%
Charlotte Dialysis	DaVita	Charlotte	36	78.47%
Charlotte East Dialysis	DaVita	Charlotte	26	92.31%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	66.67%
DSI Glenwater Dialysis	DSI	Charlotte	42	77.38%
FMC Charlotte	BMA	Charlotte	43	82.50%
FMC Matthews	BMA	Matthews	21	114.29%
FMC of Southwest Charlotte**	BMA	Charlotte	10	0.00%
FMC Regal Oaks**	BMA	(none listed)	12	0.00%
Huntersville Dialysis**	DaVita	Huntersville	10	0.00%
Mint Hill Dialysis	DaVita	Mint Hill	11	100.00%
North Charlotte Dialysis Center	DaVita	Charlotte	31	99.29%
South Charlotte Dialysis	DaVita	Charlotte	23	82.50%

*Facility is not currently in operation.

**Facility under development.

As shown in the table above, 10 of the 14 operational Mecklenburg County dialysis facilities are operating above 80 percent utilization (3.2 patients per station), and 13 of the 14 facilities are operating at or above 75 percent utilization (3.0 patients per station).

In Section N.1, page 53, the applicant discusses how the proposed project would have a positive impact on the cost-effectiveness, quality, and access to the proposed services. The applicant states:

“The expansion of Charlotte East Dialysis will have no effect on competition in Mecklenburg County. The addition of three [sic] stations at this facility serves to address the needs of a population already served (or projected to be served, based on historical growth rates) by DaVita and not any other providers in the service area. The expansion of Charlotte East Dialysis will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and other [sic] involved in the dialysis process to receive services.”

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

The information in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes 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 for the project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates it will provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.
- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1) and (13) is incorporated herein by reference.

Therefore, the application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Exhibit O-3, the applicant identifies three kidney disease treatment centers located in North Carolina, owned and operated by the applicant, that were cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. In Section O.3, page 54, the applicant states all three facilities are back in full compliance with CMS Guidelines as of the date of submission of this application. Exhibit O-3 contains copies of letters documenting that the facilities were determined to be back in compliance by CMS and the Division of Health Service Regulation. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

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

C

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

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

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

(1) *Utilization rates;*

-C- In Section G.1, page 31, the applicant provides the utilization rates for Charlotte East. The December 31, 2014 utilization rate was reported in the July 2015 SDR as 92.3 percent with 96 in-center patients dialyzing on 26 stations.

(2) *Mortality rates;*

-C- In Section C.9, pages 19-20, the applicant provides the Charlotte East mortality rates, as follows:

	Beginning In-Center and Home Patients	Ending In-Center and Home Patients	Average	Deaths	% Gross Mortality
2014	71	96	83.5	4	4.79%
2013	70	71	70.5	14	19.86%
2012	74	70	72	11	15.28%

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

-C- In Section C.8, page 19, Charlotte East reports having 15 home hemodialysis patients and 38 home peritoneal dialysis patients as of December 31, 2014.

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

-C- In Section C.10, page 20, the applicant states that there were six transplants performed or referred by Charlotte East in 2014.

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

-C- In Section C.10, page 20, the applicant states that Charlotte East had 13 patients on the transplant waiting list as of December 31, 2014.

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

- C- In Section C.11, page 20, the applicant states that during 2014 there were 22 dialysis-related hospitalizations and 98 non-dialysis related hospitalizations for hospital admission rates of 18 percent and 82 percent, respectively.
- (7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*
- C- In Section C.10, page 20, the applicant states that there were two patients with infectious disease at Charlotte East as of December 31, 2014 and one patient who converted to infection status in 2014.
- (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:*
 - (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 is an existing facility.
 - (2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with 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 is an existing facility.
 - (3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
 - NA- Charlotte East is an existing facility.

- (4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C- Exhibit K-1(f) contains written policies and procedures for back up electrical service in the event of a power outage.
- (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 is an existing facility.
- (6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*
- C- In Section K.1(g), page 43, the applicant states: “Charlotte East Dialysis will provide service in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply and other relevant health and safety requirements” See also Section H.2, page 34.
- (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 C.1, page 13, the applicant provides projected patient origin by county for Charlotte East based on the patients who currently dialyze there. The applicant’s assumptions and methodology for its projections are provided on pages 13-15 of the application. The discussion regarding population to be served found in Criterion (3) is incorporated herein by reference.
- (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 is an existing facility.
- (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 L.3(c), page 50, the applicant states, “Charlotte East Dialysis makes no effort to categorize patients into groups according to their financial ability to obtain medical care. Physicians identify the patients in need of dialysis

services and only then will a financial counselor and/or social worker evaluate their medical insurance and financial status.”

10A NCAC 14C .2203 PERFORMANCE STANDARDS

(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 is an existing facility.

(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 C.1, pages 13-15, the applicant documents the need for the project and demonstrates that it will serve a total of 112 in-center patients on 34 stations at the end of the first operating year, which is 3.29 patients per station per week or a utilization rate of 82.3 percent. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C.1, pages 13-15, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

10A NCAC 14C .2204 SCOPE OF SERVICES

To be approved, the applicant must demonstrate that the following services will be available:

(1) *diagnostic and evaluation services;*

-C- In Section I.1, page 38, and Exhibit I-3, the applicant states that patients in need of diagnostic and evaluation services will be referred to Carolinas Medical Center.

(2) *maintenance dialysis;*

-C- In Section I.1, page 38, the applicant states that in-center maintenance dialysis is provided at Charlotte East.

(3) *accessible self-care training;*

- C- In Section I.1, page 38, the applicant states that self-care training is provided by Charlotte East.
- (4) *accessible follow-up program for support of patients dialyzing at home;*
- C- In Section I.1, page 38, the applicant states that an accessible follow-up program for support of patients dialyzing at home is provided by Charlotte East.
- (5) *x-ray services;*
- C- In Section I.1, page 38, and Exhibit I-3, the applicant states that patients in need of x-ray services will be referred to Carolinas Medical Center.
- (6) *laboratory services;*
- C- In Section I.1, page 38, and Exhibit I-3, the applicant states that laboratory services will be provided by DaVita Laboratory Services, Inc.
- (7) *blood bank services;*
- C- In Section I.1, page 38, and Exhibit I-3, the applicant states that patients in need of blood bank services will be referred to Carolinas Medical Center.
- (8) *emergency care;*
- C- In Section I.1, page 38, and Exhibit I-3, the applicant states that patients in need of emergency care will be referred to Carolinas Medical Center.
- (9) *acute dialysis in an acute care setting;*
- C- In Section I.1, page 38, and Exhibit I-3, the applicant states that patients in need of acute dialysis services will be referred to Carolinas Medical Center.
- (10) *vascular surgery for dialysis treatment patients;*
- C- In Section I.1, page 38, and Exhibit I-3, the applicant states that patients in need of vascular surgery services will be referred to Surgical Specialists of Charlotte.
- (11) *transplantation services;*
- C- In Section I.1, page 38, the applicant states that patients in need of transplantation services will be referred to Carolinas Medical Center. Exhibit I-3 contains a copy of an August 2015 letter from Sawsan Yateem, RN, the facility administrator for Charlotte East, which documents the provision of transplantation services to Charlotte East.
- (12) *vocational rehabilitation counseling and services; and*

-C- In Section I.1, page 38, and Exhibit I-3, the applicant states that vocational rehabilitation counseling services are provided by the North Carolina Division of Vocational Rehabilitation Services.

(13) *transportation.*

-C- In Section I.1, page 38, and Exhibit I-3, the applicant states that transportation services will be provided by the Mecklenburg Transportation System.

10A NCAC 14C .2205 STAFFING AND STAFF TRAINING

(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 [replaced with 42 C.F.R. Section 494].*

-C- In Section H.2, page 34, the applicant states that it will comply with 42 C.F.R. Section 494 (previously 42 CFR Section 405.2100). In Section H.1, page 33, the applicant provides a staffing chart. The discussion regarding proposed staffing found in Criterion (7) is incorporated herein by reference.

(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 H.4, page 35, the applicant discusses its training at DVA facilities.