

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: June 15, 2012

PROJECT ANALYST: Tanya S. Rupp

CON CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: F-8809-12 / DVA Healthcare Renal Care d/b/a Charlotte East Dialysis Center / Add 4 in-center dialysis stations and relocate facility for a facility total of 20 in-center stations / Mecklenburg County

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

### C

DVA Healthcare Renal Care d/b/a Charlotte East Dialysis Center (“**Charlotte East**”) proposes to relocate the existing facility to a new location not more than 0.6 mile from the current location, and add four in-center dialysis stations for a total of 20 stations upon completion of this project, Project ID #F-7861-07 [Transfer six existing stations from the existing facility], and Project ID #F-8229-08 [Add six new stations to the existing facility].

The 2012 State Medical Facilities Plan (2012 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2012 Semiannual Dialysis Report (SDR), the county need methodology shows there is no need for additional dialysis stations or facilities in Mecklenburg County. However, an applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR is at least 3.2 patients per station, or 80%. In this application, Charlotte East is eligible to apply for additional stations in its existing facility based on the facility need methodology, because the utilization rate reported in the January 2012 SDR is 4.6 patients per station, or 117%. This utilization rate was calculated based on 75 in-center dialysis patients and 16 certified dialysis stations as of June 30, 2011 (75 patients / 16 stations = 4.68 patients per station). Therefore,

application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table.

**APRIL 1 REVIEW**

Required SDR Utilization		80%
Center [6/30/11] Utilization Rate		117.2%
Certified Stations		16
Pending Stations		0
<b>Total Existing and Pending Stations</b>		<b>16</b>
In-Center Patients as of [6/30/11] (SDR2)		75
In-Center Patients as of [12/31/10] (SDR1)		74
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	1
	Multiply the difference by 2 for the projected net in-center change.	2
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/10	0.0270270
(ii)	Divide the result of by 12	0.0022523
(iii)	Multiply the result of by the number of months from the most recent month reported in the January 2012 SDR (6/30/11) until the end of calendar year 2011 (6 months).	0.0135135
(iv)	Multiply the result by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2.	76.0135
(v)	Divide the result by 3.2 patients per station	23.7542
	and subtract the number of certified and pending stations as recorded in SDR2 [24] to determine the number of stations needed.	<b>8</b>

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.*” As shown in the table above, based on the facility need methodology for dialysis stations, the Charlotte East dialysis facility has a need for eight stations. The applicant proposes in this application to add only four new stations and, therefore, the application is consistent with the facility need determination for dialysis stations.

In addition, SMFP Policy ESRD-2, on page 33 of the 2012 SMFP is applicable to this review. Policy ESRD-2 states:

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

1. *demonstrate that the proposal shall not result in a deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
2. *demonstrate that the proposal shall not result in a surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.*

In this application, the applicant proposes to relocate add four existing dialysis stations from a facility in Mecklenburg County, and relocate the facility within the host county of Mecklenburg. Consequently, there is no change in the inventory in Mecklenburg County. Furthermore, the proposed site is less than one mile from the current site and is on a route served by public transportation; thus it will not prevent a hardship for existing or projected dialysis patients. Therefore, the application is conforming to Policy ESRD-2 of the 2012 SMFP.

There is another policy in the 2012 SMFP that is applicable to this review. Policy GEN-3, on page 40 of the 2012 SMFP states:

*“A CON 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 (SMFP) 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 CON 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 CON applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the SMFP as well as addressing the needs of all residents in the proposed service area.”*

#### Promote Safety and Quality

In Section II.3, pages 17 – 18, the applicant describes the methods it uses to ensure quality care. On page 17, the applicant states:

*“DaVita 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 RN and Biomedical Quality Management Coordinators working under the direction of our Director of Quality Management and Director of Integrated Quality Development. ...The program exemplifies DaVita’s total commitment to enhancing the quality of patient care through its willingness to devote the necessary resources to achieve our clinical goals.”*

...

*The Charlotte East Dialysis Center is attended by Metrolina Nephrology Associates, admitting Nephrologists who directly oversee the quality of care of the dialysis facility. In addition, Dr. Joel Bruce serves as Medical Director and provides the overall medical supervision of the dialysis unit. ... the Quality Management Program is reviewed by the Quality Assurance Committee consisting of the Nephrologists, Unit Administrator, clinical teammates, social worker and the dietician. ...”*

In addition, in Exhibit 23, the applicant provides a copy of the DaVita, Inc. Health and Safety Policy and Procedure Manual, which applies to all DaVita facilities.

The applicant adequately demonstrates how its proposal will promote safety and quality in the provision of dialysis services in Harnett County.

#### Promote Equitable Access

In Section VI.1, page 31, 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 patients without regard to race, sex, age, handicap, or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay [sic].*

*The Copperfield Dialysis Center makes every reasonable effort to accommodate all of its patients; especially those with special needs such as the handicapped, patients attending school or patients who work. Charlotte East Dialysis Center provides dialysis six days per week to accommodate patient need. The facility also operates a third shift on Monday, Wednesday, and Friday.*

*Charlotte East Dialysis Center does not require payment upon admission to its services; therefore, services are available to all patients including low income persons, racial and ethnic minorities, women, handicapped persons, elderly and other underserved persons....”*

The applicant adequately documented its plans for providing access to health care by the underserved groups.

#### Maximize Healthcare Value

In Section III.9, pages 22 – 23, the applicant states,

- *“The 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.*

- *The Charlotte East Dialysis Center utilizes the reuse process that contains costs and the amount of dialyzer waste generated by the facility. The dialyzers are purchased under a national contract in order to get the best quality dialyzer for the best price.*
- *The Charlotte East Dialysis Center has installed an electronic patient charting system that reduces the need for paper in the facility. Much of the other documentation in the facility is also done on computer which reduces the need for paper.*
- *The Charlotte East Dialysis Center Bio-medical Technician assigned to the facility conducts preventative maintenance on the dialysis machines on a monthly, quarterly and semi-annual schedule that reduces the need for repair maintenance and parts. This extends the life of the dialysis machines.*
- *The Charlotte East Dialysis Center also 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 how its proposal will maximize healthcare value. Additionally, the applicant demonstrates projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served. See Criteria (3) and (13c) for additional discussion.

SMFP Policy GEN-4, regarding Energy Efficiency and Sustainability for Health Service Facilities is not applicable in this review because the projected capital cost of the project is less than \$2 million.

In summary, the application is consistent with the facility need methodology, Policy ESRD 2 and Policy GEN-3, and the application is conforming to this criterion.

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

## C

DVA Healthcare Renal Care d/b/a Charlotte East Dialysis Center proposes to relocate the existing facility to a new location no more than 0.6 mile from the current location, and add four in-center dialysis stations for a total of 20 stations upon completion of this project, Project ID #F-7861-07 [Transfer six existing stations from the existing facility], and Project ID #F-8229-08 [Add six new stations to the existing facility].

Population to be Served

In Section III.7, page 21 of the application, the applicant projects the following patient origin, based on the current patient origin at the Charlotte East facility:

COUNTY	OPERATING YEAR 1 2014	OPERATING YEAR 2 2015	COUNTY PATIENTS AS PERCENT OF TOTAL	
	IN-CENTER PATIENTS	IN-CENTER PATIENTS	YEAR 1	YEAR 2
Mecklenburg	67	70	100.0%	100.0%
TOTAL	67	70	100.0%	100.0%

The applicant adequately identifies the population it proposes to serve following the four-station expansion.

Demonstration of Need

In Section II, pages 12 – 15, and in Section III.7, pages 21 - 22, the applicant provides the assumptions and methodology it used to project its need for four additional dialysis stations at Charlotte East Dialysis Center. Specifically, on page 12, the applicant states the Charlotte East facility was operating at a 120% utilization rate with 77 in-center patients on 16 certified stations as of December 31, 2011 [ $77 / 16 = 4.81$ ;  $4.81 / 4 = 1.20$ ]. In *Table A: Inventory of Dialysis Stations and Calculation of Utilization Rates* in the January 2012 SDR, the Charlotte East facility reported a 117% utilization rate with 75 in-center patients dialyzing on 16 stations as of June 31, 2011, six months prior to the data provided by the applicant in this application [ $75 / 16 = 4.68$ ;  $4.68 / 4 = 1.17$ ].

In Section II, pages 12 – 13, the applicant describes this proposal in relation to two other projects (Project ID#F-7861-07 and Project ID#F-8229-08) The applicant states:

*“On May 15, 2007 DVA Healthcare Renal Care, Inc. submitted a Certificate of Need application to develop a 10-station in-center dialysis facility in Mecklenburg County to be known as the Mint Hill Dialysis Center. The Mint Hill Dialysis Center CON application calls for the transfer of six dialysis stations and 19 in-center patients from the Charlotte East Dialysis Center. That Certificate of Need was approved. The Mint Hill facility is scheduled to open on or about March 15, 2012.*

*On September 15, 2008 DVA Healthcare Renal Care, Inc. d/b/a Charlotte East Dialysis Center submitted a CON application to expand the facility by six stations once the Mint Hill facility is certified. This CON application takes into consideration that the Charlotte East facility has 16 stations (16 stations prior to submission of the Mint Hill CON - 6 stations transferred to Mint Hill + 6 stations added back with the 9/15/08 CON). This CON application takes into consideration that the Charlotte East facility has 58 in-center patients (77 in-center patients as of 12/31/12 [sic] based on the facility*

*patient census on that day — 19 patients projected to transfer to the Mint Hill facility on 3/15/12).*”

Thus, in this application, the applicant takes into account the two pending projects in Mecklenburg County that will affect this project.

In Section III, pages 21 – 22, the applicant provides the methodology and assumptions used to project utilization for the Charlotte East facility. The applicant states:

*“Based on the patients and stations above, Charlotte East Dialysis Center is projected to have at least 67 in-center patients by the end of operating year 1 for a utilization rate of 84% or 3.35 patients per station and at least 70 in-center patients by the end of operating year 2 for a utilization rate of 88% or 3.5 patients per station. This information is based on the calculations below. We have used a growth rate of 5.1% for the 58 in-center patients who live in Mecklenburg County.*

*The period of the growth begins with January 1, 2012 forward to December 31, 2015. The following are the in-center patient projections using the 5.1% Average Annual Change Rate for the Past Five Years as indicated on page 20 of the January 2012 Semiannual Dialysis Report for the 58 in-center patients residing in Mecklenburg County.*

*January 1, 2012-December 31, 2012—58 patients X 1.051 = 60.958*

*January 1, 2013-December 31, 2013 — 60.958 patients X 1.051 = 64.066858*

*January 1, 2014-December 31, 2014—64.066858 patients X 1.051 = 67.33426775*

*January 1, 2015-December 31, 2015 —67.33426775 X 1.051 = 70.7683154*

*Operating Year One is projected to begin January 1, 2014 and end on December 31, 2014*

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

Therefore, in Operating Year one, the applicant projects to serve 67 in-center patients on 20 stations, which is 3.3 patients per station, or 84% utilization [ $67 / 20 = 3.35$ ;  $3.35 / 4 = 0.838$ ]. Likewise, in Operating Year two, the applicant projects to serve 70 in-center patients on 20 stations, which is 3.5 patients per station, or a 88% utilization rate [ $70 / 20 = 3.5$ ;  $3.5 / 4 = 0.875$ ]. In operating year one, the applicant projects to serve in excess of 3.2 patients per station per day, which exceeds the 3.2 patients per station required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and supported assumptions regarding continued growth in the Charlotte East Dialysis Center, including: 1) the facility’s historical utilization, and 2) application of the Mecklenburg County Five Year AACR of 5.1% as reported in the January 2012 SDR.

In addition, the applicant proposes to relocate the facility to a new location that is no more than 0.6 mile from the existing facility. In Exhibit 11, the applicant provides a letter from Dr. Joel Bruce, current medical director of the facility, which states in part:

*“I have been informed that DaVita, Inc. operating as DVA Healthcare Renal Care, Inc. d/b/a Charlotte East Dialysis Center, is submitting a Certificate of Need application to the State of North Carolina to relocate and expand the facility by four ESRD outpatient dialysis stations.*

*The relocation and expansion of this facility will provide a needed additional dialysis stations [sic] for our growing in-center patient population at the Charlotte East Dialysis Center.”*

In summary, the applicant adequately identified the population to be served and adequately demonstrated the need to relocate the Charlotte East Dialysis facility and add four additional dialysis stations. Consequently, the application is conforming to this criterion.

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

### C

In response to question I.8 in the application, on page 3, the applicant states,

*“This application is for relocation and four-station expansion of the Charlotte East Dialysis Center. The expansion is on the facility need methodology. The project will include costs associated with the upfit of a new facility which will include purchase of additional dialysis machines, dialysis chairs and individual TVs for the patients.”*

The applicant proposes to relocate the existing Charlotte East Dialysis facility and add four stations, pursuant to the Facility Need methodology in the 2012 SMFP.

In Section II, pages 12 – 13, and Section III, pages 21 - 22, the applicant states that Charlotte East Dialysis had 77 in-center dialysis patients as of December 31, 2012, all of whom are from Mecklenburg County. The applicant projects that 19 patients will transfer to the Mint Hill dialysis facility when that facility is complete. In addition, the information contained in Exhibit 19 and in Section XI indicates that the proposed primary site is two blocks from the current facility; and the proposed secondary site is 0.6 miles from the current facility. In Sections XI.2 and XI.3 the applicant states both proposed sites are served by the Charlotte Area Transit System. It is reasonable to conclude that, since each of the proposed sites is less than one mile from the current Charlotte East location, and since the applicant projects that



100% of its patient population will be residents of Mecklenburg County based on historical utilization of the existing facility, then those residents who choose to remain at Charlotte East will continue to be adequately served when the facility is relocated.

In summary, the applicant has demonstrated that the needs of the population presently served at Charlotte East Dialysis Facility will continue to be adequately met following the relocation of the existing facility, as well as the applicant's planned expansion of the Charlotte East Dialysis facility after the completion of the proposed project, Project ID #F-7861-07 [Transfer six existing stations from the existing facility], and Project ID #F-8229-08 [Add six new stations to the existing facility]. See Criterion (13) for discussion of access for the medically underserved. Therefore, the application is conforming to this criterion.

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

#### CA

The applicant proposes to relocate the existing dialysis facility to a location that is less than one mile from the current facility location, and add four in-center dialysis stations to its existing facility, for a facility total of 20 stations after completion of this project, Project ID#F-7861-07 (Transfer six dialysis stations from Charlotte East Dialysis Center and four dialysis stations from South Charlotte Dialysis Center to develop 10-station Mint Hill Dialysis Center), and Project ID#F-8229-08 (Add six dialysis stations for a total of 16 dialysis stations upon completion of project.) The applicant states in Section III.9, page 22 that it considered one other alternative before proposing this project, which was to do nothing, thereby maintaining an overcrowded dialysis facility. The applicant adequately explains why it chose to increase the number of stations and relocate the facility over the other alternative. Furthermore, the application is conforming to all other applicable statutory review criteria. See Criteria (1), (3), (3a), (5), (6), (7), (8), (12), (13), (14), (18a) and (20) for additional discussion. Therefore, the applicant adequately demonstrates that the selected proposal is its least costly or most effective alternative to meet the identified need. Consequently, the application is conforming to this criterion and is approved subject to the condition in 10A NCAC 14C §.2204(6), and the following conditions:

- 1. DVA Healthcare Renal Care d/b/a Charlotte East Dialysis Center shall materially comply with all representations made in its certificate of need application.**
- 2. DVA Healthcare Renal Care d/b/a Charlotte East Dialysis Center develop no more than four additional dialysis stations for a total of no more than 20 dialysis stations, which shall include any home hemodialysis training or isolation stations, upon completion of this project and Project ID#F-7861-07 (Transfer six dialysis stations from Charlotte East, four dialysis stations from South Charlotte, and develop 10-station Mint Hill Dialysis Center), and Project ID#F-8229-08 (Add six dialysis stations for a total of 16.)**

3. **DVA Healthcare Renal Care d/b/a Charlotte East Dialysis Center shall install plumbing and electrical wiring through the walls for no more than four additional dialysis stations, which shall include any home hemodialysis training or isolation stations.**
  4. **DVA Healthcare Renal Care d/b/a Charlotte East Dialysis Center shall not offer or develop home hemodialysis or peritoneal dialysis training services as part of this project.**
  5. **DVA Healthcare Renal Care 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 issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII.2, page 40, the applicant projects the total capital cost of the project will be \$1,803,569, including \$1,153,000 in construction costs, \$223,890 for dialysis machines, \$95,000 for RO water treatment, \$70,000 for architect and engineering fees, \$179,330 for other furniture and equipment, \$18,900 for dialysis chairs, \$30,000 for televisions, and \$33,449 for chair side computer terminals. In Section IX, page 44, the applicant states there will be no start-up or initial operating expenses associated with this project. In Section VIII.2, page 41, the applicant states the entire capital cost will be financed with the cash reserves of DVA Healthcare Renal Care. In Exhibit 16, the applicant provides a March 12, 2012 letter signed by the Chief Accounting Officer of DaVita, Inc., the parent company of DVA Healthcare Renal Care that states in part:

*"I am the Chief Accounting Officer of DaVita, Inc., the parent and owner of DVA Healthcare Renal Care, Inc. We are submitting a Certificate of Need application to relocate and expand our Charlotte East Dialysis Center by four ESRD dialysis stations.*

*The project calls for a capital expenditure of \$1,803,569. This letter will confirm that DaVita Inc. has committed cash reserves in the total sum of \$1,803,569 for the project capital expenditure. DaVita 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, Inc.:*

In Exhibit 17, the applicant provides a copy of DaVita Inc. consolidated financial statements for years ending December 31, 2010 and December 31, 2011. The balance sheets show that, as of December 31, 2011, DaVita Inc. had total current assets in the amount of \$2,281,608,000, including cash and cash equivalents in the amount of \$393,752,000. The

applicant adequately demonstrated the availability of sufficient funds for the capital needs of the project.

In Section X, pages 45 and 48, the applicant projects operating costs and net revenue for each of the first two operating years of the proposed project, as shown in the following table:

PROJECTED OPERATING COSTS AND NET REVENUE	OP. YEAR 1	OP. YEAR 2
Operating Costs	\$2,929,869	\$3,047,839
Net Revenue	\$3,267,482	\$3,417,202

As shown in the table above, the applicant projects that revenues will exceed operating costs in each of the first two operating years of the project. The reimbursement rates in Section X.1 of the application are consistent with the standard Medicare/ Medicaid rates.

The applicant adequately demonstrated that the financial feasibility of the proposal is based on reasonable projections of revenues and operating costs. Consequently, the application is conforming to this criterion.

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

C

DVA Healthcare Renal Care proposes to add four stations to the existing Charlotte East dialysis facility based on the facility need methodology found on page 366 of the 2012 SMFP, and relocate the entire facility to a new location approximately one-half mile from the current facility in Charlotte. The facility need methodology provides a basis for demonstrating a need for additional dialysis stations in facilities when the current utilization is 3.2 patients per station or greater. The January 2012 SDR shows the Charlotte East Dialysis facility had a utilization rate of 120%, based on 4.68 patients per station [75 patients / 16 stations = 4.68], based on a schedule of two shifts per day on Tuesday, Thursday and Saturday; and three shifts per day on Monday, Wednesday and Friday. This project will follow two other DaVita Inc. projects: Project ID#F-7861-07 (Transfer six dialysis stations from Charlotte East Dialysis Center and four dialysis stations from South Charlotte Dialysis Center to develop 10-station Mint Hill Dialysis Center), and Project ID#F-8229-08 (Add six dialysis stations for a total of 16 dialysis stations upon completion of project.). In Section III.7, page 21, the applicant states:

*“The Mint Hill Dialysis Center CON application calls for the transfer of six dialysis stations and 19 in-center patients from the Charlotte East Dialysis Center. That Certificate of Need was approved. The Mint Hill facility is scheduled to open on or about March 15, 2012.*

*... This CON application takes into consideration that the Charlotte East facility has 58 in-center patients (77 in-center patients as of 12/31/12 based on the facility patient*

*census on that day -19 patients projected to transfer to the Mint Hill facility on 3/15/12)."*

After completion of all three projects, Charlotte East Dialysis Center will have 20 in-center dialysis stations. The applicant adequately demonstrates that the 20 in-center dialysis stations will be utilized at an 88% utilization rate in the second year of operation, based on 70 patients per station [70 / 20 = 3.5]. This utilization is based on the Five Year Average Annual Change Rate (AACR) in Mecklenburg County which has been 5.1% for the past five years, as published in the North Carolina State Health Coordinating Council's January 2012 Semi Annual Dialysis Report. The applicant adequately demonstrates the need to add four in-center dialysis stations to the existing facility for a total of 20 stations upon completion of this project, Project ID #F-7861-07, and Project ID #F-8229-08. Therefore, the applicant adequately demonstrates that the proposed project will not result in the unnecessary duplication of existing or approved dialysis facilities in Mecklenburg County, and the application is conforming to this criterion.

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

C

In Section VII.1, page 35, the applicant provides current and projected staffing for the Charlotte East facility following the addition of four stations, as illustrated in the following table:

POSITION	CURRENT FTES	# OF FTE POSITIONS TO BE ADDED	TOTAL FTE POSITIONS
RN	3.0	0.5	3.5
PCT	8.0	2.0	10.0
Bio-Medical Technician	0.7	0	0.7
Admin	1.0	0	1.0
Dietitian	0.7	0	0.7
Social Worker	0.7	0	0.7
Unit Secretary	1.0	0	1.0
Other - Reuse	1.0	0	1.0
MD	Contract Position		
<b>Totals</b>	<b>16.6</b>	<b>2.5</b>	<b>18.6</b>

In Section V.4(c), page 28, the applicant states that Dr. Joel Bruce currently serves as medical director of Charlotte East. Exhibit 11 contains a letter dated March 14, 2012 signed by Dr. Bruce, confirming that he is the current medical director of Charlotte East, and that he supports the project. The information provided in Section VII and the pro forma financial statements regarding projected staffing is reasonable and credible and supports a finding of conformity to this criterion.

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

C

In Section V.1, page 26, the applicant states that the Presbyterian Hospital will provide ancillary and support services to the dialysis facility, including diagnostic and emergency services, transplantation services, blood bank services, and acute dialysis in an acute care setting. The applicant states laboratory services will be provided by Dialysis Laboratories and transportation services will be provided by the Department of Social Services and “*Various Providers.*” 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 care system. Therefore, the application is conforming to this criterion.

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

NA

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

NA

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

C

In Section XI.6(g), page 56 of the application, the applicant states it will construct 9,576 square feet of space for the relocated dialysis facility in Charlotte. In Section XI.2(a), page 50, the applicant states the site is “an existing structure with enough available square footage for the relocation of the Charlotte East Dialysis Center.” In addition, in Section XI.6(h), page 56, the applicant provides a table that illustrates the estimated square feet of the proposed facility. In Section XI.6(d), page 54 of the application, the applicant states:

*“The facility is constructed with energy-efficient glass, mechanically operated patient access doors and energy-efficient cooling and heating.”*

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. See Criterion (5) for discussion of costs and charges. Therefore, the application is conforming to this criterion.

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

C

In Section VI.1, page 31, the applicant provides the current in-center dialysis payor mix at Charlotte East, as shown in the table below:

CHARLOTTE EAST DIALYSIS CENTER PAYOR SOURCE	PERCENT OF TOTAL
Medicare	28.2%
Medicaid	5.1%
Medicare/Medicaid	28.2%
Commercial Insurance	9.0%
VA	3.8%
Medicare/Commercial	25.7%
<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 as of June 2010 and Calendar Year 2008 – 2009 respectively. The data in the table was obtained on June 4, 2012. More current data, particularly with regard to the estimated uninsured percentages, was not available.

COUNTY	TOTAL # MEDICAID ELIGIBLES AS % OF TOTAL POPULATION JUNE 2010	TOTAL # MEDICAID ELIGIBLES AGE 21 AND OLDER AS % OF TOTAL POPULATION JUNE 2010	% UNINSURED CY 2008 - 09 (ESTIMATE BY CECIL G. SHEPS CENTER)
Mecklenburg	14.6%	5.1%	20.1%
Statewide	17.0%	6.7%	19.7%

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly with respect to dialysis services.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

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 applicants' 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.

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;

C

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.1, page 31, 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.”*

In Section VI.6, page 34, the applicant states *“there have been no civil rights equal access complaints filed within the last five years.”* In Section VI.1(f), page 32, the applicant states it is under no obligation from Federal Regulations to provide uncompensated care. In Section VI.1(d), page 32, the applicant states the Charlotte East facility *“maintains an open door policy of accepting all patients, regardless of ability to pay, who develop end stage renal disease while residing in the service area of the Charlotte East Dialysis Center.”* 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 32, the applicant projects the following payor mix at Charlotte East, based on its historical payor mix:

CHARLOTTE EAST DIALYSIS CENTER PAYOR SOURCE	PERCENT OF TOTAL
Medicare	28.2%
Medicaid	5.1%
Medicare/Medicaid	28.2%
Commercial Insurance	9.0%
VA	3.8%
Medicare/Commercial	25.7%
<b>Total</b>	<b>100.0%</b>



In Section VI.1, pages 31 - 32, the applicant states it has historically served medically underserved groups at the Charlotte East Dialysis facility and will continue to do so following the relocation of the facility and the addition of the four in-center dialysis stations. The applicant demonstrates it will provide adequate access to medically underserved groups. 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 33 of the application, the applicant states that all patients with End Stage Renal Disease will be admitted to Charlotte East through the patient's primary physician, specialty physician, or one of the Nephrologists in the Mecklenburg area and surrounding counties. In addition, in Section VI.5(b), page 33, the applicant states referrals will come from Presbyterian Hospital. The application is conforming to this criterion

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

C

In Section V.3(a), page 28, the applicant states Charlotte East has existing agreements with the Brookstone and Kaplan nursing programs. In Exhibit 10, the applicant provides a copy of an existing *Student Training Agreement* it has with ECPI College of Technology. The applicant adequately demonstrates that it will continue to 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

See Sections II, III, V, VI and VII. In particular, see Section V.7, pages 29 - 30, in which the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition include a positive impact on cost-effectiveness, quality and access to dialysis services in Mecklenburg County. This determination is based on the information in the application, and the following:

- ◆ The applicant adequately demonstrates the need to add four stations to the existing facility and that it is a cost-effective alternative;
- ◆ The applicant has and will continue to provide quality services; and
- ◆ The applicant has and will continue to provide adequate access to medically underserved populations.

Therefore, the application is conforming to this criterion.

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

### C

The Charlotte East Dialysis Center is an existing dialysis facility in Mecklenburg County. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, no incidents occurred within the eighteen months immediately preceding the date of this decision for which any sanctions or penalties related to quality of care were imposed by the State. 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.

### CA

The application is conforming or conditionally conforming to all applicable Criteria and Standards for End Stage Renal Disease Services. The specific criteria are discussed below.

**SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES**

**.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- See Section II, pages 12 - 15, and Section III.7, pages 21 - 22.
- (2) *Mortality rates;*  
-C- See Section II, page 10, and Section IV, page 24.
- (3) *The number of patients that are home trained and the number of patients on home dialysis;*  
-C- In Section IV.3, page 24, the applicant states it has an agreement with the Charlotte Dialysis Center to provide home training for its patients who require home training.
- (4) *The number of transplants performed or referred;*  
-C- See Section II, page 10, and Section IV, page 24.
- (5) *The number of patients currently on the transplant waiting list;*  
-C- See Section II, page 10, and Section IV, page 24.
- (6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*  
-C- See Section II, page 10, and Section IV.6, page 25.
- (7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*  
-C- See Section II, page 10, and Section IV, page 25.
- (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.*  
-C- In Section II, page 11, the applicant responds to this question by stating that the application “*does not seek to establish a new facility.*” However, as explained in Criterion III and as supported by the cited evidence in the application, the applicant does propose a new facility by way of relocating the existing stations. Since the proposed site of the new facility is either two blocks or 0.6 miles from the current facility, it is

reasonable to conclude that the applicant will maintain the existing relationship it has with the Presbyterian Hospital, as reported in Section V.

- (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 is an existing facility and seeks to relocate to a site that is less than one mile from the existing facility's location.

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

-C- See Exhibit 19, in which the applicant provides evidence of full water and power availability at both the primary site and secondary site. The applicant states the information in response to this question is in Exhibit 8, but Exhibit 8 contains copies of DaVita Inc.'s internal policies regarding steps to take in the event of a power failure or other emergency.

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

-C- In Exhibit 8, the applicant provides copies of written policies and procedures for back up for 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.*

-C- The applicant provides documentation regarding each of the proposed locations in Exhibit 19.

- (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 XI.6(g), pages 54 - 55, the applicant provides documentation that services will be provided in conformity with applicable laws and regulations concerning staffing, fire safety, physical environment, and health and safety.
  - (7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C- The information regarding patient origin and all of the assumptions provided by the applicant are found in Section II, pages 12 - 15, and in Section III, pages 21 - 22 of the application.
  - (8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
- NA- The proposal is to relocate an existing facility less than one mile from the current location.
  - (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- The applicant states in Section II, page 12 of the application that “*DVA Healthcare Renal Care, Inc. d/b/a Charlotte East Dialysis Center 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**

- (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- The applicant is relocating existing stations and adding four in-center stations to the 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 II, pages 12 - 15, and in Section III, pages 21 – 22 , the applicant documents the need for four additional stations at the Charlotte East Dialysis Center based on utilization of 3.5 patients per station per week as of the end of the first operating year of the additional stations. See Criterion (3) for discussion of applicant’s projections.

- (c) *An applicant shall provide all assumptions, including the specific methodology by which patient utilization is projected.*
- C- The applicant provides documentation of its assumptions in Section II, pages 12 - 15 and in Section III, pages 21 - 22. See Criterion (3) for discussion.

**.2204 SCOPE OF SERVICES**

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

(1) *diagnostic and evaluation services;*

-C- See Section V.1, page 26.

(2) *maintenance dialysis;*

-C- See Section V.1, page 26.

(3) *accessible self-care training;*

-C- See Section V.1, page 26.

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

-C- See Section V.2, pages 27 - 28.

(5) *x-ray services;*

-C- See Section V.1, page 26.

(6) *laboratory services;*

-CA In Section II, page 15, the applicant refers to Section V.1 of the application; however, Section V.1 provides no information regarding laboratory services for the Charlotte East Dialysis Center. Likewise, in the Exhibit list, there is no evidence of a laboratory services agreement. Therefore, the application is conforming to this criterion, subject to the following condition:

**Prior to the issuance of a Certificate of Need, the applicant shall provide to the Certificate of Need Section, a copy of a laboratory services agreement with the Charlotte East Dialysis Center.**

(7) *blood bank services;*

-C- See Section V.1, page 26.

(8) *emergency care;*

-C- See Section V.1, page 26.

(9) *acute dialysis in an acute care setting;*

-C- See Section V.1, page 26.

(10) *vascular surgery for dialysis treatment patients;*

-C- See Section V.1, page 26.

(11) *transplantation services;*

-C- See Section V.1, page 26.

(12) *vocational rehabilitation counseling and services; and*

-C- See Section V.1, page 26.

(13) *transportation.*

-C- See Section V.1, page 26.

**.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.*
- C- The applicant states in Section II that staffing at the proposed facility will be sufficient to meet the requirements in 42 CFR 405.2100. See also Section VII.1, page 35, and Section VII.10, pages 37 and 38.
- (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 37, and Exhibit 15.