

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: June 7, 2013
PROJECT ANALYST: Fatimah Wilson
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: F-10111-13 / DVA Healthcare Renal Care, Inc. d/b/a Charlotte Dialysis Center / Add one dialysis station to the existing facility for a total of 35 stations upon project completion / 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, Inc. d/b/a Charlotte Dialysis Center currently operates a 34-station dialysis facility located at 2321 West Morehead Street, Charlotte, NC. The applicant now proposes to expand the facility by one station for a total of 35 certified dialysis stations upon project completion.

The 2013 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 January 2013 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of six dialysis stations in Mecklenburg County. However, there is no need determination for additional facilities, as some are operating below 80% capacity. The applicant is currently eligible to apply for additional stations in its existing facility based on the application of the facility need methodology because the utilization rate reported for Charlotte Dialysis Center in the January 2013 SDR is 3.47 patients per station. This utilization rate was calculated based on 111 in-center dialysis patients and 32 certified dialysis stations as of June 30, 2012 (111 patients / 32 stations = 3.46875 patients per station). Therefore, application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table.

**ESRD Facility Need Methodology
 April Review – January 2013 SDR**

Required SDR Utilization		80%
Center Utilization Rate as of 6/30/2012		86.72%
Certified Stations		32
Pending Stations		2
Total Existing and Pending Stations		34
In-Center Patients as of 6/30/2012 (SDR2)		111
In-Center Patients as of 12/31/2011 (SDR1)		111
Step	Description	
(i)	Difference (SDR2 - SDR1)	0
	Multiply the difference by 2 for the projected net in-center change.	0
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/2011	0.0000
(ii)	Divide the result of Step (i) by 12	0.0000
(iii)	Multiply the result of Step (ii) by the number of months from the most recent month reported in the January [2013] SDR (6/30/12) until the end of calendar year 2012 (6 months)	0.0000
(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	111.0000
(v)	Divide the result of Step (iv) by 3.2 patients per station	34.6875
	and subtract the number of certified and pending stations as recorded in SDR2 [20] to determine the number of stations needed	1

[NOTE: "Rounding" to the nearest whole number is allowed only in ... Step ... (v). In these instances, fractions of 0.5000 or greater shall be rounded to the next highest whole number.]

Step (C) of the facility need methodology states: "The facility may apply to expand to meet the need established, [...] up to a maximum of 10 stations." As shown in the table above, based on the facility need methodology for dialysis stations, the number of stations needed is one station, and the applicant proposes to add one new station and, therefore, is consistent with the facility need determination for dialysis stations.

Policy GEN-3 in the 2013 SMFP is applicable to this review. Policy GEN-3 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

The applicant discusses its quality index in Section I, pages 7-8. Also, in Section II.3, pages 17-18, 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 Dialysis Center is attended by Dr. Joel Bruce, admitting Nephrologist who directly oversees the quality of care of the dialysis facility. In addition, Dr. Bruce serves as Medical Director and provides the overall medical supervision of the dialysis unit. The facility unit administrator is the day to day manager of the facility and maintains the the company’s Quality Management Program that monitors the overall care of the patients. The Quality Management Program is reviewed by the Quality Assurance Committee consisting of the Nephrologists, Unit Administrator, clinical teammates, social worker and the dietitian.

...

Continuous Quality Improvement teams address facility issues with the goal of improving patient care patient outcomes.”

The applicant also discusses its safety measures in Section XI.6(g), pages 53-54. In Exhibit 4, the applicant provides a copy of DaVita’s Quality Incentive Program Results. In Exhibit 15, the applicant provides a copy of its isolation policies and procedures, in Exhibit 23, a copy of the safety training outline, and in Exhibit 24, a copy of its in-service training schedule. The

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

Promote Equitable Access

In Section VI, page 30, the applicant provides information about accessibility to Charlotte Dialysis Center. On page 30, the applicant states,

“Charlotte 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.

Charlotte 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 Dialysis Center provides dialysis six days per week with two patient shifts per day to accommodate patient need. The facility also provides a third shift for patients on Monday, Wednesday and Friday for convenience of the patients who prefer to receive their treatments in the late afternoon.

Charlotte 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 under-served persons. Charlotte Dialysis Center works with patients who need transportation, when necessary.”

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

Maximize Healthcare Value

In Section III.9, page 23, the applicant states,

“The Charlotte Dialysis Center promotes cost-effective approaches in the facility in the following ways:

- *The parent corporation, DaVita Healthcare Partners, Inc., operates over 1,800 dialysis facilities nationwide. The corporation has a centralized purchasing department that negotiates national contracts with numerous vendors in order to secure the best product available at the best price.*
- *The Charlotte 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 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 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 Dialysis Center Bio-medical Technician assigned to the facility conducts preventive 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 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.

The application is consistent with Policy GEN-3.

The application is consistent with the facility need determination in the 2013 SMFP and Policy GEN-3. Therefore, the application is conforming with 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, Inc. d/b/a Charlotte Dialysis Center currently operates a 34-station dialysis facility located at 2321 West Morehead Street, Charlotte, NC. The applicant now proposes to expand the facility by one additional station for a total of 35 certified dialysis stations upon project completion. The January 2013 SDR indicates a total of 32 certified stations at Charlotte Dialysis Center, as of June 30, 2012. Based on patient origin information provided in the table in Section III.7, page 21 of the application, the applicant is projecting to provide home training at this facility. In Section IV.3, page 24, the applicant states, *“The Charlotte Dialysis Center had 43 PD patients and 19 home hemodialysis patients as of December 31, 2012.”*

Population to be Served

In Section IV.1, page 24, the applicant states the number of in-center patients served at Charlotte Dialysis Center as of December 31, 2012 as follows:

County of Residence	# of Patients Dialyzing In-Center
Mecklenburg	116
Gaston	4
Total	120

In Section III.7, page 21, the applicant provided the projected patient origin for Charlotte Dialysis Center for the first two years of operation following completion of the project as follows:

COUNTY	OPERATING YEAR 1 2014		OPERATING YEAR 2 2015		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CENTER PATIENTS	HOME DIALYSIS PATIENTS	IN-CENTER PATIENTS	HOME DIALYSIS PATIENTS	YEAR 1	YEAR 2
Mecklenburg	119	46	126	49	94.8%	95.1%
Gaston	4	3	4	3	4.0%	3.8%
Union	0	2	0	2	1.2%	1.1%
TOTAL	123	51	130	54	100.0%	100.0%

The applicant adequately identifies the population it proposes to serve.

Demonstration of Need

In Section II, pages 14-15, the applicant provides the assumptions and methodology it used to project need for one additional dialysis station at Charlotte Dialysis Center. The applicant states:

“The Charlotte Dialysis Center had 111 in-center patients as of June 30, 2012 based on information included on Page 6 of Table A of the January 2013 Semiannual Dialysis Report (SDR). This is a station utilization rate of 84% based on the 34 [32] certified stations in the facility. Of the 111 in-center patients cited in the SDR, 107 of those patients lived in Mecklenburg County. The other 4 patients live in Gaston County. The Charlotte Dialysis Center is applying for a one-station expansion.

The January 2013 SDR indicates on page 2 of Table B that Mecklenburg County has experienced an average annual change rate of 5.6% for the past five years. We have grown the patient population of the Charlotte Dialysis Center patients beginning with January 1, 2013 through the projected operating year 2. The calculations below begin with 107 in-center patients living in Mecklenburg County:

January 1, 2013-December 31, 2013 – 107 patients X 1.056 = 112.992
January 1, 2014-December 31, 2014 – 112.992 patients X 1.056 = 119.319552
January 1, 2015-December 31, 2015 – 119.319552 patients X 1.056 = 126.0014469
January 1, 2014 - December 31, 2014 (operating year 1)
January 1, 2015 - December 31, 2015 (operating year 2)”

At the end of operating year one, the Charlotte Dialysis Center is projected to have an in-center patient census of 119 patients (Mecklenburg County patients) for a utilization rate of 85% or 3.4 patients per station. At the end of operating year two, the Charlotte Dialysis Center is projected to have an in-center patient census of 126 patients (Mecklenburg County patients) for a utilization rate of 90% or 3.6 patients per station.

Projected patient utilization at the end of Year One is 3.4 in-center patients per station per week which satisfies the 3.2 in-center patients per station required by 10A NCAC 14C .2203(b); and the number of in-center patients projected to be served is based on reasonable and supported assumptions regarding future growth.

Access

In Section VI, page 31, the applicant projects that 88.6% of the patients at Charlotte Dialysis Center will be covered by Medicare and Medicaid. The applicant demonstrates adequate access for the underserved at Charlotte Dialysis Center.

In summary, the applicant adequately identifies the population to be served and demonstrates the need for four additional dialysis stations based on the population it proposes to serve. Therefore, the application is conforming with 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.

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In Section III.9, page 23, the applicant discusses the alternatives considered prior to the submission of this application, which include:

- 1) Maintain the Status Quo – The applicant did not choose this alternative because Charlotte Dialysis Center is rapidly growing and in need of additional stations. The facility is operating at 86.7% utilization and has a third shift as a result of capacity.
- 2) Add One Station to the Existing Facility – The applicant chose this alternative to meet the growing demand for dialysis services at Charlotte Dialysis Center. The applicant projects an annual growth rate of 5.6% with an accompanying 85% utilization rate by the end of the first operating year.

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

- 1. DVA Healthcare Renal Care, Inc. d/b/a Charlotte Dialysis Center shall materially comply with all representations made in its certificate of need application and supplemental responses. In those instances where representations conflict, Charlotte Dialysis Center shall materially comply with the last-made representation.**
- 2. DVA Healthcare Renal Care, Inc. d/b/a Charlotte Dialysis Center shall develop and operate no more than one additional dialysis station for a total of 35 certified stations which shall include any home hemodialysis training or isolation stations upon completion of this project.**
- 3. DVA Healthcare Renal Care, Inc. d/b/a Charlotte Dialysis Center shall install plumbing and electrical wiring through the walls for no more than one additional dialysis stations for a total of no more than 35 dialysis stations which shall include any isolation stations.**
- 4. DVA Healthcare Renal Care, Inc. d/b/a Charlotte 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.

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In Section VIII.1, page 39, the applicant states that the capital cost is projected to be \$199,411. In Section IX.3, page 43, the applicant further states that there will be no start-up or initial operating expenses associated with the proposed project. On page 40, the applicant states that the capital cost will be financed with cash reserves.

Exhibit 18 includes a letter dated March 15, 2013 from the Chief Accounting Officer of DaVita, Inc., the parent and owner of DVA Healthcare Renal Care, Inc., which states in part:

“The project calls for a capital expenditure of \$199,411. This letter will confirm that DaVita Healthcare Partners Inc. has committed cash reserves in the total sum of \$199,411 for the project capital expenditure. DaVita Healthcare Partners Inc. will make these funds, along with any other funds that are necessary for the development of the project, available to DVA Healthcare Renal Care, Inc.”

In Exhibit 19, the applicant provides the audited financial statements for DaVita, Inc. for the fiscal year ended December 31, 2012. As of December 31, 2012, DaVita, Inc. had cash and cash equivalents totaling \$533,748,000 with \$16,018,596,000 in total assets and \$4,508,740,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds, for the proposed project.

In Section X.1, page 44, the applicant projects the following charge per treatment for each payment source:

Payor	In-Center Charge
Medicare	\$240.00
Medicaid	\$143.00
Medicare/Medicaid	\$240.00
Commercial Insurance	\$1,442.00
VA	\$193.00
Medicare/Commercial	\$240.00

The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services. The applicant projects net revenue in Section X.2 of the application and operating expenses in Section X.4 of the application. The applicant projects revenue in excess of expenses in each of the first two operating years following completion of the project, as illustrated in the table below.

	Operating Year 1	Operating Year 2

Total Revenue	\$8,246,401	\$8,711,588
Total Operating Costs	\$6,264,065	\$6,542,994
Profit	\$1,982,336	\$2,168,594

Source: Application pages 44 and 47.

Assumptions:

1. Total number of treatment times 5% for missed treatments;
2. Times payor percentage; and
3. Times payor reimbursement.

The applicant projects that revenue will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable.

The project analyst notes that the revenue for operating year one and two (OY1 \$7,699,452 and OY2 \$8,071,319) on page 47 does not reconcile with the revenue for operating year one and two (OY1 \$8,246,401 and OY2 \$8,711,588) on page 44. Therefore, due to the discrepancy, the profit is incorrect on page 47. However, the project analyst was able to clarify with the applicant that the revenue on page 47 was incorrectly transcribed. The correct revenue, operating cost and profit in the table above is correct.

In Section VII.1, page 34 and Section X pages 47-48, the applicant provides projected staffing and salaries. On page 34 and 53, the applicant states that Charlotte Dialysis Center will continue to operate within the applicable laws and regulations pertaining to staffing. Staffing by shift is provided on page 37. The applicant projects adequate staffing to provide dialysis treatments for the number of patients projected.

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

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

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The applicant proposes to add one dialysis station to its existing facility for a total of 35 certified dialysis stations upon completion of the proposed project. According to the January 2013 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of six dialysis stations in Mecklenburg County. However, there is no need determination for additional facilities, as some are operating below 80% capacity. Although the January 2013 SDR shows there is a deficit of six dialysis stations in Mecklenburg County, in this application, the applicant is applying for additional stations based on the facility need methodology. According to the January 2013 SDR, Charlotte Dialysis Center is one of 14

existing dialysis facilities in Mecklenburg County with utilization rates ranging from 66.7% to 142.9%. The applicant adequately demonstrates the need for one additional station based on the number of in-center patients it currently serves and proposes to serve. Per the January 2013 SDR, as of June 30, 2012, the 32 station Charlotte Dialysis Center facility was operating at 86.7% capacity ($111 / 32 = 3.46875$; $3.46875 / 4 = 0.8671875$ or 86.7%). The target utilization is 80% or 3.2 patients per station per week as of the end of the first operating year of the facility. Based on the calculations above, the applicant is eligible to expand its facility and may apply for additional stations. Upon completion of the proposed project, the facility will have 35 stations serving 123 in-center patients (end of year 1) which is a utilization rate of 87.9% ($123 / 35 = 3.5$; $3.5 / 4 = .87857$ or 87.9%). Therefore, the applicant is conforming with the required performance standard in 10A NCAC 14C .2203.

The applicant adequately demonstrates that the proposal would not result in the unnecessary duplication of existing or approved health service capabilities or facilities. 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 VII.1, page 34, the applicant provides the current and projected number of full-time equivalent (FTE) positions for Charlotte Dialysis Center following completion of the proposed project, as illustrated in the table below:

Position	Current # of FTEs	Total Positions to be Filled	Total FTE Positions Upon Completion
RN	7.0	0.0	7.0
HTRN	4.0	0.0	4.0
PCT	14.0	0.0	14.0
Bio-Med Tech	1.0	0.0	1.0
MD			
Admin.	1.0	0.0	1.0
Dietician	1.0	0.0	1.0
Social Worker	1.0	0.0	1.0
Unit Secretary	3.0	0.0	3.0
Other-Reuse	2.0	0.0	2.0
TOTAL	34.0	0.0	34.0

No additional FTE positions are to be added. As shown in the above table, the applicant proposes to employ a total of 34 full-time equivalent (FTE) positions to staff the Charlotte Dialysis Center upon completion of the proposed project. Exhibit 13 contains a letter signed by Joel Brue, MD, a physician of Metrolina Nephrology Associates, PA, which states he is a practicing Nephrologist and Medical Director for the Charlotte Dialysis Center facility. In Section VII.1, page 34, the applicant states:

“The Medical Director is not employed by the facility. There is a signed agreement between the facility and the Medical Director. The fee to be paid is estimated to be \$150,000 annually for the Medical Director responsibilities.”

In Section VII.10, page 37, the applicant provides the projected direct care staff upon project completion for each shift offered in the facility as shown in the table below:

	Shift Times	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Morning	6:00am to 10:30am	11	11	11	11	11	11
Afternoon	11:00am to 4:00pm	11	11	11	11	11	11
Evening	4:00pm to 9:00pm	3	0	3	0	3	0

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

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

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In Section V.1, page 26, the applicant lists the providers of the necessary ancillary and support services. The applicant states the method for providing these services in response to 10A NCAC 14C .2204, pages 15-16 of the application. Emergency care, diagnostic and evaluation services, x-ray services, blood bank services, acute dialysis in an acute care setting, transplantation services and vascular surgery will be provided by Presbyterian Hospital. An agreement between Presbyterian Hospital and Charlotte Dialysis Center is provided in Exhibit 10. Most of the other services will be provided by the applicant.

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 VI.1(a), page 30, the applicant discusses Charlotte Dialysis Center's history of providing dialysis services to the underserved populations of North Carolina. The applicant states:

“Charlotte 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.

Charlotte 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 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 under-served persons. ...”

In Section VI.1, page 30, the applicant states that historically, 88.6% of patients at Charlotte Dialysis Center have some or all of their services paid for by Medicare or Medicaid and an additional 2.4 % are covered by VA. Thus, 91% of the center revenue is derived from government payors. The table below illustrates the current payor mix for the facility.

Historical Payor Source

Payor Source	In-Center
Medicare	24.1%
Medicaid	5.4%
Medicare/Medicaid	24.7%
Commercial Insurance	9.0%
VA	2.4%
Medicare/Commercial	34.4%
Total	100.0%

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for 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 CY 2009 (Estimate by Cecil G. Sheps Center)
Mecklenburg	15.0%	5.1%	20.1%
Statewide	17.0%	6.7%	19.7%

Source: <http://www.ncdhhs.gov/dma/countyreports/index.htm>

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

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the services offered by Charlotte Dialysis Center. In fact, only 5.8% of all 2011 Incident ESRD patients in North Carolina's Network 6 were under the age of 35.

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 and gender. However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The Centers for Medicare & Medicaid Services (CMS) website states,

“Although the ESRD population is less than 1% of the entire U.S. population it continues to increase at a rate of 3% per year and includes people of all races, age groups, and socioeconomic standings. ...

Almost half (46.6%) of the incident patients in 2004 were between the ages of 60 and 79. These distributions have remained constant over the past five years. While the majority of dialysis patients are White, ESRD rates among Blacks and Native Americans are disproportionately high. While Blacks comprise over 12% of the national population, they make up 36.4% of the total dialysis prevalent population. In 2004 males represented over half of the ESRD incident (52.6%) and prevalent (51.9) populations.”¹

Additionally, the United States Renal Data System, in its 2012 USRDS Annual Data Report (page 225) provides these national statistics for FY 2010:

“On December 31, 2010, more than 376,000 ESRD patients were receiving hemodialysis therapy...”

The report validates the statistical constancy reported by CMS above. Of the 376,000 ESRD patients, 38.23% were African American, 55.38% were white, 55.65% were male and 44.65% were 65 and older. The report further states:

“Nine of ten prevalent hemodialysis patients had some type of Medicare coverage in 2010, with 39 percent covered solely by Medicare, and 32 percent covered by Medicare/Medicaid. ... Coverage by non-Medicare insurers continues to increase in the dialysis population, in 2010 reaching 10.7 and 10.0 percent for hemodialysis and peritoneal dialysis patients, respectively.”

¹ www.cms.gov/medicare/end-stage-renal_disease/esrdnetworkorgainziations/downloads/esrdnetworkprogrambackgroundpublic.pdf

The report provides 2010 ESRD spending, by payor as follows:

ESRD Spending by Payor		
Payor	Spending in Billions	% of Total Spending
Medicare Paid	\$29.6	62.32%
Medicare Patient Obligation	\$4.7	9.89%
Medicare HMO	\$3.4	7.16%
Non-Medicare	\$9.8	20.63%

Source: 2012 United States Renal Data System (USRDS) Annual Data Report, page 340

The Southeastern Kidney Council (SKC) provides Network 6 2011 Incident ESRD patient data by age, race and gender demonstrating the following:

Number and Percent of Dialysis Patients by Age, Race and Gender		
	# of ESRD Patients	% of Dialysis Population
Ages		
0-19	89	1.0%
20-34	451	4.8%
35-44	773	8.3%
45-54	1,529	16.4%
55-64	2,370	25.4%
65-74	2,258	24.2%
75+	1,872	20.0%
Gender		
Female	4,237	45.35%
Male	5,105	54.65%
Race		
African American	5,096	54.55%
White/Caucasian	4,027	43.11%
Other	219	2.3%

Source: Southeastern Kidney Council (SKC) Network 6
 Includes North Carolina, South Carolina and Georgia

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(f), page 31 applicant states:

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

In Section VI.6(a), page 33, the applicant states, *“There have been no civil rights equal access complaints filed within the last five years.”* The application is conforming to this criterion.

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

C

In Section VI.1(c), page 31, the applicant does not anticipate any change to the future payor mix as indicated in this table.

Projected Payor Source

Payor Source	In-Center
Medicare	24.1%
Medicaid	5.4%
Medicare/Medicaid	24.7%
Commercial Insurance	9.0%
VA	2.4%
Medicare/Commercial	34.4%
Total	100.0%

As shown in the table above, the applicant projects that 88.6% of all in-center patients will have some or all of their services paid for by Medicare or Medicaid with VA covering another 2.4%.

In Section VI.1(d), page 31, the applicant states, *“The Charlotte Dialysis Center 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 Dialysis Center.”*

In Section VI.2, page 32, the applicant states the facility design satisfies all state requirements and local building codes to allow equal access for handicapped patients and ensures access by these individuals by providing wheelchair ramps, handicapped bathrooms, wheelchair scales and ADA complaint doors.

The applicant demonstrates it will provide adequate access to elderly and medically underserved populations. 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, page 32, the applicant states:

“Patients with End Stage Renal Disease have access to dialysis services upon referral to a Nephrologist with privileges at Charlotte Dialysis Center. These referrals most commonly come from primary care physicians or specialty physicians in Mecklenburg County or transfer referrals from other Nephrologists outside of the immediate area.

...

By policy, the Charlotte Dialysis Center admits new patients only from a Board Certified Nephrologist with admission privileges as determined by Medical Staff Bylaws and who have agreed to provide Nephrology coverage for the patient.”

The applicant adequately demonstrates that it will provide a range of means by which a person can access services. Therefore, the application is conforming to this criterion.

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

C

In Section V.3, page 28, the applicant states the Charlotte Dialysis Center has agreements with Kings College in Charlotte and Winthrop University in Rock Hill, South Carolina. Exhibit 12 contains copies of community college documentation. The information provided in Section V.3 is reasonable and credible. The applicant adequately demonstrates that the facility will accommodate the clinical needs of health professional training programs in the proposed service area. The application is conforming to this criterion.

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

C

The applicant proposes to add one dialysis station to its existing facility for a total of 35 certified dialysis stations upon completion of this project. According to the January 2013 SDR, Charlotte Dialysis Center is one of 14 existing dialysis facilities in Mecklenburg County with utilization rates ranging from 66.7% to 142.9%. See table below for a list of Mecklenburg County dialysis facilities by stations:

Facility	Number of Dialysis Stations as of December 21, 2012				
	Certified	CON Issued/Not Certified	Decision Rendered (Conditional Approvals)	Decision Pending	Total
BMA West Charlotte	27		2		29
BMA of Beaties Ford	32				32
BMA of North Charlotte	27				27
CMC	9				9
DSI Charlotte Latrobe Dialysis	24				24
DSI Glenwater Dialysis	34	8			42
South Charlotte Dialysis	17	3			20
Charlotte Dialysis	34				34

Charlotte East Dialysis	16	4			20
North Charlotte Dialysis Center	25			10	35
BMA of Charlotte	40		-4		36
BMA of East Charlotte	24				24
BMA of Nations Ford	24		-6		18
FMC of Matthews	21				21
FMC of Southwest Charlotte	Proposed new site consisting of existing stations				
Mint Hill Dialysis Center	Proposed new site consisting of existing stations				

Source: January 2013 SDR

In Section V.7, page 29, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The applicant states its proposal is not intended to be a competitive venture. The applicant further states:

“...The effect of other facilities in Mecklenburg County and surrounding counties would be difficult to determine since most patients from Mecklenburg County already receive treatment in established facilities operated by several different providers.

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

See also Sections II, III, V, VI, and VII. The information provided by the applicant in each of these sections is reasonable, 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 a review of the information in the sections of the application referenced above and the following analysis:

- The applicant adequately demonstrates the need to add one dialysis station and that it is a cost-effective alternative to meet that need;
- The applicant will continue to provide quality services; and
- The applicant 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.

The applicant currently provides dialysis services at Charlotte Dialysis Center. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, Charlotte Dialysis Center has operated in compliance with all Medicare Conditions of Participation within the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

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

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services in 10A NCAC 14C .2200. The specific findings 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 II.1, page 10, the applicant indicated that the utilization rate is reported in the January 2013 SDR (Exhibit 7, Table A) of 86.7% with 3.47 ($111 / 34 = 3.46875$) patients per station.
- (2) Mortality rates;
- C- In Section IV.2, page 24, the applicant provides the mortality rates as 13.1%, 5.7% and 6.5% for 2010, 2011 and 2012, respectively.
- (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, "*The Charlotte Dialysis Center had 43 PD patients and 19 home hemodialysis patients as of December 31, 2012.*"

- (4) The number of transplants performed or referred;
- C- In Section IV.4, page 24, the applicant states Charlotte Dialysis Center referred 14 patients for transplant evaluation and two patients received transplants in 2012.
- (5) The number of patients currently on the transplant waiting list;
- C- In Section IV.5, page 25, the applicant states “*Charlotte Dialysis Center has nine patients on the transplant waiting list.*”
- (6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;
- C- In Section IV.6, page 25, the applicant states that there were 218 total hospital admissions in 2012, 31 (14.2%) of which were dialysis related and 187 (85.8%) non-dialysis related.
- (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 IV.7, page 25, the applicant states that there were three patients dialyzing at the Charlotte Dialysis Center as of December 31, 2012 with an infectious disease.

(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 Dialysis Center is an existing facility.

(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 Dialysis Center is an existing facility.

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

-NA- Charlotte Dialysis Center 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- See Exhibit 8 for a copy of Charlotte Dialysis Center's Power Supply Documentation and Backup Agreement which has 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 Dialysis Center 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 XI.6(g), page 53, the applicant states, "*Charlotte Dialysis Center has and will continue to operate within the applicable laws and regulations pertaining to staffing and fire safety equipment, physical environment and other relevant health safety requirements.*" See also Sections II.3, pages 17-18; VII.2, pages 34-35 and, XI.6(e), page 53.

(7) The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.

-C- See Section III.7, pages 21-22 for the methodology and assumptions the applicant uses to project patient origin as presented in the following table:

COUNTY	OPERATING YEAR 1 2014		OPERATING YEAR 2 2015		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CENTER PATIENTS	HOME DIALYSIS PATIENTS	IN-CENTER PATIENTS	HOME DIALYSIS PATIENTS	YEAR 1	YEAR 2
Mecklenburg	119	46	126	49	94.8%	95.1%
Gaston	4	3	4	3	4.0%	3.8%
Union	0	2	0	2	1.2%	1.1%
TOTAL	123	51	130	54	100.0%	100.0%

Also see discussion in Criterion (3) which is incorporated hereby as if fully set forth herein.

(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 Dialysis Center 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 II.1, pages 12, the applicant states, “*DVA Healthcare Renal Care, Inc. d/b/a Charlotte 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.*”

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 Dialysis Center does not propose to establish a new End Stage Renal Disease 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 Sections II.1, pages 12-13 and Section III.7, pages 21-22, Charlotte Dialysis Center projects utilization of 123 patients as of the end of the first operating year (3.5 patients per station per week). Assumptions are provided in Section II.1, pages 12-13 and Section III.7, pages 21-22.

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

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected in Section II.1, pages 12-13 and Section III.7, pages 21-22. The applicant projects an increase in its current Mecklenburg County patient utilization using the county 5-year AACR.

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 V.1, page 26, the applicant states that diagnostic and evaluation services will be provided by Presbyterian Hospital.

(2) maintenance dialysis;

-C- In Section V.1, page 26, the applicant states that dialysis/maintenance will be provided by the applicant.

(3) accessible self-care training;

-C- Based on patient origin information provided in the table in Section III.7, page 21 of the application, the applicant proposes to service 51 home dialysis patients in operating year one and 54 home dialysis patients in operating year two. In Section IV.3, page 24, the applicant states, "*The Charlotte Dialysis Center had 43 PD patients and 19 home hemodialysis patients as of December 31, 2012.*" In Section V.1, page 26, the applicant states that self-care training will be provided by the applicant.

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

-C- Based on patient origin information provided in the table in Section III.7, page 21 of the application, the applicant proposes to service 51 home dialysis patients in operating year one and 54 home dialysis patients in operating year two. In Section

IV.3, page 24, the applicant states, “*The Charlotte Dialysis Center had 43 PD patients and 19 home hemodialysis patients as of December 31, 2012.*” In Section V.1, page 26, the applicant states that hemodialysis will be provided by the applicant.

(5) x-ray services;

-C- In Section V.1, page 26, the applicant states that x-ray services will be provided by Presbyterian Hospital.

(6) laboratory services;

-C- In Section V.1, page 26, the applicant states that laboratory services will be provided by Dialysis Laboratories.

(7) blood bank services;

-C- In Section V.1, page 26, the applicant states that blood bank services will be provided by Presbyterian Hospital.

(8) emergency care;

-C- In Section V.1, page 26, the applicant states that emergency care will be provided by Presbyterian Hospital.

(9) acute dialysis in an acute care setting;

-C- In Section V.1, page 26, the applicant states that acute dialysis in acute care setting will be provided by Presbyterian Hospital.

(10) vascular surgery for dialysis treatment patients;

-C- In Section V.1, page 26, the applicant states that vascular surgery will be provided by Presbyterian Hospital.

(11) transplantation services;

-C- In Section V.1, page 26, the applicant states that transplantation services will be provided by Presbyterian Hospital.

(12) vocational rehabilitation counseling and services; and

-C- In Section V.1, page 26, the applicant states that vocational rehabilitation services will be provided by the North Carolina Division of Vocational Rehabilitation Services.

(13) transportation.

- C- In Section V.1, page 26, the applicant states that transportation services will be provided by DSS/Various Providers.

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.

- C- In Section VII.1, page 34, the applicant provides the proposed staffing. In Section VII.2, pages 34-35, the applicant states the proposed facility will comply with all staffing requirements set forth in 42 C.F.R. Section 405.2100. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. See Criterion (7) for further discussion on staffing which is incorporated hereby as if fully set forth herein.

(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 Exhibits 17, 23 and 24.