

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

FINDINGS: November 21, 2013

PROJECT ANALYST: Gene DePorter  
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: J-10203-13/ DVA HealthCare Renal Care, Inc. d/b/a  
Durham Dialysis Center / Add 5 dialysis stations for a  
total of 29 dialysis stations upon completion of this project /  
Durham

### 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. [DVA] d/b/a Durham Dialysis Center [DDC], whose parent company is DaVita HealthCare Partners Inc, proposes to add five dialysis stations to its existing dialysis facility located at 201 Hood Street in Durham, for a total of 29 dialysis stations upon project completion.

The 2013 State Medical Facilities Plan [2013 SMFP] provides a county need methodology and facility need methodology for determining the need for additional dialysis stations. According to the July 2013 Semiannual Dialysis Report (SDR) the county need methodology shows there is a surplus of 15 stations and thus no need for an additional facility in Durham County. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported for DDC in the July 2013 SDR is 3.75 patients per station and a utilization rate of 93.75% for 24 certified stations.

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

**DVA Durham Dialysis Center**  
ESRD Facility Need Methodology  
Semiannual Dialysis Facility Need

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/2012		93.75%
Certified Stations		24
Pending Stations		0
Total Existing and Pending Stations		24
In-Center Patients as of 12/31/12 (SDR2-January 2013)		90
In-Center Patients as of 6/30/12 (SDR1-July 2013)		78
Step	Description	Result
(i)	Difference (SDR2 – SDR1)	12
	Multiply the difference by 2 for the projected net in-center change	24
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/12 (SRD 1)	.3076923
(ii)	Divide the result of step (i) by 12	.0256410
(iii)	Multiply the result of step (ii) by the number of months from the most recent month reported in the July 2013 SDR (12/31/2012) until the end of calendar year 2013 (12 months)	.3076923
(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	117.6923
(v)	Divide the result of step (iv) by 3.2 patients per station	36.7788
	and subtract the number of certified and pending stations as recorded in SDR2 [24] to determine the number of stations needed	12.78

As shown in the above table, based on the facility need methodology for dialysis stations the potential number of stations needed is 12.0 stations. However, Step (v) of the facility need methodology, page 381 of the 2013 SMFP, states; “*The facility may apply to expand to meet the need established... up to a maximum of 10 stations.*”

The applicant proposes to add five dialysis stations and therefore is consistent with the facility need determination for dialysis stations.

POLICY GEN-3: Basic Principles, in the 2013 SMFP is applicable to this review. Policy GEN-3 states:

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

#### Promote Safety and Quality

In Section II., page 16, the applicant states how this proposal will promote safety and quality:

*“DaVita HealthCare Partners Inc. is committed to providing quality care to the ESRD population through a comprehensive Quality Management Program. ...Our Quality Management Program includes the following Quality Programs:*

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

*...Our goal is to have each facility to serve as a quality improvement laboratory where successful outcomes can be disseminated throughout DaVita.”*

Exhibit 4 includes DDC's Quality Incentive Program Results.

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

### Promote Equitable Access

In Section VI.1 (b), page 30, the applicant's Source of Payment Table illustrates that 94.5% of its patients in the past year were Medicaid or Medicare recipients. In Section VI.1(c), page 31, the applicant projects to continue to serve the same payer mix upon project completion. Further in Section VI.1 (a), page 30, the applicant states:

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

The applicant adequately demonstrates how the proposal will promote equitable access.

### Maximize Healthcare Value

In Section III.9, page 21, the applicant states how the addition of five certified stations will allow Durham Dialysis Center to maximize healthcare value. The applicant states:

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

- *The parent corporation, DaVita HealthCare Partners, Inc., operates over 1,900 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.*
- *Durham 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.*
- *Durham 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.*
- *Durham 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.*
- *Durham 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.*

- *Durham 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 the 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.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, page 43 of the 2013 SMFP states:

*“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.*

*In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, the Certificate of Need Section shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds emergency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.*

*Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”*

The capital cost of the proposed project is \$81,923. Therefore, Policy GEN-4 is not applicable because the capital investment is below the \$2 million threshold.

The application is consistent with the facility need determination in the July 2013 SDR and Policy GEN 3. Consequently, the application is conforming to this criterion.

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

The applicant, Durham Dialysis Center, proposes to add five dialysis stations to its existing 24 station facility located at 201 Hood Street in Durham for a total of 29 stations upon completion of this project.

Population to be Served

In Section IV.1, page 23, the applicant identifies, in the following table, the patient population it served, as of December 31, 2012:

**Durham Dialysis  
Patient Population by County  
December 31, 2012**

County of Residence	# of Patients Dialyzing In-Center	# of Patients Home Trained
Durham	81	0
Onslow	1	0
Granville	2	0
Vance	1	0
Orange	2	0
Person	2	0
Franklin	1	0
<b>Total</b>	<b>90</b>	<b>0</b>

In Section III.7, page 20, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, as illustrated in the following table:

**Durham Dialysis  
In-Center and Home Dialysis Projections by County of Origin  
Operating Years 1 and 2**

County	Operating Year 1 FY 2014/2015		Operating Year 2 FY 2015/2016		County Patients as a Percent of Total	
	In-Center Patients	Home Dialysis	In-Center Patients	Home Dialysis	Year 1	Year 2
Durham	92	0	97	0	91.0%	91.6%
Onslow	1	0	1	0	1.0%	0.9%
Granville	2	0	2	0	2.0%	1.9%
Vance	1	0	1	0	1.0%	0.9%
Orange	2	0	2	0	2.0%	1.9%
Person	2	0	2	0	2.0%	1.9%
Franklin	1	0	1	0	1.0%	0.9%
<b>Total</b>	<b>101</b>	<b>0</b>	<b>106</b>	<b>0</b>	<b>100.0%</b>	<b>100.0%</b>

The applicant adequately identified the population to be served.

Need Analysis

In Section III.7, pages 20-21, the applicant states:

*“Durham Dialysis Center had 90 in-center patients as of December 31, 2012 based on information contained in Table A of the July 2013 Semiannual Dialysis Report. This is a station utilization of 93% based on the 24 certified stations in the facility. The January 2013 Semiannual Dialysis Report indicated that Durham Dialysis Center had 78 in-center patients as of June 30, 2012, which is an increase of 12 in-center patients in a six month period. This calculates to a growth of 15%.*

*Based on the patients and stations above, Durham Dialysis Center is projected to have at least 101 in-center patients by the end of operating year 1 for a utilization rate of 87% or 3.4 patients per station and at least 106 in-center patients by the end of operating year 2 for a utilization rate of 91% or 3.6 patients per station. This information is based on the calculations below.*

*The period of growth begins with January 1, 2013 forward to June 30, 2016. The following are the in-center patient projections using a conservative growth rate of 5%;*

*January 1, 2013-June 30, 2013 –90 in-center patients X 1.0225=92.25*

*July 1, 2013-June 30, 2014 – 92.25 in- center patients X 1.05=96.8625*

*July 1, 2014-June 30, 2015 – 96.8625 in-center patients X 1.05=101.705625*

*July 1, 2015 – June 30, 2016-101.705625 in-center patients X 1.05 = 106.7909062*

*Operating Year one is projected to begin July 1, 2014 and end June 30, 2015*

*Operating Year one (sic) is projected to begin July 1, 2015 and end June 30, 2016*

The applicant does not provide home dialysis training.

The applicant projects to serve 101 in-center patients or 3.48 patients per station (101/29 = 3.48) by the end of Year 1 and 106 in-center patients or 3.65 patients per station (106/29 = 3.65) by the end of Year 2 for the proposed 29 station facility. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b). Proposed utilization is based on reasonable and supported assumptions regarding continued growth.

Access

In Section VI, page 30, the applicant projects that 94.5% of the patients at DDC will be covered by Medicare and Medicaid. The applicant demonstrates adequate access for the underserved at DDC.

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

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

NA

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

CA

In Section III.9, page 21 of the application, the applicant describes the alternatives it considered to meet the need for the proposed services: do nothing or expand by 5 stations. The applicant states that it dismissed the alternative to do nothing.

In Section III. 9, page 21, the applicant states that developing additional stations is the only way to serve the growing ESRD population choosing to dialyze at Durham Dialysis Center. The applicant is requesting 5 additional dialysis stations although it could have asked for more based on the facility need methodology. The applicant indicates that for reasons of capital expense they have chosen to develop 5 stations at this time.

The applicant adequately demonstrated the need for five additional stations based on the number of in-center patients it now serves and proposes to serve. See Criterion (3) for discussion on need which is hereby incorporated by reference as if fully set forth herein. The application is conforming to all other applicable statutory and regulatory review criteria and is thus approvable. A project that cannot be approved cannot be an effective alternative. The applicant adequately demonstrates that this project is its least costly or most effective alternative to meet the need for additional dialysis stations at this facility. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1. DVA Healthcare Renal Care, Inc. d/b/a Durham Dialysis Center, shall materially comply with all representations made in its certificate of need application.**
- 2. DVA Healthcare Renal Care, Inc. d/b/a Durham Dialysis Center shall develop and operate no more than five additional dialysis stations for a total of no more**

**than 29 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 Durham Dialysis Center shall install plumbing and electrical wiring through the walls for no more than five additional dialysis stations for a total of 29 stations, which shall include any home hemodialysis training or isolation stations.**
  - 4. DVA Healthcare Renal Care, Inc. d/b/a Durham Dialysis Center shall not offer or develop home hemodialysis or peritoneal dialysis training services as part of this project.**
  - 5. DVA Healthcare Renal Care, Inc. d/b/a Durham 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.1, page 39, the applicant projects the total capital cost of the project will be \$81,923, including \$59,279 for dialysis machines, \$7,035 for furniture, \$4,875 for dialysis chairs, \$3,234 for chair-side computers, and \$7,500 for televisions. The applicant projects no initial start-up costs or initial operating expenses. The applicant states the capital costs for the proposed project will be funded by cash reserves from DaVita HealthCare Properties, Inc., the parent company of DVA Healthcare Renal Care, Inc. has provided a Capital Funds availability letter from the Chief Accounting Officer of DaVita dated September 6, 2013 [Reference Exhibit 18], which states:

*"I am the Chief Accounting Officer of DaVita HealthCare Partners Inc., the parent and owner of DVA HealthCare Renal Care, Inc. We are submitting a Certificate of Need application to expand our Durham Dialysis Center by five ESRD dialysis stations.*

*The project calls for a capital expenditure of \$81,923. This letter will confirm that DaVita HealthCare Partners Inc. has committed cash reserves in the total sum of \$81,923 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 HealthCare Partners Inc. As of December 31, 2012, DaVita HealthCare Partners, Inc. had \$533,748,000 in cash and cash equivalents, \$2,878,794,000 in total current assets and \$4,508,740,000 in

net assets (total assets 16,018,596,000 less total liabilities 11,509,856,000). Therefore, the applicant adequately demonstrated the availability of funds for the capital needs of the project.

The rates in the following table were provided by the applicant in application Section X.1, page 44 and are the facility's allowable charge per treatment for each payment source and are consistent with the standard Medicare/Medicaid rates established by the Center for Medicare and Medicaid Services. ❶

**Durham Dialysis Center  
 In-Center Medicare/Medicaid Rates**

	In-Center
Commercial Insurance	\$ 1,442.00
Medicare	\$ 202.84
Medicaid	\$ 143.00
Medicare/Medicaid	\$ 253.55
Medicare/Commercial	\$ 253.55
VA	\$ 193.00

In Section X.4, page 47, the applicant projected revenue in excess of expenses in each of the first two operating years following completion of the project, as illustrated in the following table:

**Durham Dialysis Center  
 Net Revenue and Operating Expenses**

	Project Year 1	Project Year 2
Net Revenue	\$3,977,847	\$4,179,626
Operating Expenses	\$3,621,683	\$3,784,154
Profit	\$356,164	\$395,472

The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable. See Section X, pages 44-48, for the applicant's assumptions.

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

❶ [http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/End\\_Stage\\_Renal\\_Disease\\_Pro prospective\\_Payment\\_System\\_INC905143.pdf](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/End_Stage_Renal_Disease_Pro prospective_Payment_System_INC905143.pdf)

- (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

The applicant proposes to add five dialysis stations to the existing DDC facility for a total 29 dialysis stations upon completion of this project. According to the June 2013 SDR, the county need methodology shows there is a surplus of 15 stations in Durham County. However, the applicant is applying for additional stations based on the facility need methodology. The applicant adequately demonstrates the need for five additional stations based on the number of in-center patients it currently serves and proposes to serve. Per the June 2013 SDR, as of December 31, 2012, the 24 station Durham Dialysis Center was operating at 93.75% capacity ( $90/24 = 3.75$ ;  $3.75/4 = .9375$ ). The target utilization is 80% or 3.2 patients per station per week as of the end of the first year of operations after project completion. Based on the calculations above, the applicant is eligible to expand its facility and may apply for additional stations. Upon completion of this project, the facility will have 29 stations serving 101 patients (end of Year 1) which is a utilization rate of 87.07% ( $101/29 = 3.48$ ;  $3.48/4 = .8707$ ). Therefore, the applicant is conforming to the required performance standard in 10A NCAC 14C .2203.

There are eight dialysis facilities in Durham County. The following table shows the distribution of ESRD facilities in Durham County and utilization of dialysis stations based upon data in the July 2013 North Carolina Semiannual Dialysis Report.

**Durham County Dialysis Facilities**

Facility (Stations)	City	Certified Stations	CON Issued Not Certified	Total Stations as of 6/21/2013	Pts. Per Station	% Utilized
Duke Univ. Hospital ESRD	Durham	16	0	16	3.25	81.25%
Durham Dialysis	Durham	24	0	24	3.75	93.75%
Durham West Dialysis	Durham	29	0	29	3.34	83.62%
FMC-Briggs Avenue	Durham	29	0	29	2.55	63.79%
FMC-West Pettigrew	Durham	20	0	20	2.20	55.00%
FMC South Durham	Durham	12	0	12	3.08	77.08%
Freedom Lake Dialysis	Durham	22	0	22	3.27	81.82%
Southpoint (DaVita)	Durham	12	0	12	3.83	95.83%

Source: 2013 North Carolina Semiannual Dialysis Report Table A, Durham County.

The applicant adequately demonstrates that the proposed project will 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.

## C

In Section VII.1, page 34, the applicant provides the current and projected staffing for DDC as shown in the following table:

**Durham Dialysis Center Current and Projected Staffing**

	<b># of Current FTEs</b>	<b># of FTE Positions to be Added</b>	<b># of Projected FTE Positions</b>
RN	5	0	5
PTC	10	2	12
Bio-Med Tech.	1	0	1
Medical Director	Contract Position		
Administrator	1	0	1
Dietitian	1	0	1
Social Worker	1	0	1
Unit Secretary	1	0	1
<b>Total</b>	<b>20</b>	<b>2</b>	<b>22</b>

The applicant indicates a total of 20.0 current FTEs and projects staffing of 22.0 FTEs which includes 2.00 additional PTC positions, upon project completion. The applicant indicates in Section VII.4, page 35; that it does not expect any difficulty in recruiting staff. The information regarding staffing provided in application Section VII and the estimated annual salaries and revenues are reasonable and credible.

In Section VII. 10, page 36, the applicant provides the projected direct care staff upon project completion for each shift as shown below.

**Projected Staffing**

	Times	S	M	T	W	TH	F	SA
Morning	6-10:30A	0	8	8	8	8	8	8
Afternoon	11A-4P	0	8	8	8	8	8	8
Evening	4P-9 P	0	0	0	0	0	0	0

Exhibit 13 contains a letter dated August 13, 2013 in which the current facility Medical Director (a practicing Nephrologist) indicates that he will continue as Medical Director. The applicant adequately documents the availability of resources, including health manpower and management personnel, for the provision of the services to be provided. Therefore, the application is conforming to this criterion.

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

**C**

In Section V. 1, page 25, the applicant includes a list of providers for the necessary ancillary and support services. Duke University Medical Center will provide acute dialysis in an acute setting, emergency care, diagnostic evaluation services, transplantation services, X-Ray

services, blood bank, pediatric nephrology and vascular surgery. Most of the other services will be provided by the applicant. Exhibit 10 includes an agreement between Duke University Medical Center and DDC for "*Transplant Center Evaluation Services.*" Section V.4 (b), page 27 contains a list of physicians who a) support this proposal and/or b) who have expressed a willingness to refer patients to DDC.

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;

C

In Section VI.1 (a), page 30, the applicant states that “Durham Dialysis Center, *by policy, has always made dialysis services available to all residents in its service area without qualifications.*”

Furthermore the applicant states: “*Durham 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. Durham Dialysis Center provides dialysis six days per week with two patient shifts per day to accommodate patient need.*”

*Durham 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 (b), page 30, the applicant indicates that 94.5% of patients at Durham Dialysis Center have some or all of their services paid for by Medicare or Medicaid. The table below illustrates the payer mix for the facility.

Payer Source	Percentage
Medicare	25.6%
Medicaid	17.8%
Medicare/Medicaid	27.8%
Commercial Insurance	4.4%
VA	1.1%
Medicare/Commercial	23.3%
<b>Total</b>	<b>100.0%</b>

The applicant further states in Section VI.1 (d), page 31 of the application:

*“The Durham 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 Durham Dialysis Center.”*

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 and statewide.

**Durham County-State of North Carolina Comparison  
Percent Medicaid and Uninsured**

County	Total # of Medicaid Eligible's as % of Total Population	Total # of Medicaid Eligible's Age 21 and older as % of Total Population	% Uninsured CY 2008 & 2009 (Estimate by Cecil G. Sheps Center)
Durham	15.6%	5.7%	20.1%
Statewide	16.5%	6.7%	19.7%

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

The majority of Medicaid 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 DDC. In fact, in 2011 only 5.8% of all newly-diagnosed ESRD patients (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 are available by age, race or gender. However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender do 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.

According to the CMS website, in 2008, about 95% of dialysis patients were covered by Medicare. About 25% of the Medicare-covered patients had employer group health plans as primary insurance, with Medicare as the secondary payer. Also, the 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 four 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.”*

Additionally, the United States Renal Data System, in its 2012 USRDS Annual Data Report provides these national statistics for FY 2010: *“On December 31, 2010, more*

than 376,000 ESRD patients were receiving hemodialysis therapy.” 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.”*

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

<b>ESRD Spending by Payor</b>		
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%

The Southeastern Kidney Council (SKC) provides Network 6, 2011 Incident ESRD patient data by age, race and gender, as shown below:

<b>Number and Percent of Dialysis Patients by Age, Race, and Gender</b>		
Age	# of ESRD Patients	% of Dialysis Population
0-19	89	1.0%
20-34	451	4.8%
35-44	773	8.3%
45-54	1529	16.4%
55-64	2370	25.4%
65-74	2258	24.2%
75+	1872	20.0%
<b>Gender</b>		
Female	4,237	45.35%
Male	5,105	54.65%
<b>Race</b>		
African-American	5,096	54.55%
White	4,027	43.11%
Other	219	2.3%
Total	9,342	100.0%

The applicant demonstrated 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

In Section VI.1 (f), page 31 the applicant states:

*“Durham 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.”* Therefore, the application is conforming to this criterion.

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

C

In Section VI.1(c), page 31, the applicant does not anticipate a change in the payer mix resulting from this proposal, as illustrated in the table below.

**Projected Payer Mix**

Payer Source	Percentage
Medicare	25.6%
Medicaid	17.8%
Medicare/Medicaid	27.8%
Commercial Insurance	4.4%
VA	1.1%
Medicare/Commercial	23.3%
<b>Total</b>	<b>100.0%</b>

As illustrated in the above table, the applicant projects that 94.5% percent of patients at DDC will have some or all their services paid for by Medicare or Medicaid.

The applicant demonstrated that it will provide adequate access to the elderly and the 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 (a), page 32, the applicant states:

*“Patients with End Stage Renal Disease have access to dialysis services upon referral to a Nephrologist with privileges at Durham Dialysis Center. These referrals most commonly come from primary care physicians or specialty physicians in Durham County or transfer referrals from other Nephrologists outside of the immediate area. Patients, families and friends can obtain access by contacting a Nephrologist with privileges at the facility. Should a patient contact the Durham Dialysis Center directly or indirectly, the patient is referred to a qualified Nephrologist for evaluation and subsequent admission if medically necessary. Patients from outside the Durham Dialysis Center catchment area requesting transfer to this facility are processed in accordance with the Durham Dialysis Center transfer and transient policies which comprise Exhibit 14.”*

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 application Section V.3 (a), page 27, the applicant indicates that Exhibit 12 contains a Student Training Agreement with Durham Technical Community College in which DDC is offered as a training site for nursing students at the community college.

The information provided in application Section V is reasonable and credible and supports a finding of conformity with 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 five dialysis stations to its existing facility, for a total of 29 stations upon completion of the project.

According to the July 2013 SDR, Durham Dialysis Center is one of eight existing dialysis facilities in Durham County with utilization rates ranging from 55% to 96%. See the following table for a list of Durham County dialysis facilities and number of stations.

**Durham County Dialysis Facilities**

Facility (Stations)	City	Certified Stations	CON Issued Not Certified	Total Stations as of 6/21/2013	Pts. Per Station	% Utilized
Duke Univ. Hospital ESRD	Durham	16	0	16	3.25	81.25%
Durham Dialysis	Durham	24	0	24	3.75	93.75%
Durham West Dialysis	Durham	29	0	29	3.34	83.62%
FMC-Briggs Avenue	Durham	29	0	29	2.55	63.79%
FMC-West Pettigrew	Durham	20	0	20	2.20	55.00%
FMC South Durham	Durham	12	0	12	3.08	77.08%
Freedom Lake Dialysis	Durham	22	0	22	3.27	81.82%
Southpoint (DaVita)	Durham	12	0	12	3.83	95.83%

Source: 2013 North Carolina Semiannual Dialysis Report Table A, Durham County.

In Section V.7 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 that this proposal will not have any effect on competition in Durham County. DVA Healthcare Renal Care operates Southpoint Dialysis and Durham West Dialysis Center. The Nephrologists from Duke University Medical Center are the only physicians that admit and round patients at Southpoint Dialysis, Durham West Dialysis Center and Durham Dialysis Center.

Fresenius Medical Care operates four other dialysis facilities in Durham County. They receive patients from a separate group of Nephrologists located in Durham. The applicant maintains that they do not compete with the Fresenius facilities for patients. See Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition include a positive impact on cost-effectiveness, quality, and access to services in Durham County. This determination is base on information in the application and the following analysis:

- The applicant adequately demonstrates the need to add five dialysis stations, and that it is a cost-effective alternative to meet the patient volume at the Durham Dialysis Center;
- The applicant adequately demonstrated that it will continue to provide quality services;

- The applicant adequately demonstrated that it will continue to provide adequate access to medically underserved populations.

Therefore, the application is conforming to this application.

- (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 applicant currently provides dialysis services at Durham Dialysis Center. According to files of the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, Durham Dialysis Center operated in compliance with the Medicare Conditions of Participation within the 18 months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

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

C

The Criteria and Standards for End Stage Renal Disease Services, as promulgated in 10A NCAC 14C Section .2200, are applicable to this review. The proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services as required by 10A NCAC 14C .2200. The specific findings are discussed below.

**.2202 INFORMATION REQUIRED OF APPLICANT**

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

*.2202(a)(1) Utilization rates;*

-C- Utilization-July 2013 SDR-93.75% or 3.75 patients per station

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

-C- In Section IV.2, page 23 the applicant provides the following mortality rates-Year 2010-17.0%, 2011-11.5%, and 2012-12.7%.

- .2202(a)(3) *The number of patients that are home trained and the number of patients on home dialysis;*  
-C- Home Training is provided through Durham West Dialysis
- .2202(a)(4) *The number of transplants performed or referred;*  
-C- See Section IV.4, page 24, Transplants referred-6 and Transplants performed-1, in 2012.
- .2202(a)(5) *The number of patients currently on the transplant waiting list;*  
-C- See Section IV.5, page 24, 6 patients on the waiting list.
- .2202(a)(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related.*  
-C- See Section IV.6, page 24.-Dialysis related-77 and non-dialysis related-112.
- .2202(a)(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.*  
-C- See Section IV.7, page 24-0.

(b) *An applicant that proposed develop a new facility, to increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:*

- .2202(b)(1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.*  
-NA- DDC is an existing facility.
- .2202(b)(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*  
(A) *timeframe for initial assessment and evaluation of patients for transplantation,*  
(B) *composition of the assessment/evaluation team at the transplant center,*  
(C) *method for periodic re-evaluation,*  
(D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and*  
(E) *signatures of the duly authorized persons representing the facilities and the agency providing the services.*  
-NA- DDC is an existing facility.
- .2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*  
-NA- DDC is an existing facility.
- .2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*

- C- See Section XI.6 (f), page 53.
- .2202(b)(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*
- NA- DDC is an existing facility.
- .2202(b)(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, and other relevant health and safety requirements.*
- C- See Section XI.6 (g), page 53.
- .2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C- See Section III.7, pages 20-21, and discussion in Criterion (3) for discussion which is hereby incorporated by reference as if fully set forth herein.
- .2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
- NA- DDC is an existing facility.
- .2202(b)(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*
- C- See Section II, 10A NCAC 14C .2202 (9) page 12.

### **.2203 PERFORMANCE STANDARDS**

- .2203(a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per 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- DDC is an existing facility.

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

-C- In Section III.7, pages 20-22 the applicant projects to serve 101 in-center patients by the end of Year 1, which equates to 3.48 patients per station per week [101 / 29 = 3.48]. Further, the applicant projects to serve 106 in-center patients by the end of Year 2, which equates to 3.66 patients per station per week [106 / 29 = 3.66]. See Criterion (3) for discussion which is hereby incorporated by reference as if fully set forth herein.

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

-C- See Section II.1, pages 12-17, In Section III.7, pages 20-22, the applicant provides the assumptions and methodology used to project utilization of the additional stations. See Criterion (3) for discussion which is hereby incorporated by reference as if fully set forth herein.

#### **.2204 SCOPE OF SERVICES**

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

.2204(1) *Diagnostic and evaluation services;*

-C- See Section V.1 (e), page 25. Duke University Medical Center

.2204(2) *Maintenance dialysis;*

-C- See Section V.1 (c), page 25. Provided by the applicant on Site.

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

-C- Provided through Durham West Dialysis.

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

-C- Provided through Durham West Dialysis.

.2204(5) *X-ray services;*

-C- See Section V.1 (g), page 25. Duke University Medical Center

.2204(6) *Laboratory services;*

C See Section V. 1, page 25, Dialysis Laboratories.

.2204(7) *Blood bank services;*

-C- See Section V.1, page 25. Duke University Medical Center.

.2204(8) *Emergency care;*

-C- See Section V.1 (b), emergency care provided by Duke University Medical Center.

.2204(9) *Acute dialysis in an acute care setting;*

-C- See Section V.1 (a), page 25. Duke University Medical Center

- .2204(10) *Vascular surgery for dialysis treatment patients;*
  - C- See Section V.1 (p), page 26. Duke University Medical Center
- .2204(11) *Transplantation services;*
  - C- See Section V.1 (f), page 25. Duke University Medical Center
- .2204(12) *Vocational rehabilitation counseling and services; and*
  - C- See Section V. 1 (o), page 25. North Carolina Department of Vocational Rehabilitation.
- .2204(13) *Transportation*
  - C- See Section V.1 (q), page 26. DSS/First Transit.

## **.2205 STAFFING AND STAFF TRAINING**

- .2205(a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R., Section 494 (formerly 405.2100)*
  - C- See Section VII.1, page 34 the applicant provides the existing and proposed staffing. In Section VII, 2, page 34-35 the applicant states, the proposed facility will comply with all staffing requirements set forth in the Federal code. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. See Criterion (7) for discussion which is incorporated hereby as if set forth fully herein.
- .2205(b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*
  - C- See Section VII.5, page 36 and Exhibit 17 for outline of continuing education programs.