

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: November 21, 2013  
PROJECT ANALYST: Gene DePorter  
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: J-10212-13/ DVA Healthcare Renal Care, Inc. d/b/a Southpoint Dialysis / Add four dialysis stations for a total of 16 stations/ Durham 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

The applicant, DVA Healthcare Renal Care, Inc. d/b/a Southpoint Dialysis (SPD), operates 12 certified dialysis stations at 415 West Highway 54, Durham. The applicant proposes to add four additional dialysis stations for a total of 16 stations upon project completion.

The 2013 State Medical Facilities Plan (2013 SMFP) provides a county need and a 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 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 Southpoint Dialysis in the July 2013 SDR is 3.83 patients per station and the utilization percentage is 95.83%. The utilization was calculated based on 46 in-center dialysis patients and 12 certified dialysis stations as of 12/31/2012 [46 patients / 12 stations = 3.83 patients per stations, 3.83 patients per station / 4 patients per station =

DVA d/b/a Southpoint Dialysis  
 J-10212-13 Add Four Stations  
 Page 2

95.83%]. Therefore, the application of the facility need methodology indicates additional stations are needed for this facility, as illustrated in the following table.

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

Required SDR Utilization		80%
Center Utilization Rate as of 12/31/12		96%
Certified Stations		12
Pending Stations		0
Total Existing and Pending Stations		12
In-Center Patients as of 12/31/12 (SDR2-January 2013)		46
In-Center Patients as of 6/30/12 (SDR1-July 2013)		38
Step	Description	Result
(i)	Difference (SDR2 – SDR1)	8
	Multiply the difference by 2 for the projected net in-center change	16
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/12 (SRD 1)	.4210526
(ii)	Divide the result of step (i) by 12	.0350877
(iii)	Multiply the result of step (ii) by the number of months from the most recent month reported in the July 2013 SDR (12/31/12) until the end of calendar year 2013. (12 months)	.4210524
(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	65.36842
(v)	Divide the result of step (iv) by 3.2 patients per station	20.42763
	and subtract the number of certified and pending stations as recorded in SDR2 [12] to determine the number of stations needed	8

As shown in the above table, based on the facility need methodology for dialysis stations the potential number of stations needed is 8.0 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 four dialysis stations and therefore is consistent with the facility need determination for dialysis stations.

Policy GEN-3: Basic Principles, on pages 42-43 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.3, page 17, the applicant states how the proposed plan will insure quality care. The applicant states:

*“DaVita HealthCare Partners Inc. is committed to providing quality care to the ESRD population through a comprehensive Quality Management Program. DaVita’s Quality Management Program is facilitated by a dedicated clinical team of RN and Biomedical Quality Management Coordinators working under the direction of our Director of Quality Management and Director of Integrated Quality Development. Those efforts receive the full support and guidance of the clinical executive leadership team of DaVita. Combined, this group brings hundreds of years of ESRD experience to the program. 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. 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 improvement programs.*

- *Quality Biomedical Team – experienced specialists in all aspects of Biomedical requirements (i.e., water treatment, reuse, disinfection and machine maintenance).*

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

- *Improve patient outcomes*
- *Provide patient and staff training*
- *Develop Quality Improvement Programs*
- *Facilitate the Quality Improvement Process*
- *Continuously improve care delivered*
- *Assure facilities meet high quality standards”*

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 82.6% 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:

*“Southpoint Dialysis, 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, pages 21-22, the applicant states how the addition of four certified stations will allow Southpoint Dialysis to maximize healthcare value. The applicant states:

*“Southpoint Dialysis 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.*
- *Southpoint Dialysis 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.*
- *Southpoint Dialysis 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.*
- *Southpoint Dialysis 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.*
- *Southpoint Dialysis 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.*
- *Southpoint Dialysis 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. 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 energy efficiency 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 \$65,439. Therefore, Policy GEN-4 is not applicable.

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.

## C

The applicant, DVA Healthcare Renal Care, Inc. d/b/a Southpoint Dialysis, proposes to add four dialysis stations for a total of 16 stations upon completion of this project. The facility is located at 415 West Highway 54, Durham. The July 2013 SDR indicates a total of 46 in-center patients being served on 12 certified stations as of December 31, 2012.

### Population to be Served

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

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

County of Residence	# of Patients Dialyzing In-Center	# of Patients Home Trained	Percentage
Durham	39	0	85.0%
Wake	5	0	11.0%
Chatham	1	0	2.2%
Orange	1	0	2.2%
<b>Total</b>	<b>46</b>	<b>0</b>	<b>100.0%</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:

**Southpoint 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	47	0	51	0	86.0%	85.0%
Wake	6	0	7	0	11.0%	12.0%
Chatham	1	0	1	0	2.0%	2.0%
Orange	1	0	1	0	2.0%	2.0%
<b>Total</b>	<b>55</b>	<b>0</b>	<b>60</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:

*“Southpoint Dialysis had 46 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 95% based on 12 certified stations in the facility. The January 2013 Semiannual Dialysis Report indicated that Southpoint Dialysis had 38 in-center patients as of 6/30/2012, which is an increase of eight in-center patients in a six month period. This calculates to a growth of 21%*

*...Based on the patients and stations above, Southpoint Dialysis is projected to have at least 55 in-center patients by the end of operating year1 for a utilization of 85% or 3.4 patients per station and at least 60 in-center patients by the end of*

*operating year 2 for a utilization rate of 93% or 3.7 patients per station. This information is based on the calculations below.*

*The period of the growth begins with January 1, 2013 forward to December 31, 2016. The following are the in-center patient projections using a conservative growth rate of 8% or less than one half of the 2012 Southpoint Dialysis growth rate.*

*January 1, 2013-June 30, 2013 –46 in-center patients X 1.04=47.84*

*July 1, 2013-June 30, 2014 – 47.84 in- center patients X 1.08=51.6672*

*July 1, 2014-June 30, 2015 – 51.6672 in-center patients X 1.08=55.800576*

*July 1, 2015–June 30, 2016-55.800576 in-center patients X 1.08 = 60.264622*

*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 55 in-center patients or 3.44 patients per station ( $55/16 = 3.44$ ) by the end of Year 1 and 60 in-center patients or 3.75 patients per station ( $60/16 = 3.75$ ) by the end of Year 2 for the proposed 16 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 82.6% of the patients at SPD will be covered by Medicare and Medicaid. The applicant demonstrates adequate access for the underserved of SPD.

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 four 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, the applicant discusses the two alternatives it considered to meet the need for the proposed services. The first alternative is to do nothing. This alternative was dismissed since the facility has a need for 8 additional dialysis stations. The applicant is only requesting 4 additional stations. The second alternative of adding 4 stations to continue to meet the “rapidly growing demand” for dialysis services at Southpoint Dialysis was chosen. The application is conforming to the facility need methodology for additional stations. The application is conforming to all other applicable statutory and regulatory review criteria, and thus is approvable. A project that cannot be approved cannot be an effective alternative. The applicant adequately demonstrated that the proposal to add four dialysis stations is its least costly or most effective alternative. Consequently, the application is conforming to this criterion and approved subject to the following conditions:

1. **DaVita Healthcare Renal Care, Inc. d/b/a Southpoint Dialysis shall materially comply with all representations made in the certificate of need application.**
2. **DaVita Healthcare Renal Care, Inc. d/b/a Southpoint Dialysis shall develop no more than four additional stations for a total of 16 stations upon completion of this project, which shall include any home hemodialysis training or isolation stations.**
3. **DVA Healthcare Renal Care, Inc. d/b/a Southpoint Dialysis shall install plumbing and electrical wiring through the walls for no more than a total of 16 dialysis stations, including any home hemodialysis training or isolation stations.**
4. **DVA Healthcare Renal Care, Inc. d/b/a Southpoint Dialysis shall not offer or develop home hemodialysis or peritoneal dialysis training services as a part of this project.**

5. **DVA Healthcare Renal Care, Inc. d/b/a Southpoint Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to insurance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII.1, page 39, the applicant projects the total capital cost of the project will be \$65,439. The following table shows the capital cost components and related estimated capital expenses, as follows:

**Southpoint Dialysis-Project Capital Costs**

<b>Miscellaneous</b>	<b>Capital Cost</b>
Dialysis Machines	\$ 47,423
Equipment and Furniture	\$ 5,960
Dialysis Chairs (Other)	\$ 3,900
Televisions	\$ 6,000
Chairside Computers	\$ 2,156
<b>Total Capital Costs</b>	<b>\$ 65,439</b>

The applicant projects no initial start-up costs or initial operating expenses. The applicant states the capital costs for the proposed project will be funded by cash reserves from DaVita HealthCare Partners, Inc, the parent company of DVA Healthcare Renal Care, Inc. In Exhibit 18, the applicant provided a Capital Funds Availability letter dated September 6, 2013, which states:

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

*The project calls for a capital expenditure of \$65,439. This letter will confirm that DaVita HealthCare Partners Inc. has committed cash reserves in the total sum of \$65,439 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 Medicare/Medicaid rates in Section X.1, page 44 of the application and the following table, are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services.

**Allowable Charge per Treatment  
 By Payment Source**

Source of Payment	
Medicare	\$202.84
Medicaid	\$143.00
Medicaid/Medicare	\$253.55
Commercial Insurance	\$1,442.00
VA	\$193.00
Medicare/Commercial	253.55

In Section X.4, page 47, 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.

**Net Revenue and Operating Expenses**

	Project Year 1	Project Year 2
Net Revenue	\$3,425,281	\$3,715,543
Operating Expenses	\$2,493,384	\$2,665,901
Profit	\$931,897	\$1,049,642

In summary, the applicant adequately demonstrates the availability of sufficient funds for the operating expenses of this project. The applicant also demonstrates that the financial feasibility of the proposal is based on reasonable projections regarding 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.

C

The Southpoint Dialysis Center proposes to add four dialysis stations to the existing facility for a total of 16 stations upon completion of the proposed project. According to the June 2013 SDR, the County need methodology shows there is a surplus of 15

dialysis stations in Durham County. However, the applicant is applying for additional stations based on the facility need methodology. The applicant adequately demonstrated the need for four additional stations based on the number of in-center patients it currently serves and proposes to serve. The June 2013 SDR data for December 31, 2012, indicates that Southpoint Dialysis was operating at 95.83% capacity ( $46/12 = 3.83$ ;  $3.83/4 = .9583$ ). The target utilization is 80% and 3.2 patients per station per week as of the end of the first operating year 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 16 stations serving 55 patients (end of Year 1) which is a utilization rate of 85.94% ( $55/16 = 3.44$ ;  $3.44/4 = .8594$ ). Therefore, the applicant is conforming to the required performance standard in 10A NCAC 14C. 2203.

There are eight dialysis facilities in Durham County including Southpoint Dialysis. The following table shows the distribution, operating profile and utilization of ESRD facilities in Durham County 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.

Five of the eight facilities are currently operating with utilization above 80% including Southpoint Dialysis with utilization of 95.83%. See Criteria (1) and (3) for additional discussion. Consequently, the applicant adequately demonstrated that the proposal would not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Therefore, the application is conforming to this criterion.

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

In Section VII.1 page 34, the applicant provides current and projected staffing by position and salary for Southpoint Dialysis. The applicant anticipates adding 3.9 FTEs.

In Section VII. 11, page 34, the applicant provides the following table indicating current and projected direct care staff.

**Southpoint Dialysis Staffing**

Position Title	Current FTEs	Project Year 1	Projected Annual Salary Year 1/FTE	Projected Annual Salary Year 2/FTE
<b>RN</b>	2.0	2.0	\$70,019	\$72,120
<b>PCT</b>	4.5	6.0	\$26,523	\$27,319
<b>Bio-Med Tech</b>	0.3	0.5	\$43,709	\$45,020
<b>MD</b>	Contract Position		\$72,000	\$72,000
<b>Admin</b>	0.0	1.0	\$79,567	\$81,954
<b>Dietitian</b>	0.4	0.5	\$58,350	\$60,101
<b>Social Worker</b>	0.4	0.5	\$58,350	\$60,101
<b>Unit Secretary</b>	0.0	1.0	\$28,957	\$29,826
<b>Total</b>	<b>7.6</b>	<b>11.5</b>		

The applicant indicates a total of 7.6 current FTEs and projects staffing of 11.5 FTEs. The applicant indicates in Section VII. 4, page 35 that it does not expect any difficulty in recruiting staff.

Exhibit 13 contains a support letter dated August 13, 2013 from the current medical director at Southpoint Dialysis. On page 34 the applicant indicates that the facility complies with all staffing requirements as stated in 42 C.F.R. Section 405.2100.

In Section VII. 10, page 36 the applicant provides the projected direct care staff for each shift offered in the facility as shown in the table below.

**Projected Staffing**

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

The applicant adequately demonstrated the availability of resources, including health manpower and management personnel for the proposed service. Therefore, the applicant 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 states that 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. The applicant lists the following exhibits that document agreements with providers of the necessary ancillary and support services:

Exhibit 9 -Patient Transfer Agreement,  
Exhibit 10-Transplant Agreement,  
Exhibit 11-Home Training Referral Agreement

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 SPD. 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. The information in Section V, pages 25-28 and the above referenced exhibits is reasonable and credible and supports a finding of conformity with this criterion. Therefore, the applicant 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

NA

- (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 “*Southpoint Dialysis, by policy, has always made dialysis services available to all residents in its service area without qualifications.*”

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

*Southpoint Dialysis 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 82.6% of patients at Southpoint Dialysis have some or all of their services paid for by Medicare or Medicaid. The table below illustrates the payer mix for the facility.

**Historical Payer Mix**

Payer Source	Percentage
Medicare	19.6%
Medicaid	13.0%
Medicare/Medicaid	17.4%
Commercial Insurance	17.4%
VA	0.0%
Medicare/Commercial	32.6%
<b>Total</b>	<b>100.0%</b>

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

*“Southpoint Dialysis 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 Southpoint Dialysis.”*

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	Total # of Medicaid Eligible’s Age 21 and older as % of Total Population	% Uninsured CY 2008& 2009 (Estimate by Cecil G. Sheps Center)

	Population		
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, were 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 Southpoint Dialysis. 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:

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

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	19.6%
Medicaid	13.0%
Medicare/Medicaid	17.4%
Commercial Insurance	17.4%
Medicare/Commercial	32.6%
<b>Total</b>	<b>100.0%</b>

As illustrated in the above table, the applicant projects that 82.6% percent of patients at Southpoint Dialysis will have some or all their services paid for by Medicare or Medicaid.

In Section VI.2, page 32, the applicant states that SPD satisfies all state requirements and local building codes to allow equal access for handicapped

persons and ensures access by these individuals by providing wheelchair ramps, handicapped bathrooms, wheelchair scales and ADA doors.

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 Southpoint Dialysis. 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 Southpoint Dialysis directly or indirectly, the patient is referred to a qualified Nephrologist for evaluation and subsequent admission if medically necessary. Patients from outside the Southpoint Dialysis catchment area requesting transfer to this facility are processed in accordance with the Southpoint Dialysis 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, page 27, the applicant indicates that Exhibit 12 contains a copy of a letter from the applicant to Durham Technical Community College offering the use of Southpoint Dialysis as a clinical training site. The applicant adequately demonstrates that the facility will accommodate the clinical needs of health professional training programs in the service area. Therefore, the application is conforming to this criterion.

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

C

Southpoint Dialysis Center proposes to add four dialysis stations to its existing facility for a total of 16 stations upon completion of this project.

According to the July 2013 SDR, Southpoint Dialysis is one of 8 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	Number of Dialysis Stations as of 12/31/ 2012				Utilization
	Certified Stations	CON Issued/ Not Certified	Decision Rendered-CA	Decision Pending	
Duke University Hospital	16	0	0	0	81.25%
Durham Dialysis	24	0	0	0	93.75%
Durham West Dialysis	29	0	0	0	83.62%
FMC Dialysis Services- Briggs Avenue	29	0	0	0	63.79%
FMC Dialysis Services-West Pettigrew	20	0	0	0	55.00%
FMC South Durham Dialysis	12	0	0	0	77.08%
Freedom Lake Dialysis	22	0	0	0	81.82%
Southpoint Dialysis	12	0	0	0	95.83%
Total	164	0	0	0	

Source: July 2013 SDR

In Section V.7, page 28, 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 also 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 and are supported by a separate group of Nephrologists located in Durham. The applicant indicates that they do not compete with the Fresenius facilities for patients.

According to the applicant, adding four stations will reduce utilization measures to more acceptable levels and support positive outcomes related to cost-efficiency, quality and access at Southpoint Dialysis. See also Sections II, III, V, VI and VII. 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 based on information in the application and the following analysis:

- Southpoint Dialysis adequately demonstrates the need to add four dialysis stations and that it is a cost-effective alternative to meet the patient volume at Southpoint Dialysis,
- The applicant adequately demonstrates 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 applicant 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 Southpoint Dialysis. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, Southpoint Dialysis 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.

**.2202 INFORMATION REQUIRED OF APPLICANTS**

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

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

-C- July 2013 SDR utilization rate was 95.83% or 3.83 patients per station as of December 31, 2012.

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

-C- See Section IV.2, page 23. The 2012 mortality rate was 14.3%.

*.2202(a)(3) The number of patients that are home trained and the number of patients on home dialysis;*

-C- See Section IV.3, page 23. Home Dialysis Training is provided by Durham West Dialysis Center.

*.2202(a)(4) The number of transplants performed or referred;*

-C- See Section IV.4, page 23. Sixteen patients were referred in 2011 for transplant. Four kidney transplants were received in 2012.

*.2202(a)(5) The number of patients currently on the transplant waiting list;*

-C- See Section IV.5, page 24. There are eight patients on the kidney transplant wait 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. There were 27 dialysis related hospital admissions in 2012 and 42 non-dialysis related hospital admissions.

.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. As of 12/31/2012 there were no dialysis patients with Hepatitis B and 1 patient with AIDS. No patients converted to infectious status during the last year.

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

.2202(b)(1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.*

-NA- Southpoint Dialysis 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- Southpoint Dialysis 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- Southpoint Dialysis 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- Exhibit 8 contains written policies and procedures for electrical service in the event of a power outage.

- .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- Southpoint Dialysis 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- In Section XI. 6(g), page 53, the applicant states “Southpoint Dialysis 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.”
- .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, for assumptions and methodology. See Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.
- .2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
- NA- Southpoint Dialysis 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, the applicant states that it will admit and provide dialysis services to patients who have no insurance or other source of payment, if payment for dialysis is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for

such service.

### **.2203 PERFORMANCE STANDARDS**

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

-NA- Southpoint Dialysis 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 55 in-center patients or 3.4 patients per station [ $55 / 16 = 3.4$ ] by the end of Year 1 for the proposed 16-station facility.

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

-C- In Section III.7, pages 20-21, the applicant provided the assumptions and methodology used to project utilization for four additional stations. See Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.

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

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

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

-C- See Section V.1, page 25.-Diagnostic evaluation services will be provided by Duke University Medical Center. See Exhibit 9.

*.2204(2) Maintenance dialysis;*

-C- See Section V.1, page 25. Provided by the applicant on site.

- .2204(3) *Accessible self-care training;*  
-C- See Section V.1, page 25. Self Care Training provided by Durham West Dialysis. See Exhibit 11.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*  
-C- See Section V.1, page 25. Support of patients dialyzing at home is provided by Durham West Dialysis. See Exhibit 11.
- .2204(5) *X-ray services;*  
-C- See Section V.1 (g), page 25. Provided at Duke University Medical Center.
- .2204(6) *Laboratory services;*  
-C- See Section V.1 (h)(1-3), page 25. Provided by Dialysis Laboratories
- .2204(7) *Blood bank services;*  
-C- See Section V.1 (i), page 25. Provided by Duke University Medical Center.
- .2204(8) *Emergency care;*  
-C- See Section V.1, page 25. Provided by Duke University Medical Center. See Exhibit 9.
- .2204(9) *Acute dialysis in an acute care setting;*  
-C- See Section V.1, page 25. Provided by Duke University Medical School.
- .2204(10) *Vascular surgery for dialysis treatment patients;*  
-C- See Section V.1, page 25. To be provided by Duke University Medical Center. See Exhibit 9.
- .2204(11) *Transplantation services;*  
-C- See Section V.1, page 25. Service to be provided by Duke University Medical Center. See Exhibit 10.
- .2204(12) *Vocational rehabilitation counseling and services;*  
-C- See Section V.1, page 25. Provided by the North Carolina Department of Vocational Rehabilitation.

.2204(13) *Transportation*

-C- See Section V.1, page 25. To be provided by 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 405.2100.*

-C- See Section VII, page 34.

.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 Exhibits 16 and 17.