

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: December 17, 2018

Findings Date: December 17, 2018

Project Analyst: Bernetta Thorne-Williams

Team Leader: Gloria Hale

Project ID #: J-11600-18

Facility: Southpoint Dialysis

FID #: 090117

County: Durham

Applicant: DVA Renal Healthcare, Inc.

Project: Add six dialysis stations for a total of 16 dialysis stations upon completion of this project and Project I.D. # J-11544-18

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §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 Renal Healthcare, Inc., (DVA) d/b/a Southpoint Dialysis, whose parent company is DaVita, Inc., proposes to add six dialysis stations for a total of 16 dialysis stations upon completion of this project and Project I.D. # J-11544-18 (relocate six dialysis stations from Southpoint Dialysis and four stations from Durham West Dialysis to develop a new 10 station facility to be known as Hope Valley Dialysis).

Need Determination

The 2018 State Medical Facilities Plan (2018 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table D in the July 2018 Semiannual Dialysis Report (SDR) the county need methodology shows there is a surplus of 22 dialysis stations in Durham County. An applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. 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 in the July 2018 SDR is 4.75 patients per station per week, or 118.75% ($4.75 / 4$ patients per station = 1.1875). This utilization rate was calculated based on 76 in-center dialysis patients and 16 certified dialysis stations (76 patients / 16 stations = 4.75 patients per station per week).

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

OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/17		118.75%
Certified Stations		16
Pending Stations		0
Total Existing and Pending Stations		16
In-Center Patients as of 12/31/17 (July 2018 SDR) (SDR2)		76
In-Center Patients as of 6/30/17 (Jan 2018 SDR) (SDR1)		79
Step	Description	Result
	Difference (SDR2 - SDR1)	-3
(i)	Multiply the difference by 2 for the projected net in-center change	-6
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/17	-0.0759
(ii)	Divide the result of Step (i) by 12	-0.0063
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/16 until 12/31/17)	-0.0759
(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	70.2278
(v)	Divide the result of Step (iv) by 3.2 patients per station	21.9462
	and subtract the number of certified and pending stations to determine the number of stations needed	5.9462

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

Policies

Policy GEN-3 on page 33 of the 2018 SMFP is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

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

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B.4, page 9, Section K.1(g), page 39, Section N.1, page 49, Section O, page 50, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B.4, page 10, Section C, page 13, Section L, pages 43-47, Section N.1, page 49, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section B.4, page 11, Section C.1, pages 13-15, Section F, pages 23-27, Section K, pages 38-39, Section N, page 49, and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would maximize healthcare value.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 proposes to add six dialysis stations for a total of 16 dialysis stations upon completion of this project and Project I.D. # J-11544-18 (relocate six dialysis stations to Hope Valley Dialysis).

Patient Origin

On page 365, the 2018 SMFP defines the service area for dialysis stations as, “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Durham County. Facilities may serve residents of counties not included in their service area.

In Section C.1, page 13 and Section C.8, page 18, the applicant provides the projected and historical patient origin for Southpoint Dialysis, respectively, as illustrated in the table below.

Southpoint Dialysis
J-11600-18
Page 5

	Southpoint Dialysis*					
	CURRENT AS OF 12/31/2017		OPERATING YEAR 1 CY2020	OPERATING YEAR 2 CY2021	COUNTY PATIENTS AS A PERCENT OF TOTAL IN-CENTER PATIENTS	
	IN-CENTER PATIENTS	% OF TOTAL	IN-CENTER PATIENTS	IN-CENTER PATIENTS	OY1	OY 2
Durham	59.0	77.6%	33.0 [35.0]	35.0 [36.0]	66.0% [67.3%]	67.3% [67.9%]
Alamance	1.0	1.3%	1.0	1.0	2.0% [1.9%]	1.9%
Chatham	1.0	1.3%	1.0	1.0	2.0% [1.9%]	1.9%
Orange	6.0	7.9%	6.0	6.0	12.0% [11.5%]	11.5% [11.3%]
Wake	8.0	10.5%	8.0	8.0	16.0% [15.4%]	15.4% [15.1%]
Georgia	1.0	1.3%	1.0	1.0	2.0% [1.9%]	1.9%
TOTAL	76.0	100.0%	50.0 [52.0]	52.0 [53.0]	100.0%	100.0%

*Project Analyst's corrections are in brackets which are based on Section C, page 14, and the pro forma financial statements.

In the table on page 13, the applicant projects to serve 50 in-center patients in OY1 and 52 in-center patients in OY2. However, based on information provided in Section C, page 14, and the pro forma financial statements, the applicant actually projects to serve 52 in-center patients in OY1 and 53 patients in OY2. In Section C, pages 13-15, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 13-15, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services.

On page 13, the applicant states,

“Southpoint Dialysis had 76 in-center patients as of December 31, 2017 based on information included in Table B of the July 2018 Semiannual Dialysis Report (SDR). This is a station utilization rate of 118.75% based on the 16 certified stations.”

Table B of the July 2018 SDR confirms the utilization rate mentioned above at Southpoint Dialysis.

On pages 13-15, the applicant provides the following assumptions:

- In Project I.D. # J-11544-18, the applicant proposed to relocate six stations from Southpoint Dialysis and four stations from West Durham Dialysis to develop a new 10 station facility, Hope Valley Dialysis. As a part of that project, the applicant projected to transfer 28 in-center patients from Southpoint Dialysis to the proposed new facility as of January 1, 2020.
- The applicant uses the Five-Year Average Annual Change Rate (AACR) for Durham County, which is 3.0%, to project the Durham County patient population forward.
- The applicant does not project an increase in the patient population from the 17 patients who reside outside of Durham County.
- Operating Year 1 (OY1) = Calendar Year (CY) 2020.
Operating Year 2 (OY2) = Calendar Year (CY) 2021.

Projected Utilization

In Section C, page 14, the applicant provided the methodology used to project in-center utilization, as illustrated in the following table,

Projected In-center Utilization Southpoint Dialysis

Beginning service area census	Start date	# of service area patients	x	Growth Rate	=	Service Area year end census	+	# out of service area patients	=	Total Year- end census	Year-end date
Current Year	1/1/18	59	x	1.03	=	60.77	+	17	=	77.77	12/31/18
Interim Period	1/1/19	60.77	x	1.03	=	62.5931	+	17	=	79.5931	12/31/19
Census OY 1	1/1/20	62-28=34	x	1.03	=	35.02	+	17	=	52.02	12/31/20
Census OY2	1/1/21	35.02	x	1.03	=	36.0706	+	17	=	53.0706	12/31/21

The applicant provides the assumptions for the projected in-center utilization on pages 13-15, as summarized below:

- OY1 is the period from January 1 through December 31, 2020.
- OY2 is the period from January 1 through December 31, 2021.
- As of January 2020, 34 in-center patients from Durham County and 17 patients from outside Durham County will continue to dialyze at Southpoint Dialysis.
- Six stations will be relocated to Hope Valley Dialysis and 28 patients are projected to transfer their care to the proposed new facility.
- The Durham County patient census will grow at the Durham County Five Year AACR of 3.0%, as reported in the July 2018 SDR, and the Alamance, Chatham, Orange, and Wake counties patient census will be held constant as will the one patient from Georgia.

On page 14, the applicant projects to serve 52 in-center patients in OY1 and 53 in-center patients in OY2. Thus, the applicant projects that Southpoint will have a utilization rate of

81.3% or 3.25 patients per station per week ($52 \text{ patients} / 16 \text{ stations} = 3.5 / 4 = 0.8125$ or 81.3%) in OY1. However, this differs from the total projected patients by county information on page 13. On page 13, the applicant reports that Southpoint Dialysis will have 50 in-center patients in OY1 and 52 in-center patients in OY2. If indeed, the applicant serves only 50 in-center patients in OY1 it will not meet the minimum standard of 3.2 patients per station per week at the end of OY1 [$50 / 16 = 3.125 / 4 = 0.78125$ or 78%].

However, in other Sections of the application, including the pro forma financial statements in Section R, the applicant based its expenses on 51.5 (rounded to 52) patients in OY1 and 52.5 (rounded to 53) patients in OY2. Thus, the analyst assumes that the projected in-center patients reported on page 13, is in error. Therefore, the projections on pages 14-15 and the pro forma financial statements of 52 in-center patients in OY1 at Southpoint Dialysis exceed the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Projected utilization is reasonable and adequately supported for the following reasons:

- the applicant begins its utilization projections with the existing patients of Southpoint Dialysis,
- the applicant grows the Durham County patient population by the July 2018 SDR Durham County Five Year AACR and holds the patient population from outside Durham County constant,
- the applicant subtracts the 28 patients projected to transfer to Hope Valley Dialysis, and
- the resulting utilization rate at Southpoint Dialysis by the end of the first year is above the minimum standard of 3.2 patients per station per week.

Home Hemodialysis and Peritoneal Dialysis

On page 15, the applicant states Southpoint Dialysis does not currently provide home hemodialysis (HHD) or peritoneal dialysis (PD) training nor does the applicant propose adding a home training program in the proposed project. On page 34, the applicant states that those patients who desire HHD and PD training will be referred to Durham West Dialysis.

Access

In Section C.3, page 15, the applicant states the facility will serve patients without regard to race, sex, age or handicap, ethnic or socioeconomic situation. In Section L.7, page 47, the applicant provides the historical payor mix for calendar year (CY) 2017 for Southpoint Dialysis, as illustrated below.

Payor Source	Percent of Total Patients
Medicare	26.3%
Medicaid	5.3%
Commercial Insurance	11.8%
Medicare / Commercial	42.1%
Medicare / Medicaid	14.5%
Total	100.0%

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

(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

The applicant does not propose to:

- reduce a service
- eliminate a service
- relocate a facility or service

Therefore, Criterion (3a) is not applicable to this review.

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

CA

The applicant proposes to add six dialysis stations for a total of 16 dialysis stations upon completion of this project and Project I.D. # J-11544-18 (relocate six dialysis stations to Hope Valley Dialysis).

In Section E.1, page 22, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo - The applicant states that maintaining the status quo is not an effective alternative because of the growth rate at Southpoint Dialysis. Therefore, this alternative was rejected.
- Relocate stations from another DaVita facility - The applicant states of the five DaVita facilities operating in Durham, two are operating at less than 80% capacity. However, to relocate stations from either of those facilities would negatively impact the patients being served at Duke Hospital Dialysis and West Durham Dialysis. Therefore, this alternative was rejected.

On page 22, the applicant states its proposal is the most effective alternative to help meet the growing demand for dialysis services at Southpoint Dialysis.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- the facility operated above 80% capacity as of December 31, 2017, as reported in Table B of the July 2018 SDR and referenced throughout this application.
- the facility need methodology indicates a need for additional stations at the facility, and
- to maintain the status quo does not address the need for additional stations at the facility and would result in higher utilization and potentially restrict patient admissions.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. DVA Renal Healthcare, Inc., d/b/a Southpoint Dialysis shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to the facility need determination in the July 2018 SDR, DVA Renal Healthcare, Inc., shall develop no more than six additional dialysis stations for a total of no more than 16 dialysis stations upon completion of this project and Project I.D. # J-11544-18 (relocate six dialysis stations to Hope Valley Dialysis), which shall include any home hemodialysis training or isolation stations.**
 - 3. DVA Renal Healthcare, Inc., d/b/a Southpoint Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency 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

The applicant proposes to add six dialysis stations for a total of 16 dialysis stations upon completion of this project and Project I.D. # J-11544-18 (relocate six dialysis stations to Hope Valley Dialysis).

Capital and Working Capital Costs

In Section F.1, page 23, the applicant projects no capital cost for the proposed project. In Section F.10, pages 25-26, the applicant projects no start-up expenses or initial operating expenses because Southpoint Dialysis is an existing operational facility.

Financial Feasibility

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

	Operating Year 1 CY2020	Operating Year 2 CY2021
Total Treatments	7,632	7,781
Total Gross Revenues (Charges)	\$2,667,994	\$2,720,426
Total Net Revenue	\$2,575,423	\$2,626,058
Average Net Revenue per Treatment	\$337	\$337
Total Operating Expenses (Costs)	\$2,180,235	\$2,226,670
Average Operating Expense per Treatment	\$286	\$286
Net Income	\$395,188	\$399,388

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section R of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates the availability of sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

- (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 six dialysis stations for a total of 16 dialysis stations upon completion of this project and Project I.D. # J-11544-18 (relocate six dialysis stations to Hope Valley Dialysis).

On page 365, the 2018 SMFP defines the service area for dialysis stations as *“the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* Thus, the

service area is Durham County. Facilities may serve residents of counties not included in their service area.

According to the July 2018 SDR, there are currently nine operational dialysis facilities and four facilities under development in Durham County. Of those facilities, eight are operated by DaVita, as illustrated below.

DURHAM COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of December 31, 2017				
Dialysis Facility/Owner	Certified Stations 6/1/18	# In-center Patients	Percent Utilization	Patients per Station
Bull City (DaVita)*	10	0	0	0
Downtown Durham Dialysis (DaVita)*	10	0	0	0
Duke Hospital Dialysis** (DaVita)	16	40	62.50%	2.500
Durham Dialysis (DaVita)	28	96	85.71%	3.4286
Durham Regional Dialysis (DaVita)*	10	0	0	0
Durham West Dialysis (DaVita)	30	95	79.17%	3.1667
FMC Dialysis Services of Briggs Ave. (BMA)	29	97	83.62%	3.3448
FMC Dialysis Ser. W. Pettigrew (BMA)	24	69	71.88%	2.8750
Freedom Lake Dialysis Unit (BMA)	26	90	86.54%	3.4615
FMC Eno River (BMA)*	10	0	0	0
FMC South Durham (BMA)	18	63	87.50%	3.5000
Research Triangle Park Dialysis (DaVita)	10	11	27.50%	1.1000
Southpoint Dialysis (DaVita)	16	76	118.75%	4.7500
Totals	237	736	77.64%	3.1055

Source: July 2018 SDR

*New stations approved but not certified as of 6/1/18

**Acquired by DaVita on December 31, 2017

As shown in the table above, three facilities are under development, two of which are owned by DaVita. Of DaVita's operational facilities, utilization ranged from 27.50% at Research Triangle Park Dialysis to 118.75% at Southpoint Dialysis. On December 31, 2017, DaVita, Inc. submitted a request for an exemption to acquire Duke Hospital Dialysis. Those 16 stations will be relocated and operated in the facility known as Bull City Dialysis. Research Triangle Park Dialysis is a new 10-station facility, therefore it would not be appropriate to relocate stations to Southpoint Dialysis from this facility. Durham West Dialysis is operating at 79 percent, therefore it would not be in a position to relocate stations from this facility since its utilization is nearly 80 percent. Overall, the

operational facilities in Durham County owned/operated by DaVita operated with a utilization above 80%.

In Section G, page 29, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Durham County. The applicant states, *“While adding stations at this facility does increase the number of stations in Durham County, it is based on the facility need methodology. It ultimately serves to meet the needs of the facility’s growing population of patients ... The addition of stations, therefore, serves to increase capacity rather than duplicate any existing or approved services in the service area.”*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the applicant adequately demonstrates that the proposed addition of six new dialysis stations at Southpoint Dialysis is needed in addition to the existing or approved dialysis stations.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 H, page 30, the applicant provides current and projected staffing for the proposed services. The applicant does not project a change in the staffing of Southpoint Dialysis with the addition of the six dialysis stations, as illustrated in the following table.

POSITION	CURRENT # FTES CY2017	PROJECTED # FTES OY2 (CY2021)
Registered Nurse	2.00	2.00
Technician (PCT)	6.00	6.00
Administrator	1.00	1.00
Dietician	1.00	1.00
Social Worker	1.00	1.00
Administrative Assistant	1.00	1.00
Biomed Tech	0.50	0.50
Total	12.50	12.50

The assumptions and methodology used to project staffing are provided in Sections C, H and R. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, page 55, which is found in Section R. In Section H, pages 31-32, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Exhibit I.3, the applicant provides a letter from the medical director indicating his interest in continuing to serve as the medical director of Southpoint Dialysis.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 I, page 34, the applicant provides a list of the necessary ancillary and support services for the proposed services, as illustrated below.

Southpoint Dialysis Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	Southpoint Dialysis (on site)
Self-care training (in-center)	Southpoint Dialysis (on site)
Home training HH PD Accessible follow-up program	Referred to Durham West Dialysis
Psychological counseling	Southpoint Dialysis (on site)
Isolation – hepatitis	Southpoint Dialysis (on site)
Nutritional counseling	Southpoint Dialysis (on site)
Social Work services	Southpoint Dialysis (on site)
Acute dialysis in an acute care setting	Duke University Hospitals
Emergency care	Duke University Hospitals
Blood bank services	Duke University Hospitals
Diagnostic and evaluation services	Duke University Hospitals
X-ray services	Duke University Hospitals
Laboratory services	DaVita Laboratory Services, Inc.
Pediatric nephrology	Duke University Hospitals
Vascular surgery	Duke University Hospitals
Transplantation services	Duke University Medical Center
Vocational rehabilitation & counseling	NC Division of Vocational Rehab. Services
Transportation	Durham County DSS

In Section I, page 35, the applicant explains how each ancillary and support service will be made available and provides supporting documentation in Exhibit I-1. In Section I.4, page, 36, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-1. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (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

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (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

The applicant does not propose to construct new space nor renovate the existing space. Therefore, Criterion (12) is not applicable to this review.

- (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 L.7, page 47, the applicant provides the historical payor mix for calendar year (CY) 2017 for Southpoint Dialysis, as illustrated below.

Payor Source	Percent of Total Patients
Medicare	26.3%
Medicaid	5.3%
Commercial Insurance	11.8%
Medicare / Commercial	42.1%
Medicare / Medicaid	14.5%
Total	100.0%

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Durham	13%	52%	58%	16%	7%	13%
Wake	11%	51%	40%	9%	6%	9%
Orange	13%	52%	31%	13%	6%	10%
Statewide	16%	51%	37%	15%	10%	12%

Source: <http://www.census.gov/quickfacts/table/US/PST045217>

Latest Data 7/1/17 as of 7/17/18

* Excludes "White alone, not Hispanic or Latino"

** "Estimates are not comparable to other geographic levels due to methodology differences that may exist between different data sources. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states. The 2016 Annual Report does not provide state-specific ESRD patient data, but the aggregate data is likely to be similar to North Carolina's based on the Network's recent annual reports which included state-specific data.

The IPRO SA Network 6 2016 Annual Report (pages 25-26¹) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately documents 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. Therefore, the application is conforming to this criterion.

¹<https://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/07/NW6-2016-Annual-Report-FINAL.pdf>

- (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

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 46, the applicant states:

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

In Section L, page 46, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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 L, page 44, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Projected Payor Mix OY2

Payor Source	Percent of Total Patients
Medicare	26.3%
Medicaid	5.3%
Commercial Insurance	11.8%
Medicare / Commercial	42.1%
Medicare / Medicaid	14.5%
Total	100.0%

As shown in the table above, during the second full fiscal year of operation, the applicant projects its payor source will be the same as its historical payor source. Thus, the applicant projects that will consist of 68.4% Medicare patients (includes Medicare and Medicare/Commercial) and 19.8% Medicaid patients (includes Medicaid and a combination of Medicare/Medicaid).

On pages 44-45, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical utilization by payor source at Southpoint Dialysis.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

In Section L.4, page 46, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

In Section M, page 48, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and 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

The applicant proposes to add six dialysis stations for a total of 16 dialysis stations upon completion of this project and Project I.D. # J-11544-18 (relocate six dialysis stations to Hope Valley Dialysis).

On page 365, the 2018 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Durham County. Facilities may serve residents of counties not included in their service area.

According to the July 2018 SDR, there are currently nine operational dialysis facilities and four facilities under development in Durham County. Of those facilities, eight are operated by DaVita, as illustrated below.

DURHAM COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of December 31, 2017				
Dialysis Facility/Owner	Certified Stations 6/1/18	# In-center Patients	Percent Utilization	Patients per Station
Bull City (DaVita)*	10	0	0	0
Downtown Durham Dialysis (DaVita)*	10	0	0	0
Duke Hospital Dialysis** (DaVita)	16	40	62.50%	2.500
Durham Dialysis (DaVita)	28	96	85.71%	3.4286
Durham Regional Dialysis (DaVita)*	10	0	0	0
Durham West Dialysis (DaVita)	30	95	79.17%	3.1667
FMC Dialysis Services of Briggs Ave. (BMA)	29	97	83.62%	3.3448
FMC Dialysis Ser. W. Pettigrew (BMA)	24	69	71.88%	2.8750
Freedom Lake Dialysis Unit (BMA)	26	90	86.54%	3.4615
FMC Eno River (BMA)*	10	0	0	0
FMC South Durham (BMA)	18	63	87.50%	3.5000
Research Triangle Park Dialysis (DaVita)	10	11	27.50%	1.1000
Southpoint Dialysis (DaVita)	16	76	118.75%	4.7500
Totals	237	736	77.64%	3.1055

Source: July 2018 SDR

*New stations approved but not certified as of 6/1/18

**Acquired by DaVita on December 31, 2017

In Section N.1, page 49, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 49, the applicant states:

“The expansion of this facility is not expected to have an unfavorable impact on the competition nor cost effectiveness, quality, and access to the proposed services.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and R of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

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

C

In Section A.11, page 5, the applicant states that DaVita, Inc., operates over 85 facilities in North Carolina. In Exhibit A-11, the applicant provides a list of its facilities.

In Exhibit O-3, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in two facilities, Southeastern Dialysis Center-Wilmington and Goldsboro South Dialysis. The applicant states in Section O.3, page 50, and in Exhibit O-3, that both facilities are currently back in full compliance with all CMS requirements. The applicant provides documentation regarding the

deficiencies and subsequent compliance with CMS Conditions for Coverage for Southeastern Dialysis Center -Wilmington and Goldsboro South Dialysis in Exhibit O-3. After reviewing and considering information provided by the applicant and considering the quality of care provided at all DaVita facilities, the applicant provided sufficient evidence that quality care has been provided in the past. 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 application is conforming to all applicable criteria, as discussed below.

10 NCAC 14C .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 C, pages 14-15, the applicant demonstrates that Southpoint Dialysis will serve a total of 52 in-center patients in OY1 for a utilization rate of 87.5% or 3.5 patients per

station per week (52 patients / 16 stations = 3.25 / 4 = 0.8125 or 81.25%). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C.1, pages 14-15, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.