

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 9, 2018

Findings Date: February 9, 2018

Project Analyst: Bernetta Thorne-Williams

Team Leader: Fatimah Wilson

Project ID #: J-11413-17

Facility: Durham West Dialysis

FID #: 010285

County: Durham

Applicant(s): DVA Renal Healthcare, Inc.

Project: Add four dialysis stations to the existing facility for a total of 25 stations upon completion of this project, Project I.D. #J-10319-14 (relocate 3 stations), Project I.D. #J-10350-14 (add four stations), Project I.D. # J-11216-16 (relocate 7 stations) and Project I.D. #J-11273-16 (relocate 2 stations).

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

DVA Renal Healthcare, Inc. (DVA and/or the applicant), d/b/a Durham West Dialysis proposes to add four dialysis stations to the existing facility for a total of 25 stations upon completion of this project, Project I.D. #J-10319-14 (relocate 3 stations), Project I.D. #J-10350-14 (add four stations), Project I.D. # J-11216-16 (relocate 7 stations) and Project I.D. #J-11273-16 (relocate 2 stations). The parent company of DVA is DaVita, Inc. Durham West Dialysis offers a peritoneal

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dialysis (PD) program and a home hemodialysis (HHD) program, which the facility plans to continue offering following completion of the proposed project.

Need Determination

The 2017 State Medical Facilities Plan (2017 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2017 Semiannual Dialysis Report (SDR), the county need methodology shows there is a surplus of 15 dialysis station in Durham County. However, the 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 Durham West Dialysis in the July 2017 SDR is 3.3793 patients per station per week, or 84.48% ($3.3793 / 4$ patients per station = 0.8448 or 84.48%). This utilization rate was calculated based on 98 in-center dialysis patients and 29 certified dialysis stations (98 patients / 29 stations = 3.3793 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 12/31/16		84.5%
Certified Stations		30
Pending Stations		0
Total Existing and Pending Stations		30
In-Center Patients as of 12/31/16 (July 2017 SDR) (SDR2)		98
In-Center Patients as of 6/30/16 (Jan 2017 SDR) (SDR1)		89
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	9
	Multiply the difference by 2 for the projected net in-center change	18
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/16	0.2022
(ii)	Divide the result of Step (i) by 12	0.0169
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/15 until 12/31/16)	0.2022
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	117.8202
(v)	Divide the result of Step (iv) by 3.2 patients per station	36.8188
	and subtract the number of certified and pending stations to determine the number of stations needed	6.8188

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

Policies

There is one policy in the 2017 SMFP which is applicable to this review. *POLICY GEN-3: BASIC PRINCIPLES* on page 33 of the 2017 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, pages 9-10, Section K.1(g), page 42, Section N.1, page 52 and Section O, page 53, 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, page 10, Section I, pages 37-39, Section L, pages 46-50, and referenced exhibits and Section N.1, page 52. 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, page 11, Section F, pages 26-31, Section K, pages 41-45, Section N, page 52, 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 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 information in the application, including any exhibits, is reasonable and adequately supported because the applicant relies on existing policies, historical data, and verifiable sources to provide future projections and demonstrate conformity with Policy GEN-3.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

C

DVA proposes to add four dialysis stations to Durham West Dialysis for a total of 25 stations upon completion of this project, Project I.D. #J-10319-14 (relocate 3 stations), Project I.D. #J-10350-14 (add four stations), Project I.D. # J-11216-16 (relocate 7 stations) and Project I.D. #J-11273-16 (relocate 2 stations). The parent company of DVA is DaVita, Inc. Durham West Dialysis offers a peritoneal dialysis (PD) program and a home hemodialysis (HHD) program, which the facility plans to continue offering following completion of the proposed project.

Patient Origin

On page 373, the 2017 SMFP defines the service area for dialysis stations as “*the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty*

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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.8, page 21, the applicant provides a table showing the historical patient origin for in-center (IC), peritoneal and home hemodialysis patients served by Durham West Dialysis, as shown below:

DURHAM WEST DIALYSIS PATIENTS AS OF DECEMBER 31, 2016			
COUNTY	IC PATIENTS	HH PATIENTS	PD PATIENTS
Durham	74	6	8
Alamance	2	1	0
Chatham	0	1	0
Edgecombe	2	0	0
Guilford	0	0	2
Granville	2	3	0
Johnston	0	0	2
Orange	13	1	4
Person	0	2	0
Vance	0	4	0
Wake	2	3	5
Warren	0	1	0
Wilkes	1	0	0
Other States	2	0	0
Total	98	22	21

In Section C.1, page 13, the applicant provides the projected patient origin for Durham West Dialysis for the first two years of operation following project completion, as follows:

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DURHAM WEST DIALYSIS PROJECTED PATIENTS BY COUNTY								
	OPERATING YEAR 1 CY 2019			OPERATING YEAR 2 CY 2020			COUNTY PATIENTS AS % OF TOTAL	
COUNTY	IC PATIENTS	HH PATIENTS	PD PATIENTS	IC PATIENTS	HH PATIENTS	PD PATIENTS	OY 1	OY 2
Durham	59	9	11	61	10	12	59.8%	61.0%
Alamance	2	1	0	2	1	0	2.3%	2.2%
Chatham	0	1	0	0	1	0	0.8%	0.7%
Edgecombe	2	0	0	2	0	0	1.5%	1.5%
Guilford	0	0	2	0	0	2	1.5%	1.5%
Granville	2	3	0	2	3	0	3.8%	3.7%
Johnston	0	0	2	0	0	2	1.5%	1.5%
Orange	13	1	4	13	1	4	13.6%	13.2%
Person	0	2	0	0	2	0	1.5%	1.5%
Vance	0	4	0	0	4	0	3.0%	2.9%
Wake	2	3	5	2	3	5	7.6%	7.4%
Warren	0	1	0	0	1	0	0.8%	0.7%
Wilkes	1	0	0	1	0	0	0.8%	0.7%
Other States	2	0	0	2	0	0	1.5%	1.5%
Total	83	25	24	85	26	25	100%	100%

The applicant provides the assumptions and methodology for the projections above on pages 13-16. The applicant adequately identifies the population it proposes to serve.

Analysis of Need

The applicant proposes to add four dialysis stations to Durham West Dialysis for a total of 25 stations upon completion of this project, Project I.D. #J-10319-14 (relocate 3 stations), Project I.D. #J-10350-14 (add four stations), Project I.D. # J-11216-16 (relocate 7 stations) and Project I.D. #J-11273-16 (relocate 2 stations). In Section B.2, page 7, the applicant states the application is filed pursuant to the facility need methodology in the 2017 SMFP utilizing data from the July 2017 SDR. In Section C.1, pages 13-16, the applicant provides the assumptions used to demonstrate the need for the project. The facility’s patients who reside in Durham County have increased at a rate commensurate with the Five-Year Average Annual Change Rate for Durham County, which is 4.0%. The applicant does not project growth of the 24 patients residing in other counties; those existing patients were added at appropriate points in the methodology.

Operating Year 1 (OY1) = Calendar Year (CY) 2019
 OY2 = CY2020

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Projected Utilization

In Section C, page 15, the applicant provided the methodology used to project in-center utilization, as illustrated in the following table,

Begin with Durham County patients dialyzing at Durham West Dialysis as of January 1, 2017 and subtract the 7 in-center patients projected to transfer their care to Research Triangle Park (See Project I.D. # J-10319-14). The applicant projects Durham County patient population forward for 1 year using the five year annual growth rate of 4.0 percent.	$74 - 7 = 67$ $(67 \times 1.04) = 69.68$
Interim - Begin with the Durham County patient population as of January 1, 2018 and subtract 9 in-center patients projected to transfer their care to Durham Regional Dialysis (See Project I.D. # J-11216-16). Project the Durham County patient population forward for one year to December 31, 2018.	$69 - 9 = 60$ $(60 \times 1.04) = 62.4$
Begin with the Durham County patient population as of January 1, 2019 and subtract 5 in-center patients projected to transfer their care to Downtown Durham Dialysis (See Project I.D. # J-11273-16). Project the Durham County patient population forward one year to December 31, 2019.	$62 - 5 = 57$ $(57 \times 1.04) = 59.28$
OY1: Add 24 patients from outside Durham County. This is the projected census for OY 1.	$59.28 + 24 = 83.28$
Project the Durham County patient population forward one year to December 31, 2020.	$(59 \times 1.04) = 61.36$
OY2: Add 24 patients from outside Durham County. This is the projected census for OY 2.	$61 + 24 = 85.36$

On page 15, the applicant states it rounded the patient population down. Thus, the applicant projects that Durham West Dialysis will serve a total of 83 in-center patients at the end of OY1 for a utilization rate of 83% or 3.32 patients per station per week ($83 \text{ patients} / 25 \text{ stations} = 3.32 / 4 = 0.83$ or 83%). The projected utilization of 3.32 patients per station per week at the end of OY1 exceeds the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Projected utilization for in-center patients is based on reasonable and adequately supported assumptions regarding continued growth.

Home Hemodialysis and Peritoneal Dialysis

On pages 15-16 of the application, the applicant states Durham West Dialysis currently provides peritoneal and home hemodialysis training and that it will continue to offer those services. The applicant projects that the HHD patients will grow at a rate of at least one patient per year. Thus,

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the applicant projects to have 25 HHD patients in OY1 (2019) and 26 HHD patients in OY2 (2020). Additionally, the applicant also projects that its PD patients will grow at a rate of at least one patient per year. Thus, the applicant projects to have 24 PD patients in OY1 and 25 PD patients in OY2.

Access

In Section L.1(a), pages 46-47, the applicant states Durham West Dialysis will continue to provide services to the medically underserved population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, or other underserved persons regardless of their ability to pay. In Section L.7, page 50, the applicant provides the historical payor mix for calendar year (CY) 2016 for Durham West Dialysis, as illustrated below.

Payor Mix CY2016

Payment Source	Percent of Total Patients	Percent of IC Patients	Percent of HH Patients	Percent of PD Patients
Medicare	25.4%	30.6%	17.4%	13.6%
Medicaid	6.2%	7.1%	0.0%	9.1%
Commercial Insurance	13.8%	14.1%	17.4%	9.1%
Medicare / Commercial	36.9%	32.9%	47.8%	40.9%
Medicare/Medicaid	16.9%	14.1%	17.4%	27.3%
VA	0.8%	1.2%	0.0%	0.0%
Total	100.0%	100.0%	100.0%	100.0%

As illustrated in the table above, in CY2016 84.7% of Durham West Dialysis in-center patients were Medicare or Medicaid recipients and 85.4% of all of its patients had some or all of the services paid by Medicare or Medicaid. On page 47, the applicant projects the same percentage of Medicare and Medicaid recipients in project year (PY) 2, as were historically served by Durham West Dialysis in CY2016. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

Conclusion

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The population to be served by the proposed project will be from the same counties as they have historically served.
- The applicant uses reasonable assumptions and methodologies to project the number of in-center patients to be served at the facility.

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- The applicant projects that the facility will serve a similar percentage of Medicaid and Medicare recipients as it has historically.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that 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

DVA Renal Healthcare, Inc. does not propose the reduction or elimination of a service in the proposed application, but rather the addition of four dialysis stations pursuant to the facility need methodology in the 2017 SMFP, 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

In Section E.1, page 25, the applicant discusses the alternatives considered prior to submitting this application, which include:

- Maintain the status quo - The applicant states that maintaining the status quo is not an effective alternative considering the growth rate at Durham West Dialysis. The applicant states that utilization at Durham West Dialysis will be greater than 80% by the end of OY1 (See application, page 15). Therefore, this alternative was rejected.
- Relocate stations from another DaVita Facility - The applicant states that all three DaVita facilities in Durham County are operating above 80% utilization. Thus, to relocate stations from any of those facilities would have a negative impact on the patients currently being served at those facilities. Therefore, this alternative was rejected.

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Thus, after considering the above alternatives, the applicant states that its proposal to add four stations to Durham West Dialysis pursuant to the facility need methodology is the most effective alternative to meet the identified need.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that the proposal is its most effective alternative to meet the identified need.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the application is conforming to this criterion and approved subject to the following conditions.

- 1. DVA Renal Healthcare, Inc. d/b/a Durham West Dialysis shall materially comply with all representations made in the certificate of need application as conditioned.**
 - 2. Pursuant to the facility need determination in the July 2017 SDR, DVA Renal Healthcare, Inc. shall develop no more than 4 additional dialysis stations for a total of no more than 25 certified stations at Durham West Dialysis upon completion of this project, Project I.D. #J-10319-14 (relocate 3 stations), Project I.D. #J-10350-14 (add four stations), Project I.D. # J-11216-16 (relocate 7 stations) and Project I.D. #J-11273-16 (relocate 2 stations).**
 - 3. DVA Renal Healthcare, Inc. d/b/a Durham West 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 4 dialysis stations to the existing facility for a total of 25 certified dialysis stations at Durham West Dialysis following completion of this project, Project I.D. #J-

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10319-14 (relocate 3 stations), Project I.D. #J-10350-14 (add four stations), Project I.D. # J-11216-16 (relocate 7 stations) and Project I.D. #J-11273-16 (relocate 2 stations).

Capital and Working Capital Costs

In Section F, pages 26, 28 and 29, the applicant projects no capital or working capital cost associated with the proposed project because Durham West Dialysis is an existing facility.

Financial Feasibility

The applicant provided pro forma financial statements for the first two 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 CY2019	Operating Year 2 CY2020
Total Treatments	12,152	12,449
Total Gross Revenues (Charges)	\$7,115,932	\$7,335,964
Total Net Revenue	\$6,893,605	\$7,107,055
Total Operating Expenses (Costs)	\$4,905,751	\$5,048,333
Net Income	\$1,987,854	\$2,058,722

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.

Conclusion

The applicant adequately demonstrates 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.

This determination is based on a review of the information in the application, including any exhibits.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

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The applicant proposes to add 4 dialysis stations to the existing facility for a total of 25 certified dialysis stations at Durham West Dialysis following completion of this project, Project I.D. #J-10319-14 (relocate 3 stations), Project I.D. #J-10350-14 (add four stations), Project I.D. # J-11216-16 (relocate 7 stations) and Project I.D. #J-11273-16 (relocate 2 stations).

On page 373, the 2017 SMFP defines the service area for dialysis stations as “*the 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 2017 SDR, there are currently eight operational dialysis facilities and three facilities under development in Durham County, as illustrated below.

DURHAM COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of DECEMBER 31, 2016				
Dialysis Facility/Owner	Certified Stations 12/31/16	# In-center Patients	Percent Utilization	Patients per Station
Downtown Durham Dialysis (DaVita)	10*	0	0	0
Duke Hospital Dialysis**	16	49	76.56%	3.0625
Durham Dialysis (DaVita)	29	100	86.21%	3.4483
Durham Regional Dialysis (DaVita)	10*	0	0	0
Durham West Dialysis (DaVita)	29	98	84.48%	3.3793
FMC Dialysis Services of Briggs Ave. (BMA)	29	90	77.59%	3.1034
FMC Dialysis Ser. W. Pettigrew (BMA)	24	64	66.67%	2.6667
Freedom Lake Dialysis Unit (BMA)	26	94	90.38%	3.6154
FMC South Durham (BMA)	18	53	73.61%	2.9444
Research Triangle Park Dialysis (DaVita)	10*	0	0	0
Southpoint Dialysis (DaVita)	16	76	118.75%	4.7500
Totals	217	624	71.89%	2.8756

Source: July 2017 SDR.

*New stations approved but not certified as of 6/9/12

**Acquired by DaVita on December 1, 2017

As shown in the table above, three facilities are under development, each of which is owned by DaVita. The applicant operates three of the eight operational facilities in Durham County. Of DaVita’s operational facilities utilization ranged from 84.48% at Durham West Dialysis to

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118.75% at Southpoint Dialysis. On December 1, 2017, DaVita, Inc. submitted a request for an exemption to acquire Duke Hospital Dialysis. With the acquisition of Duke Hospital Dialysis, DaVita, Inc., will own/operate seven of the existing and under development ESRD facilities in Durham. The applicant states that all three DaVita facilities in Durham County are operating above 80% utilization. Thus, to relocate stations from any of those facilities would have a negative impact on the patients currently being served at those facilities. In Section G of the application, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis facilities in Durham County.

The applicant adequately demonstrates its proposal would not result in an unnecessary duplication of existing or approved dialysis services in Durham County based on the following analysis:

- The applicant is not proposing to develop a new facility, rather it is proposing to add dialysis stations based on the facility need methodology.
- All other operational DaVita dialysis facilities in Durham County are operating over 80 percent of capacity.
- The applicant projects to serve more than 3.2 patients per station per week at the end of the first operating year as required by 10A NCAC 14C .2203(b).

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

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

C

In Section H, page 33, the applicant provides current and projected staffing in full time equivalents (FTEs) for Durham West Dialysis. The applicant does not project a change in its FTE staff, as DVA is seeking to replace four stations that were relocated to other DaVita facilities.

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POSITION	CURRENT # FTEs	PROJECTED # FTEs
Registered Nurse	4.00	4.00
Technician (PCT))	11.00	11.00
Administrator	1.00	1.00
Dietician	1.00	1.00
Social Worker	1.00	1.00
Home Training RN	3.00	3.00
Admin Assistant	1.00	1.00
Biomed Tech	1.00	1.00
Total	23.00	23.00

In Section H.7, page 36, the applicant provides the projected direct care staff for Durham West Dialysis in OY2 (CY2020). In Section H.6, page 36, the applicant states that dialysis serves will be available Monday through Saturday from 6:00am – 4:00pm.

In Section I, page 38, the applicant identifies Dr. Stephan Smith as the Medical Director of the facility. Exhibit I, of the application contains a signed letter from Dr. Smith of Duke University Hospital stating his willingness to continue to serve as the Medical Director. In Section H, pages 35-36, the applicant describes the methods used to recruit and fill vacant or new positions.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant provides appropriate documentation of the availability of adequate health manpower and management personnel for the provision of the proposed dialysis services.
- The applicant documents support from the current and continuing Medical Director of Durham West Dialysis.
- The applicant documents the availability of other resources, including methods of recruitment and documentation of staff training, necessary for the provision of the proposed dialysis services.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support

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services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section I, page 37, the applicant includes a list of providers of the necessary ancillary and support services. Exhibit I contains a letter from the medical director of the facility expressing his support and willingness to continue serving in that role. The applicant discusses coordination with the existing health care system on page 39. Exhibits I-1 contains a copy of a letter from DaVita stating acute dialysis care will be provided by Duke University Hospital, transplant services will be provided by Duke University Medical Center, vocational rehabilitation counseling will be provided through NC Division of Vocational Rehabilitation Services and transportation will be provided by Durham County DSS. Exhibit I.1, also contains a laboratory services agreement with DaVita Laboratory Services, Inc.

The information in the application, including any exhibits, is reasonable and adequately supported for the following reasons:

- The applicant documents the availability of necessary ancillary and support services for the provision of the proposed dialysis services and by whom they will be made available is documented.
- The applicant identifies nephrologists in the area who have agreed to provide medical coverage at the facility.
- The facility's Medical Director has provided a letter of support.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

Therefore, the applicant adequately demonstrates 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

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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 any new space or renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

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(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 of the application, the applicant provides the information required for this criterion. The following table illustrates the actual payor mix for West Durham Dialysis during CY 2016.

Payor Mix CY2016

Payment Source	Percent of Total Patients	Percent of IC Patients	Percent of HH Patients	Percent of PD Patients
Medicare	25.4%	30.6%	17.4%	13.6%
Medicaid	6.2%	7.1%	0.0%	9.1%
Commercial Insurance	13.8%	14.1%	17.4%	9.1%
Medicare / Commercial	36.9%	32.9%	47.8%	40.9%
Medicare/Medicaid	16.9%	14.1%	17.4%	27.3%
VA	0.8%	1.2%	0.0%	0.0%
Total	100.0%	100.0%	100.0%	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.

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Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2016 Estimate	2016 Estimate	2016 Estimate	2016 Estimate	2015 Estimate	2011-2015	2015 Estimate
Durham	12%	52%	58%	17%	7%	14%
Orange	12%	52%	31%	14%	6%	10%
Statewide	16%	51%	37%	16%	10%	13%

Source: <http://www.census.gov/quickfacts/table> Latest Data 7/1/16 as of 8/22/17

*Excludes "White alone" who are "not Hispanic or Latino"

**"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. 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., V2016) refers to the final year of the series (2010 thru 2016). Different vintage years of estimates are not comparable."

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28¹. In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6). However, a direct comparison to the applicant's current payor mix would be of little value because the population data by age, race, or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The information in the application, including any exhibits, is reasonable and adequately supported because: the applicant's historical payor mix is adequate documentation of the extent to which medically underserved populations utilize the applicant's existing services.

The application is conforming to this criterion based on a review of the:

- Information in the application, including any exhibits.
 - Information which was publicly available during the review and used by the Agency.
- (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;

¹http://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/05/2015_NW-6_Annual-Report_Final-11-29-2016.pdf

C

In Section L.3, page 49, the applicant states:

“Durham West Dialysis has no obligation under any applicable federal regulations, 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. The facility has no obligation under the Hill Burton Act.”

In Section L.6, page 49, the applicant states that there have been no patient civil rights complaints filed within in the past five years.

The application is conforming to this criterion based on a review of the:

- Information in the application, including any exhibits.
 - Information which was publicly available during the review and used by the Agency.
- (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 of the application, the applicant provides the information required by this criterion. The following table illustrates the projected payor mix during the second full fiscal year.

Projected Payor Mix OY2

Payment Source	Percent of Total Patients	Percent of IC Patients	Percent of HH Patients	Percent of PD Patients
Medicare	25.4%	30.6%	17.4%	13.6%
Medicaid	6.2%	7.1%	0.0%	9.1%
Commercial Insurance	13.8%	14.1%	17.4%	9.1%
Medicare / Commercial	36.9%	32.9%	47.8%	40.9%
Medicare/Medicaid	16.9%	14.1%	17.4%	27.3%
VA	0.8%	1.2%	0.0%	0.0%
Total	100.0%	100.0%	100.0%	100.0%

On page 47, the applicant states that the payor mix projections are based on historical performance at the facility.

The applicant is conforming to this criterion based on a review of the:

- Information in the application, including any exhibits.
 - Information which was publicly available during the review and used by the Agency.
- (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 49, the applicant states:

“Patients with End Stage Renal Disease have access to dialysis services upon referral by a Nephrologist with privileges at Durham West Dialysis. ... Patients from outside the facility catchment area requesting transfer to this facility will be processed in accordance with the facility transfer and transient policies ... The patient ... will be referred to a qualified nephrologist for final evaluation and then admission ...”

Therefore, the application is conforming to this criterion.

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

C

In Section M, page 51, the applicant states that Durham West Dialysis offered the facility as a site for clinical rotations for Durham Technical Community College’s nursing students. Exhibit M.2 contains a student training agreement between Durham Technical Community College and DVA Renal Healthcare, Inc.

The information in the application, including any exhibits, is reasonable and adequately supported because the applicant has demonstrated its intent to offer the facility as a clinical training site. Therefore, the applicant adequately demonstrates that the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.

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- (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 4 dialysis stations to the existing facility for a total of 25 certified dialysis stations at Durham West Dialysis following completion of this project, Project I.D. #J-10319-14 (relocate 3 stations), Project I.D. #J-10350-14 (add four stations), Project I.D. # J-11216-16 (relocate 7 stations) and Project I.D. #J-11273-16 (relocate 2 stations).

On page 373, the 2017 SMFP defines the service area for dialysis stations as “*the 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 2017 SDR, there are currently eight operational dialysis facilities and three facilities under development in Durham County, as illustrated below.

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DURHAM COUNTY DIALYSIS FACILITIES EXISTING & APPROVED CERTIFIED STATIONS & UTILIZATION as of DECEMBER 31, 2016				
Dialysis Facility/Owner	Certified Stations 12/31/16	# In-center Patients	Percent Utilization	Patients per Station
Downtown Durham Dialysis (DaVita)	10*	0	0	0
Duke Hospital Dialysis**	16	49	76.56%	3.0625
Durham Dialysis (DaVita)	29	100	86.21%	3.4483
Durham Regional Dialysis (DaVita)	10*	0	0	0
Durham West Dialysis (DaVita)	29	98	84.48%	3.3793
FMC Dialysis Services of Briggs Ave. (BMA)	29	90	77.59%	3.1034
FMC Dialysis Ser. W. Pettigrew (BMA)	24	64	66.67%	2.6667
Freedom Lake Dialysis Unit (BMA)	26	94	90.38%	3.6154
FMC South Durham (BMA)	18	53	73.61%	2.9444
Research Triangle Park Dialysis (DaVita)	10*	0	0	0
Southpoint Dialysis (DaVita)	16	76	118.75%	4.7500
Totals	217	624	71.89%	2.8756

Source: July 2017 SDR.

*New stations approved but not certified as of 6/9/12

**Acquired by DaVita on December 1, 2017

As shown in the table above, three facilities are under development, each of which is owned by DaVita. The applicant operates three of the eight operational facilities in Durham County. Of DaVita's operational facilities utilization ranged from 84.48% at Durham West Dialysis to 118.75% at Southpoint Dialysis. On December 1, 2017, DaVita, Inc. submitted a request for an exemption to acquire Duke Hospital Dialysis. With the acquisition of Duke Hospital Dialysis, DaVita, Inc., will own/operate seven of the existing and under development ESRD facilities in Durham. The applicant states that all three DaVita facilities in Durham County are operating above 80% utilization. Thus, to relocate stations from any of those facilities would have a negative impact on the patients currently being served at those facilities.

In Section N.1, page 52, the applicant discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. The applicant states:

“The expansion of Durham West Dialysis will have no effect on competition in Durham County. ... this project primarily serves to address the needs of a population already

served (or projected to be served, based on historical growth rates) by DVA Renal Healthcare, Inc.

The expansion of Durham West Dialysis will enhance accessibility to dialysis for our patients, and by reducing the economic and physical burdens on our patients, this project will enhance the quality and cost effectiveness of our services because it will make it easier for patients, family members and other [sic] involved in the dialysis process to receive services.”

In addition, the applicant states that it must operate efficiently as a result of fixed Medicare and Medicaid reimbursement rates and projects that greater than 85.4% of all the patients at Durham West Dialysis will have their services covered by Medicare or Medicaid.

Conclusion

The application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates the need for the proposed project and that it is a cost effective alternative.
- The applicant adequately demonstrates that Durham West Dialysis will continue to provide quality dialysis services.
- The applicant adequately demonstrates that Durham West Dialysis will continue to provide access to medically underserved populations.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

(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 DVA Renal Healthcare, Inc. is a subsidiary of DaVita Inc., which operates over 70 facilities North Carolina. In Section O, page 53 and Exhibit O.3, the applicant identifies the two kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company that did not operate in compliance with the Medicare conditions of participation during the 18 month look-back period. Those two facilities had immediate jeopardy citations: Southeastern Dialysis Center - Kenansville and

Durham Dialysis. Both facilities are back in compliance with the Medicare conditions of participation. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision.

The applicant provided sufficient evidence that quality care has been provided in the past. The applicant adequately demonstrates that 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- Durham West Dialysis 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.

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-C- In Section C, pages 13-16, the applicant demonstrates that Durham West Dialysis will serve a total of 83 in-center patients at the end of OY1 for a utilization rate of 83% or 3.32 patients per station per week (83 patients / 25 stations = 3.32 / 4 = 0.83 or 83%). 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 13-16, 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.