

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 14, 2017

Findings Date: June 14, 2017

Project Analyst: Gregory F. Yakaboski

Team Leader: Fatimah Wilson

Project ID #: F-11322-17

Facility: Union County Dialysis

FID #: 955953

County: Union

Applicant(s): DVA Healthcare Renal Care, Inc.

Project: Add three dialysis stations to the existing facility for a total of 33 stations upon completion of this project and Project I.D. #F-11259-16 (add two dialysis stations).

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

DVA Healthcare Renal Care, Inc. (DVA and/or the applicant), d/b/a Union County Dialysis (Union County Dialysis and/or the facility) proposes to add three dialysis stations to the existing facility for a total of 33 stations upon completion of this project and Project I.D. #F-11259-16 (add two dialysis stations). The parent company of DVA is DaVita, Inc. Union County Dialysis offers a peritoneal program but does not offer a home hemodialysis program.

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 January 2017 Semiannual Dialysis Report (SDR), the county need methodology shows

there is a deficit of five dialysis stations in Union County, thus the applicant cannot apply to add any additional stations based on the county need methodology. However, 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 Union County Dialysis in the January 2017 SDR is 3.5 patients per station per week, or 87.50% (3.5 / 4 patients per station = 0.875 or 87.5%). This utilization rate was calculated based on 98 in-center dialysis patients and 28 certified dialysis stations (98 patients / 28 stations = 3.5 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:

APRIL 1 REVIEW-JANUARY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/16		87.50%
Certified Stations		28
Pending Stations		2
Total Existing and Pending Stations		30
In-Center Patients as of 6/30/16 (SDR2)		98
In-Center Patients as of 12/31/15 (SDR1)		92
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	6
	Multiply the difference by 2 for the projected net in-center change	12
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/15	0.1304
(ii)	Divide the result of step (i) by 12	0.0109
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/16 until 12/31/16)	0.0652
(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	104.3913
(v)	Divide the result of step (iv) by 3.2 patients per station	32.6223
	and subtract the number of certified and pending stations to determine the number of stations needed	3

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

In summary, the applicant 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 9-11, Section K.1, page 39, Section N.1-2, page 49 and all referenced exhibits and 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, pages 10-11, Section I, pages 34-36, Section L, pages 43-47 and 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, page 11, Section F, pages 23-28, Section K, pages 38-42 and 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 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

In summary, the applicant adequately demonstrates that the proposal is consistent with the facility need methodology in the January 2017 SDR and Policy GEN-3. Therefore, 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 three dialysis stations to the existing facility for a total of 33 stations upon completion of this project and Project I.D. #F-11259-16 (add two dialysis stations). Union County Dialysis offers a peritoneal program but does not offer a home hemodialysis program.

Patient Origin

On page 373, the 2017 SMFP defines the service area for dialysis services 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 North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Union County. Facilities may also serve residents of counties not included in their service area.

In Section C, page 18, the applicant provides a table showing the historical patient origin for both in-center (IC) patients and peritoneal (PD) patients served by Union County Dialysis, as shown below:

Dialysis Patients as of 6/30/2016

COUNTY	IC	PD
Union	91	15
Anson	2	3
Mecklenburg	1	0
South Carolina	4	0
Total	98	18

In Section C, page 13, the applicant provides the projected patient origin for Union County Dialysis for both IC patients and PD patients for operating year one (OY1) and operating year 2 (OY2) following completion of the proposed project and Project I.D. #F-11259-16 (add two dialysis stations), as shown below:

COUNTY	OPERATING YEAR 1 CY2019			OPERATING YEAR 2 CY2020			COUNTY PATIENTS AS % OF TOTAL	
	IC	HH	PD	IC	HH	PD	OY 1	OY 2
Union	116	0	19	125	0	20	93.1%	93.5%
Anson	2	0	3	2	0	3	3.4%	3.2%
Mecklenburg	1	0	0	1	0	0	0.7%	0.6%
South Carolina	4	0	0	4	0	0	2.8%	2.6%
Totals	123	0	22	132	0	23	100.0%	100.0%

The applicant provides the assumptions and methodology used to project patient origin on pages 13-16. The applicant adequately identifies the population to be served.

Analysis of Need

The applicant proposed to add three dialysis stations to the existing facility for a total of 33 stations upon completion of this project and Project I.D. #F-11259-16 (add two dialysis stations). In Section B-2, pages 6-7, the applicant states the need for the proposed project is based on the facility need methodology. The discussion regarding the need determination found in Criterion (1) is incorporated herein by reference. See also Section C-2, page 15. In Section N.1, page 49, the applicant states, *“The expansion of Union County 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.”*

Projected In-Center Utilization

In Section C, page 13, the applicant provides projected utilization during the first two years of operation following project completion, as illustrated in the table below:

COUNTY	OPERATING YEAR 1 CY2019			OPERATING YEAR 2 CY2020			COUNTY PATIENTS AS % OF TOTAL	
	IC	HH	PD	IC	HH	PD	OY 1	OY 2
Union	116	0	19	125	0	20	93.1%	93.5%
Anson	2	0	3	2	0	3	3.4%	3.2%
Mecklenburg	1	0	0	1	0	0	0.7%	0.6%
South Carolina	4	0	0	4	0	0	2.8%	2.6%
Totals	123	0	22	132	0	23	100.0%	100.0%

In Section C, pages 13-16, the applicant provides the assumptions and methodology used to project utilization. On page 13, the applicant illustrates how in-center patient utilization was projected, which is summarized below:

- OY1 is January 1, 2019 – December 31, 2019 (OY1)
- OY2 is January 1, 2019 – December 31, 2020 (OY2)

- In-center patient population is projected to grow at 7.4%, the Five Year Average Annual Growth Rate (AAGR) for Union County pursuant to Table B in the January 2017 SDR.
- Union County Dialysis had 98 in-center patients as of June 30, 2016. Seven of the 98 in-center patients were not from Union County. In projecting utilization no growth calculations were performed on the seven in-center patients dialyzing at Union County Dialysis who were not residents of Union County.

The following table illustrates application of these assumptions and the methodology used.

Begin with the Union County patients dialyzing at Union County Dialysis as of July 1, 2016.	91
Project the Union County patient population forward six months to December 31, 2016 using the Five-Year Average Annual Change Rate for Union County of 7.4%.	$1.037 \times 91 = 94.367$
Project this patient population forward one year to December 31, 2017.	$1.074 \times 94.367 = 101.35$
Project this patient population forward one year to December 31, 2018.	$1.074 \times 101.35 = 108.8499$
Project this patient population forward one year to December 31, 2019.	$1.074 \times 108.8499 = 116.905$
OY1: Add seven patients from outside the county. This is the projected ending census for OY 1 (CY2019).	$116.905 + 7 = 123.905$
Project the Union County patient population forward one year to December 31, 2020.	$1.074 \times 116.905 = 125.556$
OY2: Add seven patients from outside the county. This is the projected ending census for OY 2 (CY2020).	$125.556 + 7 = 132.556$

Projected patients for OY1 and OY2 are rounded down to the nearest whole number. Therefore, at the end of OY1 the facility is projected to serve 123 in-center patients and at the end of OY2 the facility is projected to serve 132 in-center patients.

- OY1: 3.73 patients per station per week or 93.25% ($123 \text{ patients} / 33 \text{ stations} = 3.73 / 4 = .9325$ or 93.25%).
- OY2: 4.0 patients per station per week or 100.0% ($132 \text{ patients} / 33 \text{ stations} = 4/4 = 1.0$ or 1000.0%).

The projected utilization of 3.73 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 in-center utilization is based on reasonable and adequately supported assumptions regarding continued growth at Union County Dialysis.

Projected Utilization-Home PD Patients

The applicant does not currently nor does the applicant propose to provide home hemodialysis. Those services are provided through a service agreement with Charlotte East Dialysis Center to provide home hemodialysis training. See Exhibit I-1.

The applicant does, however, provide peritoneal dialysis training and plans to continue providing that service. The applicant assumes the PD patient population will grow at a rate of one patient per year. In Section C, page 15, the following table illustrates application of the applicant's assumptions and the methodology used to project PD utilization.

Begin with the Union County Dialysis' PD patient population as of July 1, 2016.	18
Grow the PD patient population by one patient per year. This is the ending patient population for 12/31/16.	$18 + 1 = 19$
Project this patient population forward one year to December 31, 2017.	$19 + 1 = 20$
Project this patient population forward one year to December 31, 2018.	$20 + 1 = 21$
OY1: Project this patient population forward one year to December 31, 2019. This is the projected ending PD census for OY 1 (CY2019)	$21 + 1 = 22$
OY2: Project the PD patient population forward one year to December 31, 2020. This is the projected ending PD census for OY 2. (CY2020)	$22 + 1 = 23$

Projected PD utilization is based on reasonable and adequately supported assumptions regarding continued growth at Union County Dialysis upon project completion.

Access

In Section L, page 43, the applicant states that Union County Dialysis makes services available to all patients in the service area without qualifications which includes low-income, racial and ethnic minorities, women, handicapped, elderly, and other traditionally underserved persons.

In Section L, page 47, the applicant reports that 86.0% of the in-center patients who received treatments at Union County Dialysis had some or all of their services paid for by Medicare or Medicaid in CY 2016, as illustrated in the table below.

Historical Payor Mix CY 2016

Payment Source	IC Patients	PD Patients	Percent of Total Patients
Medicare	34.0%	26.7%	33.0%
Medicaid	8.0%	6.7%	7.8%
Commercial Insurance	10.0%	13.3%	10.4%
Medicare/Commercial	25.0%	53.3%	28.7%
Medicare/Medicaid	19.0%	0.0%	16.5%
VA	4.0%	0.0%	3.5%
Total	100.0%	100.0%	100.0%

The applicant projects that 86.0% of its IC patients will be Medicare or Medicaid recipients. (See application page 44.) 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

In summary, the applicant adequately identifies the population to be served, demonstrates the need that population has for the services proposed and the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

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

NA

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

CA

In Section E-1, page 22, the applicant discusses the alternatives considered prior to submitting this application, which include:

1. Maintain the Status Quo – based on the growth rate at Union County Dialysis the applicant dismissed this option as not effective
2. Relocate existing stations from other DaVita facility in Union County- The applicant states that there are two DaVita facilities in Union County: 1) Union County Dialysis and 2) Marshville Dialysis. DVA states that Marshville Dialysis operates at less than 80.0% capacity. However, the applicant further states that relocating dialysis stations from Marshville Dialysis is not an effective alternative because the facility operates

three days per week to meet the needs of its patients and physicians and therefore, relocating any dialysis stations to Union County Dialysis would negatively impact the existing Marshville Dialysis patients.

After considering these alternatives to its proposal, the applicant believes the most effective and least costly alternative is to add three stations to ensure adequate access for the patients of Union County Dialysis.

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 this proposal is the least costly or most effective alternative to meet the identified need for three more stations at Union County Dialysis. Therefore, the application is conforming to this criterion subject to the following conditions:

- 1. DVA Healthcare Renal Care, Inc. d/b/a Union County Dialysis shall materially comply with all representations made in the certificate of need application.**
 - 2. DVA Healthcare Renal Care, Inc. d/b/a Union County Dialysis shall develop and operate no more than three additional dialysis stations for a total of 33 certified stations upon completion of this project and Project ID #F-11259-16 (add two dialysis stations) which shall include any home hemodialysis training or isolation stations.**
 - 3. DVA Healthcare Renal Care, Inc. d/b/a Union County Dialysis shall install plumbing and electrical wiring through the walls for three additional dialysis stations for a total of 33 dialysis stations which shall include any home hemodialysis training or isolation stations.**
 - 4. DVA Healthcare Renal Care, Inc. d/b/a Union County Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to the 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

DVA proposes to add three dialysis stations to the existing facility for a total of 33 stations upon completion of this project and Project I.D. #F-11259-16 (add two dialysis stations). Union County Dialysis offers a peritoneal program but does not offer a home hemodialysis program.

Capital and Working Capital Costs

In Section F, page 23, the applicant projects the capital cost for the proposed project, as summarized in the table below:

Projected Capital Costs	
Construction Contract	\$250,000
Dialysis Machines	\$46,095
(RO) water treatment equipment	\$95,000
Equipment/furniture not included above	\$49,478
Architect/engineering fees	\$35,000
Total	\$475,573

In Section F, pages 25-26, the applicant states that there are no working capital needs for the proposed project since Union County Dialysis is an existing facility.

Availability of Funds

In Section F, page 24, the applicant states it will finance the capital costs with accumulated reserves/owner’s equity of DVA.

Exhibit F contains a letter dated September 14, 2016, from the Chief Accounting Officer of DaVita, the parent company and 100% owner of DVA, which authorizes and commits cash reserves for the project capital costs of \$475,573. Exhibit F-7 DaVita’s Form 10-K for the fiscal year ended December 31, 2015. As of December 30, 2015, DaVita had \$1,499,116,000 in cash and cash equivalents, \$18,514,875,000 in total assets and \$5,084,172,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project.

Financial Feasibility

In the projected revenue and expense statement (Section R, 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.

UNION COUNTY DIALYSIS		
Revenue and Expenses		
	OY1	OY2
Treatments	20,826	22,235
Gross Patient Revenue	\$6,916,435	\$7,381,998
Deductions form Gross Patient Revenue	(\$315,496)	(\$337,061)
Net Patient Revenue	\$6,600,939	\$7,044,937
Operating Expenses	(\$5,145,728)	(\$5454,392)
Net Income	\$1,455,211	\$1,590,545

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. 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.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the operating needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

C

DVA proposes to add three dialysis stations to the existing facility for a total of 33 stations upon completion of this project and Project I.D. #F-11259-16 (add two dialysis stations). Union County Dialysis offers a peritoneal program but does not offer a home hemodialysis program.

On page 373, the 2016 SMFP defines the service area for dialysis services 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 North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Union County. Facilities may also serve residents of counties not included in their service area.

According to the January 2017 SDR indicates there are three existing and one approved dialysis facilities in Union County, as shown below.

**Union County Dialysis Facilities
 as of June 30, 2016**

Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
Fresenius Kidney Care Indian Trail*	BMA	0	Indian Trail	0	0	0.00%
Marshville Dialysis	DVA	34	Marshville	12	0	70.83%
Metrolina Kidney Center**	BMA	76	Monroe	21	0	90.48%
Union County Dialysis	DVA	98	Monroe	28	0	87.50%

Source: Table A, January 2017 SDR

*Note: Fresenius Kidney Care Indian Trail, Project ID# F-11208-16, received a certificate of need dated 12/15/16, to develop a new 10-station in-center dialysis facility by relocating 10 existing in-center dialysis stations from Metrolina Kidney Center (a/k/a BMA Monroe).

**Note: Metrolina Kidney Center submitted an application, Project F-11242-16, which was conditionally approved 11/29/2016 to add five dialysis stations for a total of 16 inpatient dialysis stations and to develop a peritoneal and home hemodialysis training program.

As illustrated above, two of the four facilities in Union County are operated by DVA and two are operated by BMA. Based on the most recent SDR, two of the three existing facilities operated in Union County operated at 80.0% utilization rate or above, and one, Marshville Dialysis, operated at a utilization rate of 70.83%. The Marshville Dialysis facility only operates three days per week to accommodate patient needs and physician schedules, the operation of the facility would be negatively impacted if any of its stations were transferred. See Section E, page 22 and Section G, page 29.

In Section C, pages 13-18, the applicant demonstrates that Union County Dialysis will service a total of 123 in-center patients at the end of OY1 (CY2019) for a utilization rate of 93.25% or 3.73 patients per station per week (123 patients / 33 stations = 3.73 / 4 = 0.9325 or 93.25%). The projected utilization of 3.73 patients per station per week for Operating Year One satisfies the 3.2 in-center patients per station per week threshold as required by 10A NCAC 14C .2203(b).

The applicant proposes to add three dialysis stations to the existing Union County Dialysis facility in Monroe, in Union County. The applicant adequately demonstrates the need to add three additional stations at Union County Dialysis based on the number of in-center patients it proposes to serve. The discussion on projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved dialysis stations in Union County. Consequently, the application is conforming to this criterion.

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

C

In Section H, page 30, the applicant provides the following table to illustrate the projected staffing in full time equivalents (FTEs) for Union County Dialysis. The applicant states the Medical Director will not be employed by the facility, and thus is not reflected on the staffing chart.

UNION COUNTY DIALYSIS			
POSITION	CURRENT # FTEs	# FTEs TO BE ADDED	PROJECTED # FTEs
Registered Nurse	4.0	1.0	5.0
Technician (Patient Care)	11.0	2.0	13.0
Administrator	1.0	0.0	1.0
Dietician	1.0	0.0	1.0
Social Worker	1.0	0.0	1.0
Home Training RN	1.0	0.0	1.0
Administrative Assistant	1.0	0.0	1.0
Bio-med Technician	1.0	0.0	1.0
Total	21.0	3.0	24.0

As illustrated in the table above, the applicant projects a total of 24.0 FTEs at Union County Dialysis.

In Section H-7, page 33, the applicant provides the projected direct care staff for Union County Dialysis in OY2 (CY2020), as shown below in the table:

UNION COUNTY DIALYSIS					
DIRECT CARE POSITIONS	# FTEs	HOURS PER YEAR PER FTE	TOTAL ANNUAL FTE HOURS	TOTAL ANNUAL HOURS OF OPERATION	# FTE HOURS PER HOUR OF OPERATION
Registered Nurse	5	2,080	10,400	3,120	3.3
Patient Care Tech	13	2,080	27,040	3,120	8.7
Total	18	2,080	37,440	3,120	12.0

In Section I-3, page 35, the applicant identifies Dr. Stuart Haigler, as the Medical Director of the proposed facility. In Exhibit I, the applicant provides a copy of a February 15, 2017 letter signed by Dr. Haigler, supporting the project and confirming his commitment to serve as Medical Director. In Section H-3, pages 31, the applicant states that vacant staff positions are filled by one or more of the following: the DaVita Teammate Recruiter, Teammate Referral Program and/or Student Internship Program. The applicant states on page 32 that DaVita offers a wide range of teammate benefits and maintains a competitive salary structure in order to attract qualified teammates.

The applicant documents the availability of adequate health manpower and management personnel, including the Medical Director, for the provision of the proposed dialysis services. Therefore, the application is conforming to this criterion.

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

In Section I-1, page 34, the applicant identifies the necessary ancillary and support services and indicates how they will be made available. The applicant discusses coordination with the existing health care system on pages 35-36. Exhibit I contains copies of agreements with Charlotte East Dialysis (home hemodialysis training) and DaVita Laboratory Services, Inc. Exhibit I also contains a letter from Dr. Stuart Haigler, medical director of the facility expressing his support for the proposed project and a letter from the Facility's Administrator stating that acute dialysis and transplant services will be provided by Carolinas Medical Center. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

In Section K.2, page 39, the applicant states it proposes to add 2,030 square feet of new construction and renovate 160 square feet of existing space for a total facility of 7,960 square feet upon project completion located at 615 Comfort Lane in Monroe. The applicant states the facility will be constructed in compliance with all laws and regulations pertaining to staffing, fire and safety equipment, physical environment and other relevant health safety requirements. (See page 39 of the application.) In Section K, page 38, the applicant describes its plans for energy-efficiency and water conservation. Costs and charges are described by the applicant in Section R of the application. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, that energy saving features have been incorporated into the construction plans, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

- (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, page 48, the applicant reports that 86.0% of the in-center patients who received treatments at Union County Dialysis had some or all of their services paid for by Medicare or Medicaid in CY 2016, as illustrated in the table below.

Historical Payor Mix CY 2016

Payment Source	IC Patients	PD Patients	Percent of Total Patients
Medicare	34.0%	26.7%	33.0%
Medicaid	8.0%	6.7%	7.8%
Commercial Insurance	10.0%	13.3%	10.4%
Medicare/Commercial	25.0%	53.3%	28.7%
Medicare/Medicaid	19.0%	0.0%	16.5%
VA	4.0%	0.0%	3.5%
Total	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.

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2014 Estimate	2014 Estimate	2014 Estimate	2014 Estimate	2010-2014	2010-2014	2014 Estimate
Union	11%	51%	27%	11%	6%	16%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>, 2014 Estimate as of December 22, 2015.

*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., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consists of North Carolina, South Carolina and Georgia. IPRO SA Network 6 provides a 2015 Annual Report which includes aggregate ESRD patient data from all three states. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*¹ percentages for North Carolina and the aggregate data for all three states in IPRO SA Network 6 shows very little variance; therefore the statistics for IPRO SA Network 6 are representative of North Carolina.

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28². 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).

The applicant adequately demonstrates that it currently provides access to medically underserved populations. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section L.3, page 46, the applicant states “*Union County Dialysis has no obligation under any federal regulations to provide uncompensated care, community service or*

¹<http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

²<http://esrd.ipro.org/wp-content/uploads/2016/11/2015-NW-6-Annual-Report-Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf>

access by minorities and handicapped persons except those obligations which are placed on 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 46, the applicant states *“There have been no civil rights equal access complaints filed within the last five years.”* The application is conforming to this criterion.

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

C

In Section L.1, page 43, the applicant states:

“Union County Dialysis, by policy, makes dialysis services available to all residents in its service area without qualifications. We serve patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability.”

In Section L.1, page 44, the applicant projects that 86.0% in-center patients who will receive dialysis treatments at Union County Dialysis will have all or part of their services paid for by Medicare and or Medicaid, as illustrated below:

**Union County Dialysis
Projected Payor Mix OY2 (CY2020)**

Payment Source	IC Patients	PD Patients	Percent of Total Patients
Medicare	34.0%	26.7%	33.0%
Medicaid	8.0%	6.7%	7.8%
Commercial Insurance	10.0%	13.3%	10.4%
Medicare/Commercial	25.0%	53.3%	28.7%
Medicare/Medicaid	19.0%	0.0%	16.5%
VA	4.0%	0.0%	3.5%
Total	100.0%	100.0%	100.0%

The applicant states on page 44, that projected payor mix is based on its historical payor mix detailed on page 47 with no adjustments to the rates and in Form C of the proformas.

The applicant adequately demonstrates that medically underserved populations will have access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section L-4, page 46, the applicant states:

“Patients with End Stage Renal Disease have access to dialysis services upon referral by a Nephrologist with privileges at Union County 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, found at Exhibit L-3. ...”

The applicant adequately demonstrates that it will offer a range of means by which patients will have access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section M-1, page 48, the applicant states that Union County Dialysis has been offered as a clinical training site for medical assisting students attending Brookstone College. Exhibit M-2 contains a copy of the student training agreement with Brookstone College. The information provided in Section M and referenced exhibits is reasonable and supports a finding of conformity 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

DVA proposes to add three dialysis stations to the existing facility for a total of 33 stations upon completion of this project and Project I.D. #F-11259-16 (add two dialysis stations). Union County Dialysis offers a peritoneal program but does not offer a home hemodialysis program.

On page 373, the 2016 SMFP defines the service area for dialysis services 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 North Carolina counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Union County. Facilities may also serve residents of counties not included in their service area.

According to the January 2017 SDR indicates there are three existing and one approved dialysis facilities in Union County, as shown below.

**Union County Dialysis Facilities
as of June 30, 2016**

Dialysis Facilities	Owner	# of Patients	Location	# of Certified Stations	# of Approved Stations	Percent Utilization
Fresenius Kidney Care Indian Trail*	BMA	0	Indian Trail	0	0	0.00%
Marshville Dialysis	DVA	34	Marshville	12	0	70.83%
Metrolina Kidney Center**	BMA	76	Monroe	21	0	90.48%
Union County Dialysis	DVA	98	Monroe	28	0	87.50%

Source: Table A, January 2017 SDR

*Note: Fresenius Kidney Care Indian Trail, Project ID# F-11208-16, received a certificate of need dated 12/15/16, to develop a new 10-station in-center dialysis facility by relocating 10 existing in-center dialysis stations from Metrolina Kidney Center (a/k/a BMA Monroe).

**Note: Metrolina Kidney Center submitted an application, Project F-11242-16, which was conditionally approved 11/29/2016 to add five dialysis stations for a total of 16 inpatient dialysis stations and to develop a peritoneal and home hemodialysis training program.

As illustrated above, two of the four facilities in Union County are operated by DVA and two are operated by BMA. Based on the most recent SDR, two of the three existing facilities operated in Union County operated at 80.0% utilization rate or above, and one, Marshville Dialysis, operated at a utilization rate of 70.83%. The Marshville Dialysis facility only operates three days per week to accommodate patient needs and physician schedules, the operation of the facility would be negatively impacted if any of its stations were transferred. See Section E, page 22 and Section G, page 29.

In Section C, pages 13-18, the applicant demonstrates that Union County Dialysis will service a total of 123 in-center patients at the end of OY1 (CY2019) for a utilization rate of 93.25% or 3.73 patients per station per week ($123 \text{ patients} / 33 \text{ stations} = 3.73 / 4 = 0.9325$ or 93.25%). The projected utilization of 3.73 patients per station per week for Operating Year One satisfies the 3.2 in-center patients per station per week threshold as required by 10A NCAC 14C .2203(b).

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

“The expansion of Union County Dialysis will have no effect on competition in Union County. Although the addition of stations at this facility could serve to provide more patients another option to select a provider that gives them the highest quality service and better

meets their needs, this project primarily serves to address the needs of a population already served (or projected to be served...) by DVA Renal Healthcare, Inc.

The expansion of Union County 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.”

See also Sections C, F, G, H, L and P where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in the sections referenced above is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application, and the following analysis:

- The applicant adequately demonstrates the need for the proposed project and that it is an effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that Union County Dialysis will continue to provide quality dialysis services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates that Union County Dialysis will continue to provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1), (3) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

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

C

In Section B-4, pages 9-10, the applicant discusses the methods it uses to ensure and maintain quality. In Section O, page 50 and Exhibit O-2, the applicant states that the most recent recertification survey for Union County Dialysis was completed on May 13, 2016 and no condition-level deficiencies were cited.

In Section A.11, page 5, and .Exhibit O-3, the applicant states that out of the 70 facilities located in North Carolina operated by the applicant only the four listed below were not in compliance

with Medicare conditions of participation during the 18 months prior to submission of the application.

DVA Quality Care			
Facility	Survey Date	Back in Compliance	
Southeastern Dialysis Center-Kenansville	3/22/2016	Yes	6/10/2016
Durham Dialysis	3/22/2016	Yes	5/31/2016
Marshville Dialysis	2/29/2016	Yes	4/15/2016
Durham West Dialysis	10/7/2015*	Yes	9/30/2015

***Back in compliance prior to survey on 10/7/2015 per the applicant in Project I.D. # P-11248-16**

Based on a review of this certificate of need application and publicly available information, 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 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 application is conforming with all applicable Criteria and Standards for End-Stage Renal Disease Services. The specific criteria are discussed below.

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

10A NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- The applicant is not proposing to establish a new End Stage Renal Disease facility

- (b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.
- C- In Section C-1, pages 13-18, the applicant demonstrates that Union County Dialysis will service a total of 123 in-center patients at the end of OY1 (CY2019) for a utilization rate of 93.25% or 3.73 patients per station per week ($123 \text{ patients} / 33 \text{ stations} = 3.73 / 4 = 0.9325$ or 93.25%). The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.
- C- In Section C, pages 13-18, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.