

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 28, 2018

Findings Date: November 28, 2018

Project Analyst: Gregory F. Yakaboski

Chief: Martha J. Frisone

Project ID #: F-11547-18

Facility: Huntersville Dialysis

FID #: 040271

County: Mecklenburg

Applicant: DVA Healthcare Renal Care, Inc.

Project: Relocate 4 stations from North Charlotte Dialysis for a total of 18 stations upon project completion

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 Huntersville Dialysis proposes to relocate four dialysis stations from North Charlotte Dialysis to Huntersville Dialysis for a total of 18 dialysis stations at Huntersville Dialysis. The parent company of DVA is DaVita, Inc. Huntersville Dialysis does not offer either a peritoneal program or a home hemodialysis program.

Need Determination

The county and facility need methodologies in the July 2018 Semiannual Dialysis Report (SDR) and the 2018 State Medical Facilities Plan (SMFP) are not applicable to this review.

Policies

There is one policy in the 2018 SMFP applicable to this review: *Policy ESRD-2: Relocation of Dialysis Stations*, on page 27.

Policy ESRD-2

Policy ESRD-2 states:

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to a contiguous county shall:

- 1. Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
- 2. Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 3. Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

Huntersville Dialysis and North Charlotte Dialysis are both located in Mecklenburg County. Therefore, the proposed project is consistent with Policy ESRD-2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion because the applicant adequately demonstrates that the proposal is consistent with Policy ESRD 2.

- (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 relocate four dialysis stations from North Charlotte Dialysis to Huntersville Dialysis for a total of 18 dialysis stations at Huntersville Dialysis. Huntersville Dialysis does not offer either a peritoneal program or a home hemodialysis program.

Patient Origin

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

The following table illustrates current and projected patient origin for in-center (IC) patients.

Huntersville Dialysis: Historical and Projected Utilization

County	Current (6/30/18)	OY2 (CY2020)
	IC	IC
Mecklenburg	48	52
Cabarrus	1	1
Lincoln	2	2
Gaston	2	2
Other States	3	3
Total	56	60

Source: Tables on pages 13 and 17 of the application.

In Section C, pages 13-15, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 13-15, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On pages 13-14, the applicant states:

- The first two full operating years (OYs) of the project will be
OY1: January 1, 2019 – December 31, 2019 (CY2019), and
OY2: January 1, 2020 – December 31, 2020 (CY2020).
- 47 patients were receiving in-center dialysis treatments at Huntersville Dialysis as of December 31, 2017.

- 56 patients were receiving in-center dialysis treatments at Huntersville Dialysis as of June 30, 2018, an increase of 9 in-center patients in six months.
- Huntersville Dialysis currently has 14 stations. Therefore, as of June 30, 2018 Huntersville Dialysis was at 100% utilization [56 patients/ 14 stations = 4.0/ 4 = 1.00 or 100%]

The information is reasonable and adequately supported because Huntersville Dialysis was at 100% utilization as of June 30, 2018 based on historical, not projected, data.

Projected Utilization

In Section Q, the applicant provides historical and projected utilization, as illustrated in the following table.

Huntersville Dialysis: Historical and Projected Utilization		
County	Current (6/30/18)	OY2 (CY2020)
	IC	IC
Mecklenburg	48	52
Cabarrus	1	1
Lincoln	2	2
Gaston	2	2
Other States	3	3
Total	56	60

Source: Tables on pages 13 and 17 of the application.

On pages 13-14, the applicant describes how in-center patient utilization was projected, which is summarized as follows:

- Operating Year One (OY1) is January 1, 2019 – December 31, 2019.
- Operating Year Two (OY2) is January 1, 2020 – December 31, 2020.
- As of June 30, 2018, Huntersville Dialysis had 56 in-center patients, consisting of 48 residents of Mecklenburg County and 8 patients residing in other counties.
- Utilization by Mecklenburg County residents is projected to grow at 3.9%, the Five-Year Average Annual Growth Rate (AAGR) for Mecklenburg County, as shown in Table D in the July 2018 Semi-Annual Dialysis Report (SDR).
- The applicant projects no growth for the remaining patients.
- The applicant does not project that any patients currently dialyzing at North Charlotte Dialysis will transfer their care to Huntersville Dialysis as part of this proposed project.

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

Huntersville Dialysis	In-Center Patients
Begin with Huntersville’s in-center ESRD patient population from Mecklenburg County, as of June 30, 2018.	48
Project the Mecklenburg County population forward six months to December 31, 2018, using the Five Year AACR for Mecklenburg County.	$48 \times 1.0195 = 48.936$
Project the Mecklenburg County population forward one year to December 31, 2019, using the Five Year AACR for Mecklenburg County.	$48.936 \times 1.039 = 50.844$
Add the 8 other patients currently dialyzing at Huntersville Dialysis. This is the patient census at the end of OY1.	$50.844 + 8 = \mathbf{58.844}$
Project the Mecklenburg County population forward one year to December 31, 2020, using the Five Year AACR for Mecklenburg County.	$50.844 \times 1.039 = 52.826$
Add the 8 other patients currently dialyzing at Huntersville Dialysis. This is the patient census at the end of OY2.	$52.826 + 8 = \mathbf{60.826}$

The applicant states on page 14 that the number of projected patients for OY1 and OY2 is rounded down to the nearest whole number. Therefore, at the end of OY1 (CY 2019) and OY2 (CY2020) the facility is projected to serve 58 and 60 in-center patients, respectively.

The projected utilization rates for the first two operating years are as follows:

- OY1: 3.22 patients per station per week, or 80.5% ($58 \text{ patients} / 18 \text{ stations} = 3.22 / 4 = 0.805$ or 80.5%).
- OY2: 3.33 patients per station per week, or 83.25% ($60 \text{ patients} / 18 \text{ stations} = 3.33 / 4 = 0.8325$ or 83.25%).

The projected utilization of 3.22 patients per station per week at the end of OY1 meets the minimum standard of 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

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

- The applicant starts with the 48 existing Mecklenburg County patients.
- The Mecklenburg County patients are projected to increase based on 3.9% per year which is the Five Year Average Annual Change Rate (AACR) for Mecklenburg County as reported in Table D of the July 2018 SDR.
- The non-Mecklenburg County patients are existing patients and no growth is projected.

Access

In Section C, page 15, the applicant states “*By policy, the proposed services will be made available to all residents in its service area without qualifications. The facility will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.*” In Section L.1, page 45, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Payor Category	Percent of Total Patients
Medicaid	1.8%
Medicare	25.0%
Medicare/Medicaid	12.5%
Medicare/Commercial	48.2%
Commercial Insurance	12.5%
Total	100.0%

Source: Table, page 45 of the application.

On page 45, the applicant states the projected payor mix is based on the payor mix during the last year of operation. The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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

DVA proposes to relocate four dialysis stations from North Charlotte Dialysis to Huntersville Dialysis for a total of 18 dialysis stations at Huntersville Dialysis. Huntersville Dialysis does not offer either a peritoneal program or a home hemodialysis program.

Per the July 2018 SDR North Charlotte Dialysis had 37 certified stations as of June 1, 2018. In previously approved, but undeveloped, projects, North Charlotte Dialysis was approved, in total, to relocate 17 dialysis stations to other facilities and add 9 stations.

- Project ID #F-11019-15 (relocate 4 stations to Copperfield)
- Project ID #F-11108-15 (relocate 10 stations to Sugar Creek)
- Project ID #F-11252-16 (add 9 stations)
- Project ID #F-11452-18 (relocate 3 stations to Cannon Dialysis)

One project was relinquished: Project ID #F-11019-15 (relocate 4 stations to Copperfield).

Therefore, once all previously approved projects are completed there will be a total of 33 stations at North Charlotte Dialysis [$37 - 3 - 10 + 9 = 33$]. The proposed project is to relocate 4 stations from North Charlotte Dialysis to Huntersville Dialysis which will leave North Charlotte Dialysis with 29 stations [$33 - 4 = 29$] upon completion of all projects.

The assumptions and methodology used to project utilization at North Charlotte Dialysis was provided in response to a request from the Agency and is summarized in the following table.

North Charlotte Dialysis Center	In-Center Patients
Begin with North Charlotte's in-center ESRD patient population from Mecklenburg County, as of January 1, 2018.	99
Project the Mecklenburg County population forward six months to June 30, 2018, using the Five Year AACR for Mecklenburg County.	$99 \times 1.0195 = 100.93$
Subtract out 11 Mecklenburg County patients currently dialyzing at North Charlotte Dialysis expected to transfer to Sugar Creek Dialysis [Project ID#F-11108-15] as of June 30, 2018.	$100 - 11 = 89$
Project the Mecklenburg County population forward six months to December 31, 2018, using the Five Year AACR for Mecklenburg County.	$89 \times 1.0195 = 90.7355$
Project the Mecklenburg County population forward one year to December 31, 2019, using the Five Year AACR for Mecklenburg County.	$90.7355 \times 1.039 = 94.2742$
Add 4 other patients currently dialyzing at North Charlotte Dialysis Center. This is the patient census at the end of OY1.	$94 + 4 = \mathbf{98}$
Project the Mecklenburg County population forward one year to December 31, 2020, using the Five Year AACR for Mecklenburg County.	$94.2742 \times 1.039 = 97.9508$
Add the 4 other patients currently dialyzing at North Charlotte Dialysis Center. This is the patient census at the end of OY2.	$97.9508 + 4 = \mathbf{101.9508}$

Therefore, at the end of OY1 (CY 2019) and OY2 (CY2020), the facility is projected to serve 98 and 101 in-center patients, respectively.

The projected utilization rate for the first operating year is as follows:

- 3.3793 patients per station per week, or 84.48% (98 patients / 29 stations = 3.3793/ 4 = 0.8448 or 84.48%).

Projected utilization for North Charlotte Dialysis Center is reasonable and adequately supported for the following reasons:

- The applicant assumes no patients will transfer to Huntersville Dialysis.
- The applicant starts with the 99 existing Mecklenburg County patients.
- The Mecklenburg County patients are projected to increase 3.9% per year which is the Five Year AACR for Mecklenburg County as reported in Table D of the July 2018 SDR.
- The non-Mecklenburg County patients are existing patients and no growth is projected.

Further, in Section D.2, page 21, and supplemental information the applicant states that the proposed relocation of stations will not adversely affect 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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency (if applicable)

Based on that review, the Agency concludes that the applicant adequately demonstrates that:

- The needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.

- (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

DVA proposes to relocate four dialysis stations from North Charlotte Dialysis to Huntersville Dialysis for a total of 18 dialysis stations at Huntersville Dialysis. Huntersville Dialysis does not offer either a peritoneal program or a home hemodialysis program.

In Section E, page 22, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The only alternative considered was to maintain the status quo. The applicant states that this is not the most effective alternative because maintaining the status quo would not meet patient need and access to dialysis services based on the rate of growth at Huntersville Dialysis.

On page 22, the applicant states that its proposal is the most effective alternative because the proposed project proactively meets both an established and growing patient need. The proposed project addresses both growth and access issues.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. DVA Healthcare Renal Care, Inc. shall materially comply with all representations made in the certificate of need application.**
 - 2. Pursuant to Policy ESRD-2, DVA Healthcare Renal Care, Inc. shall relocate four dialysis stations from North Charlotte Dialysis to Huntersville Dialysis for a total of 18 dialysis stations at Huntersville Dialysis upon project completion.**
 - 3. Dialysis DVA Healthcare Renal Care, Inc. shall install plumbing and electrical wiring through the walls for no more than 18 dialysis stations which shall include any isolation stations.**
 - 4. Upon completion of this project, DVA Healthcare Renal Care, Inc. shall take the necessary steps to decertify four dialysis stations at North Charlotte Dialysis for a total of 29 dialysis stations at North Charlotte Dialysis upon completion of this project and three other projects (Project ID# F-11108-15, Project ID# F-11252-16 and Project ID#F-11452-18).**
 - 5. DVA Healthcare Renal Care, Inc. 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

DVA proposes to relocate four dialysis stations from North Charlotte Dialysis to Huntersville Dialysis for a total of 18 dialysis stations at Huntersville Dialysis. Huntersville Dialysis does not offer either a peritoneal program or a home hemodialysis program.

Capital and Working Capital Costs

In Section F, page 23, the applicant projects the total capital cost of the project as shown in the table below.

Site Costs	\$0
Construction Costs	\$0
Miscellaneous Costs	\$67,880
Total	\$67,880

In Section F.1, page 23, the applicant provides the assumptions used to project the capital cost.

In Section F, pages 25-26, the applicant states that there will be no start-up costs since Huntersville Dialysis is an existing facility.

Availability of Funds

In Section F.2, page 24, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing

Type	DaVita Inc.	Total
Accumulated reserves or OE *	\$67,880	\$67,880
Total Financing	\$67,880	\$67,880

* OE = Owner's Equity

On page 25, the applicant states that DVA Healthcare Renal Care, Inc. is wholly owned by DaVita Inc. In Exhibit F, the applicant provides a letter dated July 16, 2018 from the Chief Accounting Officer of DaVita, Inc. confirming that DaVita Inc. is the parent and 100% owner of DVA Healthcare Renal Care, Inc.. The Chief Accounting Officer states

“This letter will confirm that DaVita Inc. has committed cash reserves in the total sum of \$67,880 for the project capital expenditure. DaVita, Inc. will make these funds, along with any other funds that are necessary for the development of the project, available to DVA Healthcare Renal Care, Inc.”

Exhibit F also includes a copy of the United States Securities and Exchange Commission Form 10-K for DaVita, Inc. for the fiscal year ended December 31, 2017. Form 10-K, page F-6, shows DaVita, Inc. having “Cash and cash equivalents” of \$508,234,100 and a “*Total equity*” balance of \$4,886,066,000 as of December 31, 2017.

Financial Feasibility

The applicant provided pro forma financial statements for the first two full fiscal years of operation following completion of the project. In 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.

	1st Full Fiscal Year	2nd Full Fiscal Year
Total Treatments	8,477	8,744
Total Gross Revenues (Charges)	\$3,036,303	\$3,142,712
Total Net Revenue	\$2,938,986	\$3,041,985
Average Net Revenue per treatment	\$346.70	\$347.89
Total Operating Expenses (Costs)	\$2,290,558	2,360,430
Average Operating Expense per treatment	\$270.21	\$269.95
Net Income	\$648,428	\$681,555

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- 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.

- (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 relocate four dialysis stations from North Charlotte Dialysis to Huntersville Dialysis for a total of 18 dialysis stations at Huntersville Dialysis. Huntersville Dialysis does not offer either a peritoneal program or a home hemodialysis program.

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

According to the July 2018 SDR, there are 23 dialysis facilities in Mecklenburg County, 17 of which are operational. Information on all 23 of these dialysis facilities, from Table B of the July 2018 SDR, is provided below:

**Mecklenburg County Dialysis Facilities
 Certified Stations and Utilization as of December 31, 2017**

Dialysis Facility	Owner	Location	Number of Certified Stations	Utilization
BMA Beatties Ford	BMA	Charlotte	32	89.84%
BMA Nations Ford	BMA	Charlotte	28	91.96%
BMA of East Charlotte	BMA	Charlotte	26	88.46%
BMA of North Charlotte	BMA	Charlotte	40	98.75%
BMA West Charlotte	BMA	Charlotte	29	87.93%
FMC Charlotte	BMA	Charlotte	44	89.20%
FMC Matthews	BMA	Matthews	21	115.48%
Fresenius Medical Care Southwest Charlotte	BMA	Charlotte	13	84.62%
FMC Regal Oaks	BMA	Charlotte	12	43.75%
FMC Aldersgate*	BMA	Charlotte	0	0.00%
FKC Southeast Charlotte*	BMA	Charlotte	0	0.00%
FKC Mallard Creek*	BMA	Charlotte	0	0.00%
Brookshire Dialysis*	DaVita	Charlotte	0	0.00%
Charlotte Dialysis	DaVita	Charlotte	36	86.11%
Charlotte East Dialysis	DaVita	Charlotte	34	90.44%
Huntersville Dialysis	DaVita	Huntersville	14	83.93%
Mint Hill Dialysis	DaVita	Mint Hill	16	84.38%
North Charlotte Dialysis Center	DaVita	Charlotte	37	68.24%
South Charlotte Dialysis**	DaVita	Charlotte	23	83.70%
South Charlotte Dialysis*	DaVita	Charlotte	0	0.00%
Sugar Creek Dialysis*	DaVita	Charlotte	0	0.00%
Carolinas Medical Center	CMC	Charlotte	9	25.00%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	69.79%
DSI Glenwater Dialysis	DSI	Charlotte	42	75.00%

Source: July 2018 SDR, Table B.

* Facility under development.

**Pursuant to the certificate of need for Project ID #F-11323-17 this facility is being relocated to a new location.

In Section G.2, pages 29-30, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Mecklenburg County. The applicant states:

“Adding stations at this facility does not increase the number of stations in Mecklenburg County since the stations will be transferred from North Charlotte Dialysis. The transfer of stations serves to meet the needs of the facility’s growing population of patients referred by the facility’s admitting nephrologists. The addition of stations, therefore, serves to increase capacity [at Huntersville Dialysis] rather than duplicate any existing or approved services in the service area.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The applicant adequately demonstrates that the proposed stations are needed at Huntersville Dialysis.
- The proposal will not result in an increase in the number of dialysis stations in Mecklenburg County. Existing stations will be relocated from one DaVita facility in Mecklenburg County to another DaVita facility in Mecklenburg County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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.1, page 31, the applicant provides the current and projected staffing for proposed services as illustrated in the following table.

Position	Current	2 nd Full Fiscal Year
RN	1.50	3.00
Technician (PCT)	6.00	8.00
Administrator	1.00	1.00
Dietitian	0.35	0.50
Social Worker	0.35	0.50
Admin Assistant	1.00	1.00
Biomed Tech	0.30	0.40
TOTAL	10.5	14.4

Source: Table on page 31 of the application.

The assumptions and methodology used to project staffing are provided in Section H.1, page 31 and Sections H.6 and H.7, page 34. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Sections H.3 and H.4, pages 32-33, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Exhibits H-2, H-3 and H-4, the applicant provides supporting documentation. In Section I.3, page 36, the applicant identifies the medical director. In Exhibit I-3, the applicant provides a letter from the current medical director indicating she will continue to serve as medical director for the facility.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section I.1, page 35, the applicant identifies the ancillary and support services necessary for the proposed services, as shown in the table below.

HUNTERSVILLE DIALYSIS Ancillary and Support Services	
Services	Provider
In-center dialysis/maintenance	Huntersville Dialysis
Self-care training (in-center)	Huntersville Dialysis
Home training	
HH	Charlotte East Dialysis
PD	Charlotte East Dialysis
Accessible follow-up program	Charlotte East Dialysis
Psychological counseling	Huntersville Dialysis
Isolation – hepatitis	Huntersville Dialysis
Nutritional counseling	Huntersville Dialysis
Social Work services	Huntersville Dialysis
Acute dialysis in an acute care setting	Carolinas Medical Center
Emergency care	Carolinas Medical Center
Blood bank services	Carolinas Medical Center
Diagnostic and evaluation services	Carolinas Medical Center
X-ray services	Carolinas Medical Center
Laboratory services	DaVita Laboratory Services
Pediatric nephrology	Carolinas Medical Center
Vascular surgery	Carolinas Medical Center
Transplantation services	Carolinas Medical Center
Vocational rehabilitation & counseling	NC DHHS Div of Vocational Rehab Services
Transportation	DSS and Various Providers

On page 35, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I-2.

In Section I, pages 36-37, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits I-1 and I-3.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

- (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 nor renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 48, the applicant provides the historical payor mix during 7/1/2017 to 6/30/2018 at Huntersville Dialysis and North Charlotte Dialysis for the proposed services, as shown in the table below.

Historical Payor Mix

Payor Category	Huntersville Dialysis Percent of Total Patients	North Charlotte Dialysis Percent of Total Patients
Medicaid	1.8%	7.7%
Medicare	25.0%	33.7%
Medicare/Medicaid	12.5%	24.0%
Medicare/Commercial	48.2%	22.1%
Commercial Insurance	12.5%	7.7%
VA	0.0%	4.84%
Total	100.0%	100.0%

Source: Tables on page 48 of the application.

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

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate	2017 Estimate
Mecklenburg	11%	52%	53%	12%	6%	12%
Cabarrus	13%	51%	34%	11%	7%	10%
Lincoln	18%	50%	15%	13%	12%	11%
Gaston	16%	52%	28%	16%	12%	12%
Statewide	16%	51%	37%	15%	10%	12%

Source: <http://www.census.gov/quickfacts/table/US/PST045217> Latest Data 7/1/17 as of 7/17/18

* Excludes "White alone, not Hispanic or Latino"

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

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

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

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant’s service area which is medically underserved. Therefore, the application is conforming to this criterion.

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.3, page 47, the applicant states

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

In Section L.6, page 47, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.1, page 45, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Payor Category	Percent of Total Patients
Medicaid	1.8%
Medicare	25.0%
Medicare/Medicaid	12.5%
Medicare/Commercial	48.2%
Commercial Insurance	12.5%
Total	100.0%

Source: Table on page 45 of the application.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 85.7% of total services will be provided to Medicare patients and 1.8% to Medicaid patients

On page 45, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based “*on the sources of patient payment that have been received by existing facility in the last year of operation.*”

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.4, page 47, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section M, page 49, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

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

C

DVA proposes to relocate four dialysis stations from North Charlotte Dialysis to Huntersville Dialysis for a total of 18 dialysis stations at Huntersville Dialysis. Huntersville Dialysis does not offer either a peritoneal program or a home hemodialysis program.

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

According to the July 2018 SDR, there are 23 dialysis facilities in Mecklenburg County, 17 of which are operational. Information on all 23 of these dialysis facilities, from Table B of the July 2018 SDR, is provided below:

**Mecklenburg County Dialysis Facilities
 Certified Stations and Utilization as of December 31, 2017**

Dialysis Facility	Owner	Location	Number of Certified Stations	Utilization
BMA Beatties Ford	BMA	Charlotte	32	89.84%
BMA Nations Ford	BMA	Charlotte	28	91.96%
BMA of East Charlotte	BMA	Charlotte	26	88.46%
BMA of North Charlotte	BMA	Charlotte	40	98.75%
BMA West Charlotte	BMA	Charlotte	29	87.93%
FMC Charlotte	BMA	Charlotte	44	89.20%
FMC Matthews	BMA	Matthews	21	115.48%
Fresenius Medical Care Southwest Charlotte	BMA	Charlotte	13	84.62%
FMC Regal Oaks	BMA	Charlotte	12	43.75%
FMC Aldersgate*	BMA	Charlotte	0	0.00%
FKC Southeast Charlotte*	BMA	Charlotte	0	0.00%
FKC Mallard Creek*	BMA	Charlotte	0	0.00%
Brookshire Dialysis*	DaVita	Charlotte	0	0.00%
Charlotte Dialysis	DaVita	Charlotte	36	86.11%
Charlotte East Dialysis	DaVita	Charlotte	34	90.44%
Huntersville Dialysis	DaVita	Huntersville	14	83.93%
Mint Hill Dialysis	DaVita	Mint Hill	16	84.38%
North Charlotte Dialysis Center	DaVita	Charlotte	37	68.24%
South Charlotte Dialysis**	DaVita	Charlotte	23	83.70%
South Charlotte Dialysis*	DaVita	Charlotte	0	0.00%
Sugar Creek Dialysis*	DaVita	Charlotte	0	0.00%
Carolinas Medical Center	CMC	Charlotte	9	25.00%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	69.79%
DSI Glenwater Dialysis	DSI	Charlotte	42	75.00%

Source: July 2018 SDR, Table B.

* Facility under development.

**Pursuant to the certificate of need issued for Project ID #F-11323-17 this facility is being relocated to a new location.

In Section N, page 50, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 50, the applicant states.

“The expansion of Huntersville Dialysis will have no effect on competition in Mecklenburg 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 Healthcare Renal Care, Inc.

The expansion of Huntersville 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.”

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section A, page 5, the applicant states DaVita operates more than 80 dialysis facilities in North Carolina. Exhibit A-11 contains a list of the DaVita dialysis facilities located in North Carolina.

In Section O, page 51, and Exhibit O-3 the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in two of these facilities, Southeastern Dialysis Center-Wilmington and Goldsboro South Dialysis. The applicant states that all of the problems have been corrected and that Southeastern Dialysis Center-Wilmington was back in compliance as of March 21, 2018 and that Goldsboro South Dialysis was back in compliance as of November 20, 2017. After reviewing and considering information provided by the applicant and considering the quality of care provided at all DaVita facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may

vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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, pages 13-15, the applicant demonstrates that Huntersville Dialysis will serve 58 in-center patients at the end of OY1 (CY2019) for a utilization rate of 80.5% or 3.22 patients per station per week (58 patients / 18 stations = 3.22/ 4 = 0.805 or 80.5%). 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 13-15, the applicant provides the assumptions and methodology used to project utilization. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.