

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 7, 2017

Findings Date: April 7, 2017

Project Analyst: Gloria C. Hale

Team Leader: Fatimah Wilson

Project ID #: F-11288-17

Facility: Huntersville Dialysis

FID #: 130490

County: Mecklenburg

Applicant: DVA Healthcare Renal Care, Inc.

Project: Relocate four stations from North Charlotte Dialysis Center for a total of 14 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) proposes to relocate four dialysis stations from North Charlotte Dialysis Center to Huntersville Dialysis for a total of 14 dialysis stations upon project completion. Both facilities are located in Mecklenburg County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations. Upon completion of the project, Huntersville Dialysis will be certified for 14 dialysis stations and North Charlotte Dialysis Center will be certified for 32 dialysis stations upon completion of Project I.D. #s F-11019-14 (relocate four stations), F-11108-15 (relocate 10 stations) and F-11252-16 (add nine stations).

Need Determination

The applicant proposes to relocate existing dialysis stations within Mecklenburg County; therefore, there are no need methodologies in the 2017 State Medical Facilities Plan (2017 SMFP) applicable to this review.

Policies

POLICY GEN-3: BASIC PRINCIPLES on page 33 of the 2017 SMFP is not applicable to this review because neither the county nor facility need methodology is applicable to this review.

POLICY GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES on page 33 of the 2017 SMFP is not applicable to this review because the applicant does not propose a capital expenditure greater than \$2 million.

However, *POLICY ESRD-2: RELOCATION OF DIALYSIS STATIONS* on page 27 of the 2017 SMFP is applicable to this review.

POLICY ESRD-2: RELOCATION OF DIALYSIS STATIONS 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 contiguous counties 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.”*

The applicant proposes to relocate four dialysis stations to Huntersville Dialysis from North Charlotte Dialysis. Because both facilities are located in Mecklenburg County, there is no change in the total dialysis station inventory in Mecklenburg County. Therefore, the application is consistent with Policy ESRD-2.

Conclusion

In summary, the applicant adequately demonstrates that the application is consistent with Policy ESRD-2 in the 2017 SMFP. 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.

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DVA proposes to relocate four dialysis stations from North Charlotte Dialysis Center to Huntersville Dialysis for a total of 14 stations upon project completion. Both facilities are located in Mecklenburg County.

Patient Origin

On page 373, the 2017 SMFP defines the service area for dialysis stations as “*the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area is Mecklenburg County. Facilities may serve residents of counties not included in their service area.

In supplemental information, the applicant provides the historical in-center (IC) patient origin for Huntersville Dialysis as of December 31, 2016, which is summarized in the following table:

**Huntersville Dialysis
Historical Patient Origin
12/31/2016**

County	IC Patients
Mecklenburg	35
Cabarrus	1
Out of State	1
TOTAL	37

In supplemental information, the applicant provides the projected patient origin for Huntersville Dialysis for IC patients for the first two years of operation following

completion of the project, Operating Year One (OY1), 7/1/17 through 6/30/18, and Operating Year Two (OY2), 7/1/18 through 6/30/19, as follows:

**Huntersville Dialysis
 Projected Patient Origin**

County	OY1 7/1/17 – 6/30/18	OY2 7/1/18 – 6/30/19	County Patients as Percent of Total	
	IC Patients	IC Patients	OY1	OY2
Mecklenburg	44	46	95.6%	95.8%
Cabarrus	1	1	2.2%	2.1%
Other State	1	1	2.2%	2.1%
Total	46	48	100%	100%

In supplemental information, the applicant provides the assumptions and methodology used to project patient origin. In Section C.1, page 14, the applicant states that seven IC patient letters of support were received indicating each patient’s willingness to consider transferring to Huntersville Dialysis from North Charlotte Dialysis Center. All seven dialysis patients reside in Mecklenburg County. See Exhibit C-1 for patients’ letters of support.

The applicant adequately identifies the population to be served.

Analysis of Need

The applicant proposes to relocate four dialysis stations from North Charlotte Dialysis Center to Huntersville Dialysis for a total of 14 certified stations upon project completion. Both facilities are located in Mecklenburg County.

In Section C.7, page 18, the applicant states that Huntersville Dialysis experienced a facility growth rate of 23.3% from July 1, 2016 to December 31, 2016, and further states in Section C.1, page 14, that its utilization rate was 92.5% on December 31, 2016 based on 37 IC patients and 10 dialysis stations ($37/10 = 3.7$; $3.7/4 = .925$ or 92.5%). In addition, the applicant states, in Section C.1, page 14, that seven patients living in Huntersville, Cornelius and Davidson and dialyzing at North Charlotte Dialysis Center, have stated in their letters of support that they would be willing to consider transferring to Huntersville Dialysis because it is more convenient and closer to their homes. Exhibit C-1 contains patients’ letters of support.

Projected Utilization

In supplemental information, the applicant provides the assumptions and methodology used to project utilization. The applicant states that as of December 31, 2016, Huntersville Dialysis had 37 IC patients based on ESRD data collected and reported to the Agency. Thirty-five patients were from Mecklenburg County, one was from Cabarrus County, and one was from out of state. In Section C.1, page 14, the applicant states it received seven letters of support from dialysis patients residing in Huntersville, Cornelius and Davidson who are dialyzing at North Charlotte Dialysis Center and who indicated they would be willing to consider transferring their care to Huntersville Dialysis once the four dialysis stations are relocated. All seven of the patients willing to consider transferring their care are from Mecklenburg County. The applicant's methodology is summarized in the table below:

	IC Patients
The applicant begins with the 35 patients from Mecklenburg County dialyzing at the facility as of December 31, 2016.	35
Seven IC patients transfer to Huntersville Dialysis from North Charlotte Dialysis Center by July 1, 2017. All seven are from Mecklenburg County and are added to the facility census.	$35 + 7 = 42$
The facility's Mecklenburg County patient census is projected forward one year to June 30, 2018 and is increased by the Five Year Average Annual Change Rate (AACR) of 5.0% for Mecklenburg County.	$42 \times 1.05 = 44.1$
The two patients from outside Mecklenburg County are added to the facility's census. This is the ending census for OY1.	$44.1 + 2 = 46.1$
The facility's Mecklenburg County patient census is projected forward one year to June 30, 2019 and is increased by the Five Year AACR of 5.0% for Mecklenburg County.	$44.1 \times 1.05 = 46.3$
The two patients from outside Mecklenburg County are added to the facility's census. This is the ending census for OY2.	$46.3 + 2 = 48.3$

In Section C.1, page 15, the applicant states that it rounds down to the nearest whole number and that by the end of OY1, Huntersville Dialysis will have 46 IC patients for a utilization rate of 3.29 patients per station per week (46 patients/ 14 stations = 3.29). By the end of OY2, Huntersville Dialysis will have 48 patients for a utilization rate of 3.43 patients per station per week (48 patients/ 14 stations = 3.43). Therefore, the applicant's projected utilization exceeds the minimum of 3.2 patients per station per week at the end of the first operating year as required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Access

In Section C.3, page 16, the applicant states that it serves all patients without regard to race, ethnicity, sex, age, handicap or social economic status. In addition, payment is not required upon admission. In Section L.7, page 48, the applicant states that 78.4% of patients who received dialysis at Huntersville Dialysis from April 1, 2016 to December 31, 2016 had their care covered by Medicare or Medicaid. In Section L.1(b), page 45, the applicant projects that the percentage of patients receiving dialysis at Huntersville Dialysis who will have their care covered by Medicare or Medicaid will remain the same at 78.4%.

The applicant adequately demonstrates the extent to which all residents of the area, including the medically underserved, are likely to have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for four relocated dialysis stations, and demonstrates 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.

C

DVA proposes to relocate four dialysis stations from North Charlotte Dialysis Center to Huntersville Dialysis for a total of 14 stations upon project completion. Both facilities are located in Mecklenburg County.

North Charlotte Dialysis Center will be certified for 32 dialysis stations upon completion of this project and the following projects: Project ID #F-11019-15 (41-4 = 37), Project ID #F-11108-15 (37-10 = 27), and Project ID #F-11252-16 (27+9 = 36).

In Section D.1, page 22, the applicant discusses how the needs of the population presently served at North Charlotte Dialysis Center will continue to be served adequately after the proposed relocation of four dialysis stations to Huntersville Dialysis, as follows:

- North Charlotte Dialysis Center has 41 certified dialysis stations as reported in the January 2017 SDR. Four dialysis stations will be relocated to Copperfield Dialysis Center (Project ID #F-11019-15), 10 dialysis stations will be relocated to

Sugar Creek Dialysis (formerly University City Dialysis, Project ID #F-11108-15), and nine dialysis stations will be added (Project ID #F-11252-16), leaving 36 dialysis stations at North Charlotte Dialysis Center.

- As of June 30, 2016, North Charlotte Dialysis Center had 136 IC patients. Twenty-four patients are expected to be transferred, leaving 112 IC patients. The applicant applies the Mecklenburg County Five Year AACR of 5%, thereby increasing the IC patient census to 118 as of June 30, 2017, the beginning of OY1 for the proposed project.
- Four dialysis stations will be relocated to Huntersville Dialysis at the completion of this project, as of June 30, 2017, leaving 32 dialysis stations at North Charlotte Dialysis Center ($36 - 4 = 32$).
- Based on 118 IC patients and 32 certified dialysis stations, North Charlotte Dialysis Center will have a utilization rate of 3.69 patients per station per week or 92.3% capacity as of June 30, 2017 ($118/32 = 3.69$; $3.69/4 = .923$ or 92.3%).

In Section D.2, page 22, the applicant states that the reduction in the number of stations at North Charlotte Dialysis Center will not have an adverse effect on the ability of underserved groups to obtain needed care at the facility.

Conclusion

The applicant demonstrates that the needs of the population presently served at North Charlotte Dialysis Center will continue to be adequately met following the proposed relocation of four dialysis stations to Huntersville Dialysis and that access for medically underserved groups will not be negatively impacted.

Therefore, the application is conforming to this criterion.

- (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.

C

In Section E, page 23, the applicant states that it considered one alternative, maintaining the status quo, prior to submitting this application for the proposed project. However, the applicant states that this alternative was dismissed given the growth at the facility.

Moreover, the applicant states, on page 23, that without the four relocated stations, a third shift would need to be considered as an option for patients and this would either be inconvenient, or patients would not have the option to dialyze at all at the facility. The applicant further states, *"We are committed to ensuring that all patients referred by our*

admitting nephrologists have convenient access to the facility and the chosen alternative does that effectively.”

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

In summary, the applicant adequately demonstrates that the proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1. DVA Healthcare Renal Care, Inc. d/b/a Huntersville Dialysis shall materially comply with all representations made in the certificate of need application and supplemental information provided. In those instances where representations conflict, Huntersville Dialysis shall materially comply with the last made representation.**
 - 2. DVA Healthcare Renal Care, Inc. d/b/a Huntersville Dialysis shall relocate no more than four dialysis stations from North Charlotte Dialysis Center for a total of no more than 14 certified dialysis stations upon completion of this project, which shall include any isolation or home hemodialysis stations.**
 - 3. DVA Healthcare Renal Care, Inc. d/b/a Huntersville Dialysis shall install plumbing and electrical wiring through the walls for no more than 4 dialysis stations for a total of no more than 14 dialysis stations, which shall include any isolation or home hemodialysis stations.**
 - 4. DVA Healthcare Renal Care, Inc. shall take the necessary steps to decertify four dialysis stations at North Charlotte Dialysis Center for a total of no more than 32 dialysis stations upon completion of this project and all of the following projects, #F-11019-15 (relocate four stations to Copperfield Dialysis Center), #F-11108-15 (relocate 10 stations to Sugar Creek Dialysis, formerly University City Dialysis), and #F-11252-16 (add nine stations), which shall include any isolation or home hemodialysis stations.**
 - 5. DVA Healthcare Renal Care, Inc. d/b/a Huntersville Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

DVA proposes to relocate four dialysis stations from North Charlotte Dialysis Center to Huntersville Dialysis for a total of 14 stations upon project completion. Both facilities are located in Mecklenburg County.

Capital and Working Capital Costs

In Section F.1, page 24, the applicant projects \$67,460 in capital costs to develop the proposed project. The costs are \$59,400 for dialysis machines and \$8,060 for equipment/furniture. The applicant indicates, in Sections F.10 and F.11, pages 26 and 27, respectively, that it will not have any start-up expenses or initial operating expenses.

Availability of Funds

In Section F.2, page 25, the applicant states it will finance the capital costs with accumulated reserves/owner's equity. Exhibit F-1 contains a letter dated January 13, 2017, signed by the Director of Healthcare Planning for DVA on behalf of the Chief Accounting Officer of DaVita, Inc., the parent and 100% owner of DVA, authorizing and committing \$67,460 in cash reserves for the project.

Exhibit F-7 contains the Consolidated Balance Sheets for DaVita Healthcare Partners Inc. for the years ending December 31, 2015 and December 31, 2014. These statements indicate that as of December 31, 2015, DaVita \$1,499,116,000 in cash and cash equivalents, \$18,514,875,000 in total assets and \$5,948,238,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project.

Financial Feasibility

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

**Huntersville Dialysis
 Projected Revenues and Operating Expenses**

	Operating Year (OY) 1 7/1/17 – 6/30/18	Operating Year (OY) 2 7/1/18 – 6/30/19
Total Number of Treatments	6,673	6,969
Gross Patient Revenue	\$2,832,061	\$2,957,756
Deductions from Gross Patient Revenue	\$66,398	\$69,347
Net Patient Revenue	\$2,765,662	\$2,888,408
Total Operating Expenses	\$2,135,447	\$2,218,291
Net Income	\$630,215	\$670,118

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 on reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital and working capital 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 relocate four dialysis stations from North Charlotte Dialysis Center to Huntersville Dialysis for a total of 14 stations upon project completion. Both facilities are located in Mecklenburg County.

On page 369, the 2017 SMFP defines the service area for dialysis stations as *“the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* Thus, the service area is Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

According to the January 2017 SDR, there are 16 operational facilities offering in-center dialysis and one facility offering only peritoneal dialysis training and support in Mecklenburg County. DVA owns and operates six of these facilities. Five additional dialysis facilities have been issued Certificates of Need (CONs) but are not yet operational and a proposal to develop one additional dialysis facility is under review. Two of the dialysis facilities issued CONs but are not yet operational are owned by DVA. The table below summarizes information provided in the January 2017 SDR on the 16 operational dialysis facilities in Mecklenburg County:

**Mecklenburg County Operational Dialysis Facilities
 Certified Stations and Utilization as of June 30, 2016**

Facility	Owner*	Location	Number of Existing/ Approved Stations	Utilization as of June 30, 2016
BMA Beatties Ford	BMA	Charlotte	32	98.4%
BMA Nations Ford	BMA	Charlotte	28	100.0%
BMA of East Charlotte	BMA	Charlotte	25	90.0%
BMA of North Charlotte	BMA	Charlotte	36	92.4%
BMA West Charlotte	BMA	Charlotte	29	83.6%
Carolinas Medical Center	CMHA	Charlotte	9	25.0%
Charlotte Dialysis	DVA	Charlotte	36	86.8%
Charlotte East Dialysis	DVA	Charlotte	34	75.0%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	63.5%
DSI Glenwater Dialysis	DSI	Charlotte	42	76.2%
FMC Charlotte	BMA	Charlotte	43	87.2%
FMC Matthews	BMA	Matthews	21	108.3%
Huntersville Dialysis	DVA	Huntersville	10	75.0%
Mint Hill Dialysis	DVA	Mint Hill	16	71.9%
North Charlotte Dialysis Center	DVA	Charlotte	41	82.9%
South Charlotte Dialysis	DVA	Charlotte	22	88.6%

*BMA is Bio-Medical Applications of North Carolina, Inc.; CMHA is The Charlotte Mecklenburg Hospital Authority; DVA is DVA Healthcare Renal Care, Inc.; DSI is U.S. Renal Care.

As shown in the table above, three of DVA's six operational dialysis facilities are operating above 80% utilization (3.2 patients per station). The applicant provides seven patient letters of support in Exhibit C-1 from in-center patients at North Charlotte Dialysis Center in Mecklenburg County indicating their willingness to transfer to Huntersville Dialysis because the facility would be closer to their homes.

The applicant is not increasing the number of dialysis stations in Mecklenburg County, rather it is relocating four of them to an existing facility, Huntersville Dialysis, which is closer to patients living in or near the area where the facility is located. Therefore, it is not duplicating services, rather it is proposing to relocate stations to better serve patients using existing stations.

The applicant adequately demonstrates the need to relocate stations to another dialysis facility in Mecklenburg County. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference. The discussion on the needs of the population presently served at Huntersville Dialysis and North Charlotte Dialysis Center, found in Criterion (3a), 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 or facilities. 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.1, page 31, the applicant provides the current and proposed staffing for Huntersville Dialysis, summarized as follows:

Position	Current # of FTE Positions	FTE Positions to be Added	Projected # of FTE Positions
Medical Director*			
RN	1.50	0.00	1.50
Patient Care Technician	4.50	1.50	6.00
Administrator	1.00	0.00	1.00
Dietitian	0.25	0.10	0.35
Social Worker	0.25	0.10	0.35
Administrative Assistant	1.00	0.00	1.00
Biomed Technician	0.30	0.00	0.30
Total FTE Positions	8.80	1.70	10.50

*The Medical Director is a contract position, not an FTE of the facility.

As illustrated in the above table, the applicant will add one and a half full-time equivalent (FTE) Patient Care Technicians and increase the FTEs of both the Dietician and Social Worker by one-tenth each. In Section H.3, pages 32-33, the applicant describes its experience and process for recruiting and retaining staff.

In Section H.7, page 34, the applicant provides the projected Direct Care Staff Hours for OY2, illustrated as follows:

Projected Direct Care Staff Hours – OY2

Direct Care Positions	# FTEs [a]	Hours / Year / FTE** [b]	Total Annual FTE Hours [c] = [a] x [b]	Total Annual Hours of Operation [d]	FTE Hours / Hours of Operation [e] = [c] ÷ [d]
Nurse	1.5	2,080	3,120	3,120	1
Patient Care Technician	6.0	2,080	12,480	3,120	4
Total	7.5	2,080	15,600	3,120	5

The applicant states, in Section H.1, page 31, that there is a signed agreement between the Medical Director and Huntersville Dialysis. In addition, in Exhibit I.2, the applicant provides a letter from the Medical Director, Dr. Jim Wood, stating his support for the proposed project.

The applicant documents the availability of adequate health manpower and management personnel, including a Medical Director, to provide 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.

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In Section I.1, page 35, the applicant includes a list of providers of the necessary ancillary and support services that will be provided to patients receiving dialysis services at Huntersville Dialysis. Exhibit I-1 contains documentation regarding the availability of laboratory services and letters from two Nephrologists, including one from the facility's Medical Director, stating their support for the project and willingness to refer patients. The applicant states, in Section I.3, page 36, that Dr. Jim Wood will continue to serve as Medical Director of the facility. In addition, the applicant states, in Section I.4, page 37, that it has established relationships with healthcare and social services providers within Mecklenburg County because it services many patients throughout the county. 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.

NA

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

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

C

In Section L.1, page 44, the applicant states that Huntersville Dialysis makes services available to all residents in the service area that patients are served “*without regard to race, color, national origin, gender, sexual orientation, age,*

religion, or disability.” In addition, the applicant states, on page 45, that it assists the uninsured or underinsured in applying for financial assistance and therefore, assures that services are available to low income persons as well.

The applicant provides the historical payor mix for Huntersville Dialysis in Section L.7, page 48, as illustrated below:

**Huntersville Dialysis
 Historical Payor Mix
 4/1/2016 through 12/31/2016**

Payor Type	Percent of In-Center Patients
Medicare	21.6%
Medicaid	2.7%
Commercial Insurance	18.9%
Medicare/Commercial	37.9%
Medicare/ Medicaid	16.2%
VA	2.7%
Total	100.0%

As illustrated in the table above, 78.4% of Huntersville Dialysis’ patients were Medicare or Medicaid recipients.

Similarly, the applicant provides the historical payor mix for North Charlotte Dialysis Center in Section L.7, page 48. Four dialysis stations will be relocated from North Charlotte Dialysis Center to the proposed facility and some patients will transfer to Huntersville Dialysis (See Exhibit C-1 for patients’ letters of support.) The historical payor mix is as follows:

**North Charlotte Dialysis Center
 Historical Payor Mix
 CY2015**

Payor Type	Percent of In-Center Patients
Medicare	31.6%
Medicaid	6.6%
Commercial Insurance	7.4%
Medicare/ Commercial	25.0%
Medicare/ Medicaid	25.0%
VA	4.4%
Total	100.0%

As illustrated in the table above, 88.2% of North Charlotte Dialysis Center’s patients were Medicare or Medicaid recipients.

In addition, the applicant describes its admission and financial policies in Section L.3, pages 45-47, and provides a copy of its admission policy in Exhibit L-3 which states that “*DaVita will accept and dialyze patients with renal failure needing a regular course of dialysis without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability...*”

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
Mecklenburg	10%	52%	51%	15%	6%	19%
Statewide	15%	51%	36%	17%	10%	15%

<http://www.census.gov/quickfacts/table> Latest Data as of 12/22/15

*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.”

However, a direct comparison to the applicant’s current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The *Southeastern Kidney Council Network 6 Inc. Annual Report¹* provides prevalence data on North Carolina dialysis patients by age, race, and gender on page 59, summarized as follows:

¹<http://esrd.ipro.org/wp-content/uploads/2017/06/2014-Network-6-Annual-Report-web.pdf>

Number and Percent of Dialysis Patients by Age, Race, and Gender 2014		
	# of ESRD Patients	% of Dialysis Population
Age		
0-19	52	0.3%
20-34	770	4.8%
35-44	1,547	9.7%
45-54	2,853	17.8%
55-64	4,175	26.1%
65+	6,601	41.3%
Gender		
Female	7,064	44.2%
Male	8,934	55.8%
Race		
African-American	9,855	61.6%
White	5,778	36.1%
Other, inc. not specified	365	2.3%

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

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

C

In Section L.3, page 47, the applicant states that it has no obligation under any federal regulation to provide uncompensated care, community service, or access by minorities and handicapped persons. However, the applicant states, in Section L.1, page 44, that its dialysis services are available to all residents without qualifications, and, as stated on page 46, it will *“accept patients in need of dialysis treatment first, and assist them with insurance and billing issues later.”*

In Section L.6, page 47, the applicant states there have been no civil rights equal access complaints filed against any DVA North Carolina facilities within the past five years. Therefore, the application is conforming to this criterion.

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

C

In Section L.1, page 45, the applicant provides the projected payor mix for the proposed project for the second operating year, (CY2020). The applicant states, on page 45, that the projected payor mix for Huntersville Dialysis is based on historical sources of patient payment since the facility has been certified. Therefore, there is no change from the historical payor mix, illustrated as follows:

**Huntersville Dialysis
Project Year Two**

Payment Source	Percent of In-Center Patients
Medicare	21.6%
Medicaid	2.7%
Commercial Insurance	18.9%
Medicare/ Commercial Insurance	37.9%
Medicare/ Medicaid	16.2%
VA	2.7%
Total	100.0%

As illustrated in the table above, the applicant projects that 78.4% of all of the patients receiving dialysis services at Huntersville Dialysis in the second year of operation will have some or all of their services paid for by Medicare or Medicaid. The applicant demonstrates that medically underserved groups will have adequate access to the services offered at Huntersville Dialysis. 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 47, the applicant states that nephrologists with privileges at Huntersville Dialysis will admit patients to the facility for dialysis. Patients who contact the facility will be referred to a nephrologist with admission privileges for evaluation and subsequent admission if necessary. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to dialysis 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 49, the applicant states that the facility has been offered to Kaplan College as a clinical training site for the college's medical assisting students. The information provided is reasonable and adequately supports a determination that 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 Center to Huntersville Dialysis for a total of 14 stations upon project completion. Both facilities are located in Mecklenburg County.

On page 369, the 2017 SMFP defines the service area for dialysis stations as *“the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* Thus, the service area is Mecklenburg County. Facilities may serve residents of counties not included in their service area.

The following table provides a summary of information provided in the January 2017 SDR on operational ESRD facilities in Mecklenburg County.

**Mecklenburg County Operational Dialysis Facilities
 Certified Stations and Utilization as of June 30, 2016**

Facility	Owner*	Location	Number of Existing/ Approved Stations	Utilization as of June 30, 2016
BMA Beatties Ford	BMA	Charlotte	32	98.4%
BMA Nations Ford	BMA	Charlotte	28	100.0%
BMA of East Charlotte	BMA	Charlotte	25	90.0%
BMA of North Charlotte	BMA	Charlotte	36	92.4%
BMA West Charlotte	BMA	Charlotte	29	83.6%
Carolinas Medical Center	CMHA	Charlotte	9	25.0%
Charlotte Dialysis	DVA	Charlotte	36	86.8%
Charlotte East Dialysis	DVA	Charlotte	34	75.0%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	63.5%
DSI Glenwater Dialysis	DSI	Charlotte	42	76.2%
FMC Charlotte	BMA	Charlotte	43	87.2%
FMC Matthews	BMA	Matthews	21	108.3%
Huntersville Dialysis	DVA	Huntersville	10	75.0%
Mint Hill Dialysis	DVA	Mint Hill	16	71.9%
North Charlotte Dialysis Center	DVA	Charlotte	41	82.9%
South Charlotte Dialysis	DVA	Charlotte	22	88.6%

*BMA is Bio-Medical Applications of North Carolina, Inc.; CMHA is The Charlotte Mecklenburg Hospital Authority; DVA is DVA Healthcare Renal Care, Inc.; DSI is U.S. Renal Care.

As shown in the table above, three of DVA’s six operational dialysis facilities in Mecklenburg County are operating above 80% utilization (3.2 patients per station).

In Section N.1, page 50, the applicant discusses how any enhanced competition will have a positive impact on cost-effectiveness, quality and access to the proposed services. The applicant states,

“The expansion of Huntersville Dialysis will have no effect on competition in Mecklenburg 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, based on historical growth rates) by DVA Healthcare Renal Care, Inc.”

In addition, the applicant states, on page 50, that accessibility to dialysis will be enhanced, economic and physical burdens will be reduced, and quality and cost-effectiveness will be enhanced because it will be easier for patients to receive services.

See also Sections B, C, D, E, H, L, and N where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in the sections referred to above is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on 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 a cost-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 it will provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant adequately demonstrates that it will provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3), (3a) 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 Exhibit O-3, the applicant identifies four of its North Carolina facilities, Southeastern Dialysis Center-Kenansville, Durham Dialysis, Marshville Dialysis, and Durham West Dialysis as having been cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. The applicant states in Exhibit O-3 and Section O.3, page 51, that all four facilities are back in full compliance with CMS Guidelines as of the date of submission of this application. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it 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 Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The proposal is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services in 10A NCAC 14C .2200. The specific findings are discussed below.

10 NCAC 14C .2203 PERFORMANCE STANDARDS

- .2203(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*
- NA- The applicant is not proposing to establish a new End State Renal Disease facility.
- .2203(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- C- In supplemental information, the applicant adequately demonstrates that Huntersville Dialysis will serve at least 46 in-center patients on 14 dialysis stations at the end of the first operating year, which is 3.29 patients per station per week, or a utilization rate of 82.3% ($46/14 = 3.29$; $3.29/4 = .823$ or 82.3%). The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.
- .2203(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In supplemental information the applicant provides the assumptions and methodology used to project utilization of the proposed facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.