

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: August 6, 2015

Findings Date: August 6, 2015

Project Analyst: Gloria C. Hale

Assistant Chief: Martha J. Frisone

Project ID #: F-11020-15

Facility: Mint Hill Dialysis

FID #: 070389

County: Mecklenburg

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

Project: Relocate one dialysis station from South Charlotte Dialysis for a total of no more than 12 stations upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

DVA Healthcare Renal Care, Inc. (DVA) d/b/a Mint Hill Dialysis proposes to relocate one dialysis station from South Charlotte Dialysis to Mint Hill Dialysis for a total of 12 dialysis stations upon completion. South Charlotte Dialysis and Mint Hill Dialysis are both located in Mecklenburg County. The applicant does not propose to establish new dialysis stations.

Need Determination

The applicant is proposing to relocate one dialysis station within Mecklenburg County; therefore, the county and facility need methodologies in the 2015 State Medical Facilities Plan (2015 SMFP) are not applicable to this review.

Policies

Policy GEN-3: Basic Principles in the 2015 SMFP is not applicable to this review because neither the county nor the facility need methodology is applicable to this review.

However, *Policy ESRD-2: Relocation of Dialysis Stations* 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 currently served by the facility. Certificate of need applicants proposing to relocate dialysis stations to contiguous counties shall:

- 1. Demonstrate that the proposal shall not result in a 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*
- 2. Demonstrate that the proposal shall not result in a 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 one dialysis station from South Charlotte Dialysis to Mint Hill Dialysis, both of which are in Mecklenburg County, for a total of 12 dialysis stations upon completion of the project. Since both facilities are located in Mecklenburg County, there is no change in the number of dialysis stations in Mecklenburg County. Therefore, the application is consistent with Policy ESRD-2.

Conclusion

The application is consistent with Policy ESRD-2 and therefore, the application is conforming to this criterion.

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

C

DVA currently operates five dialysis facilities in Mecklenburg County. In this application, DVA d/b/a Mint Hill Dialysis proposes to relocate one dialysis station from South Charlotte Dialysis in Charlotte, to Mint Hill Dialysis in Mint Hill, both of which are in Mecklenburg County. In Section III.3, page 20, the applicant states that no in-center patients are projected to transfer from South Charlotte Dialysis to Mint Hill Dialysis.

Population to be Served

On page 361, the 2015 SMFP defines the service area for a dialysis station as the *'dialysis station planning area in which the dialysis station is located.'* Thus, the service area for this facility consists of Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

In Section III, page 22, the applicant identifies the population of in-center dialysis patients it projects to serve at Mint Hill Dialysis, by county, in the first two operating years of the project, as shown in the table below:

Mint Hill Dialysis				
	Operating Year One, 2016	Operating Year Two, 2017	County Patients as a Percent of Total	
Patient's County of Residence	In-Center Patients	In-Center Patients	Year One, 2016	Year Two, 2017
Mecklenburg	36	39	90.0%	90.7%
Union	4	4	10.0%	9.3%
Total	40	43	100.0%	100.0%

The applicant adequately identifies the population to be served.

Analysis of Need

The applicant proposes to relocate one dialysis station from South Charlotte Dialysis to Mint Hill Dialysis, both in Mecklenburg County, for a total of 12 dialysis stations upon completion of the project.

In Section II.1, page 13, the applicant projects the stations will be utilized at 83.0% [82.5% rounded to 83.0%] of capacity by the end of the first year of operation, December 31, 2016, with 40 patients dialyzing on 12 in-center dialysis stations ($40/12 = 3.3$; $3.3/4 = 83.0\%$ [82.5% rounded to 83.0%]).

In Section II.1, page 13, the applicant states that it is projected to have 40 in-center patients by the end of operating year one, based on application of the January 2015 Semiannual Dialysis Report (SDR) Mecklenburg County five year average annual change

rate (AACR) of 7.1% to Mint Hill Dialysis' Mecklenburg County in-center patients. Therefore the applicant states there is a need to relocate one station to Mint Hill Dialysis to serve the projected number of in-center patients.

Projected Utilization

In Section III.1, pages 13-15, the applicant provides its assumptions and methodology used to project utilization at Mint Hill Dialysis. The applicant states that the in-center patient census of Mint Hill Dialysis was 35 as of June 30, 2014 and that the facility had 10 dialysis stations based on data reported in the January 2015 SDR. The utilization rate of the facility was 87.5%. The applicant states, on page 13, "*Mint Hill Dialysis Center had an additional dialysis station certified on January 23, 2015*" for a current total of 11 certified dialysis stations.

The applicant calculates the projected utilization for Mint Hill Dialysis by applying the January 2015 SDR AACR for Mecklenburg County of 7.1% to the facility's Mecklenburg County in-center patients only. The applicant does not calculate growth for the facility's four in-center patients from Union County. The applicant's calculations are illustrated as follows:

June 30, 2014 – 35 in-center patients: 31 from Mecklenburg County, 4 from Union County

July 1, 2014 - December 31, 2014 – 31 Mecklenburg County patients x 1.0355 (half of the 7.1% AACR for the 6-month period) = 32.10

January 1, 2015 – December 31, 2015 – 32.10 patients x 1.071 = 34.38

January 1, 2016 – December 31, 2016 – 34.38 patients x 1.071 = 36.82 + 4 patients from Union County = 40.82 patients in Operating Year One

January 1, 2017 – December 31, 2017 – 36.82 x 1.071 = 39.43 + 4 patients from Union County = 43.43 patients in Operating Year Two

The applicant states, on page 14, that the number of patients is rounded down to the nearest whole number, resulting in 40 in-center patients for Operating Year One and 43 in-center patients for Operating Year Two.

Therefore, the applicant projects to serve 40 in-center patients dialyzing on 12 stations by the end of Operating Year One for a utilization rate of 83.3% or 3.33 patients per station [$40/12 = 3.33/4.0 = 0.833$ or 83.3%]. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b). Moreover, according to the July 2015 SDR, as of December 31, 2014, Mint Hill Dialysis was already serving 40 in-center patients on 11 stations. Projected utilization is based on reasonable and adequately supported assumptions. Therefore, the

applicant adequately demonstrates the need for one additional station at Mint Hill Dialysis.

Access to Services

In Section VI.1, page 31, the applicant states,

“Mint Hill Dialysis Center, by policy, has always made dialysis services available to all residents in its service area without qualifications. We have served and will continue to serve patients without regard to race, sex, age, handicap, or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.

...

Mint Hill Dialysis Center does not require payment upon admission to its services; therefore, services are available to all patients including low-income persons, racial and ethnic minorities, women, handicapped persons, elderly and other under-served persons.”

In Section VI.1, page 32, the applicant projects that 80% of its patients will have all or part of their services covered by Medicare and/or Medicaid, and 2.5% will be covered by VA. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services.

Conclusion

The applicant adequately identifies the population to be served, adequately demonstrates the need the population projected to be served has for the proposed relocation of one dialysis station from South Charlotte Dialysis to Mint Hill Dialysis, and adequately demonstrates the extent to which all residents of the service 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

The applicant proposes to relocate one existing certified dialysis station from South Charlotte Dialysis to Mint Hill Dialysis, both in Mecklenburg County, for a total of 12 dialysis stations upon project completion.

In Section III.3, page 20, the applicant discusses how the needs of dialysis patients at South Charlotte Dialysis will continue to be met after the relocation of stations to Mint Hill Dialysis.

The applicant states that, as of June 30, 2014, South Charlotte Dialysis had 59 in-center dialysis patients, 20 stations, and a utilization rate of 73.75%, based on data in the January 2015 SDR.

In the proposed project, South Charlotte Dialysis will relocate one dialysis station to Mint Hill Dialysis and no in-center dialysis patients will be transferred, leaving 19 stations (20-1=19). However, three additional stations are projected to be certified at South Charlotte Dialysis (Project I.D. #F-10349-14) by January 1, 2016. Once these are certified, the facility will have 22 stations and a utilization rate of 67.1% ($59/22 = 2.68/4 = 67.1\%$). On page 20, the applicant states, *“Therefore, the transfer of one station to Mint Hill Dialysis will have no effect on the needs of the dialysis patients at South Charlotte Dialysis.”*

The applicant adequately demonstrates that the needs of the population presently served at South Charlotte Dialysis will continue to be adequately met following the proposed relocation of one dialysis station from South Charlotte Dialysis to Mint Hill 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.

CA

In Section III.9, pages 23-24, the applicant discusses the alternatives considered prior to submitting this application, which include:

- 1) Maintaining the status quo - the applicant states that it dismissed this alternative because utilization at the facility is growing rapidly.
- 2) Relocating one dialysis station from South Charlotte Dialysis to Mint Hill Dialysis, the proposed alternative - the applicant states that this alternative was chosen *“to help meet the growing demand for dialysis services at Mint Hill Dialysis Center.”*

After considering the above alternatives, the applicant states that the second alternative, to relocate one dialysis station from South Charlotte Dialysis to Mint Hill Dialysis, is the most effective alternative.

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

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

- 1. DVA Healthcare Renal Care, Inc. d/b/a Mint Hill Dialysis shall materially comply with all representations made in the certificate of need application.**
 - 2. DVA Healthcare Renal Care, Inc. d/b/a Mint Hill Dialysis shall relocate no more than one (1) certified dialysis station to Mint Hill Dialysis for a total of no more than 12 certified dialysis stations, which shall include any isolation or home hemodialysis stations, upon the completion of the project.**
 - 3. Prior to the issuance of the certificate of need, DVA Healthcare Renal Care, Inc. d/b/a Mint Hill Dialysis shall submit documentation of an invitation to a health professional training program in Mecklenburg County or an adjacent county to use the facility for training students.**
 - 4. DVA Healthcare Renal Care, Inc. d/b/a Mint Hill Dialysis shall install plumbing and electrical wiring through the walls for no more than one (1) additional dialysis station.**
 - 5. After certification of the relocated dialysis station at Mint Hill Dialysis, DVA Healthcare Renal Care, Inc. d/b/a South Charlotte Dialysis shall take the necessary steps to decertify one (1) dialysis station at South Charlotte Dialysis for a total of no more than 22 certified dialysis stations at South Charlotte Dialysis upon completion of this project and Project I.D. #F-10349-14 (add three stations).**
 - 6. DVA Healthcare Renal Care, Inc. d/b/a Mint Hill 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.

In Section VIII.1, page 39, the applicant states that the capital cost for the proposed project will be \$18,098, including \$12,500 for dialysis machines and \$5,598 for other equipment/furniture. In Section IX, page 44, the applicant states there will be no start-up expenses or initial operating expenses.

In Section VIII.2, page 41, the applicant states that the capital cost of the project will be funded through cash reserves.

In Exhibit 18, the applicant provides a letter dated March 10, 2015 from the Vice President of Tax of DaVita HealthCare Partners Inc., which states,

“We are submitting a Certificate of Need application to expand Mint Hill Dialysis by one ESRD dialysis station. The project calls for a capital expenditure of \$18,098. This letter will confirm that DaVita HealthCare Partners Inc. has committed cash reserves in the total sum of \$18,098 for the project capital expenditure. DaVita HealthCare Partners 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.”

Exhibit 19 contains a copy of the most recent United States Securities and Exchange Commission Form 10-K filed by DaVita Healthcare Partners, Inc. (DaVita) which includes audited financial statements for the years ended December 31, 2014 and 2013. The statement shows that as of December 31, 2014, DaVita had \$965,241,000 in cash and cash equivalents with \$17,942,715,000 in total assets and \$6,190,276,000 in net assets (total assets less total liabilities). (See page F-6 of Exhibit 19.) The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

In Section X.1, page 46, the applicant provides its allowable charges per treatment for each payment source for Mint Hill Dialysis, as illustrated below:

Mint Hill Dialysis

Source of Payment	In-Center Charge Per Treatment
Commercial Insurance	\$1,275.00
Medicare	\$239.43
Medicaid	\$143.00
VA	\$193.00
Medicare/Medicaid	\$239.43
Medicare/Commercial	\$239.43

In Sections X.2-X.4, pages 47-50, the applicant projects revenues and operating expenses for Mint Hill Dialysis, as illustrated below:

Mint Hill Dialysis

Mint Hill Dialysis	Operating Year 1 CY 2016	Operating Year 2 CY 2017
Total Net Revenue	\$2,375,099	\$2,527,842
Total Operating Expenses	\$1,865,737	\$1,962,840
Net Profit	\$509,362	\$565,002

The applicant projects that revenues will exceed operating expenses in each of the first two operating years following project completion. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable and adequately supported. See Section X, pages 46-51, for the applicant's assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates that the financial feasibility of the proposal is based on reasonable and adequately supported projections of the costs and charges to provide the proposed health services. 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

On page 361, the 2015 SMFP defines the service area for a dialysis station as the '*dialysis station planning area in which the dialysis station is located.*' 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 applicant proposes to relocate one existing certified dialysis station from South Charlotte Dialysis to Mint Hill Dialysis, both in Mecklenburg County, for a total of 12 dialysis stations upon completion of the project. According to the January 2015 SDR, there are 15 operational dialysis facilities and two dialysis facilities under development in Mecklenburg County, illustrated as follows:

Mecklenburg County Dialysis Facilities as shown in the January 2015 SDR				
Facility	Owner	Location	Number of Existing and Approved Stations	Utilization as of June 30, 2014**
BMA Beatties Ford	Bio-Medical Applications of North Carolina, Inc.	Charlotte	39	96.1%
BMA Nations Ford	Bio-Medical Applications of North Carolina, Inc.	Charlotte	28	113.5%
BMA of East Charlotte	Bio-Medical Applications of North Carolina, Inc.	Charlotte	33	69.8%
BMA of North Charlotte	Bio-Medical Applications of North Carolina, Inc.	Charlotte	32	110.7%
BMA West Charlotte	Bio-Medical Applications of North Carolina, Inc.	Charlotte	29	70.7%
Carolinas Medical Center	The Charlotte-Mecklenburg Hospital Authority	Charlotte	9	47.2%
Charlotte Dialysis	DaVita Healthcare Partners, Inc.	Charlotte	36	80.0%
Charlotte East Dialysis	DaVita Healthcare Partners, Inc.	Charlotte	26	84.4%
DSI Charlotte Latrobe Dialysis	DSI Renal, Inc.	Charlotte	24	67.7%
DSI Glenwater Dialysis	DSI Renal, Inc.	Charlotte	42	73.2%
FMC Charlotte	Fresenius Medical Care Holdings, Inc.	Charlotte	43	86.9%
FMC Matthews	Fresenius Medical Care Holdings, Inc.	Matthews	21	100.0%
FMC of Southwest Charlotte*	Fresenius Medical Care Holdings, Inc.	Charlotte	0	0
Huntersville Dialysis*	DaVita Healthcare Partners, Inc.	Huntersville	0	0
Mint Hill Dialysis	DaVita Healthcare Partners, Inc.	Mint Hill	11	87.5%
North Charlotte Dialysis Center	DaVita Healthcare Partners, Inc.	Charlotte	31	88.6%
South Charlotte Dialysis	DaVita Healthcare Partners, Inc.	Charlotte	20	73.8%

*Facility under development.

**The utilization rate is based on the number of certified dialysis stations as of June 30, 2014.

DVA Healthcare Renal Care, Inc. d/b/a Mint Hill Dialysis is not increasing the number of certified dialysis stations in Mecklenburg County or the number of facilities, rather it is relocating one station from an existing facility, South Charlotte Dialysis, to Mint Hill Dialysis. The project will not change the total number of dialysis stations in Mecklenburg County. As shown in the Mecklenburg County Dialysis Facility Data table above, Mint Hill Dialysis was operating at over 87% of capacity as of June 30, 2014, while South Charlotte Dialysis was operating at 73.8% of capacity. Furthermore, South Charlotte Dialysis was previously approved to add three more stations.

In Section III.7, pages 22-23, the applicant demonstrates that Mint Hill Dialysis will serve a total of 40 in-center patients on 12 dialysis stations at the end of the first operating year, which is 3.33 patients per station per week, or a utilization rate of 83.3% ($40/12 = 3.33$; $3.33/4 = 83.3\%$).

Consequently, the applicant adequately demonstrates the proposed project would not result in the unnecessary duplication of existing or approved dialysis services or facilities in Mecklenburg County. Therefore, 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.

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In Section VII.1, page 36, the applicant projects no change in the number of full-time equivalent (FTE) positions following completion of the proposed project. The number of projected FTE positions is illustrated in the table below.

Position	Projected # of FTEs
Registered Nurse	2.0
Patient Care Technician	5.0
Bio-Medical Technician	0.5
Medical Director*	N/A
Administrator	1.0
Dietitian	0.5
Social Worker	0.5
Unit Secretary	1.0
Total	10.5

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

In Section V.4, page 29, the applicant states that the Medical Director for Mint Hill Dialysis is Dr. Jack Lohavichan. Exhibit 13 contains a letter from Dr. Lahavichan, dated March 13, 2015, indicating his support for the proposed project. In Section VII.4, page 37, the applicant states they have an aggressive recruiting program and anticipate no difficulty in hiring staff for any openings that may occur at Mint Hill Dialysis. The applicant adequately demonstrates the availability of sufficient health manpower and

management personnel to provide the proposed 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.

C

In Section V.1, page 27, the applicant lists the providers of the necessary ancillary and support services available to patients. The applicant discusses coordination with the existing health care system on pages 29-30, stating that it has “...over the years established relationships with other agencies in Mecklenburg County and surrounding counties”. In addition, in Exhibit 9, the applicant provides a copy of a signed transfer agreement with Novant Health Presbyterian Medical Center to provide a range of services to dialysis patients, including vascular radiology, laboratory, ICU services, and acute hemodialysis. In Exhibit 10, the applicant provides a copy of an agreement with Duke University Hospital to provide transplantation services. 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 VI.1, page 31, the applicant states,

“Mint Hill Dialysis Center, by policy, has always made dialysis services available to all residents in its service area without qualifications. We have served and will continue to serve without regard to race, sex, age, handicap, or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.”

In Section VI.1, page 31, the applicant states that 80.0% of Mint Hill Dialysis' in-center patients had some or all of their services paid for by Medicare and/or Medicaid in the past year. The table below illustrates the historical payment sources for the existing facility:

Mint Hill Dialysis

Source of Payment	Percentage of In-Center Patients
Medicare	7.5%
Medicaid	5.0%
Medicare/Medicaid	17.5%
Commercial Insurance	17.5%
VA	2.5%
Medicare/Commercial	50.0%
Total	100.0%

The Division of Medical Assistance (DMA) maintains a website which provides the number of persons eligible for Medicaid in North Carolina, and estimates the percentage of uninsured people for each county. The following table illustrates those percentages for Mecklenburg County and statewide.

	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population*	2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Mecklenburg County	14.7%	5.1%	20.1%
Statewide	16.5%	6.7%	19.7%

* More current data, particularly with regard to the estimated uninsured percentages, was not available.

Although the majority of Medicaid eligibles are children under the age of 21, they represent a very small percentage of those who utilize the services offered by dialysis facilities. In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*)¹.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, as well as data sorted by age, race or gender. But it does not include information on the number of elderly, handicapped, minorities or women utilizing health services.

However, the Southeastern Kidney Council Network 6 Inc. 2014 Annual Report provides prevalence data on North Carolina dialysis patients by age, race and gender on page 59, summarized as follows:

¹ <http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.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%

Source: Southeastern Kidney Council Network 6 Inc. 2014 Annual Report. Table includes North Carolina statistics only.²

The applicant demonstrates that medically underserved populations currently have adequate access to the existing services. 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 applicants;

C

In Section VI.1, page 33, the applicant states,

“Mint Hill Dialysis Center 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.”

² <http://www.esrdnetwork6.org/utills/pdf/annual-report/2014%20Network%206%20Annual%20Report.pdf>

In Section VI.6, page 36, the applicant states, “*There have been no civil rights equal access complaints filed within the last five years.*”

The application is conforming to this criterion.

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

C

In Section VI.1, page 32, the applicant provides the projected payor mix for Mint Hill Dialysis for in-center dialysis patients, as follows,

**Mint Hill Dialysis
Projected Patient Payor Mix**

Payor Source	In-Center Patients
Medicare	7.5%
Medicaid	5.0%
Medicare/Medicaid	17.5%
Commercial Insurance	17.5%
VA	2.5%
Medicare/Commercial	50.0%
Total	100.0%

As shown in the table above, the applicant projects that 80.0% of in-center patients will have some or all of their services paid for by Medicare or Medicaid.

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

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

C

In Section VI.5, page 34, the applicant states that patients have access to services upon referral to a Nephrologist who has privileges at Mint Hill Dialysis and that the referrals typically come from primary care physicians or specialty physicians in Mecklenburg County. In addition, patients, friends or families may contact a Nephrologist with privileges at the facility directly and the patient will be evaluated and admitted for dialysis services if medically necessary. Similarly, patients from outside the primary service area who request transfer to the facility

are referred to a qualified Nephrologist for evaluation and admission if medically necessary.

The applicant adequately demonstrates that it will provide a range of means by which a person can access 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.

CA

In Section V.3, page 29, the applicant states that it has an agreement with Winthrop University in Rock Hill, South Carolina. A copy of the agreement is provided in Exhibit 12 which states that DaVita's outpatient dialysis facilities "*are willing to provide clinical training and/or observation to Students of Sponsoring Institutions...*" However, the agreement in Exhibit 12 specifically states that the agreement is between Winthrop University and each of the subsidiary and affiliate entities listed on the attached Exhibit A. Mint Hill Dialysis is not listed in Exhibit A. The applicant does not adequately demonstrate that the facility will accommodate the clinical needs of health professional training programs in the proposed service area. Therefore, the application is conforming to this criterion subject to Condition (3) in Criterion (4).

- (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

On page 361, the 2015 SMFP defines the service area for a dialysis station as the '*dialysis station planning area in which the dialysis station is located.*' 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 applicant proposes to relocate one existing certified dialysis station from South Charlotte Dialysis to Mint Hill Dialysis, both in Mecklenburg County, for a total of 12

dialysis stations upon completion of the project. According to the January 2015 SDR, there are 15 operational dialysis facilities and two dialysis facilities under development in Mecklenburg County. Six are owned by DaVita Healthcare Partners, Inc., parent company of DVA Healthcare Renal Care, Inc. A listing of all existing and approved dialysis facilities in Mecklenburg County is provided below:

Mecklenburg County Dialysis Facilities as shown in the January 2015 SDR				
Facility	Owner	Location	Number of Existing and Approved Stations	Utilization as of June 30, 2014**
BMA Beatties Ford	Bio-Medical Applications of North Carolina, Inc.	Charlotte	39	96.1%
BMA Nations Ford	Bio-Medical Applications of North Carolina, Inc.	Charlotte	28	113.5%
BMA of East Charlotte	Bio-Medical Applications of North Carolina, Inc.	Charlotte	33	69.8%
BMA of North Charlotte	Bio-Medical Applications of North Carolina, Inc.	Charlotte	32	110.7%
BMA West Charlotte	Bio-Medical Applications of North Carolina, Inc.	Charlotte	29	70.7%
Carolinas Medical Center	The Charlotte-Mecklenburg Hospital Authority	Charlotte	9	47.2%
Charlotte Dialysis	DaVita Healthcare Partners, Inc.	Charlotte	36	80.0%
Charlotte East Dialysis	DaVita Healthcare Partners, Inc.	Charlotte	26	84.4%
DSI Charlotte Latrobe Dialysis	DSI Renal, Inc.	Charlotte	24	67.7%
DSI Glenwater Dialysis	DSI Renal, Inc.	Charlotte	42	73.2%
FMC Charlotte	Fresenius Medical Care Holdings, Inc.	Charlotte	43	86.9%
FMC Matthews	Fresenius Medical Care Holdings, Inc.	Matthews	21	100.0%
FMC of Southwest Charlotte*	Fresenius Medical Care Holdings, Inc.	Charlotte	0	0
Huntersville Dialysis*	DaVita Healthcare Partners, Inc.	Huntersville	0	0
Mint Hill Dialysis	DaVita Healthcare Partners, Inc.	Mint Hill	11	87.5%
North Charlotte Dialysis Center	DaVita Healthcare Partners, Inc.	Charlotte	31	88.6%
South Charlotte Dialysis	DaVita Healthcare Partners, Inc.	Charlotte	20	73.8%

*Facility under development.

In Section V.7, page 30, the applicant discusses how any enhanced competition in the service area will promote cost-effectiveness, quality and access to the proposed services. The applicant states,

“The proposed expansion of the facility is not intended to be a competitive venture. The effect of other facilities in Mecklenburg County and surrounding counties would be difficult to determine since most patients from Mecklenburg County already receive treatment in established facilities operated by several different providers.”

The applicant further states, on page 30, that patients choose a dialysis provider based on the *“highest quality service and best meets their needs.”* In addition, the applicant states that access to services at Mint Hill Dialysis is provided through all qualified Nephrologists. See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information in the application 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 that it will continue to provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that it will continue to provide adequate access to medically underserved populations. The discussion regarding access found in Criterion (13) is incorporated herein by reference.

The application is conforming to this criterion.

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

C

In Section I.13 and referenced Exhibit, the applicant identifies the kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care

during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable criteria, which are discussed below.

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

(a) An applicant that proposes to increase stations in an existing certified facility or relocate stations must provide the following information:

.2202(a)(1) Utilization rates;

- C- Section III.3, page 20, and in Exhibit 7 (copy of the January 2015 SDR, Table A), the applicant provides the utilization rate for Mint Hill Dialysis.

.2202(a)(2) Mortality rates;

- C- In Section IV.2, page 25, the applicant reports 2013 and 2014 facility mortality rates for Mint Hill Dialysis.

.2202(a)(3) The number of patients that are home-trained and the number of patients on home dialysis;

- NA- The applicant states, in Section IV.3, page 25, that it does not currently offer home training services at Mint Hill Dialysis.

.2202(a)(4) The number of transplants performed or referred;

- C- In Section IV.4, page 25, the applicant reports that Mint Hill Dialysis referred two patients for transplant evaluation in 2014, and one patient received a transplant in 2014.

- .2202(a)(5) *The number of patients currently on the transplant waiting list;*
-C- In Section IV.5, page 26, the applicant states that Mint Hill Dialysis has four patients on the transplant waiting list.
- .2202(a)(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
-C- In Section IV.6, page 26, the applicant reports a total of 65 hospital admissions in calendar year 2014; 83.1% were non-dialysis related and 16.9% were dialysis-related.
- .2202(a)(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.*
-C- In Section IV.7, page 26, the applicant reports that there were two patients with infectious disease as of December 31, 2013 and no patients converted to infectious status in 2014.

(b) An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage Renal Disease (ESRD) Treatment application form:

- .2202(b)(1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100 (Replaced with 42 CFR Part 494).*
-NA- Mint Hill Dialysis is an existing facility.
- .2202(b)(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*
(A) *timeframe for initial assessment and evaluation of patients for transplantation,*
(B) *composition of the assessment/evaluation team at the transplant center,*
(C) *method for periodic re-evaluation,*
(D) *criteria by which a patient will be evaluated and periodically re-evaluated for transplantation, and,*
(E) *Signatures of the duly authorized persons representing the facilities and the agency providing the services.*
-NA- Mint Hill Dialysis is an existing facility.
- .2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
-NA- Mint Hill Dialysis is an existing facility.

- .2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C- Exhibit 8 contains excerpts from DaVita Inc.'s Hemodialysis Policies, Procedures & Guidelines, Vol. 1, which includes a procedure for performing operational checks on backup generators.
- .2202(b)(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*
- NA- Mint Hill Dialysis is an existing facility.
- .2202(b)(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*
- C- The applicant states, in Section XI.6, pages 54-55, that it will comply with all applicable laws and regulations listed above and that "...the Office of Licensure and Certification inspects each dialysis facility under CMS guidelines on a regular basis to ensure compliance with all applicable laws and regulations." See also Section VII.1, page 36.
- .2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C- In Section III.7, page 22, the applicant provides projected patient origin for Mint Hill Dialysis. In Section III.7, pages 22-23, the applicant provides its assumptions and methodology for its projected patient origin.
- .2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
- NA- Mint Hill Dialysis is an existing facility.
- .2202(b)(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement for such services.*
- C- In Section II.9, page 12, the applicant states, "DVA Healthcare Renal Care, Inc. d/b/a Mint Hill Dialysis Center will admit and provide dialysis services to patients who have no insurance or other source of payment if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services."

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 facility. Mint Hill Dialysis is an existing facility.

.2203(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.

-C- In Section II.1, pages 13-14, the applicant demonstrates the need for one relocated dialysis station for a total of 12 stations, projecting 40 in-center patients at the end of the first operating year for a utilization rate of 3.3 patients per station. The discussion regarding projected utilization found in Criterion (3) is incorporated by reference herein.

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

-C- In Section II.1, pages 13-15, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

10 NCAC 14C .2204 SCOPE OF SERVICES

To be approved, the applicant must demonstrate that the following services will be available:

.2204(1) Diagnostic and evaluation services;

-C- The applicant states, in Section V.1, page 27, that diagnostic and evaluation services will be provided by Novant Health Presbyterian Medical Center.

.2204(2) Maintenance dialysis;

-C- The applicant states, in Section V.1, page 27, that Mint Hill Dialysis will provide maintenance dialysis.

.2204(3) Accessible self-care training;

-C- The applicant states, in Section V.1, page 27, that self-care training is provided for hemodialysis patients and intermittent peritoneal dialysis patients by Charlotte East Dialysis Center.

- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
-C- The applicant states, in Section II.2, page 17, and in Section V.2, page 28, that Charlotte East Dialysis Center provides support, protocols and routines for patient follow-up. In addition, monitoring of home-trained patients is done by the Quality Management team.
- .2204(5) *X-ray services;*
-C- The applicant states, in Section V.1, page 27, that x-ray services will be provided by Novant Health Presbyterian Medical Center.
- .2204(6) *Laboratory services;*
-C- The applicant states, in Section V.1, page 27, that laboratory services will be provided off-site by Dialysis Laboratories.
- .2204(7) *Blood bank services;*
-C- The applicant states, in Section V.1, page 27, that blood bank services will be provided by Novant Health Presbyterian Medical Center.
- .2204(8) *Emergency care;*
-C- The applicant states, in Section V.1, page 27, that emergency care will be provided by Novant Health Presbyterian Medical Center.
- .2204(9) *Acute dialysis in an acute care setting;*
-C- The applicant states, in Section V.1, page 27, that acute dialysis in an acute care setting will be provided by Novant Health Presbyterian Medical Center.
- .2204(10) *Vascular surgery for dialysis treatment patients*
-C- The applicant states, in Section V.1, page 27, that vascular surgery will be provided by Novant Health Presbyterian Medical Center.
- .2204(11) *Transplantation services;*
-C- The applicant states, in Section V.1, page 27, that transplantation services will be provided by Duke University Hospital. A copy of an agreement between Mint Hill Dialysis and Duke University Hospital for these services is provided in Exhibit 10.
- .2204(12) *Vocational rehabilitation counseling and services; and*
-C- These services will be provided by the North Carolina Division of Vocational Rehabilitation Services, as stated in Section V.1, page 27.
- .2204(13) *Transportation*
-C- The applicant states, in Section V.1, page 27, that transportation services will be provided by the Department of Social Services and various providers.

10 NCAC 14C .2205 STAFFING AND STAFF TRAINING

- .2205(a) To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R. Section 405.2100 (Replaced with 42 CFR Part 494).*
- C- In Section VII.1, pages 36-37, the applicant states the proposed facility will comply with all staffing requirements set forth in the federal code. In addition, in Section VII.1, page 36, the applicant provides a proposed staffing chart, and on page 38, provides a table showing the number of direct care staff for each shift to be offered at the facility. The discussion regarding proposed staffing found in Criterion (7) is incorporated herein by reference.
- .2205(b) To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*
- C- The applicant states, in Section VII.5, page 37, that a copy of the facility's training program outlines are provided in Exhibit 17. Exhibit 17 provides an outline of training required for new employees. Exhibit 3 contains a document describing the company's ongoing training programs, including DaVita University, School of Leadership, School of Clinical Education and Village Gatherings. In 2014, 19,500 teammates participated.