

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: June 2, 2014

PROJECT ANALYST: Jane Rhoe-Jones
INTERIM CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: F-10267-14 / DVA Healthcare Renal Care, Inc. d/b/a Mint Hill Dialysis Center / Add one dialysis station for a total of 11 stations upon project completion / Mecklenburg County

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. d/b/a Mint Hill Dialysis Center is currently certified for 10 in-center dialysis stations. In this application, the applicant proposes to add one dialysis station for a total of 11 stations upon completion of this project.

The 2014 State Medical Facilities Plan (2014 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2014 Semiannual Dialysis Report (SDR), the county need methodology shows there is no need for an additional dialysis facility or for any additional dialysis stations in Mecklenburg County. However, an applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis facility, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. In this application, Mint Hill Dialysis Center is eligible to apply for additional stations in its existing facility based on the facility need methodology, because the utilization rate is 3.2 patients per station, or 80%. This utilization rate was calculated based on 32 in-center dialysis patients and 10 certified dialysis stations as of June 30, 2013 (32 patients / 10 stations = 3.2 patients per station). See the following table, from Section III.1, page 20 of the application:

APRIL 1 REVIEW-JANUARY SDR - MINT HILL DIALYSIS		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/13		80.0%
Certified Stations		10
Pending Stations		0
Total Existing and Pending Stations		10
In-Center Patients as of 6/30/13 (SDR2)		32
In-Center Patients as of 12/31/12 (SDR1)		18
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	14
	Multiply the difference by 2 for the projected net in-center change	28
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/12	1.5556
(ii)	Divide the result of step (i) by 12	0.1296
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/13 until 12/31/13)	0.7778
(iv)	Multiply the result of step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	56.8889
(v)	Divide the result of step (iv) by 3.2 patients per station	17.7778
	and subtract the number of certified and pending stations as recorded in SDR2 [10] to determine the number of stations needed	8

Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established, [...] up to a maximum of ten stations.*” As shown in the table above, based on the facility need methodology for dialysis stations, Mint Hill Dialysis Center has a need for eight additional stations. The applicant proposes to add one new station and therefore, the application is consistent with the facility need determination for dialysis stations.

Policy GEN-3 in the 2014 SMFP is also applicable to this review. Policy GEN-3 states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Promote Safety and Quality

In Section II.3, on pages 17-19, the applicant describes the efforts undertaken by DaVita HealthCare Partners, Inc., the parent company of Mint Hill Dialysis Center, to promote safety and quality. The applicant states:

“DaVita HealthCare Partners, Inc. is committed to providing quality care to the ESRD population through a comprehensive Quality Management Program. DaVita’s Quality Management Program is facilitated by a dedicated clinical team of Registered Nurses who make up our Clinical Support Services and Biomedical Quality Management Coordinators working under the direction of our Director of Clinical Support Services and Area Biomedical Administrator. ... The program exemplifies DaVita’s total commitment to enhancing the quality of patient care through its willingness to devote the necessary resources to achieve our clinical goals.

...

Mint Hill Dialysis Center is attended by Dr. Jack Lohavichan and admitting Nephrologists who directly oversee the quality of care of the dialysis facility. In addition, Dr. Lohavichan serves as Medical Director and will provide the overall medical supervision of the home training unit [sic]. The facility administrator is the day to day manager of the facility and maintains the company’s Quality Management Program that monitors the overall care of the patients. The Quality Management Program is reviewed by the Quality Assurance Committee consisting of the Nephrologists, Unit Administrator, clinical teammates, social worker and the dietitian. This Quality Assurance Program will address the Mint Hill Dialysis Center as a whole, then compares each sister unit to the whole and to industry standards. ... Continuous Quality Improvement teams address facility issues with the goal of improving patient care patient outcomes.”

The applicant also discusses its safety measures in Section XI.6(g), pages 52-53. In Exhibit 22, the applicant provides a copy of the prevention and safety training outline, and in Exhibit 23, a copy of its in-service training schedule. The applicant adequately demonstrates how its proposal will promote safety and quality in the provision of dialysis services in Mecklenburg County.

Promote Equitable Access

In Section VI, page 31, the applicant discusses accessibility with regard to Mint Hill Dialysis. On 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.

Mint Hill Dialysis Center makes every reasonable effort to accommodate all of its patients; especially those with special needs such as the handicapped, patients

attending school or patients who work. Mint Hill Dialysis Center provides dialysis six days per week to accommodate patient need. The facility also operates a third shift on Monday, Wednesday and Friday to accommodate patients who are working during the day or prefer an evening dialysis treatment time.

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. Mint Hill Dialysis Center works with patients who need transportation, when necessary.”

The applicant adequately demonstrates how its proposal will promote access to dialysis services for medically underserved groups.

Maximize Healthcare Value

In Section III.9, page 24, the applicant states,

“Mint Hill Dialysis Center promotes cost-effective approaches in the facility in the following ways:

- The parent corporation, DaVita Healthcare Partners, Inc., operates over 2,074 dialysis facilities nationwide. The corporation has a centralized purchasing department that negotiates national contracts with numerous vendors in order to secure the best product available at the best price. ...*
- Mint Hill Dialysis Center purchases all of the products utilized in the facility, from office supplies to drugs to clinical supplies, under a national contract in order to secure the best products at the best price.*
- Mint Hill Dialysis Center utilizes [sic] electronic patient charting system that reduces the need for paper in the facility. Much of the other documentation in the facility are [sic] done on computer which reduces the need for paper.*
- Mint Hill Dialysis Center has an inventory control plan that ensures enough supplies are available without having an inordinate amount of supplies on hand. Supply orders are done in a timely manner to ensure that the facility does not run out of supplies, thus avoiding emergency ordering, which is costly.”*

The applicant adequately demonstrates how its proposal will maximize healthcare value. Furthermore, the applicant demonstrates that projected volumes for the proposed services incorporate the basic principles in meeting the needs of dialysis patients to be served. Thus, the application is consistent with Policy GEN-3.

In summary, the application is consistent with the facility need determination in the 2014 SMFP and is consistent with Policy GEN-3. Therefore, the application is conforming to this criterion.

(2) Repealed effective July 1, 1987.

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

C

DVA Healthcare Renal Care, Inc. d/b/a Mint Hill Dialysis Center currently operates a 10-station dialysis facility located in Mint Hill, in Mecklenburg County. The applicant proposes to add one dialysis station to the existing facility for a total of 11 certified dialysis stations upon project completion. The applicant does not propose to provide home hemodialysis or peritoneal dialysis training and support at Mint Hill Dialysis Center. The January 2014 SDR reports Mint Hill Dialysis Center is currently certified for 10 in-center dialysis stations and was dialyzing 32 in-center patients as of June 30, 2013.

Population to be Served

In Section IV.1, page 25, the applicant identifies its current in-center patient population as illustrated below in the table.

MINT HILL DIALYSIS CENTER	
COUNTY OF RESIDENCE	NUMBER OF IN-CENTER PATIENTS
Mecklenburg	22
Union	10
Total	32

In Section III.7, page 22, the applicant projects patient origin for Mint Hill Dialysis Center for the first two project years following the addition of the dialysis station. See the following table:

MINT HILL DIALYSIS CENTER				
COUNTY OF RESIDENCE	OPERATING YEAR ONE	OPERATING YEAR TWO	COUNTY PATIENTS AS A % OF TOTAL	
	IN-CTR. PTS.	IN-CTR. PTS.	YEAR 1	YEAR 2
Mecklenburg	25	26	69.4%	70.3%
Union	11	11	30.6%	29.7%
Total	36	37	100.0%	100.0%

The applicant adequately identifies the population to be served.

Demonstration of Need

In Section III.7, pages 22-23, the applicant states its application is filed pursuant to the facility need methodology utilizing data from the January 2014 SDR. The applicant proposes to add one dialysis station to the existing facility for a total of 11 dialysis stations upon project completion.

In Section II.1, page 14, the applicant states:

- *“The facility had 32 in-center patients as of December 31, 2013*
- *The table in Section III.2 indicates that the facility is eligible for a one-station expansion, based [sic] facility need methodology.*
- *Mint Hill Dialysis Center is located in Mecklenburg County, which has had an average annual change rate of 6.6% over the past five years.*
- *Mint Hill Dialysis had 32 in-center patients as of June 30, 2013 based on information included in Table A of the January 2014 Semiannual Dialysis Report (SDR). This is a station utilization rate of 80% based on the 10 certified stations. There are 22 in-center patients who live in Mecklenburg and 10 in-center patients who live in Union County. We are applying for a one-station expansion of the Mint Hill facility.*
- *Based on the patients and stations above, Mint Hill Dialysis is projected to have at least 24.999823 Mecklenburg County in-center patients and at least 11.10916 Union County in-center patients by the end of operating year 1 for a total of 36 in-center patients (24.999823 + 11.10916 = 36.108992) for a utilization rate of 81% or 3.2 patients per station and at least 26.64982091 Mecklenburg County in-center patients and at least 11.170905464 Union County in-center patients by the end of operating year 2 for a total of 37 in-center patients (26.64982091 + 11.170905464 = 37.82072637) for a utilization rate of 84% or 3.3 patients per station.”*

On pages 14 and 22-23 of the application, the applicant states:

“Mecklenburg County Patients

The period of growth begins with January 1, 2014 forward to December 31, 2016. The following are the in-center patient projections using the 6.6% Average Annual Change Rate for the Past Five Years as indicated in Table B of the January 2014 SDR for the 22 in-center patients living in Mecklenburg County.

January 1, 2014 – December 31, 2014 --- 22 patients x 1.066 = 23.452

January 1, 2015 – December 31, 2015 --- 23.452 patients x 1.066 = 24.999832

*January 1, 2016 – December 31, 2016 --- 24.999832 patients x 1.066 = 26.64982091
Operating Year One is projected to begin January 1, 2015 and end on December 31, 2015*

Operating Year Two is projected to begin January 1, 2016 and end on December 31, 2016

Union County Patients

The period of growth begins with January 1, 2014 forward to December 31, 2016. The following are the in-center patient projections using the 5.4% Average Annual Change Rate for the Past Five Years as indicated in Table B of the January 2014 SDR for the 22 in-center patients living in Union County.

January 1, 2014 – December 31, 2014 --- 10 patients x 1.054 = 10.54

January 1, 2015 – December 31, 2015 --- 10.54 patients x 1.054 = 11.10916

January 1, 2016 – December 31, 2016 --- 11.10916 patients x 1.054 = 11.170905464”

Thus, by the end of Operating Year One, the applicant projects to serve a total of 36 in-center dialysis patients [25 + 11 = 36]. By the end of Operating Year Two, the applicant projects to serve 37 in-center dialysis patients [26 + 11 = 37]. Thus, the utilization rate projected for Mint Hill Dialysis is 82% in Operating Year One [36 patients / 11 stations = 3.2; 3.2 / 4 = 0.818] and 84% in Operating Year Two [37 / 11 = 3.36; 3.36 / 4 = 0.841]. The applicant’s projected in-center patient utilization at the end of Operating Year One exceeds the 3.2 in-center patients per station per week required by 10A NCAC 14C .2203(b).

Projected utilization is based on reasonable, credible and supported assumptions regarding continued growth of Mecklenburg County and Union County patients at Mint Hill Dialysis Center. The applicant adequately demonstrates the need to add one dialysis station.

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 without regard to race, sex, age, handicap, or ethnic and socioeconomic groups of patients in need of dialysis regardless of their ability to pay.”

The applicant projects 87.9% of its patients will be covered by Medicare or Medicaid. The applicant adequately demonstrates the extent to which all residents of the service area, including the medically underserved, will have access to the proposed services.

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need for one additional dialysis station at Mint Hill Dialysis Center, and adequately demonstrates the extent to which all residents in the service area, in particular underserved groups, are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income

persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

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

CA

In Section III.9, page 23, the applicant discusses two alternatives considered prior to the submission of this application, which include the following:

- 1) Maintain the status quo. The applicant states this alternative is not the most effective alternative because Mint Hill Dialysis Center is growing fast. Based on the facility need methodology, the applicant could have applied for up to eight additional stations. Between 12/31/12 and 6/30/13, the number of patients increased from 18 to 32, a 77.8% increase [$32-18 = 14$; $14/18 = 0.7777$].
- 2) Add one dialysis station. The applicant states that adding one additional station to the existing treatment space at Mint Hill Dialysis Center is the most effective alternative to meet the increasing demand for dialysis services at the facility.

The applicant adequately demonstrates the need for one additional station based on the continued growth of the ESRD patient population of Mecklenburg County and the facility's projected utilization. See Criterion (3) for discussion of need which is incorporated hereby as if set forth fully herein. Furthermore, the application is conforming to all other statutory and regulatory review criteria. An application that is not approvable 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 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 Center 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 Center shall develop no more than one additional dialysis station at Mint Hill Dialysis Center for a total of no more than 11 dialysis stations upon project completion including any home hemodialysis or isolation stations.**
- 3. DVA Healthcare Renal Care, Inc. d/b/a Mint Hill Dialysis Center shall install plumbing and electrical wiring through the walls for no more than one additional dialysis station.**

- 4. Prior to issuance of the certificate of need, DVA Healthcare Renal Care, Inc. d/b/a Mint Hill Dialysis Center shall submit documentation to the Certificate of Need Section regarding existing clinical training agreements with Kings College and Winthrop University.**
 - 5. DVA Healthcare Renal Care, Inc. d/b/a Mint Hill Dialysis Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section 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

In Section VIII.1, pages 38-40, the applicant projects the capital cost will be \$19,038, including the cost of the dialysis machine, dialysis chair, television, computer terminal and other equipment/furniture.

In Section IX, page 43, the applicant indicates that there will be no start-up or initial operating expenses associated with this project.

In Section VIII.3, page 40, the applicant states it will fund the capital needs of the proposed project from the cash reserves of DaVita Healthcare Partners Inc., the applicant's ultimate parent company.

Exhibit 17 includes a letter dated March 31, 2014 from the Chief Accounting Officer of DaVita Healthcare Partners, Inc., which states,

"I am the Chief Accounting Officer of DaVita Healthcare Partners Inc., the parent and 100% owner of DVA Healthcare Renal Care, Inc.

We are submitting a Certificate of Need application to expand our Mint Hill Dialysis Center by one ESRD dialysis station. The project calls for a capital expenditure of \$19,038. This letter will confirm that DaVita Healthcare Partners Inc. has committed cash reserves in the total sum of \$19,038. [sic] 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 DaVita Healthcare Renal Care."

In Exhibit 18, the applicant provides the audited financial statements for DaVita Healthcare Partners Inc. The report shows that, as of December 31, 2013, DaVita Health Care Partners Inc. had \$946,249,000 in cash and cash equivalents, \$17,098,877,000 in total assets and \$4,605,541,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

In Section X.1, page 45, the applicant projects the following charges per treatment for each payment source as follows.

MINT HILL DIALYSIS CENTER	
PAYMENT SOURCE	IN-CENTER CHARGE
Medicare	\$240
Medicaid	\$143
Medicare/Medicaid	\$240
Commercial Insurance	\$1,175
VA	\$193
Medicare/Commercial	\$240

The applicant projects net revenue in Section X.2, page 45, and operating expenses in Section X.4, page 48, of the application. The applicant projects revenues will exceed expenses in each of the first two operating years (OY) following completion of the project, as illustrated below in the table.

MINT HILL DIALYSIS CENTER		
	OY1 (CY 2015)	OY2 (CY 2016)
Total Projected Net Revenue	\$1,739,012	\$1,838,880
Total Projected Operating Costs	\$1,516,952	\$1,587,371
Projected Net Profit	\$222,060	\$251,509

In Section X.3, page 47, the applicant provides the following assumptions to project revenue for OY1 and OY2:

Assumptions

1. With regard to the first operating year, the number of in-center patients is based on 33 patients treated at the beginning of the year with growth during the year to 36 in-center patients;
2. With regard to the second operating year, the number of in-center patients is based on 36 in-center patients treated at the beginning of the year with growth during the year to 37 in-center patients.
3. For both operating years, the total number of treatments includes the in-center patients at an average of three treatments per week, per patient, for 52 weeks;
4. For both operating years, the total number of treatments is reduced by five percent to allow for missed treatments; and
5. For both operating years, the average reimbursement per treatment is based on the applicant's historical experience and expected future reimbursement.

In Section X.4 and X.5, pages 48-49, the applicant provides projected staffing and salaries. In Section VII, page 35, the applicant states the facility is in compliance with the requirements of 42 C.F.R. Section 494 (formerly 405.2100). Staffing by shift is provided on

page 37. The applicant projects adequate staffing to provide dialysis treatments for the number of patients projected.

The applicant adequately demonstrates that the financial feasibility of the proposal is based on 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 Healthcare Renal Care, Inc., d/b/a Mint Hill Dialysis Center proposes to add one dialysis station to the existing facility for a total of 11 certified dialysis stations upon project completion. The applicant does not propose to establish a new facility. The applicant adequately demonstrates the need for one additional station based on the number of in-center patients it proposes to serve. See Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.

According to Table A in the January 2014 SDR, as of June 30, 2013, Mint Hill Dialysis Center was operating at 80% of capacity, with 32 in-center patients on 10 stations ($32 / 10 = 3.2$; $3.2 / 4 = 0.80$). The target utilization rate is 80% or 3.2 patients per station, per week, at the end of the first operating year. Therefore, the applicant is eligible to expand its facility and may apply for additional stations, consistent with the facility need methodology in the 2014 SMFP. In Section III.7, page 22, the applicant states that at the end of Operating Year One, the facility will have 11 stations serving 36 patients, which is a utilization rate of 82% ($36 / 11 = 3.3$; $3.3 / 4 = 0.818$). Dialysis facilities that operate four shifts per week (two per day on alternate days) have a capacity of four patients per station.

Mint Hill Dialysis Center is one of 17 existing or approved dialysis facilities located in Mecklenburg County. Of the 17 facilities, the applicant or a related entity owns five existing facilities and one approved facility. In Section V.7, on page 29, the applicant states:

“Mecklenburg County is an urban county. The proposed expansion of the facility is not intended to be a competitive venture. The effect of [sic] 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.

... patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs. The Mint Hill Dialysis Center provides access to all qualified Nephrologists to admit his or her patients.”

The following table identifies the existing and approved dialysis facilities located in Mecklenburg County as reported in Table A of the January 2014 SDR. Mint Hill Dialysis Center is the only facility located in Mint Hill.

MECKLENBURG COUNTY DIALYSIS FACILITIES				
Facility	Existing	Approved	# of In-center patients	Utilization Rate as of 6/30/13
Mint Hill Dialysis*	10	0	32	80%
Huntersville Dialysis*		10		
North Charlotte Dialysis Center*	25		120	120%
FMC Matthews	21	0	90	107.14%
BMA East Charlotte	24	9	83	86.46%
BMA Nations Ford	24	2	102	106.25%
BMA West Charlotte	29	0	83	71.55%
BMA Beatties Ford	32	0	120	93.75%
Carolina's Medical Center	9	0	13	36.11%
DSI Charlotte Latrobe Dialysis	24	0	60	62.50%
DSI Glenwater Dialysis	42	0	116	69.05%
South Charlotte Dialysis*	20	0	63	78.75%
Charlotte Dialysis*	34	1	120	88.24%
Charlotte East Dialysis*	16	0	77	120.31%
BMA North Charlotte	27	0	119	110.19%
FMC Charlotte	40	7	130	81.25%
FMC Southwest Charlotte		10		

*DaVita facilities.

Fifteen of the 17 facilities listed above are existing. Twelve of the 15 existing facilities have a utilization rate above 70% with the exception of DSI Charlotte Latrobe Dialysis (62.5%), DSI Glenwater Dialysis (69.1%), and Carolinas Medical Center (36.1%).

Table B of the January 2014 SDR identifies a deficit of zero dialysis stations in Mecklenburg County. The county need methodology requires that there be a deficit of at least 10 stations and that all existing facilities operate at or above 80% capacity. However, the applicant is eligible to apply for additional stations in its existing facility based on the application of the facility need methodology because the utilization rate reported is 80.0%. The applicant adequately demonstrates the need to develop one additional dialysis station at the existing Mint Hill Dialysis facility based on the number of in-center patients projected to utilize the facility.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities 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 VII.1, page 35, the applicant provides the current and projected number of full-time equivalent (FTE) positions as shown in the following table.

MINT HILL DIALYSIS CENTER		
POSITION	NUMBER OF CURRENT FTEs	TOTAL FTEs
Registered Nurse	1.5	1.5
Patient Care Technician	5.0	5.0
Bio-Medical Technician	0.3	0.3
Administrative	1.0	1.0
Dietician*	0.3	.03
Social Worker*	0.3	.03
Unit Secretary	1.0	1.0
Total	9.4	9.4

* The applicant's projected total FTEs are in brackets.

The salaries for the dietician and social worker in the above table on page 35 are not consistent with the salaries the applicant projects for the dietician and social worker in Section X.4. and X.5., pages 48 and 49. However, the applicant states in clarifying information that the salaries and FTEs for those two positions are erroneously stated in Section VII.1. Therefore, the FTEs should remain at .3 each for the dietician and social worker. It is also reasonable to assume that since the applicant is proposing to add only one dialysis station to the facility that the applicant does not propose to add any additional staff members. As shown in the table above, the applicant proposes to continue to employ a total of 9.4 FTE positions to staff Mint Hill Dialysis Center upon completion of the proposed project.

In Section V.4, page 29, the applicant states that Dr. Jack Lohavichan will continue to serve as medical director of the facility. Exhibit 12 contains a letter of support from Dr. Lohavichan.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel 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.

C

In Sections V.1 and V.2, on pages 27-28, the applicant lists the providers of the necessary ancillary and support services that will serve the patients dialyzing at Mint Hill Dialysis Center. Novant Health Presbyterian Medical Center provides the following services: emergency, acute hemodialysis, diagnostic evaluation, X-ray, blood bank, and vascular surgery. The other services are provided by the individual providers listed in the table provided on page 27. The applicant discusses coordination with the existing health care system in Section V.2-V.6, pages 28-30. In addition, the applicant provides supporting documentation of coordination with the existing health care system in Exhibits 9, 10, 11 and 12.

The information the applicant provides in those sections and exhibits is reasonable and credible and supports a finding of conformity 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.”

The applicant’s dialysis policies, procedures and guidelines with regard to accepting patients for dialysis care are located in Exhibit 13.

In Section VI.1, page 31, the applicant reports that 87.9% of the patients who received treatments at Mint Hill Dialysis Center had some or all of the services paid for by Medicare or Medicaid in the past year. The table below illustrates the historical payor mix for the facility, as reported by the applicant.

MINT HILL DIALYSIS CENTER HISTORICAL PAYOR MIX	
PAYOR SOURCE	PERCENTAGE
Medicare	21.2%
Medicaid	3.0%
Medicare/Medicaid	24.2%
Commercial Insurance	12.1%
Medicare/Commercial	39.5%
Total	100.0%

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. 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	15%	5.1%	20.1%
Statewide	17%	6.71%	19.7%

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

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the dialysis services offered by Mint Hill Dialysis Center. In fact, in 2012 only 6.5% of all newly-diagnosed ESRD patients in North Carolina’s Network 6 were under the age of 35 (*ESRD Network 6 2012 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 01/01/2012 – 12/21/2012*, page 74).

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. 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 or women utilizing health services. Furthermore, OSBM’s website does not include information on the number of handicapped persons.

Additionally, The United States Renal Data System, in its *2013 USRDS Annual Data Report*, pages 216-223, provides the following national statistics for FY 2011:

*“The December 31, 2011 prevalent population included 430,273 patients on dialysis ...”*¹ (p. 216)

The report also provided the incidence of dialysis patients in 2011, adjusted by age, gender and race, which showed that 65.4% were White, 28.0% were African American, 15.0% were Hispanic, 4.7% were Asian, and 1.2% were Native American (p. 218). Moreover, the prevalence of ESRD for the 65-74 year old population grew by 31% since 2000 and by 48% for those aged 75 and older (p. 216). The report further states:

“In the 2011 prevalent population, 84 percent of hemodialysis patients and 81 percent of those on peritoneal dialysis had some type of primary Medicare coverage, compared to just 53 percent of those with a transplant.”(p. 216)

¹ www.usrds.org/adr.aspx

The report states that the overall Medicare expenditures for chronic kidney disease for 2011 were \$49.2 billion, including Medicare Part D (p.118). The 2013 USRDS Annual Data Report provides 2011 ESRD spending by payor, as follows:

ESRD SPENDING BY PAYOR*		
PAYOR	SPENDING IN BILLIONS	% OF TOTAL SPENDING
Medicare Paid	\$30.7	62.4%
Medicare Patient Obligation	\$4.7	9.6%
Medicare HMO	\$3.6	7.3%
Non-Medicare	\$10.2	20.7%
TOTAL	\$49.2	100.0%

*Source: 2013 United States Renal Data System (USRDS) Annual Data Report, page 327.

The Southeastern Kidney Council (SKC) Network 6 2012 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 76, summarized as follows:

Number and Percent of Dialysis Patients by Age, Race and Gender 2012		
	# of ESRD Patients	% of Dialysis Population
Ages		
0-19	73	0.5%
20-34	751	5.0%
35-44	1,442	9.7%
45-54	2,644	17.7%
55-64	4,013	26.9%
65+	5,995	40.2%
Gender		
Female	6,692	44.9%
Male	8,226	55.1%
Race		

African American	9,346	62.7%
White/Caucasian	5,191	34.8%
Other	380	2.6%

Source: Southeastern Kidney Council (SKC) Network 6.
Table includes North Carolina statistics only.²

The applicant demonstrates that medically underserved populations currently have adequate access to services available at Mint Hill Dialysis Center. 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 VI.1(f), page 32, 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...*” In Section VI.6(a), page 34, 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(c), page 32, the applicant provides the projected payor mix for the proposed dialysis services at the facility. The applicant projects no change from the current payor mix. The applicant projects 87.9% of all in-center patients will have some or all of their services paid for by Medicare and Medicaid.

The applicant demonstrates that the elderly and medically underserved populations will continue to have adequate access to the proposed dialysis 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

² www.esrdnetwork6.org/publications/reports.html

In Section VI.5, pages 33-34, the applicant describes the range of means by which patients will have access to the proposed dialysis services. The information provided in Section VI.5 is reasonable and credible and supports a finding of conformity 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 Mint Hill Dialysis has existing clinical training agreements with Kings College in Charlotte and Winthrop University in Rock Hill, South Carolina. The applicant states, “*See Exhibit 11 for copies of the agreements.*” Exhibit 11 contains a copy of a letter from the applicant addressed to the President of Central Piedmont Community College offering Mint Hill Dialysis as a clinical training site for nursing students. What Exhibit 11 does not contain are the agreements with Kings College and Winthrop University that the applicant states on page 29 are included in Exhibit 11.

The application is conforming to this criterion subject to Condition #4 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

DVA Healthcare Renal Care, Inc., d/b/a Mint Hill Dialysis Center proposes to add one dialysis station to the existing facility for a total of 11 certified dialysis stations upon project completion. The applicant does not propose to establish a new facility. The applicant adequately demonstrates the need for one additional station based on the number of in-center patients it proposes to serve. See Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.

According to Table A in the January 2014 SDR, as of June 30, 2013, Mint Hill Dialysis Center was operating at 80% of capacity, with 32 in-center patients on 10 stations ($32 / 10 = 3.2$; $3.2 / 4 = 0.80$). The target utilization rate is 80% or 3.2 patients per station, per week, at the end of the first operating year. Therefore, the applicant is eligible to expand its facility

and may apply for additional stations, consistent with the facility need methodology in the 2014 SMFP. In Section III.7, page 22, the applicant states that at the end of Operating Year One, the facility will have 11 stations serving 36 patients, which is a utilization rate of 82% ($36 / 11 = 3.3$; $3.3 / 4 = 0.818$). Dialysis facilities that operate four shifts per week (two per day on alternate days) have a capacity of four patients per station.

The following table identifies the existing and approved dialysis facilities in located in Mecklenburg County as reported in Table A of the January 2014 SDR. Mint Hill Dialysis Center is the only facility located in Mint Hill. Of the 17 existing and approved facilities, TRC owns five existing and one approved.

MECKLENBURG COUNTY DIALYSIS FACILITIES				
Facility	Existing	Approved	# of In-center patients	Utilization Rate as of 6/30/13
Mint Hill Dialysis*	10	0	32	80%
Huntersville Dialysis*		10		
North Charlotte Dialysis Center*	25		120	120%
FMC Matthews	21	0	90	107.14%
BMA East Charlotte	24	9	83	86.46%
BMA Nations Ford	24	2	102	106.25%
BMA West Charlotte	29	0	83	71.55%
BMA Beatties Ford	32	0	120	93.75%
Carolina's Medical Center	9	0	13	36.11%
DSI Charlotte Latrobe Dialysis	24	0	60	62.50%
DSI Glenwater Dialysis	42	0	116	69.05%
South Charlotte Dialysis*	20	0	63	78.75%
Charlotte Dialysis*	34	1	120	88.24%

Charlotte East Dialysis*	16	0	77	120.31%
BMA North Charlotte	27	0	119	110.19%
FMC Charlotte	40	7	130	81.25%
FMC Southwest Charlotte		10		

*DaVita facilities.

Fifteen of the 17 facilities listed above are existing. Twelve of the 15 existing facilities have a utilization rate above 70% with the exception of DSI Charlotte Latrobe Dialysis (62.5%), DSI Glenwater Dialysis (69.1%), and Carolinas Medical Center (36.1%).

Table B of the January 2014 SDR identifies a deficit of zero dialysis stations in Mecklenburg County. The county need methodology requires that there be a deficit of at least 10 stations and that all existing facilities operate at or above 80% capacity. However, the applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology because the utilization rate reported is 80.0%.

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

“Mecklenburg County is an urban county. The proposed expansion of the facility is not intended to be a competitive venture. The effect of [sic] 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.

... patient selection is the determining factor, as the patient will select the provider that gives them the highest quality service and best meets their needs. The Mint Hill Dialysis Center provides access to all qualified Nephrologists to admit his or her patients.”

See also Sections II, III, V, VI and VII, in which the applicant discusses the cost-effectiveness, quality and access to the proposed services.

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

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

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

The applicant currently provides dialysis services at Mint Hill Dialysis Center. According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, the facility operated in compliance with the Medicare Conditions of Participation and there were no incidents resulting in a determination of immediate jeopardy during the eighteen months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

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

C

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.

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

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

- (1) *Utilization rates;*
-C- In Sections II.1 and III.7, pages 12 and 22, the applicant states the utilization rate was 80% or 3.2 patients per station ($32 / 10 = 3.2$) as of date.
- (2) *Mortality rates;*

- C- In Section IV.2, page 23, the applicant states the mortality rates as NA, NA, and 0% in, 2011, 2012 and 2013 respectively. The facility did not begin operating until November 1, 2012.
- (3) *The number of patients that are home trained and the number of patients on home dialysis;*
- C- In Section IV.3, page 25, the applicant states that no home training services are offered to Mint Hill Dialysis Center patients.
- (4) *The number of transplants performed or referred;*
- C- In Section IV.4, page 25, the applicant states that Mint Hill Dialysis Center referred three patients for transplant evaluation in 2013. The applicant states two transplants were actually performed in 2013.
- (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 Center has three patients currently on the transplant waiting list.
- (6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
- C- In Section IV.6, page 26, the applicant states that there were 49 hospital admissions in 2013, four of which were dialysis related and 45 that were non-dialysis related.
- (7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*
- C- In Section IV.7, page 26, the applicant states that there were no patients at the facility in 2013 with an infectious disease.

(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:

- (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.*
- NA- Mint Hill Dialysis Center is an existing facility.
- (2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with 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 Center is an existing facility.

(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*

-NA- Mint Hill Dialysis Center is an existing facility.

(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*

-C- See Exhibit 8 for a copy of the policies and procedures for back-up electrical service in the event of a power outage for Mint Hill Dialysis Center.

(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 Center is an existing facility.

(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- In Section XI.6(g), page 52, the applicant states, “Mint Hill Dialysis Center has and will continue to operate within the applicable laws and regulations pertaining to staffing and fire safety equipment, physical environment and other relevant health safety requirements.”

(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 II.1, pages 12-15, and Section III.7, pages 22-23, the applicant provides the methodology and assumptions to project patient origin as presented in the following table:

COUNTY	OPERATING YEAR 1	OPERATING YEAR 2	COUNTY PATIENTS AS PERCENT OF TOTAL	
	IN-CTR.	IN-CTR.	YEAR 1	YEAR 2
Mecklenburg	25	26	64.9%	70.3%
Union	11	11	30.6%	29.7%
TOTAL	36	37	100.0%	100.0%

Also see discussion in Criterion (3) which is incorporated hereby as if set forth fully herein.

(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 Center is an existing facility.

(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 rate for such services.*

-C- In Section II.1, 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.*”

10A NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- Mint Hill Dialysis Center does not propose to establish a new End Stage Renal Disease facility.

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

-C- Mint Hill Dialysis Center projects 3.2 patients per station per week as of the end of the first operating year. Assumptions are provided in Section II.1, pages 12-15, and Section III.7, pages 22-23. See also Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.

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

-C- The applicant provides all assumptions, including the methodology by which patient utilization is projected in Section II.1, pages 12-15, and Section III.7, pages 22-23. See also Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.

10A NCAC 14C .2204 SCOPE OF SERVICES

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

(1) *diagnostic and evaluation services;*

-C- In Section V.1, page 27, the applicant states patients will receive diagnostic and evaluation services from Novant Health Presbyterian Medical Center.

(2) *maintenance dialysis;*

-C- In Section V.1, page 27, the applicant states patients will receive maintenance dialysis services at the facility.

(3) *accessible self-care training;*

-C- In Section II.1, page 15, the applicant refers to Section V.1, page 27, for the information which responds to this rule. However, the section of the table on page 27 that refers to self-care training is blank, but in Section IV.3, page 25, the applicant states that Mint Hill Dialysis Center does not offer home training.

(4) *accessible follow-up program for support of patients dialyzing at home;*

-C- In Section II.1, page 15, the applicant refers to Section V.1, page 27. The table on page 25 provides no information with regard to an accessible follow-up program for patients dialyzing at home. In Section IV.3, on page 25, the applicant states that Mint Hill Dialysis Center does not offer home training. However, in Section V.2(d), page 28, the applicant states: “*The Charlotte East Dialysis Center provides protocols and routines for patient follow-up. ...*”

(5) *x-ray services;*

-C- In Section V.1, page 27, the applicant states x-ray services will be provided by Novant Health Presbyterian Medical Center.

(6) *laboratory services;*

-C- In Section V.1, page 27, the applicant states laboratory services will be provided by Dialysis Laboratories.

(7) *blood bank services;*

-C- In Section V.1, page 27, the applicant states blood bank services will be provided by Novant Health Presbyterian Medical Center.

(8) *emergency care;*

-C- In Section V.1, page 27, the applicant states emergency care services will be provided by Novant Health Presbyterian Medical Center.

(9) *acute dialysis in an acute care setting;*

-C- In Section V.1, page 27, the applicant states acute dialysis services will be provided by Novant Health Presbyterian Medical Center.

(10) *vascular surgery for dialysis treatment patients;*

-C- In Section V.1, page 27, the applicant states vascular surgery services will be provided by Novant Health Presbyterian Medical Center.

(11) *transplantation services;*

-C- In Section V.1, page 27, the applicant states transplantation services will be provided Duke University Medical Center.

(12) *vocational rehabilitation counseling and services; and*

-C- In Section V.1, page 27, the applicant states vocational rehabilitation counseling and services will be provided by the North Carolina Division of Vocational Rehabilitation Services.

(13) *transportation.*

-C- In Section V.1, page 27, the applicant states transportation services will be provided by the Department of Social Services and various providers.

10A NCAC 14C .2205 STAFFING AND STAFF TRAINING

(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.*

-C- In Section VII.1, on page 35, the applicant states that all staffing requirements will be met as stated in 42 C.F.R. Section 494 (formerly 405.2100). See Criterion (7) for further discussion on staffing which is incorporated hereby as if set forth fully herein.

(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- In Section VII.5, on page 36, and in Exhibit 16 the applicant provides a copy of the applicant's training policy for nurses and technicians at the facility.