

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: March 11, 2016

Findings Date: March 11, 2016

Project Analyst: Julie Halatek

Team Leader: Lisa Pittman

Project ID #: F-11108-15

Facility: University City Dialysis

FID #: 150478

County: Mecklenburg

Applicant: DVA Healthcare Renal Care, Inc.

Project: Develop a new 10-station dialysis facility by relocating 10 dialysis stations from North Charlotte Dialysis

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. (DaVita) d/b/a University City Dialysis (UCD) proposes to develop a new 10-station dialysis facility in Charlotte by relocating 10 dialysis stations from North Charlotte Dialysis (NCDC). Both facilities are located in Mecklenburg County. The applicant does not propose to add dialysis stations to an existing facility or to establish new dialysis stations.

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services, or equipment for which there is a need determination in the 2015 State Medical Facilities Plan (SMFP).

Policies

The following two policies are applicable to this review:

- Policy ESRD-2: Relocation of Dialysis Stations
- Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities

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 develop a new 10-station dialysis facility in Mecklenburg County by relocating existing Mecklenburg County dialysis stations from NCDC. Because both facilities are located in Mecklenburg County, there is no change in dialysis station inventory in Mecklenburg County. Therefore, the application is consistent with Policy ESRD-2.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate, or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate, or add to a health service facility pursuant to G.S. 131E-178, the Certificate of Need Section shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN 4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy-GEN 4. The plan shall not adversely affect patient or resident health, safety, or infection control."

In Section B.9, pages 11-13, the applicant provides a written statement describing the proposed project's plan to assure improved energy efficiency and water conservation. The application is consistent with Policy GEN-4.

Conclusion

In summary, the applicant demonstrates that the proposal is conforming to all applicable policies in the 2015 SMFP. Therefore, the application is conforming to this criterion.

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

C

DVA Healthcare Renal Care, Inc. (DaVita) d/b/a University City Dialysis (UCD) proposes to develop a new 10-station dialysis facility in Charlotte by relocating 10 dialysis stations from North Charlotte Dialysis (NCDC). NCDC currently has 35 certified dialysis stations, as published in the July 2015 Semiannual Dialysis Report (SDR). At completion of this project and other projects associated with NCDC, UCD will be certified for 10 dialysis stations and NCDC will be certified for 27 dialysis stations.

Population to be Served

On page 361, the 2015 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

UCD will be a new facility in Mecklenburg County and therefore has no existing patient origin. In Section C.1, page 14, the applicant states in the table that 100 percent of

patients will be residents of Mecklenburg County. In Section C.2, page 16, the applicant states that the location of the proposed facility was based upon analysis showing that existing facilities serve 33 in-center patients that reside in or around zip code 28262 in Charlotte. On page 14, the applicant states that it has letters from 33 patients residing in zip codes 28262, 28213, 28215, and 28025 who express support for the project and who could be better served by dialyzing at the proposed facility. The applicant provides a table identifying the patient residence zip code and current dialysis facility of the 33 patients providing the support letters and expressing a willingness to transfer their care. On page 15, the applicant states that none of the 33 patients whose letters of support are provided in this application are the same as patients who provided letters of support for Project I.D. #F-10219-15 (develop Huntersville Dialysis by transferring 10 stations from NCDC).

Exhibit C-1 includes letters of support from the 33 dialysis patients, stating they support the proposed project and that they live closer to the proposed UCD facility. The applicant adequately identifies the population to be served.

Analysis of Need

The applicant proposes to develop a new 10-station dialysis facility by relocating 10 dialysis stations from NCDC. In Section C, pages 15-22, the applicant states that the need the population to be served has for the proposed project is based on the following factors:

- The applicant states that analysis of the patients served by DaVita facilities in Mecklenburg County shows that six existing facilities are serving 33 in-center patients who live in or around zip code 28262 in northeastern Charlotte.
- The applicant states that in order to provide better support and access to dialysis services, a new facility is needed closer to the homes of those patients residing in or around zip code 28262.
- The first two full OYs of the project are expected to be CY 2018 and CY 2019.
- The applicant assumes that 32 out of 33 patients who express support for the proposed project and a willingness to transfer care to the new facility will do so and that all will be Mecklenburg County residents.
- The applicant assumes the Mecklenburg County ESRD patient population utilizing the facility will increase at the rate of 5.8 percent per year, the Five Year Average Annual Change Rate (AACR) for Mecklenburg County as published in the July 2015 SDR.

Projected Utilization

In Section C.1, pages 14-16, the applicant provides the assumptions and methodology it uses to determine the need for a new facility developed by relocating stations from an existing facility. The applicant’s assumptions and methodology are summarized below:

- The starting patient population at the proposed facility will consist of 32 Mecklenburg County patients currently dialyzing at other DaVita facilities who have expressed a willingness to transfer care to the proposed facility.
- The Mecklenburg County patient population will grow at a rate of 5.8 percent (the Five Year AACR for Mecklenburg County as published in the July 2015 SDR) through the end of the second year of operation.
- The project is scheduled for completion on January 1, 2018. OY1 is CY 2018. OY2 is CY 2019.

In Section C.1, pages 14-16, the applicant provides the calculations used to arrive at the projected in-center patient census for OY1 and OY2 as summarized in the table below.

UCD	In-Center Dialysis
Starting point of calculations is Mecklenburg County patients dialyzing at other DaVita facilities but who are willing to transfer care to UCD. This is the projected census on January 1, 2018.	32
Mecklenburg County patient population is projected forward by one year to December 31, 2018. Projection is based on the Five Year AACR for Mecklenburg County (5.8%). This is the projected census on December 31, 2018 (OY1).	$32 \times 1.058 = 33.856$
Mecklenburg County patient population is projected forward by one year to December 31, 2019, using the Five Year AACR (5.8%). This is the projected census on December 31, 2019 (OY2).	$33.856 \times 1.058 = 35.81965$

The applicant projects to serve 33 in-center patients on 10 stations, which is 3.3 patients per station (33 patients / 10 stations = 3.3), by the end of OY1 and 35 in-center patients on 10 stations, which is 3.5 patients per station (35 patients / 10 stations = 3.5), by the end of OY2. 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). Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth.

Access

In Section L.1, pages 49-50, the applicant states that UCD will provide dialysis services to all residents in its service area without qualifications and serves patients without regard to race, color, national origin, gender, sexual orientation, age, religion, or disability. The applicant also states that it will make every reasonable effort to accommodate those with

special needs and helps uninsured and underinsured patients with applying for assistance so it can serve low-income persons, racial and ethnic minorities, women, handicapped persons, elderly persons, and other underserved persons. The applicant projects 86.1 percent of its patients will have some or all of their services paid for by Medicare or Medicaid and bases its projected payor mix on the sources of patient payment received by the 454 in-center patients utilizing existing Mecklenburg County facilities in the last full operating year. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for the proposed 10-station facility, and demonstrates the extent to which all residents of the area, including 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.

C

The applicant proposes to develop a new 10-station dialysis facility in Mecklenburg County by relocating 10 dialysis stations from NCDC, also in Mecklenburg County. In Section D.1, page 24, the applicant states that the July 2015 SDR shows NCDC serving 139 in-center patients on 35 stations as of December 31, 2014, for a utilization rate of 99.29 percent. The applicant states that the facility has 41 certified stations as of July 24, 2015 (see page 24 and Exhibit A-9).

In Section D, pages 24-25, the applicant discusses how the needs of dialysis patients at NCDC will continue to be met after the relocation of stations to the proposed UCD dialysis facility. The applicant states that the development of the proposed facility, along with development of other approved and pending projects, results in the following changes to the number of stations at NCDC.

Changes in Number of Stations - NCDC			
	Stations	Stations to be Relocated (-) or Added	Stations Remaining
As reported in July 2015 SDR (December 31, 2014)	35	--	--
As of July 24, 2015	41	--	--
At completion of Project I.D. #F-10219-13 (January 1, 2016)		-10	31
At completion of Project I.D. #F-11076-15 (January 1, 2016)		10	41
At completion of Project I.D. #F-11019-15 (January 1, 2017)		-4	37
At completion of Project I.D. #F-11108-15 (January 1, 2018)		-10	27

On pages 24-25 of the application, the applicant provides the assumptions used to project NCDC's utilization through the end of OY2 (December 31, 2019). The assumptions are summarized below:

- As of December 31, 2014, NCDC was serving 139 patients – 129 Mecklenburg County residents and 10 patients residing outside Mecklenburg County.
- The applicant projects growth of the Mecklenburg County patient population using the 5.8 percent Mecklenburg County Five Year Average Annual Change Rate as published in the July 2015 SDR.
- The applicant does not project any growth in the patient population that resides outside of Mecklenburg County.
- The applicant states that it expects 16 patients residing in Mecklenburg County to transfer from NCDC to Huntersville Dialysis upon completion of Project I.D. #F-10219-13 (on January 1, 2016).

Based on the above assumptions, the applicant projects utilization at NCDC as follows:

NCDC	In-Center Dialysis
Starting point of calculations is Mecklenburg County patients dialyzing at NCDC on January 1, 2015.	129
Mecklenburg County patient population is projected forward by one year to December 31, 2015. Projection is based on the 5.8% Five Year AACR for Mecklenburg County.	$129 \times 1.058 = 136.482$
Project I.D. #F-10219-13 (Huntersville Dialysis) is projected to be operational on January 1, 2016. As part of that project, the applicant projected that 16 NCDC patients would transfer their care from NCDC to Huntersville. The 16 patients projected to transfer are subtracted.	$136.482 - 16 = 120.482$
Mecklenburg County patient population is projected forward by one year to December 31, 2016, using the 5.8% Five Year AACR.	$120.482 \times 1.058 = 127.470$
The 10 patients residing outside Mecklenburg County are added. This is the projected census on December 31, 2016.	$127.470 + 10 = 137.470$
Mecklenburg County patient population is projected forward by one year to December 31, 2017, using the 5.8% Five Year AACR.	$127.470 \times 1.058 = 134.863$
The 32 patients projected to transfer from NCDC to the new UCD facility are subtracted from the Mecklenburg County patient population.	$134.863 - 32 = 102.863$
The 10 patients residing outside Mecklenburg County are added. This is the projected census on December 31, 2017.	$102.863 + 10 = 112.863$
Mecklenburg County patient population is projected forward by one year to December 31, 2018, using the 5.8% Five Year AACR.	$102.863 \times 1.058 = 108.829$
The 10 patients residing outside Mecklenburg County are added. This is the projected census on December 31, 2018 (OY1).	$108.829 + 10 = 118.829$ (119)
Mecklenburg County patient population is projected forward by one year to December 31, 2019, using the 5.8% Five Year AACR.	$108.829 \times 1.058 = 115.141$
The 10 patients residing outside Mecklenburg County are added. This is the projected census on December 31, 2019 (OY2).	$115.141 + 10 = 125.141$ (125)

The applicant projects to serve 119 in-center patients on 27 stations, which is 4.41 patients per station ($119 \text{ patients} / 27 \text{ stations} = 4.41$), by the end of OY1 and 125 in-center patients on 27 stations, which is 4.63 patients per station ($125 \text{ patients} / 27 \text{ stations} = 4.63$), by the end of OY2 at NCDC. On page 25, the applicant states:

“Given this projected growth of the in-center patient population, additional Certificate of Need application(s) will be submitted based on facility need as the facility approaches full capacity of stations to ensure that the needs of the facilities patients will continue to be met.”

The applicant demonstrates that the needs of the population presently served at NCDC will continue to be adequately met following the proposed relocation of 10 dialysis stations from NCDC to the proposed new facility 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 E.1, pages 26-27, the applicant discusses the alternatives considered prior to submitting this application, which include:

- Maintain the Status Quo –The applicant states that this alternative was dismissed due to growth of the patient population at DaVita facilities in Mecklenburg County.
- Apply for the Four Station Expansion – The applicant states that relocating 10 stations and developing a new facility will help meet the growing demand for services at DaVita facilities in Mecklenburg County. The applicant further states that because the combined utilization for all DaVita facilities in Mecklenburg County is 89.4 percent, and only one facility (Mint Hill) has any capacity to expand, maintaining the status quo could force Mecklenburg County patients to utilize a third shift or have no options for receiving treatment at a DaVita facility.

After considering those alternatives, the applicant states the alternative represented in the application is the most effective alternative to meet the identified need.

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

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

- 1. DVA Healthcare Renal Care, Inc. d/b/a University City Dialysis shall materially comply with all representations made in the certificate of need application.**
- 2. DVA Healthcare Renal Care, Inc. d/b/a University City Dialysis shall relocate no more than 10 dialysis stations from North Charlotte Dialysis Center.**
- 3. DVA Healthcare Renal Care, Inc. d/b/a University City Dialysis shall install plumbing and electrical wiring through the walls for no more than 10 dialysis stations, which shall include any isolation or home hemodialysis stations.**
- 4. DVA Healthcare Renal Care, Inc. shall take the necessary steps to decertify 10 dialysis stations at North Charlotte Dialysis Center for a total of no more than 27 dialysis stations at North Charlotte Dialysis Center upon completion of this project and all of the following projects: Project I.D. #F-10219-13 (relocate 10**

stations), Project I.D. #F-11019-15 (relocate 4 stations), and Project I.D. #F-11076-15 (add 10 stations).

- 5. Prior to the issuance of a certificate of need, DVA Healthcare Renal Care, Inc. d/b/a University City Dialysis shall provide to the Agency documentation of an intent to sign a written agreement or a written agreement with a transplantation center as required by 10A NCAC 14C .2202(b)(2) and .2204(11).**
 - 6. Prior to the issuance of a certificate of need, DVA Healthcare Renal Care, Inc. d/b/a University City Dialysis shall provide to the Agency documentation that power and water are available at proposed sites for the new facility as required by 10A NCAC 14C .2202(b)(3).**
 - 7. Prior to the issuance of a certificate of need, DVA Healthcare Renal Care, Inc. d/b/a University City Dialysis shall provide to the Agency a written commitment to pursue acquiring the primary site if and when the approval is granted and demonstrating that the primary and secondary sites are available for acquisition as required by 10A NCAC 14C .2202(b)(5).**
 - 8. DVA Healthcare Renal Care, Inc. d/b/a University City Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to develop a new 10-station dialysis facility by relocating 10 dialysis stations from North Charlotte Dialysis.

Capital and Working Capital Costs

In Section F.1, page 28, the applicant states that the projected capital cost is \$2,501,856, which includes \$1,650,000 in construction costs, \$144,870 for dialysis machines, \$180,341 for water treatment equipment, and \$513,645 for other equipment and costs.

In Sections F.10-12, page 31, the applicant projects \$182,779 in start-up expenses and \$542,072 in initial operating costs for the first four months of operations for a total projected working capital cost of \$724,851.

Availability of Funds

In Sections F.2, page 29, and F.13, page 32, the applicant states that cash reserves/owner's equity is being used to finance the proposed project.

Exhibit F-5 contains an October 15, 2015 letter from the Chief Accounting Officer of DaVita HealthCare Partners, stating that the company is submitting a certificate of need application to develop a new 10-station dialysis facility. The letter states that DaVita HealthCare Partners has committed cash reserves in the amount of \$3,226,707 for the project's capital and working capital expenditures.

In Section F.8(b), page 30, the applicant states:

“The financial strength of the company precludes any financial impact upon the operation and performance of the expansion that this application proposes. Therefore, there is no appreciable impact on either this application or from any that has been approved previously or is currently under review.”

Exhibit F-7 contains the most recent audited financial statements for DaVita HealthCare Partners, Inc. for years ended December 31, 2013 and 2014. As of December 31, 2014, DaVita HealthCare Partners, Inc. had \$965,241,000 in cash and cash equivalents, \$17,942,715,000 in total assets and \$5,360,311,000 in total equity. The applicant adequately demonstrates the availability of funds for the capital needs of the project.

Financial Feasibility

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

Projected Revenues and Operating Expenses		
UCD	Operating Year 1 CY 2018	Operating Year 2 CY 2019
Gross Patient Revenue	\$1,560,857	\$1,632,572
Deductions from Gross Patient Revenue	(\$64,838)	(\$67,807)
Net Patient Revenue	\$1,496,019	\$1,564,765
Total Operating Expenses	\$1,377,481	\$1,419,669
Net Income/Profit	\$118,538	\$145,097

The applicant's projections of treatments and revenues are reasonable based on the number of patients projected for the first two operating years. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

In Section H.1, page 35, the applicant provides projected staffing and salaries. Form A in Section R shows budgeted operating costs adequate to cover the projected staffing. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

Conclusion

In summary, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

C

DVA Healthcare Renal Care, Inc. (DaVita) d/b/a University City Dialysis (UCD) proposes to develop a new 10-station dialysis facility in Charlotte by relocating 10 dialysis stations from North Charlotte Dialysis (NCDC). NCDC currently has 35 certified dialysis stations, as published in the July 2015 Semiannual Dialysis Report (SDR). At completion of this project and other projects associated with NCDC, UCD will be certified for 10 dialysis stations and NCDC will be certified for 27 dialysis stations.

On page 361, the 2015 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

According to the July 2015 SDR, there are 14 operational dialysis facilities, 1 dialysis facility not in operation, and 3 dialysis facilities under development in Mecklenburg County. The applicant and its parent company operate six of the 18 facilities in Mecklenburg County. Bio-Medical Applications of North Carolina, Inc. (BMA) operates nine facilities, DSI Renal, Inc. (DSI) operates two facilities, and Carolinas Medical Center (CMC) operates one facility, as shown in the table below.

Mecklenburg County Dialysis Facilities – July 2015 SDR				
Facility	Owner	Location	Number of Existing/ Approved Stations	Utilization as of December 31, 2014
BMA Beatties Ford	BMA	Charlotte	43	88.28%
BMA Nations Ford	BMA	Charlotte	28	114.58%
BMA of East Charlotte	BMA	Charlotte	21	84.00%
BMA of North Charlotte	BMA	Charlotte	36	104.46%
BMA West Charlotte	BMA	Charlotte	29	78.45%
Carolinas Medical Center*	CMC	Charlotte	9	0.00%
Charlotte Dialysis	DaVita	Charlotte	36	78.47%
UCD Dialysis	DaVita	Charlotte	26	92.31%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	66.67%
DSI Glenwater Dialysis	DSI	Charlotte	42	77.38%
FMC Charlotte	BMA	Charlotte	43	82.50%
FMC Matthews	BMA	Matthews	21	114.29%
FMC of Southwest Charlotte**	BMA	Charlotte	10	0.00%
FMC Regal Oaks**	BMA	(none listed)	12	0.00%
Huntersville Dialysis**	DaVita	Huntersville	10	0.00%
Mint Hill Dialysis	DaVita	Mint Hill	11	100.00%
North Charlotte Dialysis Center	DaVita	Charlotte	31	99.29%
South Charlotte Dialysis	DaVita	Charlotte	23	82.50%

*Facility is not currently in operation.

**Facility under development.

As shown in the table above, 10 of the 14 Mecklenburg County dialysis facilities are operating above 80 percent utilization (3.2 patients per station), and 13 of the 14 facilities are operating at or above 75 percent utilization (3.0 patients per station).

The applicant is not adding dialysis stations in Mecklenburg County; it is relocating stations from an existing Mecklenburg County facility (NCDC). In Exhibit C-1, the applicant provides letters from 33 dialysis patients currently receiving care at DaVita dialysis facilities who have indicated that the proposed facility would be more convenient for them and closer to their residence.

In Section C.1, page 16, the applicant demonstrates that UCD will serve a total of 33 in-center patients on 10 stations at the end of the first operating year, which is 3.3 patients per station per week, or a utilization rate of 82.5 percent (33 patients / 10 stations = 3.3; 3.3 / 4 = 0.825). The applicant states that the projected utilization rates are based entirely on patients currently served at DaVita dialysis facilities who have expressed their willingness to consider transferring to the proposed UCD facility because it will be more convenient for them.

The applicant adequately demonstrates the need to relocate DaVita stations to develop a new dialysis facility in Mecklenburg County based on the number of and geographical location of the DaVita in-center patients it proposes to serve. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference. The discussion on competition found in Criterion (18a) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Mecklenburg County. Consequently, the application is conforming to this criterion.

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

C

In Section H.1, page 35, the applicant provides the following table to illustrate the projected staffing for UCD at completion of the project.

UCD – Proposed Facility Staffing	
Position	Projected # of FTEs
Medical Director*	
RN	2.0
Technician	4.0
Administrator	1.0
Dietitian	0.5
Social Worker	0.5
Admin. Assistant	1.0
Biomed Technician	0.3
Total	9.3

*The Medical Director is a contract position and is not an employee of the facility.

The following table shows the applicant’s projected number of direct care staff FTEs at UCD for OY2, as shown on page 38 of the application.

UCD – Projected Direct Care Staff Hours – OY2					
Direct Care Positions	# FTEs* [a]	Hours / Year / FTE [b]	Total Annual FTE Hours [c] = [a] x [b]	Total Annual Hours of Operation ** [d]	FTE Hours / Hours of Operation [e] = [c] ÷ [d]
RN	2.0	2,080	4,160	3,120	1.3
Technician (PCT)	4.0	2,080	8,320	3,120	2.7
Total	6.0	2,080	12,480	3,120	4.0

* FTEs should match the direct care Total FTE Positions [a + c] listed in the Facility Staffing table in Section H, Question 1.

** Total annual hours of operation from the Proposed Hours of Operation table in Section H, Question 6.

The applicant states that the Medical Director is not directly employed by the facility but provides services on a contractual basis. In Section H.2, page 36, the applicant identifies Dr. James Wood, a board certified nephrologist, as the prospective Medical Director for the proposed facility. Exhibit I-3 contains a copy of a letter from Dr. Wood supporting the proposed facility and agreeing to serve as Medical Director.

In Section H.3, pages 36-37, the applicant describes its experience and process for recruiting and retaining staff. 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 I, pages 39-41, the applicant discusses the providers of the necessary ancillary and support services for the proposed facility. The applicant discusses coordination with the existing health care system on pages 40-41. Exhibits I-1 and I-2 contain documents from DaVita Laboratory Services, the NC Division of Vocational and Rehabilitation Services, two local transportation companies, and Carolinas Medical Center, which demonstrate that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. The information found in Section I and referenced Exhibits is reasonable and supports a finding of conformity with this criterion.

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

NA

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

NA

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

C

In Section K.2, page 44, the applicant states there will be 7,827 square feet of treatment area, which includes isolation space. The applicant provides the proposed facility's line drawings in Exhibit K-1. The drawing depicts an 11,352 square foot facility, with nine main floor dialysis stations and an isolation dialysis station for a total of 10 stations. In Section F.1, page 28, the applicant lists its projected costs, including \$1,650,000 for construction, \$13,000 in site costs, and \$838,856 in miscellaneous costs (which includes dialysis machines, water treatment equipment, site costs not otherwise specified, and architect/engineering fees) for a total project cost of \$2,501,856. In Section K.1, page 43, the applicant describes the methods that will be used by the facility to maintain efficient energy operations and contain the costs of utilities. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicant adequately demonstrates that the cost, design, and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

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

C

The dialysis facility proposed in this application is a new facility and as such has no history of service. In Section L.7, page 53, the applicant provides the CY 2014 payor mix for the facility where the stations proposed to be relocated are currently located (NCDC), as illustrated in the table below.

CY 2014 Payor Mix - NCDC	
Payor Type	Percent of Patients
Medicare	28.7%
Medicaid	4.2%
Commercial Insurance	8.4%
Medicare/Commercial	29.3%
Medicare/Medicaid	23.8%
Other (unspecified)	5.6%
Total	100.0%

The *Southeastern Kidney Council Network 6 Inc. Annual Report*¹ provides prevalence data on North Carolina dialysis patients by age, race, and gender on page 59, summarized as follows:

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%

In 2014, over 85% of dialysis patients in North Carolina were 45 years of age and older and over 63% were non-Caucasian. (*Southeastern Kidney Council Network 6 Inc. 2014 Annual Report, page 59*).

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

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal

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

assistance, including the existence of any civil rights access complaints against the applicants;

C

In Section L.3(e), page 52, the applicant states:

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

In Section L.6, page 75, the applicant states that there have been no civil rights equal access complaints filed against any of the facilities owned by DaVita within the last five years.

The application is conforming to this criterion.

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

C

In Section L.1(b), page 50, the applicant provides the projected payor mix for Project Year 2, as shown in the table below.

Project Year 2 Payor Mix - UCD	
Payor Type	Percent of Patients
Medicare	28.1%
Medicaid	6.8%
Commercial Insurance	9.0%
Medicare/Commercial	29.0%
Medicare/Medicaid	22.2%
VA	4.9%
Total	100.0%

On page 50, the applicant states that the projected payor mix is based on the sources of patient payment that have been received by existing DaVita facilities in Mecklenburg County for the last full operating year. The applicant states that while the patient origin projections are based upon the letters signed by existing patients, it does not assume those actual patients represent the projected payor mix because patients leave the facility for one of several reasons.

In Section L.3(c), page 51, the applicant states:

“University City Dialysis 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.”

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 L.4, page 52, the applicant describes the range of means by which a person will have access to the dialysis services at UCD, including referrals from other providers, family, and friends, which will result in a referral to a qualified nephrologist for evaluation as to medical necessity. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to dialysis services. Therefore, the application is conforming to this criterion.

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

C

In Section M.1, page 54, the applicant states that it has offered the proposed facility as a clinical learning site for nursing students attending Central Piedmont Community College. Exhibit M-2 contains a copy of a letter from the applicant to the president of Central Piedmont Community College, offering the proposed facility as a clinical learning site for the school’s nursing students. The information provided is reasonable and adequately supports a determination that the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services

proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

DVA Healthcare Renal Care, Inc. (DaVita) d/b/a University City Dialysis (UCD) proposes to develop a new 10-station dialysis facility in Charlotte by relocating 10 dialysis stations from North Charlotte Dialysis (NCDC). NCDC currently has 35 certified dialysis stations, as published in the July 2015 Semiannual Dialysis Report (SDR). At completion of this project and other projects associated with NCDC, UCD will be certified for 10 dialysis stations and NCDC will be certified for 27 dialysis stations.

On page 361, the 2015 SMFP defines the service area for dialysis services as the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area. Thus, the service area for this facility consists of Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

According to the July 2015 SDR, there are 14 operational dialysis facilities, 1 dialysis facility not in operation, and 3 dialysis facilities under development in Mecklenburg County. The applicant and its parent company operate six of the 18 facilities in Mecklenburg County. Bio-Medical Applications of North Carolina, Inc. (BMA) operates nine facilities, DSI Renal, Inc. (DSI) operates two facilities, and Carolinas Medical Center (CMC) operates one facility, as shown in the table below.

Mecklenburg County Dialysis Facilities – July 2015 SDR				
Facility	Owner	Location	Number of Existing/ Approved Stations	Utilization as of December 31, 2014
BMA Beatties Ford	BMA	Charlotte	43	88.28%
BMA Nations Ford	BMA	Charlotte	28	114.58%
BMA of East Charlotte	BMA	Charlotte	21	84.00%
BMA of North Charlotte	BMA	Charlotte	36	104.46%
BMA West Charlotte	BMA	Charlotte	29	78.45%
Carolinas Medical Center*	CMC	Charlotte	9	0.00%
Charlotte Dialysis	DaVita	Charlotte	36	78.47%
UCD Dialysis	DaVita	Charlotte	26	92.31%
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	66.67%
DSI Glenwater Dialysis	DSI	Charlotte	42	77.38%
FMC Charlotte	BMA	Charlotte	43	82.50%
FMC Matthews	BMA	Matthews	21	114.29%
FMC of Southwest Charlotte**	BMA	Charlotte	10	0.00%
FMC Regal Oaks**	BMA	(none listed)	12	0.00%
Huntersville Dialysis**	DaVita	Huntersville	10	0.00%
Mint Hill Dialysis	DaVita	Mint Hill	11	100.00%
North Charlotte Dialysis Center	DaVita	Charlotte	31	99.29%
South Charlotte Dialysis	DaVita	Charlotte	23	82.50%

*Facility is not currently in operation.

**Facility under development.

As shown in the table above, 10 of the 14 Mecklenburg County dialysis facilities are operating above 80 percent utilization (3.2 patients per station), and 13 of the 14 facilities are operating at or above 75 percent utilization (3.0 patients per station).

In Section N.1, page 55, the applicant discusses how the proposed project would have a positive impact on the cost-effectiveness, quality, and access to the proposed services. The applicant states:

“The development of University City Dialysis will have no effect on any dialysis facilities located in Mecklenburg County or in counties contiguous to Mecklenburg County. Metrolina Nephrology Associates serves as the referral source for all of the facilities in Mecklenburg County and the counties contiguous to Mecklenburg County, except Iredell County. The patients being treated by Metrolina Nephrology Associates Nephrologists [sic] have a choice of dialysis facility. It has been our experience that patients generally choose a dialysis facility because it is closest to their home and most convenient.

The proposed University City Dialysis will not have an adverse effect on competition since the patients already being served by DaVita will be transferring their care from one DaVita facility to another DaVita facility, which will be more convenient for the patients who have indicated this in the letters they signed.”

See also Sections B, C, E, F, G, H, and L 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 the cost-effectiveness, quality, and access to the proposed services. This determination is based on the information in the application and the following analysis:

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

Therefore, the application is conforming to this criterion.

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

C

In Exhibit O-3, the applicant identifies three kidney disease treatment centers located in North Carolina, owned and operated by the applicant, that were cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. In Section O.3, page 56, the applicant states all three facilities are back in full compliance with CMS Guidelines as of the date of submission of this application. Exhibit O-3 contains copies of letters documenting that the facilities were determined to be back in compliance by CMS and the Division of Health Service Regulation. 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 application is conforming to all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria 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 Section G.1, page 34, the applicant provides utilization rates for NCDC. The December 31, 2014 utilization rate was reported in the July 2015 SDR as 99.29 percent with 139 in-center patients dialyzing on 35 stations.

(2) *Mortality rates;*

-C- In clarifying information, the applicant provides the NCDC mortality rates, as follows:

	Beginning In-Center Patients	Ending In-Center Patients	Average	Deaths	% Gross Mortality
2014	115	139	127	14	11.02%
2013	106	115	110.5	16	14.48%
2012	102	106	104	11	10.58%

(3) *The number of patients that are home trained and the number of patients on home dialysis;*

-C- In clarifying information, the applicant reports having no patients that are home trained or on home dialysis.

(4) *The number of transplants performed or referred;*

-C- In clarifying information, the applicant states that there were three transplants performed or referred by NCDC in 2014.

- (5) *The number of patients currently on the transplant waiting list;*
- C- In clarifying information, the applicant states that NCDC had nine patients on the transplant waiting list as of December 31, 2014.
- (6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
- C- In clarifying information, the applicant states that during 2014 there were 32 dialysis-related hospitalizations and 131 non-dialysis related hospitalizations for hospital admission rates of 20 percent and 80 percent, respectively.
- (7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*
- C- In clarifying information, the applicant states that there were eight patients with infectious disease at NCDC in 2014 and no patients converted to infection 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:*
 - (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).*
 - C- Exhibit I-2(a) contains a letter dated October 1, 2015, and signed by the Assistant Vice President of Carolinas HealthCare System, the parent company of Carolinas Medical Center, which states the hospital's intention to enter into an agreement with UCD to provide a range of services to patients receiving dialysis care at the facility. A listing of services to be provided by Carolinas HealthCare System is included in the letter.
 - (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.*

-CA- In Section I.2(b), page 40, the applicant states that the required documentation is included at Exhibit I-2(b). The exhibits included with the application do not contain an Exhibit I-2(b) and no exhibits contain the documentation required by this Rule. The application is conforming to this criterion, subject to the applicant providing documentation of a letter of intent to sign a written agreement or a written agreement with a transplantation center as required by this Rule. See Criterion (4) Condition 5.

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

-CA- In Section K, pages 43-48, the applicant provides information about the proposed primary site and secondary site. The applicant refers the reader to Exhibits K-4 and K-5 for information on these sites, including the information required by this Rule. However, there are no Exhibits K-4 or K-5 in the application as submitted and the required information is not located anywhere else in the application as submitted. The application is conforming to this criterion, subject to the applicant providing documentation that power and water will be available at the proposed site as required by this Rule. See Criterion (4) Condition 6.

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

-C- Exhibit K-1(f) contains written policies and procedures for back up electrical service in the event of a power outage.

(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.*

- CA- In Section K, pages 43-48, the applicant provides information about the proposed primary site and secondary site. On page 45, the applicant states the proposed primary site is located at 8210 University Executive Drive in Charlotte. On page 46, the applicant states the proposed secondary site is located at 8303 University Executive Park in Charlotte. The applicant refers the reader to Exhibits K-4 and K-5 for information on these sites, including the documentation required by this Rule. However, there are no Exhibits K-4 or K-5 in the application as submitted and the required documentation is not located anywhere else in the application as submitted. The application is conforming to this criterion, subject to the applicant providing documentation of a written commitment to pursue acquiring the primary site if and when the approval is granted and demonstrating that the primary and secondary sites are available for acquisition as required by this Rule. See Criterion (4) Condition 7.
- (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 K.1(g), page 44, the applicant states: “*University City Dialysis will provide service in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply and other relevant health and safety requirements*” See also Section H.2, page 36.
- (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 C.1, pages 14-15, the applicant provides the projected patient origin for UCD based on letters of support signed by patients. The applicant’s assumptions and methodology for its projections are provided on pages 13-15 of the application. The discussion regarding population to be served found in Criterion (3) is incorporated herein by reference.
- (8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
- C- In Section C.4, page 17, the applicant states that 100 percent of the anticipated patient population resides within 30 miles of the proposed facility. Exhibit C-1 contains letters of support signed by potential patients which list the zip code where the patient currently resides.

- (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 L.3(c), page 51, the applicant states: “*University City Dialysis will admit and provide dialysis services to patients who have no other 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.*
- C- In Section C, pages 13-22, the applicant documents the need for the project and demonstrates that it will serve a total of 33 in-center patients on 10 stations at the end of the first operating year, which is 3.3 patients per station per week, or a utilization rate of 82.5 percent. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.
- (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.*
- NA- The applicant is not 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. The applicant is seeking to develop a new 10-station dialysis facility.
- (b) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*
- C- In Section C.1, pages 13-15, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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 I.1, page 39, the applicant states that diagnostic and evaluation services will be referred to Carolinas Medical Center.

(2) *maintenance dialysis;*

-C- In Section I.1, page 39, the applicant states that in-center maintenance dialysis will be provided at UCD.

(3) *accessible self-care training;*

-C- In Section I.1, page 39, the applicant states that self-care training will be provided at UCD.

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

-C- In Section I.1, page 39, the applicant states that an accessible follow-up program for support of patients dialyzing at home is provided by East Charlotte Dialysis. See Exhibit I-1 for a copy of the service agreement between UCD and East Charlotte Dialysis.

(5) *x-ray services;*

-C- In Section I.1, page 39, the applicant states that patients in need of x-ray services will be referred to Carolinas Medical Center.

(6) *laboratory services;*

-C- In Section I.1, page 39, the applicant states that laboratory services will be provided by DaVita Laboratory Services, Inc.

(7) *blood bank services;*

-C- In Section I.1, page 39, the applicant states that patients in need of blood bank services will be referred to Carolinas Medical Center.

(8) *emergency care;*

- C- In Section I.1, page 39, the applicant states that patients in need of emergency care will be referred to Carolinas Medical Center.
- (9) *acute dialysis in an acute care setting;*
- C- In Section I.1, page 39, the applicant states that patients in need of acute dialysis services will be referred to Carolinas Medical Center.
- (10) *vascular surgery for dialysis treatment patients;*
- C- In Section I.1, page 39, the applicant states that patients in need of vascular surgery services will be referred to Carolinas Medical Center.
- (11) *transplantation services;*
- CA- In Section I.1, page 39, the applicant states that patients in need of transplantation services will be referred to Carolinas Medical Center and refers the reader to Exhibit I-2; however, there is no relevant documentation found in Exhibit I-2 or elsewhere in the application. The application is conforming to this criterion, subject to the applicant demonstrating the provision of transplantation services as required by this Rule. See Criterion (4) Condition 5.
- (12) *vocational rehabilitation counseling and services; and*
- C- In Section I.1, page 39, the applicant states that vocational rehabilitation counseling services are provided by the North Carolina Division of Vocational Rehabilitation Services.
- (13) *transportation.*
- C- In Section I.1, page 39, the applicant states that transportation services will be provided by the Mecklenburg County DSS and other providers. Exhibit I-1 contains letters from two additional transportation providers offering services to the patients at UCD.

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 [494].*
- C- In Section H.2, page 36, the applicant states that it will comply with 42 C.F.R. Section 494 (previously 42 CFR Section 405.2100). In Section H.1, page 35, the applicant provides a staffing chart. The discussion regarding proposed staffing found in Criterion (7) is incorporated herein by reference.

- (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 H.4, page 37, the applicant discusses its training at DaVita facilities. See also Exhibit H-4.