

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 8, 2015

Findings Date: June 8, 2015

Project Analyst: Mike McKillip

Team Leader: Lisa Pittman

Project ID #: F-11019-15

Facility: Copperfield Dialysis Center

FID #: 010799

County: Cabarrus

Applicant(s): Total Renal Care of North Carolina, LLC d/b/a Copperfield Dialysis Center

Project: Relocate the facility to a new location and add four stations relocated from North Charlotte Dialysis Center for a total of 31 stations upon completion this project and Project I.D. #F-10109-13, (add 6 stations by relocation from Dialysis Care of Kannapolis in Rowan 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.

CA

Total Renal Care of North Carolina, LLC d/b/a Copperfield Dialysis Center [CDC] proposes to relocate the existing facility and relocate four dialysis stations from North Charlotte Dialysis for a total of 31 certified dialysis stations upon completion of this project and Project I.D. #F-10109-13, relocate 6 dialysis stations from Dialysis Care of Kannapolis to Copperfield Dialysis Center for a total of 27 stations. The applicant proposes to relocate Copperfield Dialysis Center

from its current location at 1030 Vinehaven Drive in Concord to a nearby site “*within walking distance*” on Vinehaven Drive in Concord.

### **Need Determination**

The 2015 State Medical Facilities Plan (2015 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2015 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of eight dialysis stations in Cabarrus County; therefore, based on the county need methodology, the county’s June 30, 2015 station need determination is zero. Also, the applicant is not eligible to apply for additional stations in its existing facility based on the facility need methodology. The applicant does not propose to add new dialysis stations to an existing facility. Therefore, neither of the two need methodologies in the 2015 SMFP are applicable to the review.

### **Policies**

Policy GEN-3 is not applicable to this review since there is no identified need for additional dialysis stations in Cabarrus County based on the county need methodology, nor is there a need for new dialysis stations at Copperfield Dialysis Center based on the facility need methodology.

Policy GEN-4 is applicable to this review. 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 of 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."*

The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section IX.6, page 60, the applicant, states, *"The facility is constructed with energy-efficient glass, mechanically operated patient access doors and energy efficient cooling and heating."* However, the applicant did not include in its certificate of need application a written statement describing the project's plan to assure improved water conservation. Therefore, the application is consistent with Policy GEN-4 subject to Condition #3 in Criterion (4) of these findings.

Policy ESRD-2 is applicable to this review. Policy ESRD-2 of the 2015 SMFP 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:*

- (A) *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*
- (B) *Demonstrate that the proposal shall not result in a surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report."*

The applicant proposes to relocate four existing dialysis stations from Mecklenburg County to Cabarrus County. Therefore, the dialysis station inventory in Mecklenburg County would decrease by four stations and the dialysis station inventory in Cabarrus County would increase by four stations. Mecklenburg and Cabarrus Counties are contiguous to each other.

The applicant proposes to relocate four dialysis stations from North Charlotte Dialysis Center in Mecklenburg County to Copperfield Dialysis Center in Cabarrus County. According to the January 2015 SDR, Table B, there is a surplus of 5 dialysis stations in Mecklenburg County. Therefore, after the proposed relocation of four dialysis stations from North Charlotte Dialysis Center, there will still be a surplus of one dialysis station in Mecklenburg County. According to the January 2015 SDR, Table B, there is a deficit of 8 dialysis stations in Cabarrus County. Therefore, after the proposed relocation of four dialysis stations from North Charlotte Dialysis Center to Copperfield Dialysis Center, there will still be a deficit of four dialysis stations in

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Cabarrus. The applicant adequately demonstrates that the proposal will not result in a deficit in the number of dialysis stations in Mecklenburg County, the county that would be losing stations as a result of the proposed project. Furthermore, the applicant adequately demonstrates that the proposal will not result in a surplus of dialysis stations in Cabarrus County, the county that would gain stations as a result of the proposed project. Therefore, the application is conforming to Policy ESRD-2.

**Conclusion**

In summary, the applicant adequately demonstrates that the application is consistent, as conditioned, with Policies GEN-4 and ESRD-2. 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

The applicant, Copperfield Dialysis Center (CDC) proposes to relocate the existing facility and relocate four dialysis stations from North Charlotte Dialysis for a total of 31 certified dialysis stations upon completion of this project and Project I.D. #F-10109-13, (relocate 6 dialysis stations from Dialysis Care of Kannapolis to Copperfield Dialysis Center). The applicant proposes to relocate Copperfield Dialysis Center from its current location at 1030 Vinehaven Drive in Concord to a nearby site “*within walking distance*” on Vinehaven Drive in Concord. On page 3, the applicant describes the project as follows:

*“The facility is currently certified for twenty-one End Stage Renal Disease dialysis stations. A Certificate of Need for a six-station transfer from Dialysis Care of Kannapolis to the Copperfield Dialysis Center has been approved, and the project is under development. This certificate of need application is for a four-station expansion via transfer of stations from the North Charlotte Dialysis Center located in Mecklenburg County. This will be a transfer of stations across a county line. This project also calls for the relocation of the Copperfield Dialysis Center and the addition of a home training center of excellence which will include home training and support for home hemodialysis and peritoneal dialysis patients. The project will include up-fit of the relocated facility and the purchase of new equipment.”*

**Population to be Served**

In Section III.7, page 23, the applicant provides the projected patient origin for CDC for in-center and home patients for the first two years of operation following completion of the project as follows:

CDC	OPERATING YEAR 1 CY2017		OPERATING YEAR 2 CY2018		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	IN-CENTER	HOME	IN-CENTER	HOME	YEAR 1	YEAR 2
Cabarrus	99	11	104	12	93.3%	93.6%
Rowan	5	0	5	0	4.2%	4.0%
Stanly	3	0	3	0	2.5%	2.4%
Total	107	11	112	12	100%	100%

The applicant adequately identifies the population to be served.

**Analysis of Need**

In Section III.7, pages 23-24, the applicant describes its assumptions and methodology for projecting utilization as follows:

*“Assumptions:*

- *Copperfield Dialysis Center assumes that there is a need for four additional dialysis stations in Cabarrus County according to Table B of the January 2015 SDR which indicates there is an eight-station deficit of stations in Cabarrus County.*
- *Copperfield Dialysis Center proposes [sic] is not eligible to add stations via the Facility Need Methodology since the facility is not at the required 80% utilization [when 6 pending stations are added].*
- *Copperfield Dialysis Center has experienced an in-center patient growth of 4 patients in 2014 for a growth rate of 5.5% [Actual rate is 5.8%].*
- *Cabarrus County has a flat five year average annual change rate.*
- *Total Renal Care of North Carolina assumes that the Copperfield Dialysis Center will continue to grow at a rate of at least 5.5% in operating years one and two.*
- *Copperfield Dialysis Center has a CON for the transfer of six dialysis stations from Dialysis Care of Kannapolis and 20 in-center patients who are currently receiving dialysis at DC of Kannapolis.*
- *It is assumed for the purpose of the chart above that the 20 in-center patients transferring to the Copperfield Dialysis Center will be residents of Cabarrus County. However, no assumption of where these patients live is identified in the calculations below.*

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In Section IV.1, page 27, the applicant identifies its in-center patient population at CDC as of June 30, 2014 as shown in the table below.

<b>Copperfield Dialysis Center</b>	
<b>COUNTY OF RESIDENCE</b>	<b>NUMBER OF IN-CENTER PATIENTS</b>
Cabarrus	66
Rowan	5
Stanley	3
<b>Total</b>	<b>74</b>

*Projected Utilization*

The applicant's methodology is described in the following table.

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	In-Center
CDC begins with the facility census of Cabarrus County in-center residents as of June 30, 2014.	66 patients
The census of Cabarrus County patients is increased by 2.75% for six months to December 31, 2014.	$66 \times 1.0275 = 67.815$
The census of Cabarrus County patients is increased by 5.5% for one year to December 31, 2015.	$67.815 \times 1.055 = 71.544825$
The census of Cabarrus County patients is increased by 5.5% for one year to December 31, 2016, which is the projected completion date for the project.	$71.544825 \times 1.055 = 75.47979037$
The census of Cabarrus County patients is again increased by 5.5% for one year to December 31, 2017.	$75.47979037 \times 1.055 = 79.63117884$
CDC adds 8 patients residing in Rowan and Stanly counties and 20 patients transferring from Dialysis Center of Kannapolis (Project I.D. # F-10109-13) to project the total ending census for Operating Year 1.	$79 + 8 + 20 = 107$
The census of Cabarrus County patients is again increased by 5.5% for one year to December 31, 2018.	$79.63117884 \times 1.055 = 84.01089367$
CDC adds 8 patients residing in Rowan and Stanly counties and 20 patients transferring from Dialysis Center of Kannapolis (Project I.D. # F-10109-13) to project the total ending census for Operating Year 2.	$84 + 8 + 20 = 112$

CDC currently operates 21 certified stations, and proposes to have a total of 31 certified dialysis stations upon completion of this project, which includes the transfer of four stations from North Charlotte Dialysis Center, and Project I.D. #F-10109-13, to relocate 6 dialysis stations from Dialysis Care of Kannapolis to Copperfield Dialysis Center ( $21 + 6 + 4 = 31$ ). As shown in the table above, the applicant projects to serve 107 in-center patients or 3.4 patients per station ( $107/31 = 3.4$ ) by the end of Operating Year 1, and 112 in-center patients or 3.6 patients per station ( $112/31 = 3.6$ ) by the end of Operating Year 2 for the proposed 31-station facility. 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). The following table shows the historical utilization of CDC.

**Copperfield Dialysis Center**

<b>SDR Table A Inventory Dates</b>	<b>Certified Stations</b>	<b>In-Center Patients</b>	<b>Percent Change (Semiannual)</b>
December 31, 2012	21	63	---
June 30, 2013	21	68	7.9%
December 31, 2013	21	69	1.5%
June 30, 2014	21	74	7.2%

Source: SDRs for July 2013-January 2015, Table A.

The July 2014 and the January 2015 SDR indicate that CDC operated at a utilization rate of 82 percent and 88 percent, respectively. In this application, the applicant assumes a projected annual rate of growth of 5.5 percent for the Cabarrus County in-center patient census at CDC, which is supported by the historical rates of growth in utilization at CDC in recent years (CY2013-CY2014), as shown in the table above. Projected utilization is based on reasonable and supported assumptions regarding continued growth.

In addition to in-center patients, CDC projects to serve 11 home dialysis patients in Operating Year 1, and 12 home dialysis patients in Operating Year 2. On page 25, the applicant states

*“Copperfield Dialysis Center will build a home training center of excellence at the relocated facility. It is reasonable to assume that the home-trained patients living in Cabarrus County and receiving home training services at Dialysis Care of Kannapolis will transfer their care to Copperfield Dialysis Center. As of December 31, 2014, there were 21 home-trained patients living in Cabarrus County receiving training and follow-up at the Dialysis Care of Kannapolis facility. It is reasonable to assume that at least 10 of the home-trained patients living in Cabarrus County will transfer their care to the Copperfield Dialysis Center home training program. Total Renal Care of North Carolina finds that it is reasonable to assume that Copperfield Dialysis Center will experience a growth of one home-trained patient in each of the first two operating years with 11 home-trained patients at the end of operating year one and 12 home-trained patients at the end of operating year two.”*

Projected utilization of CDC’s home dialysis program is based on reasonable and supported assumptions.

**Access**

In Section VI.1(a), page 33, the applicant states that CDC makes dialysis services available to all residents of the service area without restrictions or qualifications, including low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons. The applicant projects 82% of its in-center patients will be covered by Medicare or Medicaid. 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 four additional stations at CDC, 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

CDC proposes to relocate the existing facility and relocate four dialysis stations from North Charlotte Dialysis for a total of 31 certified dialysis stations upon completion of this project and Project I.D. #F-10109-13, relocate 6 dialysis stations from Dialysis Care of Kannapolis to Copperfield Dialysis Center. The applicant proposes to relocate Copperfield Dialysis Center from its current location at 1030 Vinehaven Drive in Concord to a nearby site, also on Vinehaven Drive in Concord. In Section III.3, page 21, the applicant states:

*“This certificate of need application involves the transfer of four dialysis stations from North Charlotte Dialysis in Mecklenburg County. North Charlotte Dialysis has 35 certified stations and an approved Certificate of Need for an additional six dialysis stations. Therefore, the facility will have a capacity of 41 in-center stations when the stations under development are certified. This CON application does not involve the transfer of any patients from North Charlotte Dialysis.*

*The Copperfield Dialysis Center has 21 certified dialysis stations and a Certificate of Need to add 6 additional stations, which will give the facility 27 stations. There is no room in the current facility for additional stations. The facility is land-locked, meaning there is no room for a building expansion. This project seeks to relocate the facility within walking distance from the current location.*

*The stations being relocated from North Charlotte Dialysis are needed in the adjoining county. The effect of the transfer of four stations will also decrease the surplus of stations in Mecklenburg County and decrease the station deficit in Cabarrus County.”*

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In Section III.3(c), page 21, the applicant describes the impact of the proposed transfer of stations from North Charlotte Dialysis Center as follows:

*“North Charlotte Dialysis has 35 certified stations and an approved Certificate of Need for 6 additional stations that are under development and should be certified by May 1, 2015. North Charlotte Dialysis had 124 in-center patients as of June 30, 2014 as indicated in the January 2015 Semiannual Dialysis Report for a utilization rate of 88.57% based on 35 certified dialysis stations. Taking into consideration that an additional six dialysis stations are projected to be certified on May 1, 2015, the facility utilization rate based on 41 dialysis stations is 75.6%.*

*Relocating 4 dialysis stations from North Charlotte Dialysis to the Copperfield Dialysis Center will result in a reduction from 41 to 37 dialysis stations. Based on 37 dialysis stations, North Charlotte Dialysis will have a utilization rate of 83%. If North Charlotte Dialysis has a substantial increase in patient population, the facility will apply for additional stations when indicated.”*

The applicant proposes to relocate four existing dialysis stations from North Charlotte Dialysis Center, but no existing patients are projected to transfer. According to the January 2015 SDR, North Charlotte Dialysis Center had 124 in-center patients dialyzing on 35 stations as of June 30, 2014, for a utilization rate of 89%. After the certification of six additional stations (Project I.D. # F-10268-14), and the proposed relocation of four stations in this application, North Charlotte Dialysis Center would operate 37 stations ( $35 + 6 - 4 = 37$ ). On April 29, 2014, North Charlotte Dialysis Center was approved to relocate 10 stations to Huntersville (Project I.D. F-10219-13). Therefore, upon completion of this project, Project I.D. #F-10268-14, and Project I.D. #F-10219-13, North Charlotte Dialysis Center would operate 27 dialysis stations ( $35 + 6 - 10 - 4 = 27$ ). Also, the applicant projected that 16 existing North Charlotte Dialysis patients would transfer to the new Huntersville Dialysis Center. Therefore, assuming 16 patients transferred with the 10 stations to be relocated to Huntersville, the projected utilization of North Charlotte Dialysis Center would be 4 patients per station, or 100 percent of capacity [ $124 - 16 = 108$  in-center patients;  $108 / 27$  stations = 4 patients/station]. The applicant demonstrates that the needs of the population presently served at the North Charlotte Dialysis Center facility will continue to be adequately met.

The applicant adequately demonstrates that the facility from which dialysis stations would be transferred would have sufficient capacity following the transfer of stations to the proposed Copperfield Dialysis Center facility. Thus, the applicant adequately demonstrates that the needs of the population presently served will be met adequately by the proposed relocation of dialysis stations. Therefore, the application is conforming to this criterion.

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

C

In Section III.9, pages 25-26, the applicant discusses the alternatives considered prior to the submission of this application. The applicant states the only alternative it considered was to maintain the status quo, but rejected this alternative because it would not address need for the growing demand for dialysis services at CDC.

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 need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1. Total Renal Care of North Carolina, LLC d/b/a Copperfield Dialysis Center shall materially comply with all representations made in the certificate of need application.**
- 2. Total Renal Care of North Carolina, LLC d/b/a Copperfield Dialysis Center shall develop and operate no more than four additional dialysis stations for a total of no more than 31 certified stations upon completion of this project and Project I.D. # F-10109-13, which shall include any isolation or home hemodialysis stations.**
- 3. Total Renal Care of North Carolina, LLC d/b/a Copperfield Dialysis Center shall provide a written statement describing the project's plan to assure improved water conservation.**
- 4. Total Renal Care of North Carolina, LLC d/b/a Copperfield Dialysis Center shall install plumbing and electrical wiring through the walls for no more than four additional dialysis stations for a total of no more than 31 dialysis stations, which shall include any isolation or home hemodialysis stations.**
- 5. Total Renal Care of North Carolina, LLC shall take the necessary steps to decertify four stations at North Charlotte Dialysis Center for a total of no more than 27 stations upon completion of this project, Project I.D. #F-10219-13 and Project I.D. # F-10268-14.**
- 6. Total Renal Care of North Carolina, LLC d/b/a Copperfield Dialysis Center 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

In Section VIII.1, page 43, the applicant projects \$3,718,878 in capital costs will be incurred for the proposed project. In Section VIII.2, the applicant states the capital costs will be financed with the cash reserves of the parent company, DaVita Healthcare Partners, Inc. In Section IX, page 47, the applicant states there will be no start-up or initial operating expenses associated with the proposed project. In Section VIII.5, page 45, the applicant states

*“Jay Leibowitz, Tax Vice President of DaVita HealthCare Partners Inc. and Total Renal Care of North Carolina, LLC has submitted a letter stating that the funds are available (See Exhibit 18 of the application).”*

However, Application Exhibit 18 does not contain the letter referred to by the applicant. In Exhibit 19, the applicant provides the audited financial statements (Form 10-K) for DaVita Healthcare Partners, Inc. for the years ended December 31, 2013 and 2014. As of December 31, 2014, DaVita Healthcare Partners, Inc. had cash and cash equivalents totaling \$965 million with \$17.9 billion in total assets and \$6.2 billion in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital needs of the proposed project.

In Section X.1, page 49, the applicant projects the following charge per treatment for each payment source:

<b>Payer</b>	<b>In-Center Charge</b>
Commercial	\$1,275.00
Medicare	\$239.43
Medicaid	\$143.00
VA	\$193.00
Medicare/Medicaid	\$239.43
Medicare/Commercial	\$239.43

In Section X.4, page 54, the applicant reported projected revenues and expenses as follows:

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<b>Copperfield Dialysis Center</b>		
	<b>Operating Year 1 CY2017</b>	<b>Operating Year 2 CY2018</b>
Total Net Revenue	\$6,057,042	\$6,351,348
Total Operating Costs	\$4,682,989	\$4,879,856
Net Profit	\$1,374,052	\$1,471,492

The applicant projects that revenue will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro forma financial statements, including the number of projected treatments, are reasonable. See Section X of the application for the applicant’s assumptions.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and operating expenses of this project. The applicant also adequately demonstrates that the financial feasibility of the proposal is based on reasonable projections of revenues (charges) and operating costs. 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

CDC proposes to relocate the existing facility and relocate four dialysis stations from North Charlotte Dialysis for a total of 31 certified dialysis stations upon completion of this project and Project I.D. #F-10109-13, relocate 6 dialysis stations from Dialysis Care of Kannapolis to Copperfield Dialysis Center. The applicant proposes to relocate Copperfield Dialysis Center from its current location at 1030 Vinehaven Drive in Concord to a nearby site “*within walking distance*” on Vinehaven Drive in Concord. CDC was serving 74 in-center patients weekly on 21 stations, which is 3.5 patients per station or 88% of capacity, as of June 30, 2014. Dialysis facilities that operate four shifts per week (2 per day on alternate days) have a capacity of four patients per station. The applicant does not propose to establish a new facility. The applicant provides reasonable projections for the in-center patient population it proposes to serve on pages 23-25 of the application. The growth projections are based on a projected 5.5% average annual growth rate in the number of Cabarrus County dialysis patients at the CDC facility. At the end of Operating Year Two, CDC projects the utilization will be 3.6 in-center patients per station (112 patients / 31 dialysis stations = 3.6), which is 90% of capacity.

The applicant operates two dialysis centers in Cabarrus County. There are no other providers of dialysis services in Cabarrus County.

**Cabarrus County Dialysis Facilities**

<b>Dialysis Facility</b>	<b>Certified Stations 12/31/13</b>	<b>% Utilization</b>	<b>Patients Per Station</b>
Copperfield Dialysis Center	21	88.10%	3.52
Harrisburg Dialysis Center	19	75.00%	3.00

Source: January 2015 SDR, Table A.

As shown in the table above, one of the two Cabarrus County dialysis facilities is operating above 80% utilization (3.2 patients per station), and both of the Cabarrus County facilities are operating at or above 75% utilization (3.0 patients per station).

The applicant adequately demonstrates the need to relocate four additional dialysis stations to the existing facility, and to relocate the existing facility, based on the number of in-center patients it proposes to serve. 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

The following table shows current and projected staffing for CDC, as provided by the applicant in Section VII.1, page 38:

<b>Copperfield Dialysis Center</b>			
<b>Position</b>	<b>Current FTEs</b>	<b># of FTE Positions to be Added</b>	<b>Total FTE Positions</b>
RN	3.00	3.00	6.00
HTRN	0.00	1.00	1.00
PCT	8.00	5.00	13.00
Bio-Med Technician	1.00	0.00	1.00
Medical Director	Contracted Position		
Admin.	1.00	0.00	1.00
Dietician	0.50	0.50	1.00
Social Worker	0.50	0.50	1.00
Unit Secretary	1.00	0.00	1.00
Reuse	1.00	0.00	1.00
<b>Total</b>	<b>16.00</b>	<b>10.00</b>	<b>26.00</b>

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As shown in the above table, the applicant proposes to employ a total of 26 full-time equivalent (FTE) positions to staff CDC upon completion of the proposed project. In Section V.2, page 39, the applicant states that John Gerig, M.D., a nephrologist, will serve as medical director of the facility. Exhibit 13 contains a letter from Dr. Gerig stating his intention to continue as the medical director for CDC.

In Section VII.10, page 40, the applicant provides the following table showing the projected number of direct care staff for each shift offered at CDC after the addition of the four dialysis stations.

	<b>Shift Times</b>	<b>Monday</b>	<b>Tuesday</b>	<b>Wednesday</b>	<b>Thursday</b>	<b>Friday</b>	<b>Saturday</b>
Morning	7:00 am to 12:00 pm	8	8	8	8	8	8
Afternoon	12:00 pm to 5:00 pm	8	8	8	8	8	8
Evening	N/A						

The applicant has documented the availability of adequate health manpower and management personnel, including the medical director, for the provision of 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 Section V.1, page 29, the applicant includes a list of providers of the necessary ancillary and support services. Exhibit 13 contains a letter from the medical director of the facility expressing his support for the proposed project. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health system. Therefore, the application is conforming to this criterion.

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

NA

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

NA

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

NA

The applicant proposes to develop the project in 18,914 square feet of leased space in a building to be developed on Vinehaven Drive in Concord. In Section XI.1, page 56, the applicant states, *“The landlord will be determined after the Certificate of Need is issued.”*

- (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



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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(b), page 33, the applicant reports that 82.4% of the in-center patients who received treatments at CDC had some or all of their services paid for by Medicare or Medicaid in the past year. The table below shows the historical payment source of the facility:

Payment Source	In-Center
Medicare	14.86%
Medicaid	9.46%
Medicare/Medicaid	25.68%
Commercial Insurance	12.16%
VA	5.41%
Medicare/Commercial Insurance	32.43%
<b>Total</b>	<b>100.00%</b>

The Division of Medical Assistance (DMA) maintains a website which provides the number of persons eligible for Medicaid in North Carolina, and estimates the percentage of uninsured people for each county. The following table illustrates those percentages for Cabarrus 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) *
Cabarrus County	14%	4.9%	18.5%
Statewide	17%	6.7%	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 services offered by dialysis facilities. In fact, in 2013 only 6.6% of all newly-diagnosed ESRD patients in North Carolina were under the age of 35, according to the ESRD Network 6 2013 Annual Report.

*(ESRD Network 6 2013 Annual Report/Data Table 1: ESRD Incidence – One Year Statistics as of 1/1/2013 – 12/31/2013, page 99).*<sup>1</sup>

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina, as well as data sorted by age, race or gender. However, a direct comparison to the applicant's current payer mix would be of little value. The population data by age, race or gender do not include information on the number of elderly, handicapped, minorities or women utilizing health services.

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

*“The December 31, 2011 prevalent population included 430,273 patients on dialysis ....”*<sup>2</sup> (p. 216)

The report also provides the incidence of dialysis patients in 2011, adjusted by age, gender and race, which show 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. 223). 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).

The *2013 USRDS Annual Data Report* provides 2011 ESRD spending by payor, as follows:

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<sup>1</sup><http://www.esrdnetwork6.org/utills/pdf/annualreport/2013%20Network%206%20Annual%20Report.pdf>

<sup>2</sup>[www.usrds.org/adr.aspx](http://www.usrds.org/adr.aspx)

<b>ESRD Spending by Payor</b>		
<b>Payor</b>	<b>Spending in Billions</b>	<b>% of Total Spending</b>
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%
<b>Total</b>	<b>\$49.2</b>	<b>100.0%</b>

The Southeastern Kidney Council (SKC) Network 6 2013 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender on page 101, summarized as follows:

<b>Number and Percent of Dialysis Patients by Age, Race, and Gender 2013</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Age</b>		
0-19	65	0.4%
20-34	766	5.0%
35-44	1,498	9.7%
45-54	2,746	17.8%
55-64	4,039	26.2%
65+	6,275	40.8%
<b>Gender</b>		
Female	6,845	44.5%
Male	8,544	55.5%
<b>Race</b>		
African-American	9,559	62.1%
White/Caucasian	5,447	35.4%
Other	383	2.5%

Source: SKC Network 6. Table includes North Carolina statistics only.<sup>3</sup>

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

<sup>3</sup><http://www.esrdnetwork6.org/utills/pdf/annual-report/2013%20Network%206%20Annual%20Report.pdf>

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

C

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. On page 35, the applicant states:

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

In Section VI.6 (a), page 37, the applicant states there have been no civil rights access complaints filed within the last five years. Therefore, the application is conforming to this criterion.

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

C

In Section VI.1(c), page 34, the applicant provides the projected payment source for the proposed services at CDC, which is shown below:

<b>Payment Source</b>	<b>In-Center</b>
Medicare	14.86%
Medicaid	9.46%
Medicare/Medicaid	25.68%
Commercial Insurance	12.16%
VA	5.41%
Medicare/Commercial Insurance	32.43%
<b>Total</b>	<b>100.00%</b>

The applicant projects no change from the current payment source for in-center dialysis services, which is 82.4% Medicare and Medicaid. The applicant

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

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

C

In Section VI.5, page 36, the applicant states,

*“Patients with End Stage Renal Disease have access to dialysis services upon referral by a Nephrologist with privileges at the Copperfield Dialysis Center. These referrals most commonly come from primary care physicians or specialty physicians in Cabarrus County and surrounding counties or transfer referrals from other Nephrologists outside the immediate area.”*

The applicant adequately demonstrates that CDC will provide a range of means by which a person can access the 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 V.3, page 31 the applicant states, *“The Copperfield Dialysis Center has agreements with Kings College in Charlotte and Winthrop University in Rock Hill, South Carolina.”* Exhibit 12 contains copies of a *“Student Training Agreement”* between the applicant and area health professional training programs. The information provided in Section V.3 is reasonable and credible and supports a finding of conformity 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

CDC proposes to relocate the existing facility and relocate four dialysis stations from North Charlotte Dialysis for a total of 31 certified dialysis stations upon completion of this project and Project I.D. #F-10109-13, relocate 6 dialysis stations from Dialysis Care of Kannapolis to Copperfield Dialysis Center. The applicant proposes to relocate Copperfield Dialysis Center from its current location at 1030 Vinehaven Drive in Concord to a nearby site “*within walking distance*” on Vinehaven Drive in Concord. The applicant operates two dialysis centers in Cabarrus County. There are no other providers of dialysis services in Cabarrus County.

**Cabarrus County Dialysis Facilities**

<b>Dialysis Facility</b>	<b>Certified Stations 12/31/13</b>	<b>% Utilization</b>	<b>Patients Per Station</b>
Copperfield Dialysis Center	21	88.10%	3.52
Harrisburg Dialysis Center	19	75.00%	3.00

Source: January 2015 SDR, Table A.

As shown in the table above, one of the two Cabarrus County dialysis facilities is operating above 80% utilization (3.2 patients per station), and both of the Cabarrus County facilities are operating at or above 75% utilization (3.0 patients per station).

In Section V.7, page 32, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The applicant states,

*“The proposed expansion of the facility is an effort to provide dialysis services to Cabarrus and surrounding communities and is not intended to be a competitive venture. The effect on the other facilities in surrounding counties would be difficult to determine since most patients from Cabarrus County already receive treatment at facilities operated by TRC. They are the Harrisburg Dialysis Center and Copperfield Dialysis, both located in Cabarrus County and Dialysis Care of Kannapolis, located in Rowan County, but just two miles from the Cabarrus County line.*

*The effect upon competition is unknown. However, 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 Copperfield Dialysis Center provides access to all qualified Nephrologists to admit his or her patients.”*

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information 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 dialysis services. This determination is based on the information in the application and the following analysis:

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

The application is conforming to this criterion.

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

C

In Section I.13 and referenced Exhibits, the applicant identifies the kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the

Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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

**10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT**

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

*.2202(a)(1) Utilization rates;*

-C- See Section IV.1, page 27, which indicates the facility had 74 in-center patients and a 88% utilization rate as of June 30, 2014.

*.2202(a)(2) Mortality rates;*

-C- In Section IV.2, page 27, the applicant reports 2012, 2013 and 2014 facility mortality rates of 21.3%, 25.7% and 19.7%, respectively.

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

-NA- In Section IV.3, page 27, the applicant states that CDC does not currently operate a home dialysis program.

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

-C- In Section IV.4, page 27 the applicant states CDC referred 11 patients for transplant evaluation in 2014, and had one patient receive a transplant in 2014.

*.2202(a)(5) The number of patients currently on the transplant waiting list;*

-C- In Section IV.5, page 28, the applicant states that CDC has four patients on the transplant waiting list.



.2202(a)(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus Non-dialysis related;*

-C- See Section IV.6, page 28, the applicant reports a total of 170 hospital admissions in 2014; 136 were non-dialysis related and 34 were dialysis-related.

.2202(a)(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.*

-C- In Section IV.7, page 28, the applicant reports that in 2014 there was one patient with an infectious disease, and no patients converted to infectious status in 2014.

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

.2202(b)(1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100*

-NA- CDC is an existing facility.

.2202(b)(2) *For new facilities, a letter of intent to sign a written agreement or a written agreement with a transplantation center describing the relationship with the dialysis facility and the specific services that the transplantation center will provide to patients of the dialysis facility. The agreements must include the following:*

- (A) *timeframe for initial assessment and evaluation of patients for transplantation,*
- (B) *composition of the assessment/evaluation team at the transplant center,*
- (C) *method for periodic re-evaluation,*
- (D) *criteria by which a patient will be evaluated and periodically Re-evaluated for transplantation, and,*
- (E) *Signatures of the duly authorized persons representing the facilities and the agency providing the services.*

-NA- CDC is an existing facility.

- .2202(b)(3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- C- In Exhibit 21, the applicant provides documentation that power and water are available to the proposed site.
- .2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C- Exhibit 8 contains a copy of written policies and procedures for back up for electrical service in the event of a power outage.
- .2202(b)(5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*
- NA- CDC is an existing facility. In Exhibit 21, the applicant identifies the site as Lot 7B of the Sycamore Ridge Development on Vinehaven Drive in Concord.
- .2202(b)(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*
- C- See Section XI.6(g), pages 60-61.
- .2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C- In Section III.7, page 23, CDC provides projected patient origin based on historical experience for the first two years of operation following completion of the project.
- .2202(b)(8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
- NA- CDC is an existing facility.
- .2202(b)(9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom*

*payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement for such services.*

- C- In Section II.1, page 12, the applicant states, “*Total Renal Care of North Carolina d/b/a Copperfield Dialysis Center will admit and provide dialysis services to patients who have no insurance or other source of payment, if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*”

#### **10 NCAC 14C .2203 PERFORMANCE STANDARDS**

- .2203(a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*

- NA- CDC is an existing facility.

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

- C- In Section II.1, page 13, the applicant projects to serve 107 in-center patients by the end of Operating Year 1, which is 3.4 patients per station ( $107 / 31 = 3.4$ ). The discussion regarding utilization assumptions found in Criterion (3) is incorporated herein by reference.

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

- C- In Section II.1, pages 12-13 and Section III.7, pages 23-25, the applicant provides the assumptions and methodology used to project utilization of the proposed facility. The discussion regarding utilization assumptions found in Criterion (3) is incorporated herein by reference.

#### **10 NCAC 14C .2204 SCOPE OF SERVICES**

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

.2204(1) *Diagnostic and evaluation services;*

-C- These services are provided by Northeast Medical Center. See Section V.1, page 29.

.2204(2) *Maintenance dialysis;*

-C- Provided at CDC. See Section V.1, page 29.

.2204(3) *Accessible self-care training;*

-C- Provided by referral to Dialysis Care of Kannapolis currently, and will be provided at CDC upon completion of the proposed project. See Section V.2(d), pages 30-31.

.2204(4) *Accessible follow-up program for support of patients dialyzing at home;*

-C- Provided by referral to Dialysis Care of Kannapolis currently, and will be provided at CDC upon completion of the proposed project. See Section V.2(d), pages 30-31.

.2204(5) *X-ray services;*

-C- These services are provided by Northeast Medical Center. See Section V.1, page 29.

.2204(6) *Laboratory services;*

-C- Provided by Dialysis Laboratories, Inc. See Section V.1, page 29.

.2204(7) *Blood bank services;*

-C- Provided by Northeast Medical Center. See Section V.1, page 29.

.2204(8) *Emergency care;*

-C- Provided by Northeast Medical Center. See Section V.1, page 29.

.2204(9) *Acute dialysis in an acute care setting;*

-C- Provided by Northeast Medical Center. See Section V.1, page 29.

.2204(10) *Vascular surgery for dialysis treatment patients*

-C- Provided by Northeast Medical Center. See Section V.1, page 29.

.2204(11) *Transplantation services;*

-C- Provided by Carolinas Medical Center. See Section V.1, page 29.

.2204(12) *Vocational rehabilitation counseling and services; and,*

-C- Provided by referral to Division of Vocational Rehabilitation. See Section V.1, page 29.

.2204(13) *Transportation*

-C- Provided by Cabarrus County Transportation Services. See Section V.1, page 29.

#### **10 NCAC 14C .2205 STAFFING AND STAFF TRAINING**

.2205(a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R. Section 405.2100.*

-C- In Section VII.1, page 38, the applicant provides the proposed staffing. In Section VII.2, pages 38-39, the applicant states the proposed facility will comply with all staffing requirements set forth in 42 C.F.R. Section 405.2100. The applicant adequately demonstrates that sufficient staff is proposed for the level of dialysis services to be provided. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

.2205(b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*

-C- See Section VII.5, page 39, and Exhibits 17 and 24.