

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: May 6, 2013

PROJECT ANALYST: Gloria C. Hale

TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: F-10109-13/ Total Renal Care of North Carolina, LLC d/b/a Copperfield Dialysis Center/ Relocate 6 dialysis stations from Dialysis Care of Kannapolis to Copperfield Dialysis Center for a total of 27 dialysis stations upon project completion / Cabarrus County

### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

Total Renal Care of North Carolina, LLC d/b/a Copperfield Dialysis Center, whose parent company is DaVita Healthcare Partners, Inc. (DaVita), proposes to relocate six in-center dialysis stations from Dialysis Care of Kannapolis to Copperfield Dialysis Center for a facility total of 27 in-center dialysis stations upon completion of this project. The applicant does not propose to add new dialysis stations to an existing facility or to establish new dialysis stations. Therefore, neither of the two need methodologies in the 2013 State Medical Facilities Plan (SMFP) is applicable to this review. Additionally, Policy GEN-3 is not applicable because the applicant is not proposing to develop a new institutional health service for which there is a need determination in the 2013 SMFP. However, Policy ESRD-2 is applicable to this review.

Policy ESRD-2: RELOCATION OF DIALYSIS STATIONS, on page 36 of the 2013 SMFP is applicable to this review. The policy states:

*“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties currently served by the facility. Certificate of need applicants proposing to relocate dialysis stations to contiguous counties shall:*

- 1. Demonstrate that the proposal shall not result in a deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report, and*
- 2. Demonstrate that the proposal shall not result in a surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

The applicant proposes to relocate six dialysis stations from DC of Kannapolis in Rowan County to CDC in Cabarrus County. The two counties are contiguous. According to the January 2013 SDR, Rowan County has a surplus of 19 dialysis stations and Cabarrus County has a deficit of 13 dialysis stations. Relocating six stations from Rowan County to Cabarrus County will reduce Rowan County’s surplus of dialysis stations and reduce the deficit of dialysis stations in Cabarrus County. Therefore, the application is consistent with Policy ESRD-2 and 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

Total Renal Care of North Carolina, LLC d/b/a Copperfield Dialysis Center proposes to add six in-center dialysis stations to the existing facility by relocating them from Dialysis Care of Kannapolis (DC of Kannapolis), located in Rowan County, a contiguous county to Cabarrus County. This will result in a facility total of 27 stations upon completion of this project.

Population to be Served

In Section III.7, page 22, the applicant provides CDC's projected patient origin during the first two operating years as illustrated below:

COUNTY	OPERATING YEAR 1 CY 2014	OPERATING YEAR 2 CY 2015	COUNTY PATIENTS AS PERCENT OF TOTAL	
	IN-CENTER PATIENTS	IN-CENTER PATIENTS	YEAR 1	YEAR 2
Cabarrus	85	89	96.6%	96.7%
Rowan	2	2	2.3%	2.2%
Stanly	1	1	1.1%	1.1%
<b>Total</b>	<b>88</b>	<b>92</b>	<b>100.0%</b>	<b>100.0%</b>

The applicant adequately identifies the population it proposes to serve.

Demonstration of Need

According to the January 2013 SDR, Cabarrus County has a deficit of 13 dialysis stations and Rowan County has a surplus of 19 dialysis stations. The applicant proposes to relocate six dialysis stations from DC of Kannapolis, located in Rowan County, to CDC in Cabarrus County. This relocation would not only reduce the surplus of stations in Rowan County and reduce the deficit in Cabarrus County, it would address the applicant's need to create more space in DC of Kannapolis to address its growing need for home dialysis training as stated in Section III.3(a), page 20.

In Section II, pages 12-15, the applicant provides the assumptions and methodology used to project patient utilization and the need for six additional dialysis stations at CDC, summarized as follows:

- Based on the data reported in Table A, page 1 of the January 2013 SDR, CDC had 62 in-center patients as of June 30, 2012. There are 21 certified dialysis stations at the facility and a utilization rate of 74%.
- The applicant used a 4.1% Five-Year Average Annual Change Rate for Cabarrus County, as indicated on page 1 of Table B of the January 2013 SDR.
- As of June 30, 2012, CDC had an in-center patient census of 62 patients, 60 of whom were from Cabarrus County. The applicant applied the 4.1% Five-Year Average Annual Change Rate only to the 60 patients from Cabarrus County.

- The applicant expects an additional 20 patients to transfer to CDC from DC of Kannapolis. CDC projects having 88 in-center patients by the end of Operating Year One (January 1, 2014 - December 31, 2014) and 92 in-center patients by the end of Operating Year Two (January 1, 2015 – December 31, 2015).

The applicant illustrates this methodology as follows:

*“January 1, 2013 – December 31, 2013 – 60 patients X 1.041 = 62.46*

*January 1, 2014 – December 31, 2014 – 62.46 Copperfield patients + 20 DC Kannapolis transferring to Copperfield = 82.46 X 1.041 = 85.84056*

*January 1, 2015 – December 31, 2015 – 85.84056 patients X 1.041 = 89.36002296*

*...*

*The number of patients stated in the chart above was rounded down to the nearest whole number.*

*We did not provide a growth rate for the two patients living in Rowan County and the one patient living in Stanley [sic] County. Therefore, the Copperfield Dialysis Center is projected to have 88 in-center patients at the end of operating year one (85 Cabarrus County patients, 2 Rowan County patients and one Stanley [sic] County patient = 88 patients). The facility is projected to have 92 in-center patients at the end of operating year two (89 Cabarrus County patients, 2 Rowan County patients and one Stanley [sic] County patient = 92 patients).”*

Projected utilization at the end of Year One is 3.26 patients per station per week which exceeds the minimum of 3.2 patients per station per week as required by 10A NCAC 14C .2203(b).

In summary, the applicant adequately identified the population to be served and adequately demonstrated the need for six additional dialysis stations at the CDC facility. Consequently, the application is conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

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

CA

The applicant proposes to add six in-center dialysis stations to its existing facility, through relocation of stations from DC of Kannapolis, for a facility total of 27 in-center dialysis stations following project completion. In Section III.9, page 23, the applicant states that it considered the alternative of not applying for six additional stations at the facility before proposing this project, however this alternative would not provide an opportunity for patients dialyzing at DC of Kannapolis to receive services closer to home and in their home county. In Section III.9, page 24, the applicant states that it also considered the alternative of complete renovation of DC of Kannapolis to expand the growing home training department. The proposed project allows for existing patients at DC of Kannapolis who live closer to CDC to transfer to CDC, and also provides an opportunity for DC of Kannapolis to utilize vacated space to expand its home training program. The applicant adequately explains why it chose the selected alternative over the status quo. Furthermore, the application is conforming to all other applicable statutory review criteria. See Criteria (1), (3), (5), (6), (7), (8), (13), (14), (18a) and (20) for additional discussion. Therefore, the applicant adequately demonstrates that the selected proposal is its least costly or most effective alternative to meet the identified facility need for six additional dialysis stations at CDC. Consequently, the application is conforming to this criterion and is 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 its 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 six additional dialysis stations for a total of 27 certified stations which shall include any home hemodialysis training or isolation stations.**
3. **Total Renal Care of North Carolina, LLC d/b/a Copperfield Dialysis Center shall install plumbing and electrical wiring through the walls for six additional dialysis stations for a total of 27 dialysis stations which shall include any isolation stations.**
4. **Total Renal Care of North Carolina, LLC d/b/a Copperfield Dialysis Center shall not offer or develop home hemodialysis or peritoneal dialysis training services as part of this project.**

**5. 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 Certificate of Need Section in writing prior to issuance of the certificate of need.**

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Sections VIII.1(b), page 40, the applicant indicates that the capital cost is projected to be \$46,870. In Sections IX.1 and IX.2, page 44, the applicant states that there are no start-up or initial operating expenses since the facility is already in operation.

In Section VIII.2, page 41, the applicant indicates that this project will be funded from cash reserves. Exhibit 19 includes a letter dated March 15, 2013 from the Interim Chief Financial Officer and Chief Accounting Officer of DaVita Healthcare Partners, Inc. and Total Renal Care, Inc., which states in part:

*“This letter will confirm that DaVita Healthcare Partners, Inc. has committed cash reserves in the total sum of \$46,870 for the project capital expenditure. DaVita Healthcare Partners Inc. will make these funds, along with any other funds that are necessary for the development of the project, available to Total Renal Care of North Carolina, LLC.”*

In Exhibit 20, the applicant provides United States Securities and Exchange Commission Form 10-K for DaVita Healthcare Partners, Inc. for the year ended December 31, 2012. As of December 31, 2012, DaVita Healthcare Partners, Inc. had cash and cash equivalents totaling \$533,748,000 with \$16,018,596,000 in total assets and \$3,928,048,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the capital needs of the proposed project.

Based on information provided by the applicant in Section X.1, page 46, the applicant lists the following charges per treatment for each payment source:

**Applicant Projected Allowable  
 In-Center Charges**

<b>SOURCE OF PAYMENT</b>	<b>CHARGE PER TREATMENT</b>
Medicare	240.00
Medicaid	143.00
Medicare/Medicaid	240.00
Commercial Insurance	1,442.00
VA	193.00
Medicare/Commercial	240.00

The rates shown above are consistent with the standard Medicare/Medicaid rates established by the Centers for Medicare and Medicaid Services. In Sections X.2-X4, pages 46-49, the applicant reported projected revenues and expenses as follows:

	<b>OPERATING YEAR 1</b>	<b>OPERATING YEAR 2</b>
Total Net Revenue	\$3,669,137	\$3,817,835
Total Operating Costs	\$3,167,950	\$3,282,190
Net Profit	\$501,187	\$535,645

The applicant projects that revenues will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro formas, including the number of projected treatments, are reasonable, credible and supported. See Section X, pages 47-48 of the application, for the applicant’s assumptions.

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

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Total Renal Care of North Carolina, LLC d/b/a Copperfield Dialysis Center (CDC) proposes to add six in-center dialysis stations to the existing facility in Concord, Cabarrus County. The six additional stations will be relocated from DC of Kannapolis which is located in Rowan County, just over the Cabarrus County line to the north. Twenty patients currently receiving services at DC of Kannapolis are considering transferring to CDC since it is closer to their homes. According to the January 2013 SDR, CDC is currently serving 62 patients, six days a week with 2 shifts per day, and has 21 stations. Dialysis facilities that operate four shifts per week (2 patients dialyzing per day at each station on alternate days) have a capacity of four patients per station. This equates

to 2.95 patients per station, which is 73.81% of capacity ( $62/21 = 2.95$ ;  $2.95/4 = 73.81\%$ ). The target utilization rate is 80%. According to the January 2013 SDR, Cabarrus County has a deficit of 13 stations. The only other dialysis facility in Cabarrus County is Harrisburg Dialysis Center, which is operating at 100% of capacity. Therefore, the addition of six stations at CDC will not duplicate services being provided by Harrisburg Dialysis Center. Projections for the in-center patient population at CDC are provided in Section II, page 15 of the application. At the end of operating year two, with 27 dialysis stations and 92 patients projected, the applicant's projected utilization will be 3.41 patients per station operating at 85.3% of capacity ( $92 \text{ patients} / 27 \text{ stations} = 3.41$ ;  $3.41/4 = 85.3\%$ ). This utilization projection is based on applying the Five Year Average Annual Change Rate (AACR) of 4.1% for Cabarrus County to only the patients from Cabarrus County while keeping the number of existing patients from three other counties static. The applicant adequately demonstrates the need to add six dialysis stations to the existing facility based on the number of in-center patients it proposes to serve. Therefore, the applicant adequately demonstrates that the proposed project will not result in the unnecessary duplication of existing or approved dialysis facilities in Cabarrus County, and the application is conforming to this criterion.

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

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In Section VII.1, page 35, the applicant provides current and projected staffing for CDC following the addition of six stations, as illustrated in the following table:

POSITION	CURRENT FTES	# OF FTE POSITIONS TO BE ADDED	TOTAL FTE POSITIONS
Registered Nurse	3.0	1.0	4.0
Patient Care Technician	9.0	2.0	11.0
Biomedical Technician	0.6	0.2	0.8
Medical Doctor	Contract	Contract	Contract
Administrator	1.0	0	1.0
Dietician	0.6	0.2	0.8
Social Worker	0.6	0.2	0.8
Unit Secretary	1.0	0	1.0
Other - Reuse	1.0	0.5	1.5
<b>Total</b>	<b>16.8</b>	<b>4.1</b>	<b>20.9</b>

In Exhibit 14 of the application, the applicant provides a letter of support from the Medical Director of CDC, Dr. John Gerig, for the addition of six in-center dialysis stations. In Section VII.2, page 36, the applicant states that Dr. Gerig is a Board Certified Nephrologist with several years of experience in the care of ESRD patients. The information provided in

Section VII is reasonable and credible. The applicant adequately demonstrates the availability of adequate health manpower and management personnel, including a 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.

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In Section V.1, pages 27-28, the applicant provides a table listing all ancillary and support services, indicating whether these services are provided on premises or off site, and if off site, by whom. Northeast Medical Center will provide most ancillary and support services to CDC dialysis patients, including emergency care and diagnostic evaluation services, while DC of Kannapolis will provide hemodialysis, CAPD, and CCPD. Dialysis/ maintenance, psychological counseling, isolation, nutrition counseling, and social work services will be provided on-site. Other services will be provided by stated providers.

The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

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

NA

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

NA

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

NA

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

C

In Section VI.1(a), page 31, the applicant states:

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

*Copperfield Dialysis Center makes every reasonable effort to accommodate all of its patients; especially those with special needs such as the handicapped, patients attending school or patients who work. Copperfield Dialysis Center provides dialysis six days per week with two patient shifts per day.*

*Copperfield Dialysis Center does not require payment upon admission to its services; therefore, services are available to all patients including low-income persons, racial and ethnic minorities, women, handicapped persons,*

*elderly and other under-served persons. Copperfield Dialysis Center works with patients who need transportation, when necessary.”*

In addition, in Section VI.1(b), page 31, the applicant provides the current in-center dialysis payor mix at CDC, as shown in the table below:

<b>CDC PAYOR SOURCE</b>	<b>PERCENT OF TOTAL</b>
Medicare	20.6%
Medicaid	1.6%
Medicare/Medicaid	42.8%
Commercial Insurance	4.8%
VA	0%
Medicare/Commercial	30.2%
Private Pay	0%
<b>Total</b>	<b>100.0%</b>

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages as of June 2010 and Calendar Year 2008 – 2009, respectively. The data in the table was obtained on April 24, 2013. More current data, particularly with regard to the estimated uninsured percentages, was not available.

<b>COUNTY</b>	<b>TOTAL # MEDICAID ELIGIBLES AS % OF TOTAL POPULATION JUNE 2010</b>	<b>TOTAL # MEDICAID ELIGIBLES AGE 21 AND OLDER AS % OF TOTAL POPULATION JUNE 2010</b>	<b>% UNINSURED CY 2008 - 09 (ESTIMATE BY CECIL G. SHEPS CENTER)</b>
Cabarrus	14.0%	4.9%	18.5%
Statewide	17.0%	6.7%	19.7%

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 with respect to dialysis services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicant’s current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM’s website does not include information on the number of handicapped persons.

In addition, the Centers for Medicare & Medicaid Services (CMS) website states:

*“Although the ESRD population is less than 1% of the entire U.S. population, it continues to increase at a rate of 3% per year and includes people of all races, age groups, and socioeconomic standings. ...*

*Almost half (46.6%) of the incident patients in 2004 were between the ages of 60 and 79. These distributions have remained constant over the past five years. While the majority of dialysis patients are White, ESRD rates among Blacks and Native Americans are disproportionately high. While Blacks comprise over 12% of the national population, they make up 36.4% of the total dialysis prevalent population. In 2004 males represented over half of the ESRD incident (52.6%) and prevalent (51.9%) populations.”<sup>1</sup>*

Additionally, the United States Renal Data System, in its 2012 *USRDS Annual Data Report* (page 225) provides the following national statistics for FY 2010:

*“On December 31, 2010, more than 376,000 ESRD patients were receiving hemodialysis therapy.”<sup>2</sup>*

Of the 376,000 ESRD patients, 38.23% were African American, 55.38% were white, 15.75% were Hispanic, 1.51% were Native American, 55.65% were male, and 44.65% were 65 and older. The report further states:

*“Nine of ten prevalent hemodialysis patients had some type of Medicare coverage in 2010, with 39 percent covered solely by Medicare, and 32 percent covered by Medicare/Medicaid. ...Coverage by non-Medicare insurers continues to increase in the dialysis population, in 2010 reaching 10.7 and 10.0 percent for hemodialysis and peritoneal dialysis patients, respectively.”*

The report provides 2010 ESRD spending, by payor, as follows:

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<sup>1</sup>[www.cms.gov/medicare/end-state-renal-disease/esrdnetworkorganizations/downloads/esrdnetworkprogrambackgroundpubic.pdf](http://www.cms.gov/medicare/end-state-renal-disease/esrdnetworkorganizations/downloads/esrdnetworkprogrambackgroundpubic.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	\$29.6	62.32%
Medicare Patient Obligation	\$4.7	9.89%
Medicare HMO	\$3.4	7.16%
Non-Medicare	\$9.8	20.63%

Source: 2012 United States Renal Data System (USRDS) Annual Data Report, page 340.

The Southeastern Kidney Council (SKC) Network 6 2011 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender summarized as follows:

<b>Number and Percent of Dialysis Patients by Age, Race and Gender 2011</b>		
	<b># of ESRD Patients</b>	<b>% of Dialysis Population</b>
<b>Ages</b>		
0-19	70	0.48%
20-34	757	5.20%
35-44	1,399	9.61%
45-54	2,697	18.52%
55-64	3,921	26.92%
65+	5,720	39.27%
<b>Gender</b>		
Female	6,606	45.36%
Male	7,958	54.64%
<b>Race</b>		
African American	9,221	63.31%
White/Caucasian	4,908	33.70%
Other	435	2.99%

Source: Southeastern Kidney Council (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.

- (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;

<sup>3</sup> [www.esrdnetwork6.org/publications/reports.html](http://www.esrdnetwork6.org/publications/reports.html)

C

In Section VI.6 (a), page 34, 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 32, the applicant provides the projected payor mix for the proposed services at CDC. The applicant projects no change from the current payor mix for dialysis visits, illustrated in the table below:

MCDC PAYOR SOURCE	PERCENT OF TOTAL
Medicare	20.6%
Medicaid	1.6%
Medicare/Medicaid	42.8%
Commercial Insurance	4.8%
VA	0%
Medicare/Commercial	30.2%
Private Pay	0%
<b>Total</b>	<b>100.0%</b>

As shown in the table above, the applicant projects that 93.6% of all in-center patients will have some or all of their services paid for by Medicare.

In Section II.1(b)9, 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.”*

The applicant demonstrates it will provide adequate access to medically underserved populations, including the elderly. 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(a), page 33, the applicant states that patients have access to dialysis services upon referral to a Nephrologist who has privileges at CDC. Nephrologists receive referrals from primary care physicians or specialty physicians within Cabarrus County and surrounding counties. Patients, families and friends can contact CDC directly as well to obtain access through a Nephrologist with privileges. Patients requesting transfer from outside CDC's catchment area are "*processed in accordance with the facility transfer and transient policies which comprise **Exhibit 15.***" The applicant states that patients requesting transfer are provided access to services the same way as others, through contact with a Nephrologist who has privileges at the facility. [Emphasis in original.]

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 29, the applicant states that CDC is available for onsite health professional training in the fields of medical assisting and medical office assisting from Kings College in Charlotte, and for dietetics from Winthrop University in Rock Hill, South Carolina. A copy of the Student Training Agreements between CDC and each educational institution is provided in Exhibit 13. The information provided in Section V.3 and Exhibit 13 is reasonable and credible for an existing facility 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

The applicant proposes to add six dialysis stations to its existing dialysis facility in Cabarrus County for a total of 27 certified stations upon completion of the proposed project. The January 2013 SDR shows that there is a deficit of 13 dialysis stations in Cabarrus County and a surplus of 19 dialysis stations in Rowan County, a contiguous county. Six stations would be relocated to CDC in Cabarrus County from DC of Kannapolis in Rowan County, thereby lowering Cabarrus County's deficit and Rowan County's surplus. Total Renal Care of North Carolina, LLC d/b/a CDC is one of two in-center dialysis facilities in Cabarrus County, the other being Harrisburg Dialysis Center. Both dialysis centers are owned by Total Renal Care of North Carolina, LLC. According to the January 2013 SDR, Harrisburg Dialysis Center has a utilization rate of 100%.

In Section V.7, page 30, 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 of other facilities in surrounding counties would be difficult to determine since most patients from Cabarrus County already receive treatment at facilities operated by TRC. [Total Renal Care of North Carolina, LLC]. 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.”*

See also Sections II, III, V, VI and VII. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that adding six dialysis stations to the existing CDC will have a positive impact on cost-effectiveness, quality and access to the proposed services because:

- The applicant adequately demonstrates the need to relocate six dialysis stations for a total of 27 certified dialysis stations following project completion. The applicant also demonstrates that the proposed project will provide additional access to Cabarrus County residents and is a cost-effective alternative;
- The applicant adequately demonstrates it will continue to provide quality services. The information regarding staffing provided in Section VII is reasonable and

credible and demonstrates adequate staffing for the provision of quality care services in accordance with 42 C.F.R. Section 494 (formerly 405.2100). The information regarding ancillary and support services and coordination of services with the existing health care system in Sections V and VII is reasonable and credible and demonstrates the provision of quality services.

- The applicant adequately demonstrates it will continue to provide adequate access to medically underserved populations as discussed in Section VI.1.

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

According to the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, CDC operated in compliance with the Medicare Conditions of Participation within the 18 months immediately preceding the date of this decision. Therefore, the application is conforming to this criterion.

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

C

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The proposal is conforming to all applicable 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- The utilization rate as of June 30, 2012, as shown in the January 2013 SDR, is 73.81%. See Exhibit 7 (copy of the January 2013 SDR, Table A, page 1).
- . 2202(a)(2) *Mortality rates;*
  - C- In Section IV.2, page 25, the applicant reports the 2010, 2011 and 2012 facility mortality rates, which were 30.3%, 23.3%, and 21.3%, respectively.
- .2202(a)(3) *The number of patients that are home trained and the number of patients on home dialysis;*
  - NA- The applicant states, in Section IV.3, page 25, that it is not certified to provide home training services, however patients at CDC who live in Cabarrus County and surrounding counties may obtain home training for dialysis at DC of Kannapolis.
- .2202(a)(4) *The number of transplants performed or referred;*
  - C- In Section IV.4, page 25, the applicant states that CDC referred 7 patients for transplant evaluation in 2012. Three patients received transplants in 2012.
- .2202(a)(5) *The number of patients currently on the transplant waiting list;*
  - C- In Section IV.5, page 26, the applicant states that the CDC has three patients on the transplant waiting list.
- .2202(a)(6) *Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;*
  - C- The applicant reports, in Section IV.6, page 26, that there were a total of 153 hospital admissions in 2012; 71.9% were non-dialysis related and 28.1% were dialysis-related.
- .2202(a)(7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during the last calendar year.*
  - C- In Section IV.7, page 26, the applicant reports that in 2012 there were no patients with an infectious disease and no patients who converted to infectious status in 2012.

*(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.*
- NA- CDC is an existing facility.
- .2202(b)(4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
  - C- Exhibit 8 contains a copy of DaVita, Inc.'s 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.
- .2202(b)(6) *Documentation that the services will be provided in conformity with applicable laws and regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and other relevant health and safety requirements.*
  - C- The applicant provides documentation that it provides its services in conformity with all applicable laws and regulations in Section VII.1, page 35, and Sections XI.6(e) and XI.6(g), page 55.
- .2202(b)(7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
  - C- In Section III.7, page 22, CDC provides projected patient origin based on historical experience using Cabarrus County's growth rate for CDC's Cabarrus County patients. The projected patient origin for the first two years of operation following completion

of the project are provided as follows:

<b>Copperfield Dialysis Center</b>		
County	Operating Year 1 2014	Operating Year 2 2015
	In-center Patients	In-center Patients
Cabarrus	85	89
Rowan	2	2
Stanly	1	1
Total	88	92

.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(a)(9), 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 III.7, page 23, the applicant projects to serve 88 in-center patients by the end of Operating Year 1, which is 3.3 patients per station ( $88/27 = 3.3$ ) or 83% of capacity ( $3.3/4 = .83$ ).

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

- C- In Section II(c), pages 13-15 and Section III.7, pages 22-23, the applicant provides the assumptions and methodology used to project utilization of the proposed facility.

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

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

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

- C- See Section V.1, page 27. Diagnostic evaluation services are provided by Northeast Medical Center.

*.2204(2) Maintenance dialysis;*

- C- See Section V.1, page 27. CDC provides maintenance dialysis.

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

- C- See Section V.1, page 27. Hemodialysis self-care training is provided by DC of Kannapolis.

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

- C- See Section V.2(d), page 28. Accessible follow-up program for support of patients dialyzing at home is provided by DC of Kannapolis.

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

- C- See Section V.1, page 27. X-ray services are provided by Northeast Medical Center.

*.2204(6) Laboratory services;*

- C- See Section V.1, page 27. Laboratory services are provided by Dialysis Laboratories.

*.2204(7) Blood bank services;*

- C- See Section V.1, page 25. Blood bank services are provided by Northeast Medical Center.

*.2204(8) Emergency care;*

- C- See Section V.1, page 27. Emergency care is provided by Northeast Medical Center.

- .2204(9) *Acute dialysis in an acute care setting;*  
-C- See Section V.1, page 27. Acute dialysis in an acute care setting is provided by Northeast Medical Center.
- .2204(10) *Vascular surgery for dialysis treatment patients;*  
-C- See Section V.1, page 27. Vascular surgery for dialysis treatment patients is provided by Northeast Medical Center.
- .2204(11) *Transplantation services;*  
-C- See Section V.1, page 27. Transplantation services are provided by Carolinas Medical Center.
- .2204(12) *Vocational rehabilitation counseling and services; and*  
-C- See Section V.1, page 25. Vocational rehabilitation counseling and services are provided by the North Carolina Division of Vocational Rehabilitation Services.
- .2204(13) *Transportation*  
-C- See Section V.1, page 27. Transportation is provided by Cabarrus County Transportation Service.

#### **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, pages 35-36, the applicant provides the proposed staffing. In Section VII.1, page 35, 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. See Criterion (7) for discussion which is incorporated hereby as if set forth fully therein.
- .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.3, page 36 for the qualifications or certifications held or required for the CDC staff. In addition, see Exhibit 18 for DaVita's training program policy, Exhibit 24 for DaVita's Health and Safety Policy and Procedure Manual, and Exhibit 25 for CDC's Annual In-Service Training Calendar. As stated in Section XI.6(g), page 56, the Annual In-Service Training Calendar includes a "mandatory 'Annual Update' class" in addition to "additional clinical classes that improve the clinical ability and skills of patient care teammates on an ongoing basis."