

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: May 2, 2013

PROJECT ANALYST: Gloria C. Hale

TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: C-10108-13/ Total Renal Care of North Carolina, LLC d/b/a McDowell County Dialysis Center/ Add one dialysis station for a total of 14 dialysis stations upon project completion / McDowell 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.

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Total Renal Care of North Carolina, LLC d/b/a McDowell County Dialysis Center proposes to add one (1) in-center dialysis station to the existing facility for a facility total of 14 in-center dialysis stations upon completion of this project.

The 2013 State Medical Facilities Plan (2013 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2013 Semiannual Dialysis Report (SDR), the county need methodology shows there is no need for an additional dialysis facility or for any additional dialysis stations in McDowell County. However, an applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. In this application, McDowell County Dialysis Center (MCDC) is eligible to apply for an additional station in its existing facility based on the facility need methodology, because the utilization rate reported in the January 2013 SDR is 3.31 patients per station, or 82.69%. This utilization rate was calculated based on 43 in-center dialysis patients and 13 certified dialysis stations as of June 30, 2012 (43 patients / 13 stations = 3.31 patients per station).

Application of the facility need methodology indicates an additional station is needed for this facility, as illustrated in the following table:

Required SDR Utilization		80%
Center Utilization Rate as of 6/30/12		82.69%
Certified Stations		13
Pending Stations		0
Total Existing and Pending Stations		13
In-Center Patients as of 6/30/12 (SDR2)		43
In-Center Patients as of 12/31/11 (SDR1)		41
Difference (SDR2 - SDR1)		2
Step	Description	
(i)	Multiply the difference by 2 for the projected net in-center change	4
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/11	0.0976
(ii)	Divide the result of Step (i) by 12	0.0081
(iii)	Multiply the result of Step (ii) by the number of months from the most recent month reported in the January 2013 SDR (6/30/12) until the end of calendar year 2012 (6 months)	0.0486
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	45.0898
(v)	Divide the result of Step (iv) by 3.2 patients per station	14.0906
	and subtract the number of certified and pending stations as recorded in SDR2 [13] to determine the number of stations needed	1

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is (1) one station. Step (C) of the facility need methodology states, *“The facility may apply to expand to meet the need established..., up to a maximum of ten stations.”* The applicant proposed to add only one new station and, therefore, is consistent with the facility need determination for dialysis stations.

Policy GEN-3: BASIC PRINCIPLES in the 2013 SMFP is also applicable to this review. Policy GEN-3 states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan (SMFP) shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant

shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Promote Safety and Quality

The applicant, Total Renal Care of North Carolina, LLC, is a subsidiary of DaVita Healthcare Partners, Inc. The applicant describes how its proposal will promote safety and quality in Section II.3, pages 16-17. The applicant states:

“DaVita Healthcare Partners, Inc. is committed to providing quality care to the ESRD population through a comprehensive Quality Management Program. DaVita’s Quality Management Program is facilitated by a dedicated clinical team of RN and Biomedical Quality Management Coordinators working under the direction of our Director of Quality Management and Director of Integrated Quality Development.

...Our Quality Management Program includes the following Quality Programs:

- *Quality Improvement Methodology – utilizing outcome-driven, patient centered management programs to measure, monitor and manage outcomes.*
- *Computerized Information System – integrating clinical and laboratory information for comprehensive outcomes tracking and reporting.*
- *Staff and Patient Education Program – ensuring continuous updates and training to ensure high quality patient care.*
- *Quality Assessment Audit Program – systematically utilizing a comprehensive detailed assessment tool to assure the highest quality standards in every facility.*
- *Quality Management Team – experienced clinical facilitators to implement and maintain ongoing quality improvement programs.*
- *Quality Biomedical Team – experienced specialists in all aspects of Biomedical requirements (i.e., water treatment, reuse, disinfection and machine maintenance).*

...Our goal is to have each facility serve as a quality improvement laboratory where successful outcomes can be disseminated throughout DaVita.”

In addition, the applicant states, in Section I.13, pages 7-8, that it uses clinical performance measures to score a dialysis facility based on seven clinical indicators correlated to patient morbidity and mortality. The scores are used to rank each facility and to identify areas in need of improvement. The applicant states, *“This process allows resources to be mobilized to the centers with the greatest challenges, and recognition to be given to the facilities with the highest overall clinical performance. The intent is to evaluate overall clinical care and*

drive improvement to benefit dialysis patients.” Exhibit 4 contains a copy of a 2012 year-end recap of the applicant’s achievements in clinical excellence and patient service, in addition to a summary of DaVita’s Quality Incentive Program Results. The applicant adequately demonstrates how its proposal will promote safety and quality in the provision of dialysis services in McDowell County.

Promote Equitable Access

The applicant describes how its proposal will promote equitable access in Section VI.1(a), page 30, in which it states,

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

In addition, the applicant states on page 30 that it works to accommodate the special needs of the handicapped and patients’ schedules. Moreover, MCDC does not require payment upon admission, rather it accepts all patients in need of medical care first, and then evaluates their medical insurance and financial status.

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

Maximize Healthcare Value

The applicant describes how its proposal will maximize health care value for resources expended in Section III.9, pages 21-22. The approaches MCDC will use for promoting cost-effectiveness include:

- Utilizing the purchasing power of the parent corporation, DaVita Healthcare Partners, to negotiate contracts with vendors for needed equipment such as TVs, dialyzers, office supplies, drugs and other supplies to obtain the best products at the best price;
- Utilizing the reuse process to contain costs and reduce the amount of dialyzer waste generated;
- Utilizing an electronic patient charting system for reducing paper use at the facility;
- Conducting preventative maintenance on the dialysis machines on a monthly, quarterly and semi-annual schedule to reduce repair costs and extend the life of the machines; and
- Utilizing an inventory control plan to ensure that supplies are available and will not have to be ordered on an emergency basis, which is costly.

The applicant adequately demonstrates how its proposal will maximize healthcare value. Additionally, the applicant demonstrates that projected volumes for the proposed services incorporate the basic principles in meeting the needs of patients to be served. See Criteria (3) and (13c) for additional discussion.

The applicant adequately demonstrates how its proposal will promote safety and quality, promote equitable access, and maximize health care value for resources expended. Therefore, the application is consistent with Policy GEN-3, and 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.

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Total Renal Care of North Carolina, LLC d/b/a McDowell County Dialysis Center proposes to add one in-center dialysis station to the existing facility, pursuant to a Facility Need Determination, for a facility total of 14 stations upon completion of this project.

Population to be Served

In Section III.7, page 20, the applicant provides MCDC’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
McDowell	44	47	91.6[7]%	92.1[2]%
Burke	2	2	4.2%	3.9%
Mitchell	1	1	2.1%	2.0%
Rutherford	1	1	2.1%	2.0%
Total	48	51	100.0%	100.0%

The applicant adequately identifies the population it proposes to serve.

Demonstration of Need

In Section II, pages 12-13, the applicant provides the assumptions and methodology used to project patient utilization and the need for one additional dialysis station, summarized as follows:

- Based on the data reported in Table A, page 6 of the January 2013 SDR, MCDC had 43 in-center patients as of June 30, 2012. There are 13 certified dialysis stations at the facility and a utilization rate of 82.69%.

- Based on information provided by the applicant in Section III.2, and illustrated in a table provided by the analyst (see Criterion 1), the facility is eligible for one additional station based on facility need methodology.
- The applicant used a 7% Five Year Average Annual Change Rate for McDowell County, as indicated on page 2 of Table B of the January 2013 SDR.
- Of the 43 patients cited in the January 2013 SDR, 39 live in McDowell County. The applicant applied the 7% five-year average annual change rate only to the 39 patients from McDowell County.
- MCDC is projected to have 48 in-center patients by the end of operating year 1 (January 1, 2014 - December 31, 2014) and 51 in-center patients by the end of operating year two (January 1, 2015 – December 31, 2015). The applicant illustrates this as follows:

“January 1, 2013 – December 31, 2013 – 39 patients X 1.07 = 41.73

January 1, 2014 – December 31, 2014 – 41.73 patients X 1.07 = 44.6511

January 1, 2015 – December 31, 2015 – 44.6511 patients X 1.07 = 47.776677

...

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 2 patients living in Burke County or the one patient living in Mitchell County and the one patient living in Rutherford County. Therefore, the McDowell County Dialysis Center is projected to have 48 in-center patients at the end of operating year one (44 McDowell County patients, 2 Burke County patients, one Mitchell County patient and one Rutherford County patient = 48 patients). The facility is projected to have 51 in-center patients at the end of operating year two (47 McDowell County patients, 2 Burke County patients, one Mitchell County patient and one Rutherford County patient = 51 patients).”

Projected utilization at the end of Year One is 3.4 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 one additional dialysis station at the MCDC 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 one in-center dialysis station to its existing facility, for a facility total of 14 in-center dialysis stations following project completion. In Section III.9, page 21, the applicant states that it considered the alternative of not applying for an additional station at the facility before proposing this project, however as stated in Section III.9, this was dismissed due to the rapid growth of the facility. 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 one additional dialysis station at MCDC. 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 McDowell County 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 McDowell County Dialysis Center shall develop and operate no more than one additional dialysis station for a total of 14 certified stations which shall include any home hemodialysis training or isolation stations.**
3. **Total Renal Care of North Carolina, LLC d/b/a McDowell County Dialysis Center shall install plumbing and electrical wiring through the walls for one additional dialysis station for a total of 14 dialysis stations which shall include any isolation stations.**
4. **Total Renal Care of North Carolina, LLC d/b/a McDowell County 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 McDowell County 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.

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In Sections VIII.1(b), page 38, the applicant states that the capital cost is projected to be \$68,095. In Sections IX.1 and IX.2, page 43, 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 40, 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., the parent company of Total Renal Care of North Carolina, LLC, which states in part:

“This letter will confirm that DaVita Healthcare Partners, Inc. has committed cash reserves in the total sum of \$68,095 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 45, the applicant lists the following charges per treatment for each payment source:

**Applicant Projected Allowable
 In-Center Charges**

SOURCE OF PAYMENT	CHARGE PER TREATMENT
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-X.4, pages 45-48, the applicant reported projected revenues and expenses as follows:

	OPERATING YEAR 1	OPERATING YEAR 2
Total Net Revenue	\$2,040,193	\$2,172,995
Total Operating Costs	\$1,761,166	\$1,853,835
Net Profit	\$279,027	\$319,160

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 46-47 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 McDowell County Dialysis Center (MCDC) proposes to add one in-center dialysis station to the existing facility. MCDC is currently serving 43 patients, six days a week with 2 shifts per day, with 13 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 3.31 patients per station, which is 82.69% of capacity ($43/13 = 3.3077$; $3.3077/4 = 82.69\%$). The target utilization rate is 80%. The applicant does not propose to establish a new facility. Projections for the in-center patient population are provided in Section II, pages 13-14 of the application. At the end of operating year two, with 14 dialysis stations and 51 patients projected, the applicant's projected utilization will be 3.6 patients per station operating at 91% of capacity ($51 \text{ patients} / 14 \text{ stations} = 3.64$). This utilization projection is based on applying the Five Year Average

Annual Change Rate (AACR) of 7% in dialysis patients in McDowell County to the McDowell County patients while keeping the number of existing patients from three other counties static. MCDC is the only dialysis facility in McDowell County. The applicant adequately demonstrates the need to add one dialysis station 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 McDowell 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 34, the applicant provides current and projected staffing for the MCDC facility following the addition of one station, as illustrated in the following table:

POSITION	CURRENT FTES	# OF FTE POSITIONS TO BE ADDED	TOTAL FTE POSITIONS
Registered Nurse	1.50	1.00	2.50
Patient Care Technician	5.00	1.00	6.00
Biomedical Technician	0.50	0	0.50
Medical Doctor	Contract	Contract	Contract
Administrator	1.00	0	1.00
Dietician	0.50	0	0.50
Social Worker	0.50	0	0.50
Unit Secretary	1.00	0	1.00
Other - Reuse	0.50	0	0.50
Totals	10.50	2.00	12.50

In Exhibit 14 of the application, the applicant provides a letter of support from the Medical Director of MCDC, Dr. Blake Pruitt, for the addition of one in-center dialysis station. In Section VII.2, page 35, the applicant states that Dr. Pruitt 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 25-26, the applicant provides a table listing all ancillary and support services, indicating whether they are provided on premises or off site, and if off site, by

whom. Mission St. Joseph's Hospital will provide most ancillary and support services to MCDC dialysis patients, including emergency care and diagnostic evaluation services, while Asheville Kidney Center 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;

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In Section VI.1(a), page 30, the applicant states:

“McDowell County 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.”

McDowell County 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. McDowell County Dialysis Center provides dialysis six days per week with two patient shifts per day to accommodate patient need.

McDowell County 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. McDowell County Dialysis Center works with patients who need transportation, when necessary.”

In addition, in Section VI.1(b), page 30, the applicant provides the current in-center dialysis payor mix at MCDC, as shown in the table below:

MCDC PAYOR SOURCE	PERCENT OF TOTAL
Medicare	23.2%
Medicaid	14.0%
Medicare/Medicaid	25.6%
Commercial Insurance	7.0%
VA	7.0%
Medicare/Commercial	23.2%
Private Pay	0%
Total	100.0%

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages as of June 2010 and Calendar Year 2008 – 2009, respectively. The data in the table was obtained on April 9, 2013. More current data, particularly with regard to the estimated uninsured percentages, was not available.

COUNTY	TOTAL # MEDICAID ELIGIBLES AS % OF TOTAL POPULATION JUNE 2010	TOTAL # MEDICAID ELIGIBLES AGE 21 AND OLDER AS % OF TOTAL POPULATION JUNE 2010	% UNINSURED CY 2008 - 09 (ESTIMATE BY CECIL G. SHEPS CENTER)
McDowell	20.4%	9.5%	17.4%
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.”¹

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.”²

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:

ESRD Spending by Payor		
Payor	Spending in Billions	% of Total Spending
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:

¹www.cms.gov/medicare/end-state-renal-disease/esrdnetworkorganizations/downloads/esrdnetworkprogrambackgroundpubic.pdf

² www.usrds.org/adr.aspx

Number and Percent of Dialysis Patients by Age, Race and Gender 2011		
	# of ESRD Patients	% of Dialysis Population
Ages		
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%
Gender		
Female	6,606	45.36%
Male	7,958	54.64%
Race		
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.³

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;

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In Section VI.6 (a), page 33, 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

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³ www.esrdnetwork6.org/publications/reports.html

In Section VI.1(c), page 31, the applicant provides the projected payor mix for the proposed services at MCDC. 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	23.2%
Medicaid	14.0%
Medicare/Medicaid	25.6%
Commercial Insurance	7.0%
VA	7.0%
Medicare/Commercial	23.2%
Private Pay	0%
Total	100.0%

As shown in the table above, the applicant projects that 72.0% of all in-center patients will have some or all of their services paid for by Medicare, with an additional 7.0% covered by VA.

In Section II.1(b)9, page 12, the applicant states:

“Total Renal Care of North Carolina d/b/a McDowell County 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 32, the applicant states that patients have access to dialysis services upon referral to a Nephrologist who has privileges at MCDC. Nephrologists receive referrals from primary care physicians or specialty physicians within McDowell County. Patients, families and friends can contact MCDC directly as well to obtain access through a Nephrologist with privileges. Patients requesting transfer from outside MCDC’s catchment area are *“processed in accordance with the McDowell County Dialysis Center 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 MCDC 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 27, the applicant states that MCDC is available for clinical onsite training for nursing students from McDowell Technical Community College. A copy of a Student Training Agreement between MCDC and McDowell Technical Community College 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 one dialysis station to its existing dialysis facility for a total of 14 certified stations upon completion of the proposed project. The January 2013 SDR shows that there is no need for additional dialysis stations in McDowell County, however, the applicant qualifies for an additional dialysis station based on the facility need methodology in the 2013 SMFP. Total Renal Care of North Carolina, LLC d/b/a MCDC is the only provider of in-center dialysis services in McDowell County. The utilization rate currently exceeds 82%.

In Section V.7, page 28, 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:

“McDowell County is a rural county. The proposed expansion of the facility is an effort to provide dialysis services to this rural community 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 McDowell County already receive treatment at the McDowell County Dialysis Center.

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 McDowell County Dialysis Center provides access to all qualified Nephrologists to admit his or her patients.”

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 one dialysis station to the existing McDowell County Dialysis Center will have a positive impact on cost-effectiveness, quality and access to the proposed services because:

- The applicant adequately demonstrates the need, based on ‘Facility Need,’ to add one dialysis station for a total of 14 certified dialysis stations following project completion. The applicant also demonstrates that the proposed project will provide additional access to McDowell 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, MCDC 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 December 31, 2012 as shown in the January 2013 SDR is 82.69%. See Exhibit 7 (copy of the January 2013 SDR, Table A, page 6).

. 2202(a)(2) Mortality rates;

- C- In Section IV.2, page 23, the applicant reports the 2010, 2011 and 2012 facility mortality rates, which were 13.7%, 21.6%, and 7.4%, 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 23, that it is not certified to provide home training services, however patients at MCDC who live in McDowell County may obtain home training for dialysis at Asheville Kidney Center.

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

- C- In Section IV.4, page 24, the applicant states that MCDC referred 19 patients for transplant evaluation in 2012. However, only one patient received a transplant in 2012.

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

- C- In Section IV.5, page 24, the applicant states that the MCDC has two 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 24, that there were a total of 77 hospital admissions in 2012; 70.1% were non-dialysis related and 29.9% were dialysis-related.

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

- C- In Section IV.7, page 24, 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- MCDC 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- MCDC 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- MCDC 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- MCDC 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 Sections VII.1, page 34, XI.6(e), page 54, and XI.6(g), pages 54-55.

.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 20, MCDC provides projected patient origin based on historical experience using McDowell County's growth rate for MCDC's McDowell County patients. The projected patient origin for the first two years of operation following completion of the project are provided as follows:

McDowell County Dialysis Center		
County	Operating Year 1 2014	Operating Year 2 2015
	In-center Patients	In-center Patients
McDowell	44	47
Burke	2	2
Mitchell	1	1
Rutherford	1	1
Total	48	51

.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- MCDC 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 McDowell County 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- MCDC 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 20, the applicant projects to serve 48 in-center patients by the end of Operating Year 1, which is 3.4 patients per station ($48/14 = 3.43$) or 85% of capacity ($3.4/4 = .85$).

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

-C- In Section II(b), pages 12-14 and Section III.7, pages 20-21, 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 25. Diagnostic evaluation services are provided by Mission St. Joseph's Hospital.
- .2204(2) *Maintenance dialysis;*
 - C- See Section V.1, page 25. MCDC provides maintenance dialysis.
- .2204(3) *Accessible self-care training;*
 - C- See Section V.1, page 25. Hemodialysis self-care training is provided by Asheville Kidney Center.
- .2204(4) *Accessible follow-up program for support of patients dialyzing at home;*
 - C- See Section V.2(d), page 26. Accessible follow-up program for support of patients dialyzing at home is provided by Asheville Kidney Center.
- .2204(5) *X-ray services;*
 - C- See Section V.1, page 25. X-ray services are provided by Mission St. Joseph's Hospital.
- .2204(6) *Laboratory services;*
 - C- See Section V.1, page 25. 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 Mission St. Joseph's Hospital.
- .2204(8) *Emergency care;*
 - C- See Section V.1, page 25. Emergency care is provided by Mission St. Joseph's Hospital.
- .2204(9) *Acute dialysis in an acute care setting;*
 - C- See Section V.1, page 25. Acute dialysis in an acute care setting is provided by Mission St. Joseph's Hospital.
- .2204(10) *Vascular surgery for dialysis treatment patients;*
 - C- See Section V.1, page 25. Vascular surgery for dialysis treatment patients is provided by Mission St. Joseph's Hospital.
- .2204(11) *Transplantation services;*
 - C- See Section V.1, page 25. 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 26. Transportation is provided by Mountain Projects.

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 34, the applicant provides the proposed staffing. In Section VII.1, page 34, 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 35 for the qualifications or certifications held or required for the MCDC 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 MCDC's Annual In-Service Training Calendar.