

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: July 11, 2013

PROJECT ANALYST: Tanya S. Rupp

CON CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: F-10105-13 / DVA Healthcare Renal Care d/b/a Marshville Dialysis Center / Relocate two in-center dialysis stations from Union County Dialysis Center for a facility total of 12 in-center stations at the Marshville Dialysis Center / Union 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 Marshville Dialysis Center, whose parent company is DaVita Healthcare Partners, Inc. (DaVita), proposes to relocate two in-center dialysis stations from the Union County Dialysis Center in Monroe, to the Marshville Dialysis Center in Marshville, for a facility total of 12 in-center dialysis stations at the Marshville facility upon completion of this project. The applicant does not propose to add new dialysis stations to an existing facility or to establish any 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. Policy GEN-4 is not applicable because the proposed capital cost of this project is under \$2 million. 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 two dialysis stations from Union County Dialysis Center to Marshville Dialysis Center. The two dialysis facilities are in Union County; therefore, the relocation of two existing stations will be within the host 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

The applicant proposes to relocate two in-center dialysis stations from the Union County Dialysis Center to the Marshville Dialysis Center, for a facility total of 12 in-center dialysis stations at the Marshville facility upon completion of this project, and 28 in-center dialysis stations at the Union County Dialysis Center.

Population to be Served

In Section III.7, page 21, the applicant provides a table to illustrate projected patient origin at the Marshville Dialysis Center during the first two operating years, as shown below:

COUNTY	OPERATING YEAR 1	COUNTY PTS AS % OF TOTAL	OPERATING YEAR 2	COUNTY PTS AS % OF TOTAL
	IN-CTR. PTS.		IN-CTR. PTS.	
Union	44	97.8%	47	97.9%
Anson	1	2.2%	1	2.1%
Total	45	100.0%	48	100.0%

The applicant adequately identifies the population it proposes to serve.

Demonstration of Need

In Section III.7, pages 21 – 22, the applicant provides the assumptions and methodology with which it demonstrates the need to relocate the two existing, certified dialysis stations from Union County Dialysis Center to Marshville Dialysis Center. The applicant states:

“The Marshville Dialysis Center had 28 in-center patients as of June 30, 2012 based on information included on Page 9 of Table A of the January 2013 Semiannual Dialysis Report (SDR). This is a station utilization rate of 70% based on the 10 certified stations in the facility.

...

This Certificate of Need application requests an approval of a two-station transfer of stations from the Union County Dialysis Center in Monroe in Union County. The Union County Dialysis Center had 79 in-center patients as June 30, 2012 based on information included on Page 9 of Table A of the January 2013 Semiannual Dialysis Report (SDR). This is a station utilization rate of 65% based on 30 certified stations.

There are twelve in-center patients who have indicated that they would consider transfer from the Union County dialysis Center to the Marshville Dialysis Center. Eleven of the patients live in Wingate in Union County. One of the patients lives in Wadesboro in Anson County.

Based on the desire of twelve Union County Dialysis patients to transfer to the Marshville facility, the following calculations indicate the utilization of the Marshville Dialysis Center during the first two years of operation:

The following calculations indicate the in-center patient population beginning with 28 in-center patients for the current year and apply the Union County Average Annual Change Rate for the past five years of 7.9%:

January 1, 2013 – December 31, 2013 – 28 patients X 1.079 = 30.212

January 1, 2014 – December 31, 2014 – 30 (Marshville Patients) + 12 Union County transfer patients = 42 patients) X 1.079 = 45.318

January 1, 2015 – December 31, 2015 – 45.318 X 1.079 = 48.898....”

On page 22, the applicant states that operating year one is calendar year 2014, and operating year two is calendar year 2015. Therefore, using the Five Year Average Annual Change Rate (AACR) for Union County from the 2013 SDR, the applicant projects that the Marshville Dialysis Center will serve 45 in-center dialysis patients at the end of the first year of operation, and 48 in-center dialysis patients at the end of the second year of operation.

With 12 in-center dialysis stations, that yields a utilization rate of 93.7% in operating year one [45 patients / 12 stations = 3.75. $3.75 / 4 = 0.9375$]. In operating year two, the utilization rate would be 100%, with 48 patients dialyzing on 12 in-center stations [48 patients / 12 stations = 4].

In Exhibit 15, the applicant provides 15 signed patient letters, each of which indicates the patient's willingness to transfer his or her care to the Marshville Dialysis Center upon project completion. The applicant states in Section II, page 13 and in Section III.7, page 22 that one of the patients who signed a letter indicating a willingness to transfer dialysis care to the Marshville facility lives in Wadesboro, which is in Anson County, to the East of Union County. According to Mapquest,[®] the distance from Wadesboro to the Marshville Dialysis facility address is approximately 17 miles, which would be 35 miles round trip. Even if the patient from Anson County decided not to transfer his or her care to the Marshville Dialysis facility, the projected utilization would still be in excess of the 80% standard as promulgated in 10A NCAC 14C .2203(b), based on 3.2 patients per station per week, as shown in the calculations below, performed by the project analyst:

28 current in-center patients x 1.079 = 30.212 (end of CY 2013)

30 patients + 11 patients from Union County Dialysis Center = 41

41 patients x 1.079 = 44.239 patients (end of first project year; CY 2014)

Utilization rate of 91.67% [(44 / 12) / 4 = 0.916]

44 patients x 1.079 = 47.47 patients (end of second project year; CY 2015)

Utilization rate of 97.9% [(47 / 12) / 4 = 0.9792]

Access

In Section VI.1, page 30, the applicant provides a table that shows that 96.4% of its payor mix in 2012 were Medicare / Medicaid recipients. Furthermore, the applicant states that dialysis services at the Marshville Dialysis Center will continue to be provided to all patients who need dialysis care.

In summary, the applicant adequately identifies the population to be served, adequately demonstrates the need to relocate two certified dialysis stations from the Union County Dialysis facility to the Marshville Dialysis Center, and adequately demonstrates the extent to which all residents, including the medically underserved, will have access to dialysis services in Union County. 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.

The applicant proposes to relocate two existing, certified dialysis stations from the Union County Dialysis Center to the Marshville Dialysis Center, in Union County. According to the January 2013 SDR, Table A, on page 9, the utilization of the Union County Dialysis Center was dialyzing 79 patients on 24 in-center dialysis stations. In addition, the Union County Dialysis Center has been approved to add 6 in-center dialysis stations to its facility, for a total of 30 in-center dialysis stations before the relocation of stations to the Marshville Dialysis Center. Therefore, following the relocation of two dialysis stations, the Union County Dialysis Center will have 28 certified in-center dialysis stations. Utilizing the 7.9% Five Year AACR from the 2013 SDR, the projected utilization of the Union County Dialysis Center is as follows:

Union County Dialysis Center Projected Utilization

YEAR	# IN-CENTER PATIENTS	UNION COUNTY FIVE YEAR AACR	# IN-CENTER STATIONS	UTILIZATION RATE
CY 2013	79	N/A	24	83%
CY 2014	79 – 12 = 67	7.9%	28	65%
CY 2015	73	7.9%	28	70%
CY 2016	78	7.9%	28	75%

Furthermore, in Exhibit 15, the applicant provides 12 letters signed by existing patients who currently dialyze at the Union County Dialysis Center. In each of these letters, the patient stated he or she would consider transferring his or her care to the Marshville Dialysis Center once the stations are relocated.

In addition, in Section III.6, page 31, the applicant states:

“The patients remaining at the Union County Dialysis Center will not be affected by the transfer of two stations from the facility. DVA Healthcare Renal Care will ensure that continued excellent service will be afforded to low income persons, racial and ethnic minorities, women, handicapped persons and other under-served groups and the elderly.”

The applicant adequately demonstrates the needs of the population currently served and projected to be served in the Union County Dialysis Center will continue to be adequately met following the relocation of two dialysis stations to the Marshville Dialysis Center. In fact, that facility will be underutilized as a result of the station relocation.

In summary, the applicant adequately demonstrates that the needs of the population presently served will be met adequately by the proposed relocation.

- (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.

The applicant proposes to add two in-center dialysis stations to its existing Marshville Dialysis Center facility, by relocating two stations from Union County Dialysis Center, for a facility total of 12 in-center dialysis stations at the Marshville facility following project completion. In Section III.9, page 23, the applicant states that it considered one alternative of not applying for the station relocation before proposing this project; however this alternative would not provide an opportunity for patients who would elect to dialyze at the Marshville facility to receive services closer to home. 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 need to relocate two in-center dialysis stations from the Union County Dialysis facility to the Marshville Dialysis Center facility. 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 Marshville 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 Marshville Dialysis Center shall relocate no more than two certified dialysis stations for a total of 12 certified dialysis stations which shall include any home hemodialysis training or isolation stations.**
 - 3. Total Renal Care of North Carolina, LLC d/b/a Marshville Dialysis Center shall install plumbing and electrical wiring through the walls for two additional dialysis stations for a total of 12 dialysis stations which shall include any isolation stations.**
 - 4. Total Renal Care of North Carolina, LLC d/b/a Marshville 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 Marshville 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.

In Section VIII.1(b), page 38, the applicant projects the capital cost of the project is \$6,810 for chair-side TVs and accompanying technology. 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 currently in operation.

In Section VIII.2, page 40, the applicant states that the project will be funded with cash reserves. In Exhibit 20, the applicant provides a March 15, 2013 letter from the Interim Chief Financial Officer and Chief Accounting Officer of DaVita Healthcare Partners, Inc. and Total Renal Care, Inc., which states in part:

“The project calls for a capital expenditure of \$6,810. This letter will confirm that DaVita Healthcare Partners, Inc. has committed cash reserves in the total sum of \$6,810 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 DVA Healthcare Renal Care, Inc.”

In Exhibit 21, the applicant provides the 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 44, the applicant lists the following charges per treatment for each payment source:

Projected In-Center Charges

SOURCE OF PAYMENT	AMOUNT
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 44 - 48, the applicant projects revenues and expenses as follows:

	OPERATING YEAR 1	OPERATING YEAR 2
Total Net Revenue	\$1,704,328	\$1,821,704
Total Operating Costs	\$1,574,534	\$1,660,535
Net Profit	\$ 129,794	\$ 161,169

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 45 - 46 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 Marshville Dialysis Center proposes to add two in-center dialysis stations to the existing facility by relocating two existing stations from the Union County Dialysis Center in Union County. The proposed station relocation is within Union County. Twelve patients currently receiving services at Union County Dialysis Center are considering transferring to the Marshville facility, since it is closer to their homes. Each patient has submitted a letter, copies of which are in Exhibit 15, attesting to his or her willingness to transfer their care. According to the January 2013 SDR, there are three dialysis facilities in Union County, two of which are operated by the applicant and one of which is operated by another dialysis provider, Bio-Medical Applications of North Carolina [the Metrolina Kidney Center / BMA Monroe]. The January 2013 SDR reports that the Union County Dialysis facility is operating at 82% of capacity; the Marshville Dialysis facility is operating at 70% of capacity, and the Metrolina Kidney Center / BMA Monroe is operating at 54% of capacity. Therefore, the relocation of two existing, certified dialysis stations from the Union County Dialysis Center to the Marshville Dialysis Center will not result in the duplication of existing dialysis services being provided by either facility. Rather, it reduces the number of stations in Monroe. Projections for the in-center patient population at the Marshville facility are provided in Section II, page 13 and Section III.7, page 22 of the application. At the end of operating year two, with 12 dialysis stations and 48 patients projected, the applicant's projected utilization will be 4.0 patients per station operating at 100.0% of capacity $[(48 \text{ patients} / 12 \text{ stations}) / 4 = 1.00]$. This utilization projection is based on applying the Five Year Average Annual Change Rate (AACR) of 7.9% for Union County, from the January 2013 SDR, to the number of patients to be served. The applicant adequately demonstrates the need to add two 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 services in Union 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 Marshville Dialysis Center following the addition of two stations, as illustrated in the following table:

POSITION	CURRENT FTES	FTEs TO BE ADDED	TOTAL FTES
Registered Nurse	1.5	0.0	1.5
Patient Care Technician	5.0	0.0	5.0
Biomedical Technician	0.3	0.0	0.3
Administrator	1.0	0.0	1.0
Dietician	0.3	0.0	0.3
Social Worker	0.3	0.0	0.3
Unit Secretary	1.0	0.0	1.0
Other - Reuse	0.5	0.0	0.5
Total	9.0	0.0	9.0

The applicant projects no change in staffing as a result of the addition of two stations to the Marshville Dialysis Center. In Exhibit 14, the applicant provides a March 12, 2013 letter, identified in the Exhibit Table of Contents as “*Medical Director Documentation.*” The letter does not identify the doctor and the signature is illegible except for the letters “MD” following the signature. In addition, the letter is not on letterhead that identifies a particular medical practice or the Marshville Dialysis facility (the heading on the letter states “*Medical Director Letter of Support; Practice Letterhead*”). However, in the text of the letter, the physician identifies the project and the dialysis facility, and indicates support for the project. Therefore, it is reasonable to conclude that the letter is written by the current medical director and that he wishes to continue in that capacity following the relocation of two stations. 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, page 26, the applicant provides a table that lists all ancillary and support services provided at the Marshville Dialysis Center; and indicates whether these services are provided on premises or off site. If the services are provided off site, the applicant identifies the provider of those services. Presbyterian Hospital will provide most of the identified

ancillary and support services to the Marshville patients, including emergency care and diagnostic evaluation services, while Union County Dialysis Center will provide hemodialysis, CAPD, and CCPD. Psychological counseling, isolation, nutrition counseling, and social work services will be provided on-site.

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:

“Marshville 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.

Marshville 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. Marshville Dialysis Center provides dialysis six days per week with two patient shifts per day.

Marshville 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. Marshville 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 the facility, as shown in the table below:

PAYOR SOURCE	PERCENT OF TOTAL
Medicare	32.1%
Medicaid	3.6%
Medicare/Medicaid	25.0%
Commercial Insurance	3.6%
Medicare/Commercial	35.7%
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 June 17, 2013. More current data, particularly with regard to the estimated uninsured percentages, was not available.

COUNTY	TOTAL # MEDICAID	TOTAL # MEDICAID ELIGIBLES AGE 21	% UNINSURED CY 2008 - 09
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	ELIGIBLES AS % OF TOTAL POPULATION JUNE 2010	AND OLDER AS % OF TOTAL POPULATION JUNE 2010	(ESTIMATE BY CECIL G. SHEPS CENTER)
Union	11.0%	3.4%	18.0%
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

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

² www.usrds.org/adr.aspx

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, in its 2011 Annual Report provides prevalence data on North Carolina ESRD patients by age, race and gender summarized as follows:

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%

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;

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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In Section VI.1(c), page 31, the applicant provides the projected payor mix for the proposed services at the Marshville Dialysis Center following project completion. The applicant projects no change from the current payor mix for dialysis services, illustrated in the table below:

PAYOR SOURCE	PERCENT OF TOTAL
Medicare	32.1%
Medicaid	3.6%
Medicare/Medicaid	25.0%
Commercial Insurance	3.6%
Medicare/Commercial	35.7%
Total	100.0%

As shown in the table above, the applicant projects that 96.4% 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 Marshville 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.

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In Section VI.5(a), page 32, the applicant states that patients who are in need of dialysis services will have access to those services upon referral to a Nephrologist

who has privileges at the Marshville facility. The applicant states these referrals commonly come from primary care physicians or specialty physicians within Union County and surrounding counties. Additionally, patients, families and friends can contact Marshville Dialysis Center directly to obtain access through a Nephrologist who has privileges at the facility. Patients requesting transfer from outside the Marshville catchment area are “*processed in accordance with the facility transfer and transient policies which comprise **Exhibit 15.***” [Emphasis in original.]

The applicant adequately demonstrates that the Marshville Dialysis Center 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.

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In Section V.3, page 28, the applicant states that the Marshville Dialysis Center has a health professional training agreement in place with South Piedmont Community College in Monroe. A copy of the agreement 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 two dialysis stations to the Marshville Dialysis Center in Union County for a total of 12 certified stations upon completion of the proposed project. The proposed addition of stations will come from a transfer of two stations from the Union County Dialysis Center in Monroe. Therefore, the relocation of stations remains within Union County and thus the total complement of dialysis stations in Union County remains the same. Total Renal Care of North Carolina, LLC d/b/a Marshville Dialysis Center is one of three in-center dialysis facilities in Union County. Two of the three dialysis centers are owned by Total Renal Care of North Carolina, LLC.

In Section V.7, page 29, 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:

“Union County is an is a mix between urban and rural. [sic] The proposed expansion of the facility is not intended to be a competitive venture. The effect of other facilities in Union County and surrounding counties would be difficult to determine since most patients from Union County already receive treatment in established facilities operated by several different providers..

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 Marshville 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 two dialysis stations to the existing Marshville Dialysis Center will have a positive impact on cost-effectiveness, quality and access to the proposed services because:

- The applicant adequately demonstrates the need to relocate two dialysis stations for a total of 12 certified dialysis stations following project completion. The applicant also demonstrates that the proposed project will provide additional access to Union 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. Currently, 96.4% of the payor mix at the Marshville Dialysis Center is comprised of Medicare / Medicaid recipients.

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, Marshville Dialysis Center 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 70.0%. See Exhibit 7 (copy of the January 2013 SDR, Table A, page 1).
- .2202(a)(2) Mortality rates;*
-C- In Section IV.2, page 24, the applicant reports the 2011 and 2012 facility mortality rates, which were 7.8% and 11.1%, respectively.
- .2202(a)(3) The number of patients that are home trained and the number of patients on home dialysis;*
-NA- In Section IV.3, page 24, the applicant states that Union County patients who are eligible for home training may obtain home training for dialysis at Union County Dialysis Center. The patients from Marshville who are in need of home training will receive their home training at the Union County Dialysis Center.

- .2202(a)(4) *The number of transplants performed or referred;*
-C- In Section IV.4, page 24, the applicant states that the Marshville Dialysis Center referred one patient for transplant evaluation 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 Marshville Dialysis Center 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- In Section IV.6, page 25, the applicant states that there were a total of 33 hospital admissions in 2012; 87.9% were non-dialysis related and 12.1% 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 25, 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- Marshville Dialysis Center 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- Marshville Dialysis Center 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- Marshville Dialysis Center 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- Marshville Dialysis Center 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 34, and Sections XI.6(e) and XI.6(g), page 53.

.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 21, Marshville Dialysis Center provides projected patient origin based on its historical experience. The projected patient origin for the first two years of operation following completion of the project is provided as follows:

COUNTY	OPERATING YEAR 1 (2014)	OPERATING YEAR 2 (2015)
Union	44	47
Anson	1	1
Total	45	48

.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- Marshville Dialysis Center 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, “DVA Healthcare Renal Care, Inc. d/b/a Marshville 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- Marshville Dialysis Center is an existing facility.

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

-C- In Section II, pages 12 – 15, and Section III.7, page 21 - 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 26. Diagnostic evaluation services are provided by Presbyterian Hospital.

.2204(2) maintenance dialysis;

-C- See Section V.1, page 26. Marshville Dialysis Center provides maintenance dialysis.

.2204(3) accessible self-training;

-C- See Section V.1, page 26. Hemodialysis self-care training is provided by Union County Dialysis.

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

-C- See Section V.2(d), page 27. Accessible follow-up program for support of patients dialyzing at home is provided by Union County Dialysis.

- .2204(5) *x-ray services;*
-C- See Section V.1, page 26. X-ray services are provided by Presbyterian Hospital.
- .2204(6) *laboratory services;*
-C- See Section V.1, page 26. Laboratory services are provided by Dialysis Laboratories.
- .2204(7) *blood bank services;*
-C- See Section V.1, page 26. Blood bank services are provided by Presbyterian Hospital.
- .2204(8) *emergency care;*
-C- See Section V.1, page 26. Emergency care is provided by Presbyterian Hospital.
- .2204(9) *acute dialysis in an acute care setting;*
-C- See Section V.1, page 26. Acute dialysis in an acute care setting is provided by Presbyterian Hospital.
- .2204(10) *vascular surgery for dialysis treatment patients;*
-C- See Section V.1, page 26. Vascular surgery for dialysis treatment patients is provided by Presbyterian Hospital.
- .2204(11) *transplantation services;*
-C- See Section V.1, page 26. Transplantation services are provided by Presbyterian Hospital.
- .2204(12) *vocational rehabilitation counseling and services; and*
-C- See Section V.1, page 26. 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 Department of Social Services and “*various providers.*”

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 34 - 36, 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 Marshville Dialysis Center staff. In addition, see Exhibit 19 for DaVita's training program policy, Exhibit 25 for DaVita's Health and Safety Policy and Procedure Manual. As stated in Section XI.6(g), page 53, 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."