

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: January 16, 2013
PROJECT ANALYST: Julie Halatek
TEAM LEADER: Craig R. Smith

PROJECT I.D. NUMBER: A-10039-12 / Total Renal Care of North Carolina, LLC d/b/a Macon County Dialysis / Add two dialysis stations for a total of 9 dialysis stations upon completion of this project. The additional stations will be relocated from the Sylva Dialysis Center / Macon 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 (TRC) d/b/a Macon County Dialysis (Macon), whose parent company is DaVita Inc., (DaVita), proposes to add two dialysis stations to a facility under development for a total of 9 certified dialysis stations upon completion of this project. The 2012 State Medical Facilities Plan (2012 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the July 2012 Semiannual Dialysis Report (SDR), the county need methodology shows Macon County has no need for an additional facility, but there is a deficit of two dialysis stations. TRC proposes to relocate two dialysis stations from the Sylva Dialysis Center (Sylva) in Jackson County, which is a contiguous county to Macon County.

Policy ESRD-2: Relocation of Dialysis Stations, on page 33, 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 station 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 Jackson County to Macon County. The two counties are contiguous. According to the July 2012 North Carolina Semiannual Dialysis Report (SDR), Jackson County has a surplus of nine dialysis stations. According to the July 2012 SDR, Macon County has a deficit of two dialysis stations. Relocating two dialysis stations away from Jackson County will not result in a deficit in the number of dialysis stations in Jackson County. Additionally, relocating two dialysis stations to Macon County will not result in a surplus of dialysis stations in Macon County. Therefore, the application is consistent with Policy ESRD-2.

Policy GEN-3: Basic Principles, page 40 of the 2012 SMFP is 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 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

In Section II.3, page 20, the applicant states:

“DaVita 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 Registered Nurses who make up our Clinical Support Services and Biomedical Quality Management Coordinators working under the direction of our Director of Clinical Support Services and Area Biomedical Administrator. These efforts receive the full support and guidance of the clinical executive leadership team of DaVita. Combined, this group brings hundreds of years of ESRD experience to the program. The program exemplifies DaVita’s total commitment to enhancing

the quality of patient care through its willingness to devote the necessary resources to achieve our clinical goals.”

In Section I.13(c), page 7, the applicant states:

”DaVita utilizes the ‘DaVita Quality Index’, a unified measure of clinical performance for dialysis facilities. Seven individual clinical parameters have been weighted and combined in to [sic] a unified clinical metric. This simplified clinical scoring system allows for clinical differentiation among dialysis facilities. ...The index employs both a positive and negative scoring system for each of the seven clinical indicators, which were selected based on correlation to patient morbidity and mortality. The total points achieved for each indicator are combined for an overall clinical performance score. The highest possible score that a facility can obtain is 100. The scores for each facility can be ranked and improvement tended. 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.”

See Exhibit 4 for an article describing the DaVita Quality Index.

The applicant adequately demonstrates that the proposal will promote quality and safety.

Promote Equitable Access

In Section VI.1(a), page 37, the applicant states:

”Macon County Dialysis, by policy, will make dialysis services available to all residents in its service area without qualifications. We will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic status.”

Macon County Dialysis will make 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. The facility will provide dialysis six days per week with two patient shifts per day to accommodate patient need.

Macon County Dialysis will 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.”

On page 39, the applicant states its commitment to providing handicapped accessible facilities in compliance with state and local building codes. The applicant provides, in Exhibit 10, its business and admissions policy, outlining that it will accept multiple forms of

payment, including Medicare and Medicaid, and documenting that the facility will accept patients with no means of payment with approval from a Divisional Vice President.

The applicant adequately demonstrates that the proposal will promote equitable access.

Maximize Healthcare Value

In Section III.9, pages 29-30, the applicant lists some of the ways they will promote cost-effectiveness at their facility:

- Use of national contracts to supply the facility with supplies at the best possible price
- Utilizing reuse process for dialyzers that reduces waste and contains costs
- Use of electronic charting to avoid cost and waste of paper
- Preventative maintenance that will prevent the need for repair maintenance and parts
- Inventory control ordering to avoid emergency ordering, which drives up costs

The applicant adequately demonstrates that the proposal will maximize healthcare value.

Consequently, the applicant demonstrates that the projected volumes for the proposed service incorporate the basic principles in meeting the needs of the patients to be served. The application is consistent with the facility need determination in the July 2012 SDR, Policy ESRD-2, and Policy GEN-3. Therefore, the application is conforming to this criterion.

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

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Currently there are no dialysis facilities in Macon County. Patients on in-center hemodialysis receive their treatment at the Sylva Dialysis Center, which is about 23 miles from the facility under development in Macon County. In 2012, in response to a need determination in the 2012 SMFP, DaVita applied to build a 7 station dialysis facility in Franklin, in Macon County. The project was approved (project ID# A-8799-12) and development has begun.

The applicant, Macon, proposes to add two stations to the facility under development for a total of 9 certified stations upon completion of the project. The stations will be relocated from Jackson County, which is a contiguous county to Macon County.

Population to be Served

In Section III.7, page 26, the applicant identifies the patient population it proposes to serve for the first two years of operation following project completion, which is currently under development, as illustrated in the following table.

Brevard	Operating Year 1 2013/2014		Operating Year 2 2014/2015		County patients as a % of TOTAL	
	Home	In-Center	Home	In-Center	Year 1	Year 2
Macon	9	32	10	36	97.6%	97.9%
Georgia	1	0	1	0	2.4%	2.1%
Total	10	32	11	36	100%	100%

The applicant states that it expects the Macon County patients at Sylva will transfer to the Macon facility upon opening. This assumption is also used in the methodology to project patient utilization. The applicant also assumes that Macon County patients will choose to dialyze at Macon as it will be closer to their homes than Sylva. The applicant adequately identified the population to be served.

Need Analysis

In the assumptions, in Section II.1, page 12, the applicant provides the following information:

1. All ESRD patients living in Macon County currently leave the county for dialysis, as there is no dialysis facility currently in the county.
2. Patients who live in Macon County will want to dialyze in Macon County.
3. Most if not all ESRD patients living in Macon County live closer to the applicant’s facility than to another dialysis facility.
4. The applicant assumes the ESRD patient population of Macon County will continue to increase at a rate of 13.4%, the Macon County Five Year Average Annual Change Rate (AACR) published in the July 2012 SDR.
5. ESRD patients will want to keep their same nephrologists and their same dialysis providers.
6. CKD (chronic kidney disease) patients will want to be followed by the same nephrologists if they end up transitioning to dialysis.

The applicant’s methodology for in-center patients is provided in the following table:

	In-center
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July 1, 2012 patient population	25
Project the patient population forward for 12 months.	$26 \times 1.134 = 28.35$
July 1, 2013 patient population—Year 1	28.35
Project the patient population forward for 12 months.	$28.35 \times 1.134 = 32.15$
July 1, 2014 patient population—Year 2	32.15
Project the patient population forward for 12 months.	$32.15 \times 1.134 = 36.46$

The applicant projects to serve 32 in-center patients or 3.56 patients per station ($32 / 9 = 3.56$) by the end of Year 1 and 36 in-center patients or 4.00 patients per station ($36 / 9 = 4.00$) by the end of Year 2 for the proposed 9 station facility. This exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b). Projected utilization is based on reasonable and supported assumptions regarding continued growth. The applicant notes that the utilization in year two will be potentially at or higher than the maximum of 4 patients per station, assuming 2 shifts per day and 3 days of treatment per patient, and the facility operational 6 days per week.

Access

In Section VI, page 37, the applicant states, “*Macon County Dialysis, by policy, will make dialysis services available to all residents in its service area without qualifications.*” The applicant has no data to supply at this time regarding current patient utilization by access category because the facility is not yet operational. The applicant states in Section VI, pages 37-39, that they will provide services regardless of financial situation or socioeconomic status and that the facility will be handicapped accessible according to all state and local requirements. The applicant projects more than 92% of patients will have some or all of their care paid for by government programs, thus it projects adequate access for the underserved to its services.

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for the one additional station at Brevard, and demonstrates all residents of the area, including underserved groups, are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

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

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In Section III.6, page 25, the applicant states that it will relocate two additional stations to the Macon facility from the Sylva facility. Approximately 32 in-center patients will transfer to

Macon from the Sylva facility. According to the January 2012 SDR, Sylva will then have 16 certified stations and 45 in-center patients at the dialysis facility for a patient ratio of 2.8 patients per station, which does not result in an overcrowded dialysis facility.

The applicant states in Section III.6, page 25:

“The reduction in the number of dialysis stations from 18 to 16 stations will have no effect on the ability of the Sylva Dialysis Center to provide needed health care to low income persons, racial and ethnic minorities, women, handicapped persons, other served groups and the elderly.”

The applicant adequately demonstrates that the relocation of two stations from Sylva to Macon will adequately serve the remaining patients at Sylva and that the access for underserved groups will not be negatively impacted. Therefore, the application is conforming to this criterion.

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

CA

In Section III.9, pages 27-28, the applicant discusses the alternatives considered prior to the submission of this application, which include:

1. Maintain the Status Quo—Do Nothing. The applicant states that this alternative was dismissed because of the rapidly growing in-center population of Macon County dialysis patients.
2. Add two dialysis stations for a total of 9 stations at Macon. The applicant proposes to add two additional stations to the developing Macon facility to provide adequate access to dialysis services to the growing Macon County ESRD patient population.

On page 27, the applicant states:

“There were only two alternatives of meeting the needs of the proposed project considered. The first was to do nothing. This alternative was dismissed since the Macon County in-center patient population is rapidly growing. The second was to apply for the 2-station expansion through the transfer of stations from Jackson County. We chose the second alternative in order to help meet the growing demand for dialysis services in Macon County.”

The applicant adequately demonstrates the need for two additional stations based on the continued growth of the ESRD patient population of Macon County and Macon’s projected utilization. See Criterion (3) for further discussion on need which is incorporated hereby as if fully set forth herein. Developing the additional two needed dialysis stations during the construction of the approved 7 station dialysis facility is prudent and cost effective.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable.

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

- 1. Total Renal Care of North Carolina, LLC d/b/a Macon County Dialysis shall materially comply with all representations made in the Certificate of Need application.**
 - 2. Total Renal Care of North Carolina, LLC d/b/a Macon County Dialysis shall develop no more than two additional stations for a total of no more than 9 stations, which shall include any isolation stations, upon completion of this project and project ID # A-8799-12.**
 - 3. Total Renal Care of North Carolina, LLC d/b/a Macon County Dialysis shall install plumbing and electrical wiring through the walls for no more than 9 dialysis stations which shall include any isolation stations.**
 - 4. Upon completion of the project, Total Renal Care of North Carolina, LLC d/b/a Macon County Dialysis shall take the necessary steps to decertify two stations at Sylva Dialysis Center for a total of no more than 16 stations at Sylva Dialysis Center.**
 - 5. Total Renal Care of North Carolina, LLC d/b/a Macon County Dialysis 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 Section VIII.1, page 46, the applicant projects a capital cost of \$29,582 for the two station addition. This is the cost of two dialysis machines, two TVs, and two dialysis chairs. In Section IX, page 51, the applicant states there will be no start-up or initial operating expenses associated with the proposed project. Exhibit 14 provides documentation of the availability of funds for the capital cost.

In Exhibit 15, the applicant provides United States Securities and Exchange Commission Form 10-K for DaVita Inc. for the year ended December 31, 2011. As of December 31,

2011, DaVita had \$8,892,172,000 in total assets and \$2,268,125,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of funds for the proposed project.

In Section X.1, page 53, the applicant projects the following allowable charge per treatment for each payment source:

Payor	In-center
Medicare	\$192
Medicaid	\$192
Medicare/Medicaid	\$240
Commercial	\$800
VA	\$240
Medicare/Commercial	\$240

The applicant projects net revenue in Section X.2 of the application and operating expenses in Section X.4 of the application. The applicant projected revenue in excess of expenses in each of the first two operating years following completion of the project is as illustrated in the table below and supported by the accompanying assumptions.

	Project Year 1	Project Year 2
Net revenue	\$1,616,352	\$1,820,768
Operating expenses	\$1,558,229	\$1,711,891
Profit	\$58,123	\$108,897

Source:
Application pages
57

Assumptions:

1. Patients would be seen three times a week, 52 weeks per year.
2. Total treatments are reduced to factor in missed treatments by patients.
3. The actual number of treatments was multiplied by the patient payment percentage by source of revenue to obtain how many treatments would be from each source of revenue.
4. The amount paid by each source of revenue was multiplied by the treatment number by source of revenue to obtain the operating revenue totals.

In Section VII.1, page 42, the applicant provides projected staffing and salaries. On pages 42-43, the applicant states Macon will comply with all staffing requirements as stated in 42 C.F.R. Section 405.2100 (now 42 C.F.R. Section 494). Staffing by shift is provided on page 45. The applicant projects adequate staffing to provide dialysis treatments for the number of patients projected.

The applicant adequately demonstrates 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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Currently there are no dialysis facilities in Macon County. Patients on in-center hemodialysis receive their treatment at the Sylva Dialysis Center, which is about 23 miles from the facility under development in Macon County. In 2012, DaVita received a certificate of need to build a 7 station dialysis facility in Franklin, in Macon County. The project was approved (project ID# A-8799-12) and development has begun.

The applicant proposes to add two dialysis stations to an approved 7 station dialysis facility that is under development in Franklin for a total of 9 stations upon completion of both projects. The applicant adequately demonstrates the need for two additional stations based on the number of patients it proposes to serve. Per the July 2012 SDR, as of December 31, 2011, the 18 station Sylva facility, which serves both Jackson County and Macon County, was operating at 68% capacity ($49/18 = 2.7$; $2.7/4 = 68\%$). The target utilization rate is 80%. There is therefore no need for additional stations in Jackson County. The applicant proposes to develop a nine station facility in Franklin by adding two stations to its in-progress facility. Upon project completion, more than 25 patients will transfer from Sylva to Macon. The Macon facility will have 9 stations serving 32 patients (end of year 1) which is a utilization rate of 89% ($32/9 = 3.56$; $3.56/4 = 89\%$). The applicant is therefore conforming with the requirement in 10A NCAC 14C .2203.

Neither Jackson County nor Macon County has any other dialysis center. On page 363, the 2012 SMFP states, "*As a means of making ESRD services more accessible to patients, one of the goals of the N.C. Department of Health and Human Services is to minimize patient travel time to and from the center.*"

The applicant adequately demonstrates the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities. Therefore, 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 42, the applicant provides the following current and projected number of full-time equivalent (FTE) positions. The applicant projects adding 1.5 Patient Care Technicians, as illustrated below:

Position	Anticipated # of FTEs	Projected # of FTEs	Total # of FTEs
RN		0.0	1.5

HTRN	0.3	0.0	0.3
PCT	3.0	1.5	4.5
Medical Director	Not an FTE of the facility; contract position		
Bio-Med Tech	0.2	0.0	0.2
Admin.	0.5	0.0	0.5
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	0.3	0.0	0.3
Total	7.4	1.5	8.9

In Section VII.10, page 45, the applicant provides the following information on the number of direct care staff for each shift offered at Macon.

	Times	Sun	Mon	Tues	Wed	Thurs	Fri	Sat
In	Morning	0	3	3	3	3	3	3
S	Afternoon	0	3	3	3	3	3	3

Section V.4(c), page 34, the applicant states that Dr. Bryson Fleming is the medical director at Macon.

The information regarding staffing provided in Section VII and the pro forma, and statements regarding projected staffing, are reasonable and credible. Therefore, the application is conforming with 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 31 of the application, the applicant lists the providers of the necessary ancillary and support services. See also 10A NCAC 14C .2204, beginning on page 19 of these findings. Acute hospital care, diagnostic evaluation services, X-ray services, blood bank services and emergency care beyond facility capability will be provided by Mission Hospitals or Angel Medical Center. Dialysis maintenance, isolation, and social services will be provided by Macon on site. The other services will be provided at the specified facility. In Section V.2, page 32 of the application, TRC provided information regarding coordination of services, acute hospital agreement, transplant agreement, and follow-up care; Section V.4, pages 33-34, physician referral relationships and physician support; Section V.5, pages 34-35, relationships with physicians, hospitals and other health professionals; and Section VII, pages 42-45, healthcare staffing is reasonable and credible and supports a finding of conformity with this criterion.

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

NA

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

NA

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

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;

NA

- (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.1(f), page 39, the applicant states:

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

In Section VI.6(a), page 41, the applicant states,

“There have been no civil rights equal access complaints filed within the last five years against any facility operated by Total Renal Care of North Carolina, LLC or by any facility in North Carolina owned by DaVita, Inc.”

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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Historical data is not available for this facility because the facility, at the time of this application, is still under development. The applicant states:

“Macon County Dialysis, by policy, will make dialysis services available to all residents in its service area without qualifications. We will serve patients without regard to race, sex, age, or handicap. We will serve patients regardless of ethnic or socioeconomic situation.

Macon County Dialysis will make 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. The facility will provide dialysis six days per week with two patient shifts per day to accommodate patient need.

Macon County Dialysis will 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.”

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 for Macon County and statewide. More current data, particularly with regard to the estimated uninsured percentages, was not available.

	Total # of Medicaid Eligibles as % of Total Population	Total # of Medicaid Eligibles Age 21 and older as % of Total Population	% Uninsured CY 2009 (Estimate by Cecil B. Sheps Center)
Macon	17%	7.5%	19.8%
Statewide	17%	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 the services offered by Macon. In fact, only 5.8% of all 2011 Incident ESRD patients in North Carolina’s Network 6 were under the age of 35.

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 70. 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 provides these national statistics for FY 2010:

“On December 31, 2010, more than 376,000 ESRD patients were receiving hemodialysis therapy”

¹www.cms.gov/Medicare/End-Stage-Renal-Disease/ESRDNetworkOrganizations/Downloads/ESRDNetworkProgramBackgroundpublic.pdf; accessed on 12/7/2012

The report validates the statistical constancy reported by the CMS above. Of the 376,000 ESRD patients, 38.23% were African American, 55.38% were white, 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 Southeastern Kidney Council (SKC) publishes Network 6 2011 Incident ESRD patient data for North Carolina by age, race, and gender demonstrating the following:

Number and Percent of NC Dialysis Patients by Age, Race, and Gender		
	# of ESRD Patients	% of Dialysis Population
Ages		
< 45	1313	14.1%
45-64	3899	41.8%
> 65	4130	44.2%
Gender		
Female	4237	45.4%
Male	5105	54.6%
Race		
African American	5096	54.5%
White	4027	43.1%
Other	219	2.3%
Total	9342	100.0%

6, which includes South Carolina, and

In

Source: Network North Carolina, Georgia.

Section VI.1(c), page 38, the

applicant states that DaVita and TRC are totally committed to serving all patients, regardless of socioeconomic status. The applicant states that there are facilities that DaVita and TRC operate with between 95% and 100% of patients receiving Medicare

and Medicaid, and that if this proposed facility ends up being 100% Medicare and/or Medicaid, the facility will accept all of them.

Payor Source	In-Center
Medicare	15.6%
Medicaid	3.1%
Medicare/Medicaid	23.4%
Commercial Insurance	7.8%
VA	9.4%
Medicare/Commercial	40.7%
Total	100.0%

As shown in the table, the applicant projects 79.7% of all in-center patients will have some or all of their services paid for by Medicare. The applicant also projects that the VA will cover 9.4% of in-center patients and Medicaid will cover 3.1% of in-center patients.

In Section VI, page 38, the applicant states that the facility will conform to the Americans with Disabilities Act and any other applicable requirements of federal, state, and local bodies.

The applicant demonstrates it will provide adequate access to elderly and medically underserved populations. 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 39, the applicant states:

“Patients with End Stage Renal Disease will have access to dialysis services upon referral to a Nephrologist with privileges at Macon County Dialysis. These referrals will come from primary care physicians or specialty physicians in the Macon County area or transfer referrals from other Nephrologists outside of the immediate area. Patients, families and friends may obtain access by contacting a Nephrologist with privileges at Macon County Dialysis. Should a patient contact Macon County Dialysis either directly or indirectly, the patient will be referred to a qualified Nephrologist for evaluation and subsequent admission if medically necessary.”

The applicant adequately demonstrates that it will provide a range of means by which a person can access 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, page 33, the applicant states health related education and training programs can visit the facility, receive instruction and observe the operation of the unit while patients are treated. The applicant further states that it will offer itself as a clinical learning site for CAN and nursing students at Western Carolina University, Southwestern Community College, and Franklin High School. The applicant adequately demonstrates that the facility will accommodate the clinical needs of health professional training programs in the proposed service area. The application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant, Macon, proposes to add two stations to the facility under development for a total of 9 certified stations upon completion of the projects. The two stations will be relocated from Jackson County, which is a contiguous county to Macon County. The July 2012 SDR shows there is a surplus of 9 stations in Jackson County, and a deficit of two stations in Macon County.

In Section V.7, pages 35-36, 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 notes that Total Renal Care of North Carolina, LLC is the only provider of dialysis services within Macon County. The applicant additionally notes that the dialysis facility in Jackson County is also operated by TRC. The applicant notes that the only other facility in the area of Macon County is the Fresenius facility located in Clayton, GA. The applicant states that while there may be a negative impact on competition to the Fresenius facility in GA if patients currently living in Macon County choose to dialyze at Macon instead of at Fresenius, that negative impact is offset by the ESRD patients in Macon County having easier access to dialysis closer to their homes.

See also Sections II, III, V, VI, and VII.

The information the applicant provides in those sections is reasonable and credible and adequately demonstrates that adding two dialysis stations to the Macon facility will have a positive impact on cost-effectiveness, quality, and access to the proposed services because:

- The applicant adequately demonstrates the need to add two dialysis stations for a total of 9 certified dialysis stations following completion of these projects. The applicant also demonstrates that the proposed project is a cost-effective alternative to meet the need to provide additional access to Macon County patients.
- The applicant has and will continue to provide quality services. The information regarding staffing provided in Section VII and discussed in Criterion 7 is reasonable and credible and demonstrates adequate staffing for the provision of quality care services in accordance with 42 C.F.R. Section 494. The information regarding ancillary and support services and coordination of services with the existing health care system in Section V, pages 31-35, and staffing, in Section VII, pages 42-45, and referenced in exhibits is reasonable and credible and demonstrates the provision of quality care services.
- The applicant will provide adequate access to medically underserved populations. In Section VI.1, page 37, the applicant states:

“Macon County Dialysis, by policy, will make dialysis services available to all residents in its service area without qualifications.”

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.

NA

- (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 Criteria and Standards for End Stage Renal Disease Services in 10A NCAC 14C .2200. The specific findings are discussed below.

10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT

- (a) *An applicant that proposes to increase dialysis stations in an existing certified facility or relocate stations must provide the following information:*
- (1) *Utilization rates;*
-C- In Section IV.1, page 29, the applicant provides the utilization numbers for Sylva. The current utilization of Sylva is at 2.72, or 68%.
 - (2) *Mortality rates;*
-C- In Section IV.2, page 29, the applicant provides the mortality rates for Sylva as 26.1%, 18.4%, and 22.2% for 2009, 2010, and 2011, respectively.
 - (3) *The number of patients that are home trained and the number of patients on home dialysis;*
-NA- In Section IV.3, page 30, the applicant states that Sylva has 26 home-trained dialysis patients as of December 31, 2011.
 - (4) *The number of transplants performed or referred;*
-C- In Section IV.4, page 30, the applicant states Sylva referred 9 patients for transplants in 2011. One transplant was performed in 2011.
 - (5) *The number of patients currently on the transplant waiting list;*
-C- In Section IV.5, page 30, the applicant states that Sylva has 4 patients on the transplant waiting list.
 - (6) *Hospital admission rates, by admission diagnosis, i.e., dialysis versus non-dialysis related;*
-C- In Section IV.6, page 30, the applicant documents that Sylva had 81 admissions in 2011. Ten were dialysis related and 71 were non-dialysis related.
 - (7) *The number of patients with infectious disease, e.g., hepatitis, and the number converted to infectious status during last calendar year.*
-C- In Section IV.7, page 30, the applicant states as of December 31, 2011 there were no patients at Sylva with an infectious disease. No patients converted to infectious status within the last year.
- (b) *An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information requested on the End Stage renal Disease (ESRD) Treatment application form:*
- (1) *For new facilities, a letter of intent to sign a written agreement or a signed written agreement with an acute care hospital that specifies the relationship with the dialysis facility and describes the services that*

the hospital will provide to patients of the dialysis facility. The agreement must comply with 42 C.F.R., Section 405.2100.

- NA- Macon is an approved facility.
- (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- Macon is an approved facility.
- (3) *For new or replacement facilities, documentation that power and water will be available at the proposed site.*
- NA- Macon is an approved facility.
- (4) *Copies of written policies and procedures for back up for electrical service in the event of a power outage.*
- C- See Exhibit 8 for a copy of Macon's manual which has policies and procedures for testing the generator that provides back-up electrical service in the event of a power outage.
- (5) *For new facilities, the location of the site on which the services are to be operated. If such site is neither owned by nor under option to the applicant, the applicant must provide a written commitment to pursue acquiring the site if and when the approval is granted, must specify a secondary site on which the services could be operated should acquisition efforts relative to the primary site ultimately fail, and must demonstrate that the primary and secondary sites are available for acquisition.*
- C- The site has been identified.
- (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 regulations.*
- NA- Macon is an approved facility.
- (7) *The projected patient origin for the services. All assumptions, including the methodology by which patient origin is projected, must be stated.*
- C- See Section III.7, pages 25-26, for the methodology and assumptions the applicant uses to project patient origin as presented in the following table.

Macon	Operating Year 1		Operating Year 2		County patients as a % of TOTAL	
	In-Center	Home	In-Center	Home	Year 1	Year 2
Macon	32	9	36	10	97.6%	97.9%
Georgia	0	1	0	1	2.4%	2.1%
Total	32	10	36	11	100.0%	100.0%

Also see discussion in Criterion (3) which is incorporated hereby as if fully set forth herein.

- (8) *For new facilities, documentation that at least 80 percent of the anticipated patient population resides within 30 miles of the proposed facility.*
- NA- Macon is an approved facility.
- (9) *A commitment that the applicant shall admit and provide dialysis services to patients who have no insurance or other source of payment, but for whom payment for dialysis services will be made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.*
- C- In Section II.1, page 14, the applicant states:
“Total Renal Care of North Carolina, LLC d/b/a Macon County Dialysis will admit and provide dialysis services to patients who have no insurance or other source of payment if payment for dialysis services is made by another healthcare provider in an amount equal to the Medicare reimbursement rate for such services.”

10A NCAC 14C .2203 PERFORMANCE STANDARDS

- (a) *An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per stations 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- Macon does not propose to establish a new End Stage Renal Disease facility.
- (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 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- Macon projects utilization of 3.56 patients per station per week as of the end of the first operating year. Assumptions are provided in Section II.1, pages 15-17, and Section III.7, pages 26-27. See discussion in Criterion (3) which is incorporated hereby as if fully set forth herein.
- (c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

- C- The applicant provides all assumptions, including the methodology by which patient utilization is projected in Section II.1, pages 15-17, and Section III.7, pages 26-27. Additionally, see discussion in Criterion (3) which is incorporated hereby as if fully set forth herein. The applicant projects an annual increase in its current Macon County patient utilization using the county 5-year AACR. The utilization of non-resident patients is held constant through the projected years.

10A NCAC 14C .2204 SCOPE OF SERVICES

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

- (1) *diagnostic and evaluation services;*
 - C- In Section V.1, page 31, the applicant documents that diagnostic and evaluation services will be provided by Mission Hospitals and Angel Medical Center.
- (2) *maintenance dialysis;*
 - C- In Section V.1, page 31, the applicant documents that Macon will provide maintenance dialysis at its own facility.
- (3) *accessible self-care training;*
 - C- In Section II.2, page 20, the applicant states, “*The Sylva Dialysis Center will offer the Macon County Dialysis patients home hemodialysis training and follow-up.*”
- (4) *accessible follow-up program for support of patients dialyzing at home;*
 - C- In Section II.2, page 20, the applicant states, “*The Sylva Dialysis Center will offer the Macon County Dialysis patients home hemodialysis training and follow-up.*”
- (5) *x-ray services;*
 - C- In Section V.1, page 31, the applicant documents that x-ray services will be provided by Mission Hospitals and Angel Medical Center.
- (6) *laboratory services;*
 - C- In Section V.2, page 32, the applicant states that Mission Hospitals will provide a range of services to the patients of Macon, including laboratory services.
- (7) *blood bank services;*
 - C- In Section V.1, page 31, the applicant documents that blood bank services will be provided by Mission Hospitals and Angel Medical Center.
- (8) *emergency care;*
 - C- In Section V.1, page 31, the applicant documents that emergency care services will be provided by Mission Hospitals and Angel Medical Center.
- (9) *acute dialysis in an acute care setting;*
 - C- In Section V.1, page 31, the applicant documents that acute dialysis in an acute care setting will be provided by Mission Hospitals.
- (10) *vascular surgery for dialysis treatment patients;*
 - C- In Section V.1, page 31, the applicant documents that vascular surgery services will be provided by Mission Hospitals.
- (11) *transplantation services;*
 - C- In Section V.1, page 31, the applicant documents that transplantation services will be provided by Carolinas Medical Center.
- (12) *vocational rehabilitation counseling and services; and*

- C- In Section V.1, page 31, the applicant documents that vocational rehabilitation counseling and services will be provided by the N.C. Department of Vocational Rehabilitation.
- (13) *transportation.*
- C- In Section V.1, page 31, the applicant documents that transportation services will be provided by Macon County Transit.

10A NCAC 14C .2205 STAFFING AND STAFF TRAINING

- (a) *To be approved, the state agency must determine that the proponent can meet all staffing requirements as stated in 42 C.F.R., Section 405.2100.*
- C- In Section VII.1, pages 42-43, the applicant states that Macon will comply with all staffing requirements as stated in 42 C.F.R. Section 494 (formerly 405.2100). See Criterion (7) for further discussion on staffing which is incorporated hereby as if fully set forth herein.
- (b) *To be approved, the state agency must determine that the proponent will provide an ongoing program of training for nurses and technicians in dialysis techniques at the facility.*
- C- In Section II.1, page 19, the applicant states Macon will provide an outstanding and award winning ongoing program training for nurses and technicians in dialysis techniques. Exhibit 13 contains a copy of the program outlines and programs, and Exhibit 19 contains an example of a facility in-service training calendar.