# ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

#### **FINDINGS**

C = Conforming CA = Conditional NC = Nonconforming NA = Not Applicable

DECISION DATE:	August 14, 2014
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PROJECT ANALYST:Jane Rhoe-JonesINTERIM CHIEF:Martha J. Frisone

PROJECT I.D. NUMBER: Project I.D. #Q-10279-14/ Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Martin County/ Cost Overrun on Project ID #Q-10103-13 (Add 2 dialysis stations to the existing facility for a total of 25 stations upon completion of this project)/ Martin 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.

#### NA

The applicant does not propose to increase the number of licensed beds in any category, add any new health services or acquire equipment for which there is a need determination in the 2014 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations in the 2014 SMFP that are applicable to this review. Furthermore, there are no policies in the 2014 SMFP that are applicable to this review. Therefore, this criterion is not applicable to this review.

- (2) Repealed effective July 1, 1987.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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Effective June 18, 2013, Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Martin County (DC of Martin County) was issued a Certificate of Need (CON) for Project ID Q-10103-13, to add two dialysis stations to the existing facility in Martin County for a total of 25 stations upon project completion. The original project was approved for a capital cost of \$38,640. The additional stations were expected to be certified by January 1, 2015. The current CON application is for a cost overrun. The total capital cost is now expected to be \$83,571, an increase of \$44,931 [\$83,571 - \$38,640 = \$44,931] or 116% [\$44,931 / \$38,640 = 116%] of the approved capital cost. See Section VI.12, page 12.

The following table compares the previously approved capital cost and the proposed capital cost in this application.

DC of MARTIN COUNTY PREVIOUSLY APPROVED AND PROPOSED CAPITAL COSTS			
	Previously Approved Cost	Additional Cost	Proposed Total
Construction Costs	\$0	\$35,000	\$35,000
Miscellaneous Costs			
Dialysis Machines	\$29,700	\$0	\$29,700
(RO) Water Treatment Equipment	\$0	\$0	\$0
Equipment/Furniture	\$4,000	\$8,271	\$12,271
Other: Dialysis Chairs	\$1,940	\$660	\$2,600
Televisions	\$3,000	\$1,000	\$4,000
Chair Side Computer Terminals	\$0	\$3000	\$3,000
Architect/Engineering Fees	\$0	\$0	\$0
Subtotal Miscellaneous Costs	\$38,640	\$12,931	\$51,571
Total Capital Costs	\$38,640	\$47,931	\$86,571

This applicant seeks approval for an increased capital cost to convert examination/treatment rooms to home hemodialysis training rooms and replace non-medical equipment. The original project scope will not change nor will the population to be served; including access by underserved groups.

In Section II.1 and II.4, page 5, the applicant states:

"The original project, Project I.D. Q-10103-13, involved adding two dialysis stations to be utilized as home hemodialysis training and support stations at DC of Martin County. ... The costs of preparing the rooms was [sic] substantially more than the proposed capital expenditure that was identified in the CON."

In Section II.5, page 6, the applicant states, "There was no other way to install the two home hemodialysis stations without increasing the capital expenditure for this project."

In the original application, the applicant adequately demonstrated the need for the home training services; however, the applicant underestimated the capital cost necessary to complete the project. The applicant adequately demonstrates the need for the proposed cost overrun. Consequently, the cost overrun application is conforming to this criterion.

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

NA

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

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The applicant discusses the reasons for the cost overrun in Section II.1. In Section II.5, page 6, the applicant states, "*There was no other way to install the two home hemodialysis stations without increasing the capital expenditure for this project.*"

The applicant adequately demonstrates that the proposed alternative is the most effective and least costly alternative to meet the *previously* identified need for additional stations for home hemodialysis training and support services.

Furthermore, the application is conforming to all other statutory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

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

- Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Martin County shall materially comply with the representations made in Project ID # Q-10103-13 and this certificate of need application, Project ID # Q-10279-14. In those instances in which representations conflict, Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Martin County shall materially comply with the last made representation.
- 2. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Martin County shall comply with all conditions of approval on the certificate of need for Project ID # Q-10103-13, except as specifically modified by the conditions of approval for this application, Project ID # Q-10279-14.

# 3. Total Renal Care of North Carolina, LLC d/b/a Dialysis Care of Martin County shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to the 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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The current CON application is for a cost overrun. The total capital cost is now expected to be \$83,571, an increase of \$44,931 [\$83,571 - \$38,640 = \$44,931] or 116% [\$44,931 / \$38,640 = 116%] of the approved capital cost. See Section VI.12, page 12.

In Section VI.5, page 13, the applicant states the total capital cost of the project will be funded with cash reserves. In Exhibit 3, the applicant provides an April 11, 2014 letter signed by the Vice President of Tax, Davita HealthCare Partners, Inc., which states in part:

"We are submitting an Abridged Certificate of Need Application to renovate our existing ESRD facility in Martin County so that we can complete the two-station expansion of the facility. The project calls for an additional capital expenditure of \$44,931. DaVita Healthcare Partners Inc., Total Renal Care, Inc. and Total Renal Care of North Carolina, L.L.C. have committed cash reserves for this project. We will ensure that these funds are made available for the development and operation of this project."

In Exhibit 4 the applicant provides a copy of the United States Securities and Exchange Commission Form 10-K filed by DaVita Healthcare Partners, Inc., for the fiscal year ending December 31, 2013. Included in Form 10-K are the audited financial statements for the last two full fiscal years. These statements show that as of December 31, 2013, DaVita Healthcare Partners, Inc. had total assets in the amount of \$946,249,000 in cash and cash equivalents, \$17,098,877,000 in total assets and \$4,605,541,000 in total equity (total assets less total liabilities).

In Section VIII.1, page 16, the applicant states, "See Exhibit 5 for a copy of the original CON application Section X. Since the CON application to expand Dialysis Care of Martin County by two stations was submitted in 2013, there have been no changes to the documentation in Section X." [Emphasis in original.] In Project ID # Q-10103-13, the applicant projected that revenues will exceed expenses in the first two years of operation after completion of the project. That application was determined to be conforming to this criterion with regard to the financial feasibility of the proposed addition of two stations. The applicant does not propose any changes that would affect that determination.

In summary, the applicant adequately demonstrates the availability of funds for the increased capital needs of the project. Therefore, the cost overrun 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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In Project ID Q-10103-13, the applicant was approved to add two dialysis stations to the existing DC of Martin County facility for home hemodialysis training and support services. In Project ID Q-10103-13, the application was conforming to this criterion and no changes are proposed in this application that affect that determination. Consequently, the cost overrun 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 Project ID Q-10103-13, the application was conforming to this criterion, and the applicant proposes no changes in the current application that would affect that determination. Consequently, the cost overrun 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 Project ID Q-10103-13, the application was conforming to this criterion, and the applicant proposes no changes in the current application that would affect that determination. Consequently, the cost overrun 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.

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(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.

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- (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.

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- (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 Project ID Q-10103-13, the application was conforming to this criterion, and the applicant proposes no changes in the current application that would affect that determination. Consequently, the cost overrun application is conforming to this criterion.

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

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In Project ID Q-10103-13, the application was conforming to this criterion, and the applicant proposes no changes in the current application that would affect that determination. Consequently, the cost overrun 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 Project ID # Q-10103-13, the application was conforming to this criterion, and the applicant proposes no changes in the current application that would affect that determination. Consequently, the cost overrun 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 Project ID # Q-10103-13, the application was conforming to this criterion, and the applicant proposes no changes in the current application that would affect that determination. Consequently, the cost overrun 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 Project ID # Q-10103-13, the application was conforming to this criterion, and the applicant proposes no changes in the current application that would affect that determination. Consequently, the cost overrun 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.

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Project ID Q-10103-13 was conforming to this criterion, and the applicant proposes no changes in the current application that would affect that determination. Consequently, the cost overrun 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.

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The applicant currently provides dialysis services at DC of Martin County. According to the Licensure and Certification Section, Division of Facility Services, DC of Martin County has operated in compliance with all 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.

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Project ID Q-10103-13 was conforming to the Criteria and Standards for End-Stage Renal Disease Services promulgated in 10A NCAC 14C .2200, and the applicant proposes no changes in the current application that would affect that determination. Consequently, the cost overrun application is conforming to this criterion.