

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: August 1, 2014

PROJECT ANALYST: Mike McKillip

TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: O-10278-14 / Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Wilmington / Cost overrun for Project I.D. # O-8401-09, add 8 dialysis stations and renovate the facility for a total of 29 stations upon completion of the project / New Hanover

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.

CA

On March 23, 2010, Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Wilmington [**SEDC-Wilmington**] received a certificate of need (CON) for Project I.D. # O-8401-09 to renovate the existing facility and add 8 dialysis stations for a total of 29 stations upon completion of the project. The current CON application is for a “cost overrun” of the initial approval. There is no material change in scope from the originally approved project in this application.

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. However, there is one policy in the 2014 SMFP applicable to this review. *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities* states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall

include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, the Certificate of Need Section shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."

The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section IX.5, page 25, the applicant, states, *"The facility expansion will be constructed with energy efficient glass, self-closing doors, and energy efficient cooling and heating systems."* However, the applicant did not include in its certificate of need application a written statement describing the project's plan to assure improved water conservation. Therefore, the application is consistent with Policy GEN-4, and the application is conforming to this criterion, subject to Condition #3 in Criterion (4) of these findings.

- (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

On March 23, 2010, Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Wilmington [**SEDC-Wilmington**] received a certificate of need (CON) for Project I.D. # O-8401-09 to renovate the existing facility and add 8 dialysis stations for a total of 29 stations upon completion of the project. The original project was approved for a capital cost of \$976,104. The current CON application is for a "cost overrun" of the initial approval of \$2,127,660, for a total capital cost of \$3,103,764 for the project. The applicant states there is no material change in scope from the originally approved project in this application.

The following table is from Section VI.1, page 12, and lists the originally approved capital costs, the proposed costs, and the difference between the two that are associated with this cost overrun application.

Project Capital Costs

CATEGORY	PREVIOUSLY APPROVED	PROPOSED IN CURRENT APPLICATION	DIFFERENCE
A. Site Costs	\$0	\$3,600	\$3,600
B. Construction Contract*	\$700,500	\$2,060,000	\$1,359,500
C. Miscellaneous			
Dialysis Machines	\$108,800	\$442,000	\$333,200
Water Treatment Equipment	\$50,000	\$194,800	\$144,800
Equipment/Furniture	\$47,500	\$220,714	\$173,214
Architect/Engineering Fees	\$52,000	\$150,000	\$98,000
Dialysis Chairs/Computers	\$8,904	\$24,250	\$15,346
Televisions	\$8,400	\$12,000	\$3,600
Subtotal miscellaneous costs	\$275,604	\$1,043,764	\$768,160
D. Total Capital Cost	\$976,104	\$3,103,764	\$2,127,660

*Construction contract includes site costs.

As shown in the capital costs table provided in Section VI.1, page 12, the cost overrun is largely due to increased construction costs, equipment and furniture costs, and architect/engineering fees. In Section I.9, page 2, the applicant describes the reason for the cost overrun as follows:

“Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Wilmington is submitting an abridged application for Project I.D. No. O-8401-09. This project involved the complete renovation of the Wilmington facility. At one time Total Renal Care of North Carolina considered a temporary relocation of the facility so that the renovation project could be completed quicker. As the project progressed, the costs of the renovation soared, in part, because the first project manager did not account for much of the renovation work that needed to be done. Another factor was that the project had to be done at night and on weekends due to the facility continuing to operate.”

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

“The original project, Project I.D. No. O-8401-09, involved adding eight stations and the renovation of the Southeastern Dialysis Center-Wilmington located in New Hanover County. The Certificate of Need Application was submitted based on a facility based need determination. Since receipt of the Certificate of Need all of the stations have been certified. ... The original Da Vita project manager working with an architect, did not take into consideration all of the renovation work that needed to be done. When a new project manager was assigned to the project, he identified significant additional work that needed to be completed to fully renovate the facility.

...The costs of the renovation project were severely understated. TRC is not identifying any changes in the project, but is requesting approval for the additional capital expenses for the complete renovation of the Wilmington facility.”

The applicant adequately demonstrates the need for the proposed cost overrun. Consequently, the application is conforming to this criterion.

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

NA

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

CA

In Section III.5, pages 6, the applicant states that it is not proposing any changes to the previously approved project, but is seeking approval only for the additional capital expenses. 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 the proposal is the least costly or most effective alternative to meet the identified 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 Southeastern Dialysis Center-Wilmington shall comply with all conditions of approval on the certificate of need for Project I.D. #O-8401-09, except as specifically modified by the conditions of approval for this application, Project I.D. #O-10278-14.**
- 2. The total combined capital expenditure for both projects shall be \$3,103,764.**
- 3. Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Wilmington shall provide a written statement describing the project’s plan to assure improved water conservation.**
- 4. Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Wilmington shall not acquire, as part of this project, any equipment that is not included in the project’s proposed capital expenditure in Section VIII of the application and that would otherwise require a certificate of need.**

5. Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Wilmington shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.

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

C

On March 23, 2010, SEDC-Wilmington received a certificate of need for Project I.D. # O-8401-09 to renovate the existing facility and add 8 dialysis stations for a total of 29 stations for a total capital cost of \$976,104. This CON application is for a cost overrun of the initial approval of \$2,127,660, for a total capital cost of \$3,103,764 for the project. In Section VI.1, page 13, the applicant states the additional capital cost of \$2,127,660 will be financed with cash reserves of the applicant. In Section VII.1, page 15, the applicant projects no start-up expenses or initial operating expenses.

Exhibit 3 contains a letter dated April 11, 2014, from the Vice President of Tax for DaVita HealthCare Partners, Inc., the parent company of SEDC-Wilmington, which states:

“I am the Vice President of Tax of DaVita HealthCare Partners, Inc., the parent and 100% owner of Total Renal Care, Inc. I also serve as the Vice President of Tax of Total Renal Care, Inc., which owns 85% of the ownership interests in Total Renal Care of North Carolina, LLC.

We are submitting an Abridged Certificate of Need Application to renovate our existing ESRD facility in New Hanover County so that we can complete the renovation and eight-station expansion of the facility. The project calls for an additional capital expenditure of \$2,127,660. 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.”

Exhibit 4 contains the United States SEC Form 10-K filed by DaVita HealthCare Partners, Inc. for the year ended December 31, 2013. As of December 31, 2013, the consolidated financial statements show the company had \$602 million in cash and cash equivalents. The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

In Exhibit 6, the applicant provided updated revenue projections (Application Section X.2) and expense projections (Application Section X.4), which are summarized below:

	Operating Year 1	Operating Year 2
Total Net Revenue	\$10,628,716	\$11,106,297
Total Operating Costs	\$7,908,661	\$8,223,448
Profit (Loss)	\$2,720,055	\$2,882,849

The applicant projects that revenue will exceed operating expenses in each of the first two operating years. The assumptions used in preparation of the pro forma financial statements, including the number of projected treatments, are reasonable.

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

C

In Project I.D. #O-8401-09, the application was found conforming to this criterion, and the applicant was approved to renovate the existing dialysis facility, SEDC-Wilmington, and add eight dialysis stations for a total 29 stations upon completion. The applicant proposes no changes in the current application that would affect that determination. Consequently, 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.

C

In Project I.D. #O-8401-09, the application was found conforming to this criterion, and the applicant was approved to renovate the existing dialysis facility, SEDC-Wilmington, and add eight dialysis stations for a total 29 stations upon completion. The applicant proposes no changes in the current application that would affect that determination. Consequently, 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.

C

In Project I.D. #O-8401-09, the application was found conforming to this criterion, and the applicant was approved to renovate the existing dialysis facility, SEDC-Wilmington, and add

eight dialysis stations for a total 29 stations upon completion. The applicant proposes no changes in the current application that would affect that determination. Consequently, 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

The applicant proposes to renovate the existing facility. No additional construction is proposed.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs

identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Project I.D. #O-8401-09, the application was found conforming to this criterion. The applicant proposes no changes in the current application that would affect that determination. Consequently, 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;

C

In Project I.D. #O-8401-09, the application was found conforming to this criterion. The applicant proposes no changes in the current application that would affect that determination. Consequently, the application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section IV.6, page 9, the applicant provides the projected payor mix for the proposed services at SEDC-Wilmington, which is shown below:

SEDC-Wilmington In-Center Patients	
Source of Payment	Percentage
Medicare	16.2%
Medicaid	4.9%
Medicare/Medicaid	26.5%
Medicare/Commercial	33.3%
Commercial Insurance	14.7%

Veterans Administration	4.4%
Total	100.0%

The applicant projects no change from the current payor mix for in-center dialysis services, which indicates that 80.9% of patients have some or all of their services covered by Medicare and/or Medicaid. The applicant demonstrates that medically underserved populations would have adequate access to the proposed services. 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 Project I.D. #O-8401-09, the application was found conforming to this criterion. The applicant proposes no changes in the current application that would affect that determination. Consequently, 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 Project I.D. #O-8401-09, the application was found conforming to this criterion. The applicant proposes no changes in the current application that would affect that determination. Consequently, 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

In Project I.D. #O-8401-09, the application was found conforming to this criterion. The applicant proposes no changes in the current application that would affect that determination. Consequently, 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 files of the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, SEDC-Wilmington 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

In Project I.D. #O-8401-09, the application was found conforming with all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The applicant proposes no changes in the current application that would affect that determination. Consequently, the application is conforming to this criterion.