

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: October 19, 2012  
PROJECT ANALYST: Celia C. Inman  
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: Project I.D. #O-10020-12/ Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center -Burgaw/ Cost Overrun on Project ID #O-8579-10 (Add 2 dialysis stations to the existing facility for a total of 22 stations upon completion of this project)/ Pender 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 2012 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations in the 2012 SMFP that are applicable to this review. Furthermore, there are no policies in the 2012 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- (2) Repealed effective July 1, 1987.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.

C

Effective March 28, 2011, Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Burgaw (SEDC-Burgaw) was issued a Certificate of Need (CON) for Project ID #O-8579-10, to add two dialysis stations to the existing facility in Pender County for a total of 22 stations upon project completion. The original project was approved for a capital cost of \$72,400. The project was scheduled to be certified by July 1, 2011. The current CON application is for a “Cost Overrun” of the initial approval.

Population to be Served

In Section III.7, page 19 of its original application, Project ID #O-8579-10, the applicant states the population to be served and provides the projected patient origin.

**SEDC- Burgaw -Projected Patient Origin**

COUNTY	YEAR ONE: 2011/2012		YEAR TWO: 2012/2013		COUNTY PATIENTS AS A PERCENT OF TOTAL	
	In-center Patients	Home Dialysis Patients	In-center Patients	Home Dialysis Patients	Year 1	Year 2
Pender	71	0	76	0	91.0%	91.6%
New Hanover	5	0	5	0	6.4%	6.0%
Duplin	2	0	2	0	2.6%	2.4%
TOTAL	78	0	83	0	100.0%	100.0%

Source: Pender/O-8579-10 Southeastern Dialysis Center-Burgaw Findings

The applicant adequately identified the population to be served.

Demonstration of Need

This application for a cost overrun seeks only approval for increased capital cost of the project, related to additional square footage and replacement of depreciated non-medical equipment. The original project scope will not be changed.

In Section II.1 of the application, the applicant states:

*“In attempting to develop a plan for adding the two stations to the facility, we found that there was not enough treatment floor space to adequately add the two stations. In order to install the stations we need to expand the treatment floor space. We will need to add square footage to the existing treatment floor by building an expansion to the building.”* In Section VI.2, on page 12, the applicant clarifies the amount of the expansion, *“Total Renal Care of North Carolina, LLC will be building a shell space addition of 832 sq.ft. for [sic] to be used as treatment floor space for the new stations.”* In Section VI, on page 13, the applicant is proposing an increase of \$412,238 to the previously approved capital cost of \$72,400. In addition to adding floor space, the applicant proposes replacement of the RO (water treatment equipment) system and other items in

the facility that have been completely depreciated and are in need of replacement.

The following table shows the previously approved capital cost, the proposed capital cost in the Cost Overrun CON as submitted by the applicant on page 13 of the application, and the total project capital cost at completion of the project.

**Previously Approved and Proposed Capital Costs**

	Previously Approved CON Cost	Proposed Cost Overrun CON	Total Cost After Cost Overrun Addition
<b>Construction Costs</b>	<b>\$36,000</b>	<b>\$214,000</b>	<b>\$250,000</b>
<b>Miscellaneous Costs</b>			
Dialysis Machines	\$27,600	\$0	\$27,600
(RO) Water Treatment Equipment	\$0	\$95,000	\$95,000
Equipment/Furniture	\$1,200	\$40,570	\$41,770
Other: Dialysis Chairs	\$1,600	\$0	\$1,600
Televisions	\$4,000	\$14,610	\$18,610
Chair Side Computer Terminals	\$2,000	\$8,058	\$10,058
Architect/Engineering Fees	\$0	\$40,000	\$40,000
<b>Subtotal Miscellaneous Costs</b>	<b>\$36,400</b>	<b>\$198,238</b>	<b>\$234,638</b>
<b>Total Capital Cost</b>	<b>\$72,400</b>	<b>\$412,238</b>	<b>\$484,638</b>

The total capital cost of the project is \$484,638 with the increase of the cost overrun being \$412,238. The increase in total capital cost is 569% [(\$484,638/ \$72,400) – 1 = 5.693].

The applicant does not propose any additional medical equipment. In Section I.9, the applicant states:

*“Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Burgaw is submitting an abridged application for Project I.D. No. O-8579-10. It has been determined that in order to install the two station expansion we will need to build an addition to the existing facility. It was thought as [sic] the time we submitted the original CON application that we could install the stations in the building as it now exists. However, when we reviewed the facility after being awarded the CON, we found that this was not the case.”*

As shown in the table above, the major items which have caused the cost overrun include construction costs, architect and engineering fees, RO water treatment equipment and additional furniture and non-medical equipment. In Section II.4, the applicant states:

*“The need for the new stations as documented in the original CON Application continues to exist in the proposed service area. There has been an increase in the patient population to be served by the new stations. Please refer to Section III of Project ID # O-8579-10.”*

The applicant adequately demonstrates the need for the proposed cost overrun.

### Equal Access

In Section IV.2, page 9, the applicant states:

*“Southeastern Dialysis Center – Burgaw will continue to provide equal access to all patients, including low income persons, racial and ethnic minorities, women, handicapped persons, elderly patients and other underserved persons which includes the medically indigent.”*

In Project ID #O-8579-10, the application was conforming to this Criterion, and the applicant proposes no changes in the current application that would affect that determination. The applicant adequately identified the population to be served, the need the population has for the services and the likelihood that all residents of the area, including underserved groups will have access. Consequently, the application is conforming to this criterion.

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

NA

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

CA

The applicant discusses the reasons for the cost overrun in Section II.1. In Section II.5, page 6, the applicant discusses the absence of an alternative solution to this application, *“The only other alternative is to turn in the two stations which would harm the ability of the facility to adequately meet the need for all the patients presently being served and the ability to serve patients in the future.”*

The applicant adequately demonstrates that the proposed alternative is the most effective and least costly alternative to meeting its facility’s need for additional stations.

Furthermore, the application is conforming to all other statutory and regulatory 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 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-Burgaw shall materially comply with the representations made in Project ID #O-8579-10 and this certificate of need application, Project ID #O-10020-12. In those instances in which representations conflict, Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Burgaw shall materially comply with the last made representation.**
  - 2. Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Burgaw shall comply with all conditions of approval on the certificate of need for Project ID #O-8579-10, except as specifically modified by the conditions of approval for this application, Project ID #O-10020-12.**
  - 3. Total Renal Care of North Carolina, LLC d/b/a Southeastern Dialysis Center-Burgaw 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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With the addition of the cost overrun proposed in this application, the applicant projects the additional project capital cost to be \$412,238 upon completion. See Criterion (3) for specific changes in the costs by category. In Section VI.5, page 14, the applicant states the total capital cost of the project will be funded with the cash reserves of Total Renal Care of North Carolina, LLC. In Exhibit 3, the applicant provides an August 15, 2012 letter signed by the Vice President and Chief Accounting Officer of Total Renal Care of North Carolina, LLC, which states in part:

*“We are submitting an Abridged Certificate of need Application to renovate and construct an expansion [sic] our existing ESRD facility in Pender County. The project calls for an additional capital expenditure of \$412,238. DaVita 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 for the fiscal year ending December 31, 2011. Included in Form 10-K are the audited financial statements for the last three full fiscal years. These statements show that as of December 31, 2011, DaVita, Inc. had total assets in the amount of \$8,892,172,000, and current assets in the amount of \$2,281,608,000. Further, the statements show that DaVita, Inc. had cash and cash equivalents in the amount of \$393,752,000 as of the same date.

In Section VIII.1, pages 18 and 19, the applicant provides the same allowable charge per treatment for each payment source as presented in the original CON. The applicant also states, "*Medicaid reimbursement for dialysis services is \$136.00 per treatment at the time the original application was submitted.*" The applicant projects no changes in operating costs as a result of this cost overrun application and states on page 21, "*See Section X. of the original CON application.*"

In Section X, page 46 of the original application, Project ID # O-8579-10, the applicant projects revenues will exceed expenses in the first two years of operation after completion of the project. The rates in Section X.1, page 43 of the original application, are consistent with the standard Medicare/Medicaid rates established by the Center for Medicare and Medicaid Services.

In summary, the applicant adequately demonstrates the availability of funds for the capital needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable assumptions regarding 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

The applicant proposes to add two dialysis stations to the existing SEDC-Burgaw facility for a total of 22 dialysis stations upon completion of this project. In Project ID #O-8579-10, the application was conforming to this criterion and no changes are proposed in this application that affects 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 Section V.1, page 11 of the application, the applicant states, "*All of these issues were responded to in our original certificate of need application.*" In Project ID #O-8579-10, the application was conforming to this Criterion, and 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 ID #O-8579-10, the application was conforming to this Criterion, and 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.

C

In the original application, Project ID #O-8579-10, this criterion was not applicable. At that time, the applicant believed the two additional stations could be added to the existing floor plan with only minor renovation to allow installation of the stations. In Section II.1, the applicant states:

*“In attempting to develop a plan for adding the two stations to the facility, we found that there was not enough treatment floor space to adequately add the two stations. In order to install the stations we need to expand the treatment floor space. We will need to add square footage to the existing treatment floor by building an expansion to the building.”*

The applicant states in Section VI.2, page 12, *“Total Renal Care of North Carolina, LLC will be building a shell space addition of 832 sq. ft. for [sic] to be used as treatment floor space for the new stations.”* A floor plan is provided in Exhibit 5.

In Section IX.5, page 26, the applicant states, *“The facility expansion will be constructed with energy efficient glass, self-closing doors, and energy efficient cooling and heating systems.”* The cost of the project, including the cost overrun, is \$582.50 (\$484,638/832) per square foot of additional floor space and \$56.24 (\$484,638/8618) per total square foot in the facility. Costs and charges to the public remain unchanged from the original application in Project ID #O-8579-10.

In response to Section II.5, the applicant states, *“The only other alternative is to turn in the two stations which would harm the ability of the facility to adequately meet the need for all the patients presently being served and the ability to serve patients in the future.”*

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative and that the construction costs will not unduly increase the costs of the proposed services. Therefore, the applicant is conforming to this criterion.

- (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 ID #O-8579-10, the application was conforming to this Criterion, and 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 ID # O-8579-10, the application was conforming to this Criterion, and 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

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Following is a table from page 10 of the application that illustrates projected payor mix for the facility:

PAYOR SOURCE	PERCENTAGE
Medicare	20.0%
Medicaid	0.0%
Commercial Insurance	4.6%
Medicare/Commercial	33.9%
Medicare/Medicaid	36.9%
Self-Pay/Indigent/Charity Care	1.5%
VA	3.1%
<b>Total</b>	<b>100.0%</b>

In Section IV.2, page 9, the applicant states:

*“Southeastern Dialysis Center – Burgaw will continue to provide equal access to all patients, including low income persons, racial and ethnic minorities, women, handicapped persons, elderly patients and other underserved persons which includes the medically indigent.”*

The applicant also states that SEDC-Burgaw maintains an open-door policy of accepting all patients with ESRD, regardless of ability to pay. In Project ID # O-8579-10, the application was conforming to this Criterion, and the applicant proposes

no changes in the current application that would affect that determination. Consequently, the application is conforming to this Criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

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In Section IV.5, page 9 of the application, the applicant states:

*“Patients with ESRD will have access to dialysis services by referral. The referrals most commonly come from primary care physicians or specialty physicians in Pender County or transfer from other Nephrologists outside of the immediate area. Should a patient contact Southeastern Dialysis Center – Burgaw directly or indirectly, the patient would be referred to a qualified Nephrologist for evaluation and subsequent admission to the facility when medically necessary.”*

The applicant adequately demonstrated the means by which patients have access to its services. 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 ID # O-8579-10, the application was conforming to this Criterion, and 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.

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The applicant proposes to add floor space to implement the previously approved addition of the two dialysis stations to the existing facility in Pender County for a total of 22 stations upon project completion. Project ID #O-8579-10 was conforming to this Criterion, and 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

The applicant currently provides dialysis services at SEDC-Burgaw. Dialysis Facility Compare, a federal government website managed by the Centers for Medicare & Medicaid Services, accessed on October 2, 2012, indicates the applicant meets measured quality standards. According to the Licensure and Certification Section, Division of Facility Services, SEDC-Burgaw 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.

NA