

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: March 30, 2016

Findings Date: March 30, 2016

Project Analyst: Tanya S. Rupp

Assistant Chief: Martha J. Frisone

Project ID #: F-11119-16

Facility: Huntersville Dialysis

FID #: 130490

County: Mecklenburg

Applicant(s): DVA Healthcare Renal Care, Inc.

Project: Cost overrun for Project ID #F-10219-13 (Develop a new 10 station dialysis facility in Huntersville)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Agency 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

DVA Healthcare Renal Care, Inc. d/b/a Huntersville Dialysis (“the applicant”) proposes a cost overrun for Project ID #F-10219-13 which authorized the applicant to relocate ten existing dialysis stations from North Charlotte Dialysis Center and to develop a new 10-station dialysis facility in Huntersville. The certificate of need (CON) for Project ID #-F-10219-13 authorized a capital cost of \$1,983,114. As a result of the time needed to review this application, the applicant projects a four month delay in the original date for the proposed occupancy or offering of services. There is no material change in scope from the originally approved project in this application.

Need Determination

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 2016 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations in the 2016 SMFP that are applicable to this review.

Policies

Policy GEN-3: BASIC PRINCIPLES on page 39 of the 2016 SMFP is not applicable to this review and was not applicable in the original review. Policy ESRD 2: RELOCATION OF DIALYSIS STATIONS on page 33 of the 2016 SMFP was applicable in Project ID #F-10219-13 because the applicant proposed to relocate 10 existing dialysis stations to develop the proposed facility. The application was consistent with Policy ESRD-2 in Project ID #F-10219-13, and the applicant proposes no changes in the current application that would affect that determination. There are no other policies in the 2016 SMFP that are applicable to this review.

Conclusion

In summary, the applicant was previously approved to relocate ten existing dialysis stations from North Charlotte Dialysis Center to develop a new 10-station dialysis facility in Huntersville. In Project I.D. # F-10219-13, the application was conforming to this Criterion. The applicant proposes no changes in the current application that would affect that determination. 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 April 29, 2014, Total Renal Care of North Carolina, Inc. d/b/a Huntersville Dialysis was awarded a certificate of need (CON) for Project ID #F-10219-13 which authorized the applicant to relocate ten existing dialysis stations from North Charlotte Dialysis Center and to develop a new 10-station dialysis facility in Huntersville in Mecklenburg County. The original project was approved for a capital cost of \$1,983,114. The facility was projected to be certified by January 1, 2016.

The current application is for a cost overrun. In Section F.1, page 23, the applicant states the total capital cost for the project is now expected to be \$2,703,908, which is an increase of \$720,794, or 136% of the originally approved capital cost [$\$2,703,908 - \$1,983,114 = \$720,794$; $\$2,703,908 / \$1,983,114 = 1.363$]. The facility is now projected to be certified in April 2016, which reflects the time needed to review this application.

Analysis of Need

The following table compares the previously approved capital cost and the proposed capital cost in this application, as reported on pages 39-40.

HUNTERSVILLE DIALYSIS CENTER CAPITAL COST			
ITEM	PREVIOUSLY APPROVED COST	TOTAL PROPOSED COST	DIFFERENCE
Construction Contract			
Cost of Materials	\$ 777,614	\$1,011,000	\$233,386
Labor	\$ 18,410	\$ 674,000	\$155,590
Other*	\$ 19,700	\$ 19,700	\$ 0
Subtotal Construction Contract	\$1,315,724	\$1,704,700	\$388,976
Miscellaneous Project Costs			
Dialysis Machines	\$ 131,700	\$ 150,000	\$ 18,300
(RO) Water Treatment Equipment	\$ 90,000	\$ 193,125	\$103,125
Other Equipment/Furniture	\$ 222,187	\$ 400,730	\$178,543
Architect/Engineering Fees	\$ 134,100	\$ 134,100	\$ 0
Other**	\$ 89,403	\$ 121,253	\$ 31,850
Subtotal Miscellaneous Project Costs	\$ 667,390	\$ 999,208	\$331,818
Total Capital Costs	\$1,983,114	\$2,703,908	\$720,794

*Defined in Project ID #F-10219-13 as "tap fees".

**Defined in Project ID #F-10219-13 as follows: "dialysis chairs: \$17,270; Scale: \$7,983; Television System: \$28,500; Patient Computer System: \$35,650."

The applicant seeks approval of an increase in capital cost that is more than 115% of the originally approved capital cost. In Section C.14, page 17, the applicant states the increased capital cost is due to increasing construction costs in materials and labor and miscellaneous project costs related to dialysis equipment as shown in the table above. The original project scope, the population to be served and access by underserved groups will not change as a result of this application.

Conclusion

In the original application, the applicant adequately identified the population to be served, adequately demonstrated the need to relocate existing stations from North Charlotte Dialysis Center to develop Huntersville Dialysis Center and the extent to which all residents of the service area, including underserved groups, are likely to have access to its services. However, the applicant underestimated the capital cost necessary to complete the project. In this application, 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.

CA

In Section E, page 21, the applicant states the only alternative considered prior to submitting this application was to do nothing. The applicant states the development of the project as approved in Project ID #F-10219-13 requires the additional capital cost presented in this application, and the increases in the capital costs were not anticipated in October 2015 when the construction began.

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 this proposal is the least costly or most effective alternative to meet the identified need. Therefore, the cost overrun application is conforming to this criterion and approved subject to the following conditions:

- 1. DVA Healthcare Renal Care, Inc. d/b/a Huntersville Dialysis shall materially comply with all conditions of approval on the certificate of need for Project I.D. # F-10219-13 except as specifically modified by the conditions of approval for this application, F-11119-16.**
 - 2. The total approved capital expenditure for Project I.D. # F-10219-13 and Project I.D. # F-11119-16 is \$2,703,908.**
 - 3. DVA Healthcare Renal Care, Inc. d/b/a Huntersville Dialysis shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VI of the application and that would otherwise require a certificate of need.**
 - 4. Prior to issuance of the certificate of need, DVA Healthcare Renal Care, Inc. d/b/a Huntersville Dialysis shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and 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

The proposed project is for a cost overrun for Project I.D. # F-10219-13. The total capital cost is now expected to be \$2,703,908, which is an increase of \$720,794 [$\$2,703,908 - \$1,983,114 = \$720,794$, or 136% of the approved capital cost [$\$2,703,908 / \$1,983,114 = 1.363$]. See Section F.1, page 23.

Availability of Funds

In Section F.2, page 24, the applicant states the total capital cost of the project will be funded with accumulated cash reserves. In Exhibit F, the applicant provides a January 14, 2015 letter signed by the Chief Accounting Officer for DaVita, which confirms the availability of the funds necessary to complete the project and commits those funds to the development of the project.

In Exhibit F5, the applicant also provides the audited financial statements for DaVita Healthcare Partners, Inc., the parent company for DaVita Healthcare Renal Care, Inc. for the years ending December 31, 2013 and December 31, 2014. As of December 31, 2014, DaVita Healthcare Partners, Inc. had \$965,241,000 cash and cash equivalents, \$17,942,715,000 in total assets and \$6,190,276,000 in net assets (total assets less total liabilities).

Financial Feasibility

In the original application, Project I.D. # F-10219-13, the applicant projected that operating expenses would exceed revenues in each of the first two years of the project, as illustrated in the table below.

	OPERATING YEAR 1 (CY 2016)	OPERATING YEAR 2 (CY 2017)
Total Net Revenue	\$1,965,500	\$2,117,483
Total Operating Costs	\$1,748,420	\$1,843,762
Net Profit	\$217,080	\$273,721

*Source: Project ID #F-10219-13, page 60, and Section R.4, page 60, of this application.

In Section R, pages 57 – 62, the applicant provides copies of the original pro forma forms submitted in Project ID #F-10219-13. In Section F, pages 27 – 29, the applicant provides copies of the original assumptions submitted in Project ID #F-10219-13. In Section F.15, pages 27 – 28, the applicant states this application proposes no changes to the charges, estimated operating costs, revenues and expenses from the originally approved application.

The original application was determined to be conforming to this criterion with regard to the proposal. In the current application, the applicant does not propose any changes that would affect that determination.

Conclusion

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.

C

In Project I.D. # F-10219-13, the applicant was approved to relocate 10 existing dialysis stations from North Charlotte Dialysis Center to develop Huntersville Dialysis. The current application is for a cost overrun. In Project I.D. # F-10219-13, 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.

C

In Project I.D. # F-10219-13, the applicant proposed to employ a total of 9.4 full-time equivalent (FTE) positions at Huntersville Dialysis upon completion of the proposed project. The applicant does not propose any additional staff in this application. In Project I.D. # F-10219-13, 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.

C

In Project I.D. # F-10219-13, 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.

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

The current application is for a cost overrun. In Section F.1, page 23, the applicant states the total capital cost for the project is now expected to be \$2,703,908, which is an increase of \$720,794, or 136% of the originally approved capital cost [$\$2,703,908 - \$1,983,114 = \$720,794$; $\$2,703,908 / \$1,983,114 = 1.363$].

The following table compares the previously approved capital cost and the proposed capital cost in this application, as reported on pages 39-40.

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In Section C.14, page 17, the applicant states the increased capital cost is due to increasing construction costs in materials and labor and miscellaneous project costs related to dialysis equipment as shown in the table above. The cost overrun application 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 I.D. # F-10219-13, 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;

C

In Project I.D. # F-10219-13, 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

C

In Project I.D. # F-10219-13, 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.

C

In Project I.D. # F-10219-13, 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.

C

In Project I.D. # F-10219-13, 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.

C

In Project I.D. # F-10219-13, the applicant was approved to relocate 10 existing dialysis stations from North Charlotte Dialysis Center to develop Huntersville Dialysis. The current application is for a cost overrun. In Project I.D. # F-10219-13, 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

- (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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In Exhibit F-8, the applicant identifies the 67 kidney disease treatment centers located in North Carolina owned and operated by the applicant or an affiliated company. In Exhibit O-4, the applicant identifies two of its North Carolina facilities, Dialysis Care of Edgecombe County and Dialysis Care of Rowan County, that were cited in the past 18 months for deficiencies in compliance with 42 CFR Part 494, the Centers for Medicare and Medicaid (CMS) Conditions for Coverage of ESRD facilities. In Exhibit O-4, the applicant provides documentation that confirms that both facilities are back in full compliance with CMS Guidelines as of the date of submission of this application. Based on a review of the certificate of need application and publicly available data, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. 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

Project I.D. # F-10219-13 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.