

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: October 17, 2012

PROJECT ANALYST: Kim Randolph
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: K-10019-12/ DVA Healthcare Renal Care, Inc. d/b/a Henderson Dialysis Center/ Cost overrun for Project I.D. #K-8574-10 (Add six dialysis stations to the existing facility for a total of 49 dialysis stations)/ Vance 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, DVA Healthcare Renal Care, Inc. d/b/a Henderson Dialysis Center operates 43 certified dialysis stations and is located at 854 South Beckford Drive in Henderson. Effective April 12, 2012, the applicant was issued a Certificate of Need (CON) for Project I.D. #K-8574-10 to add six dialysis stations, for a total of 49 certified dialysis stations, at a total capital cost of \$150,800. The applicant submits this current application, Project I.D. #K-10019-12, to request approval for a cost overrun.

The applicant does not propose to increase the number of dialysis stations, 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,

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there are no policies in the 2012 SMFP that are applicable to this review. Consequently, 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- (2) Repealed effective July 1, 1987.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 12, 2012, DVA Healthcare Renal Care, Inc. d/b/a Henderson Dialysis Center was issued a Certificate of Need (CON) for the original application, Project I.D. #K-8574-10, to add six dialysis stations to the existing facility in Vance County for a total of 49 certified dialysis stations upon project completion. The approved capital expenditure for the original project is \$150,800. This current application, Project I.D. #K-10019-12, seeks approval for a cost overrun of \$42,363, which results in a total capital expenditure of \$193,163 for the entire project. [\$150,800 + \$42,363= \$193,163]

In Section VI.4, page 14, the applicant compares the previously approved capital costs with the proposed capital costs. The proposed increase in total capital costs is shown in the table below.

	<i>Previously Approved</i>	<i>Proposed</i>	<i>Increase</i>
Construction Costs			
Cost of Material	\$0	\$25,418	\$25,418
Cost of Labor	\$0	\$16,945	\$16,945
Subtotal Construction Costs	\$0	\$42,363	\$42,363
Miscellaneous Project Costs			
Dialysis Machines	\$82,800	\$82,800	\$0
(RO) Water Treatment Equipment	\$30,000	\$30,000	\$0
Equipment/Furniture not included above	\$13,200	\$13,200	\$0
Dialysis Chairs	\$ 4,800	\$ 4,800	\$0
Chair Side Computer Terminal	\$ 8,000	\$ 8,000	\$0
Televisions	\$12,000	\$12,000	\$0
Subtotal Miscellaneous Costs	\$150,800	\$150,800	\$0
Total Capital Costs	\$150,800	\$193,163	\$42,363

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In Section II, pages 5-6, the applicant states the scope of the project and the square feet of the facility have not changed. However, the capital cost for the project will exceed 115 percent of the approved capital cost. The proposed increase in total capital costs of the project is 28 percent more than the approved capital cost [$\$42,363 \div \$150,800 = .28092$]. In Section IX, pages 30-32 and through supplemental information, the applicant indicates that capital costs will be exceeded for the following reasons:

- The addition of the six dialysis stations was delayed due to a Certificate of Need (CON) denial based on an unfavorable facility survey. The resulting Settlement Agreement required an 18 month period, starting July 16, 2010 and ending January 16, 2012, in which DVA Healthcare Renal Care, Inc. d/b/a Henderson Dialysis Center had to remain in compliance with all Medicare Conditions of Participation before the CON would be issued for the original application, Project I.D. #K-8574-10.
- The applicant stated that after the implementation delay of the original application, it recalculated the square footage needed to install the additional six dialysis stations and determined additional space was needed. The applicant projects 9,529 square feet for the dialysis stations rather than the original 9,309 square feet, a difference of 220 square feet [$9,529 - 9,309 = 220$]. (Note: The total square footage of the existing facility has not changed. The additional 220 square feet added to the dialysis stations is deducted from the “Other” Lab/I.W. area as indicated in Section IX.3, page 30 [$1,663 - 220 = 1,443$]).
- The project construction costs have increased since the original CON application was submitted almost two years ago.

Population to be Served

In Section II.4, page 5, the applicant references Section III of the original application and indicates the population to be served has not changed. In Section III of the original application, the applicant projected 80 percent of its patient population will come from Vance County, with the other 20 percent of its patients coming from surrounding counties in the first year. In Section IV.5, page 10, of the current application, the applicant indicates end-stage renal disease (ESRD) patients are treated by referrals from primary care and specialty physicians in Vance County or transfers from other Nephrologists outside the immediate area. The applicant adequately identified the population to be served.

Demonstration of Need

This cost overrun application seeks approval for the increased capital construction costs related to meeting the additional square footage requirements of the previously approved six dialysis stations.

The applicant submitted its original application in September 2010 based on the facility based need methodology for dialysis stations. The applicant indicates the assumptions and methodology used to project utilization were provided in the original application and the applicant states utilization projections have not changed, as stated in Section III, page 7, of the current application. In Section II.4, page 5, the applicant indicates the need for the proposed dialysis facility has increased since the original application was filed, based on the projected increase in patient population to be served as discussed in Section III of the original application. Additionally, according to the non-residential construction data from the Bureau of Labor Statics, queried October 5, 2012, construction costs have been increasing since 2010. The applicant adequately demonstrated the need for the project and justifies the proposed additional costs.

Equal Access

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

Henderson Dialysis Center 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. Henderson Dialysis Center makes every effort to accommodate its patients, particularly those patients with special needs.

The original application, Project I.D. #K-8574-10, was conforming to this criterion and the applicant proposes no changes in this current application to affect that determination. The applicant adequately identified the population to be served, demonstrated the need for the proposed services, and commits to equal access for all patients, including underserved groups. Therefore, the application is conforming to this criterion.

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

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 II.5, page 6, the applicant indicates that the description of the alternatives considered was explained in the original application. The only purpose of this cost overrun application is to obtain approval for the increased capital costs for installing the previously approved six dialysis stations.

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

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

- 1. DVA Healthcare Renal Care, Inc. d/b/a Henderson Dialysis Center shall materially comply with all representations made in Project I.D. #K-8574-10 and Project I.D. #K-10019-12. In those instances in which representations conflict, DVA Healthcare Renal Care, Inc. d/b/a Henderson Dialysis Center shall materially comply with the last made representation.**
 - 2. DVA Healthcare Renal Care, Inc. d/b/a Henderson Dialysis Center shall not acquire, as part of this project or as part of the original project (Project I.D. #K-8547-10), any equipment that is not included in either projects' proposed capital expenditure in Section VI of the application or that would otherwise require a certificate of need.**
 - 3. DVA Healthcare Renal Care, Inc. d/b/a Henderson Dialysis Center 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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In the original application, Project I.D. #K-8574-10, the applicant was approved for a total capital expenditure of \$150,800. As a result of unanticipated increases in the cost of construction, the applicant proposes an increase in capital costs of \$42,363, which results in a total project capital expenditure of \$193,163 [$\$150,800 + 42,363 = \$193,163$]. See

Criterion (3) for additional discussion which is hereby incorporated by reference as if fully set forth herein. In the original project, the applicant stated there would be no start up or initial operating expenses associated with the project and proposed to finance the project with cash reserves from DaVita Inc., the parent company of DVA Healthcare Renal Care, Inc. In Section VII, page 18, of the current application, the applicant does not indicate any start up or initial operating expenses and proposes to finance the capital costs of the project with the cash reserves from DaVita, Inc. Exhibit 3 contains a letter dated August 15, 2012, signed by the Chief Accounting Officer for DaVita, which states in part:

“The project calls for an additional capital expenditure of \$42,363. DaVita Inc. and DVA Healthcare Renal Care, Inc. 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 Securities and Exchange Commission Form 10-K, audited financial statements for DaVita, Inc. As of December 31, 2011, DaVita had \$393,752,000 in cash and cash equivalents, \$17,399,000 in short term investments, \$8,892,172,000 in total assets and \$2,746,341,000 in net assets [$\$8,892,712,000$ assets – $\$6,145,831,000$ liabilities = $\$2,746,341,000$ net assets].

The applicant did not provide revised pro formas for the project. Instead, in Section VIII.4, page 24, the applicant refers to the per diem operating costs proposed in the original application, Project I.D. #K-8574-10. In Section VIII.1, page 21, of the current application, the applicant provides the same allowable charge per treatment for each source of payment as presented in the original application. In Section VIII.3, page 23, of the current application, the applicant states, *“Medicaid reimbursement for dialysis services is \$136 per Treatment at the time the original application was submitted.”*

In the original application, the applicant projected net revenues in Section X.1, and operating expenses in Section X.4, with revenues exceeding expenses in each of the first two operating years after completion of the project.

In summary, the applicant adequately demonstrated the availability of funds for the capital needs of the project. Further, the applicant adequately demonstrated that the financial feasibility of the original proposal was based on reasonable assumptions regarding revenues and operating costs. The applicant proposes no changes in this current application to affect that determination. 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.

The original application, Project I.D. #K-8574-10, was conforming to this criterion and the applicant proposes no changes in this current application to affect that determination. Therefore, the application is conforming to this criterion.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

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The original application, Project I.D. #K-8574-10, was conforming to this criterion and the applicant proposes no changes in this current application to affect that determination. Therefore, 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.

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The original application, Project I.D. #K-8574-10, was conforming to this criterion and the applicant proposes no changes in this current application to affect that determination. Therefore, 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:
1. Would be available under a contract of at least 5 years duration;
 2. Would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 3. Would cost no more than if the services were provided by the HMO; and
 4. 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.

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In the original application, Project I.D. #K-8574-10, this criterion was not applicable because the applicant did not propose any construction costs. The following table compares the previously approved costs with the proposed projected construction costs for the entire project. In Section IX.6.(b), page 32, the applicant states that due to an unfavorable facility survey and the resulting 18 month period the applicant had to remain in compliance with all Medicare Conditions of Participation, the project was delayed and “*required us to recalculate the square footage needed to install the stations.*” The applicant states that the project delay and the renovations required to add additional square footage to the previously approved six dialysis stations, caused the cost overrun for the project.

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	<i>Previously Approved</i>	<i>Proposed</i>	<i>Increase</i>
Construction Costs			
Cost of Material	\$0	\$25,418	\$25,418
Cost of Labor	\$0	\$16,945	\$16,945
Subtotal Construction Costs	\$0	\$42,363	\$42,363

See Criterion (3) for discussion regarding the factors that contributed to the increase in construction costs which is hereby incorporated by reference as if fully set forth herein. See Criterion (5) for discussion of costs and charges which is hereby incorporated by reference as if fully set forth herein. In Section IX.5, page 31, the applicant states that the renovation will be constructed with “*energy efficient glass, self-closing doors, and energy efficient cooling and heating systems.*” Costs and charges to the public remain unchanged from the original application.

The applicant adequately demonstrated that the cost, design, and means of construction represent the most reasonable alternative, and that the construction costs will not unduly increase costs and charges for health services. Therefore, the 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;

NA

The original application, Project I.D. #K-8574-10, was conforming to this criterion and the applicant proposes no changes in this current application to affect that determination. Therefore, 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;

NA

The original application, Project I.D. #K-8574-10, was conforming to this criterion and the applicant proposes no changes in this current application to affect that determination. Therefore, 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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In Section IV.6, page 10, the applicant provides the same payor mix table that was provided in the original application.

PAYOR CATEGORY	PERCENTAGE OF TOTAL UTILIZATION
Medicare	12.8%
Medicaid	2.7%
Commercial Insurance	6.7%
Medicare/Commercial	35.6%
Medicare/Medicaid	39.6%
Self-Pay (includes self pay, indigent and charity care)	0.6%
Veterans Administration	2.0%
Total	100%

The applicant stated in the original application, Project I.D. #K-8574-10, that no change was anticipated in the payor mix as a result of the six additional dialysis stations. The original application was conforming to this criterion and demonstrated the 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.

NA

The original application, Project I.D. #K-8574-10, was conforming to this criterion and the applicant proposes no changes in this current application to affect that determination. Therefore, the application is conforming to this criterion.

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- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

NA

The original application, Project I.D. #K-8574-10, was conforming to this criterion and the applicant proposes no changes in this current application to affect that determination. Therefore, 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

See Sections II, III, V, VI and VII of the original application, Project I.D. #K-8574-10. Effective April 12, 2012, DVA Healthcare Renal Care, Inc. d/b/a Henderson Dialysis Center was issued a Certificate of Need (CON) for the original application, to add six dialysis stations to the existing facility in Vance County for a total of 49 certified dialysis stations upon project completion. The original application was conforming to this criterion and the applicant proposes no changes in this current application to affect that determination. The information provided by the applicant in those sections was reasonable and credible and adequately demonstrated that the expected effects of the proposal on competition include a positive impact on cost-effectiveness, quality and access to dialysis services in Vance County. Therefore, the application is conforming to this criterion

- (19) Repealed effective July 1, 1987.

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- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In the original application, Project I.D. #K-8574-10, the applicant was found nonconforming with this criterion because the facility was not in compliance with the Medicare Conditions of Participation on July 16, 2010.

The applicant currently provides dialysis services at Henderson Dialysis Center in Vance County. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, Henderson Dialysis Center, also referred to as Vance County Dialysis, certification number 34-2543, was resurveyed on August 30, 2010, and all deficiencies were corrected. No deficiencies have been cited from July 17, 2010 through July 10, 2012. Additionally, an unannounced complaint investigation was conducted on July 10, 2012 and no deficiencies were cited. The facility was determined to be in compliance with the Medicare Conditions of Participation. Dialysis Facility Compare, a federal government website managed by the Centers for Medicare and Medicaid Services (CMS), queried October 3, 2012, indicates the applicant meets two of the three quality standards based on 2010 data. Note: The unmet quality standard is the “*percentage of patients with hemoglobin less than 10 grams per deciliter (g/dL)*” which is provided for informational purposes only on this site. Therefore, the application is conforming with 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