

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 22, 2018

Findings Date: May 22, 2018

Project Analyst: Mike McKillip

Team Leader: Gloria Hale

Project ID #: J-11456-18

Facility: Durham Regional Dialysis

FID #: 160396

County: Durham

Applicant: DVA Renal Healthcare, Inc.

Project: Cost overrun for Project I.D. #J-11216-16 (develop a new 10-station dialysis facility in Durham by relocating three dialysis stations from Durham Dialysis and seven dialysis stations from Durham West Dialysis)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. § 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

The applicant, DVA Renal Healthcare, Inc. d/b/a Durham Regional Dialysis [**Durham Regional Dialysis**] proposes a cost overrun for Project I.D. # J-11216-16 (Develop a new ten-station dialysis facility in Durham by relocating three dialysis stations from Durham Dialysis and seven dialysis stations from Durham West Dialysis).

The certificate of need was issued on December 17, 2016 for Project I.D. # J-11216-16, which authorized a capital cost of \$2,206,944. The current application is for a cost overrun of \$559,373. In Section C.14(b), page 17, the applicant states, *“There were extensive increases in the capital costs that were estimated in the previously approved application that are associated with the rising cost of building materials and equipment.”*

In Project I.D. #J-11216-16, the applicant projected occupancy and offering of services by December 15, 2017. In this cost overrun application, the applicant projects occupancy and offering of services by December 1, 2018. The applicant is not proposing any material change in scope from the previously approved project.

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 2018 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations in the 2018 SMFP that are applicable to this review.

Policies

Project I.D. # J-11216-16 was found to be consistent with Policy GEN-4 and Policy ESRD-2 in the original review. The applicant proposes no changes in the current application that would affect the determination in the previous application. There are no other policies in the 2018 SMFP that are applicable to this review.

Conclusion

In summary, in Project I.D. #J-11216-16, the applicant was approved to develop a new 10-station dialysis facility in Durham by relocating three dialysis stations from Durham Dialysis and seven dialysis stations from Durham West Dialysis. In that review, 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

Durham Regional Dialysis proposes a cost overrun for Project I.D. # J-11216-16, to develop a new 10-station dialysis facility in Durham by relocating three dialysis stations from Durham Dialysis and seven dialysis stations from Durham West Dialysis. The certificate of need was issued on December 17, 2016 for Project I.D. # J-11216-16, which authorized a capital cost of \$2,206,944. The current application is for a cost overrun of \$559,373, and a total capital cost of \$2,766,317.

Patient Origin

On page 365 the 2018 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area for this facility consists of Durham County. Facilities may also serve residents of counties not included in their service area.

In Project I.D. # J-11216-16, the applicant defined its service area as Durham County. The current application is a cost overrun for that project. In Project I.D. # J-11216-16, the applicant adequately identified the population to be served and no changes are proposed in this application that affect that determination.

Analysis of Need

In Section C.14(b), page 17, the applicant describes the reasons for the cost overrun application as follows:

“There were extensive increases in the capital costs that were estimated in the previously approved application that are associated with the rising cost of building materials and equipment.”

The following table compares the previously approved capital cost for Project I.D. # J-11216-16 and the proposed capital cost in this application, as reported in Section F.1, page 21.

Durham Regional Dialysis Previously Approved vs. Proposed Capital Expenditures			
Item/Category	Previously Approved Cost J-11216-16	Total Additional Cost J-11456-18	Total Cost Overrun
Site Costs	\$58,000	(\$315)	\$57,685
Construction Contract	\$1,461,600	\$350,775	\$1,812,375
Miscellaneous	\$687,344	\$208,913	\$896,257
Total	\$2,206,944	\$559,373	\$2,766,317

The project scope, the population to be served, and access by underserved groups as demonstrated in the original application will not change as a result of this application. The applicant’s representations regarding the need for an additional capital expenditure to offer in-center dialysis services are reasonable and adequately supported.

Projected Utilization

In Section C.15, pages 17-18, the applicant provides the projected utilization for Durham Regional Dialysis and states that there are no changes to its projected utilization from those projections provided as part of Project I.D. # J-11216-16. In Project I.D. # J-11216-16, the applicant adequately demonstrated that projected utilization was based on reasonable and

adequately supported assumptions regarding continued growth in the patient population that requires dialysis services. The applicant proposes no changes in the current application that would affect that determination.

Access

In Project I.D. #J-11216-16, the applicant adequately demonstrated the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. The applicant proposes no changes in the current application that would affect that determination.

Conclusion

In the previously approved application, Project I.D. # J-11216-17, the applicant adequately identified the population to be served, demonstrated the need for the proposed 10-station dialysis facility, and demonstrated the extent to which all residents of the service area, including underserved groups, are likely to have access to its services. The applicant proposes no change in this application that would affect that determination. In this application, 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.

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In the previously approved application, Project I.D. # J-11216-17, the applicant demonstrated that the needs of the populations presently served at Durham Dialysis and Durham West Dialysis will continue to be adequately met following the proposed relocation of three dialysis stations from Durham Dialysis and seven dialysis stations from Durham West Dialysis to Durham Regional Dialysis, and that access for medically underserved groups will not be negatively impacted. The applicant proposes no change in this application that would affect that determination. Consequently, the application is conforming to this criterion.

- (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 20, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. Specifically, the applicant states it considered maintaining the status quo, but concluded that maintaining the status quo is not an effective alternative due to

the fact that Durham Regional Dialysis cannot be completed without additional capital investment.

On page 20, the applicant states that its proposal is the most effective alternative because the proposed facility is needed by the dialysis population of Durham County, and the project is cannot be completed without the additional expenditures.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. DVA Renal Healthcare, Inc. d/b/a Durham Regional Dialysis shall materially comply with the representations in this application and the representations in Project I.D. # J-11216-16. Where representations conflict, DVA Renal Healthcare, Inc. d/b/a Durham Regional Dialysis shall materially comply with the last made representation.**
 - 2. The total approved capital expenditure for Project I.D. # J-11216-16 and Project I.D. # J-11456-18 combined is \$2,766,317, an increase of \$559,373 over the previously approved capital expenditure of \$2,206,944.**
 - 3. DVA Renal Healthcare, Inc. d/b/a Durham Regional Dialysis shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section F of the application and that would otherwise require a certificate of need.**
 - 4. DVA Renal Healthcare, Inc. d/b/a Durham Regional 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 a cost overrun for Project I.D. # J-11216-16, to develop a new 10-station dialysis facility in Durham by relocating three dialysis stations from Durham Dialysis and seven dialysis stations from Durham West Dialysis.

Capital and Working Capital Costs

The total capital cost is now expected to be \$2,766,317, an increase of \$559,373 over the previously approved Project I.D. #J-11216-16 capital cost of \$2,206,944, which is above the allowed 115 percent overage for capital expenditures.

The following table compares the previously approved capital cost for Project I.D. # J-11216-16 and the proposed capital cost in this application, as reported in Section F.1, page 21.

Durham Regional Dialysis Previously Approved vs. Proposed Capital Expenditures			
Item/Category	Previously Approved Cost J-11216-16	Total Additional Cost J-11456-18	Total Cost Overrun
Site Costs	\$58,000	(\$315)	\$57,685
Construction Contract	\$1,461,600	\$350,775	\$1,812,375
Miscellaneous	\$687,344	\$208,913	\$896,257
Total	\$2,206,944	\$559,373	\$2,766,317

In Section Q, the applicant provides the assumptions used to project capital cost.

In Section F, page 23-24, the applicant projects that start-up costs will be \$191,529 and initial operating expenses will be \$765,555 for a total working capital of \$957,084. On page 24, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

Availability of Funds

In Section F.2, page 22, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Durham Regional Dialysis	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$2,766,317	\$2,766,317
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$2,766,317	\$2,766,317

* OE = Owner's Equity

In Section F.13, page 25, the applicant states that the working capital needs of the project will be funded as shown in the table below.

Sources of Financing for Working Capital		Amount
(a)	Loans	\$
(b)	Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$957,084
(c)	Lines of credit	\$
(d)	Bonds	\$
(e)	Total	\$957,084

Financial Feasibility

The applicant provided pro forma financial statements in Section R for the first two full fiscal years of operation following completion of the project. In Form B, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project. The financial projections are identical to those provided in the previously approved application, Project I.D. # J-11216-17. In response to a request for additional information by the Agency, the applicant states the adjustment in the development timetable will have no effect on the financial projections made in the application. In the previously approved application, the assumptions used by the applicant in preparation of the pro forma financial statements were determined to be reasonable, including projected utilization, costs and charges. The applicant proposes no change in this application that would affect that determination.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Additional information provided by the applicant in response to a request from the Agency
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (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

Durham Regional Dialysis proposes a cost overrun for Project I.D. # J-11216-16, to develop a new 10-station dialysis facility in Durham by relocating three existing dialysis stations from Durham Dialysis and seven existing dialysis stations from Durham West Dialysis.

On page 365 the 2018 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area for this facility consists of Durham County. Facilities may also serve residents of counties not included in their service area.

In Project I.D. #J-11216-16, the applicant was approved to develop a new 10-station dialysis facility in Durham by relocating three existing dialysis stations from Durham Dialysis and seven existing dialysis stations from Durham West Dialysis. The current application is a cost overrun for that project. In Project I.D. #J-11216-16, the application was found to adequately demonstrate that the project would not result in unnecessary duplication of existing or approved dialysis services and no changes are proposed in this application that 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 Section H.8, page 30, the applicant states that there are no changes in the staffing levels or positions from the original project. In Project I.D. #J-11216-16, the application was found 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. #J-11216-16, the application was found 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

In Project I.D. #J-11216-16, the criterion was found to be not applicable, and the applicant proposes no changes in the current application that would affect that determination. Consequently, this criterion is not applicable to this cost overrun application.

- (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

In Project I.D. #J-11216-16, the criterion was found to be not applicable, and the applicant proposes no changes in the current application that would affect that determination. Consequently, this criterion is not applicable to this cost overrun application.

- (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 proposed project is for a cost overrun for Project I.D. #J-11216-16. In Section K, the applicant states that no changes to the facility are proposed. The following table compares the previously approved capital cost for Project I.D. # J-11216-16 and the proposed capital cost in this application, as reported in Section F.1, page 21.

Durham Regional Dialysis Previously Approved vs. Proposed Capital Expenditures			
Item/Category	Previously Approved Cost J-11216-16	Total Additional Cost J-11456-18	Total Cost Overrun
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Total	\$2,206,944	\$559,373	\$2,766,317

In Section C.14(b), page 17, the applicant describes the reasons for the cost overrun application as follows:

“There were extensive increases in the capital costs that were estimated in the previously approved application that are associated with the rising cost of building materials and equipment.”

The discussion regarding the need for the cost overrun found in Criterion (3) is incorporated herein by reference. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicant adequately demonstrates that the cost, design, and means of construction represent the most reasonable alternative, and that the construction cost 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;

C

In Project I.D. #J-11216-16, the application was found 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. #J-11216-16, the application was found 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. #J-11216-16, the application was found 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. #J-11216-16, the application was found 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. #J-11216-16, the application was found 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

Durham Regional Dialysis proposes a cost overrun for Project I.D. # J-11216-16, to develop a new 10-station dialysis facility in Durham by relocating three dialysis stations from Durham Dialysis and seven dialysis stations from Durham West Dialysis.

On page 365 the 2018 SMFP defines the service area for dialysis stations as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” Thus, the service area for this facility consists of Durham County. Facilities may also serve residents of counties not included in their service area.

Project I.D. #J-11216-16 was approved to develop a new 10-station dialysis facility in Durham by relocating three dialysis stations from Durham Dialysis and seven dialysis stations from Durham West Dialysis. In Project I.D. #J-11216-16, the application was found 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.

C

In Section B.4, pages 8-10, the applicant discusses the methods it uses to ensure and maintain quality. In Exhibit O, the applicant lists one dialysis facility in the state owned by DaVita, Goldsboro South Dialysis, that was 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. The applicant provides documentation regarding the deficiencies and subsequent compliance with CMS Conditions for Coverage in Exhibit O. In Section O.3, page 47, the applicant states the facility is 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

In Project I.D. #J-11216-16, the Criteria and Standards for End-Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 were found conforming to that review, and the applicant proposes no changes in the current application that would affect that determination. Consequently, the cost overrun application is conforming to the performance standards in this rule.