

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: September 28, 2016

Findings Date: September 28, 2016

Project Analyst: Gloria Hale

Team Leader: Lisa Pittman

Project I.D. #: J-11185-16

Facility: Duke Raleigh Hospital

FID #: 923421

County: Wake

Applicants: Duke University Health System, Inc.

Project: Cost overrun on Project I.D. #J-7941-07 (acquire linear accelerator)

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.

C

The applicant, Duke University Health System, Inc. d/b/a Duke Raleigh Hospital (DUHS), proposes a cost overrun for Project I.D. #J-7941-07 which authorized Raleigh Hematology Oncology Associates PC d/b/a Cancer Centers of North Carolina-Raleigh and AOR Management Company of Virginia, Inc., and later, DUHS, through an exemption from review and transfer for good cause, to acquire a linear accelerator and locate it at Macon Pond Center in Raleigh. The original project, Project I.D. # J-7941-07, was approved for a capital cost of \$4,336,603 and was scheduled to offer services by June 24, 2011. On January 6, 2015, the Agency approved a material compliance request from DUHS to locate the linear accelerator at Duke Raleigh Hospital instead of Macon Pond Center. In Section VI.4, page 24, the applicant states that the project will now cost \$5,981,036, an increase of \$1,644,433 or 38.4% [$(5,981,036 / 4,336,603) - 1 = 0.384$ or 38.4%]. The applicant states, in Section X, page 42, that the project will be complete by January 1, 2017. 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-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES was applicable to Project I.D. # J-7941-07, and that application was consistent with Policy GEN-4. The applicant proposes no changes in the current application that would affect that determination.

There are no policies in the 2016 SMFP that are applicable to this review.

Conclusion

In summary, the applicant was previously approved to acquire one linear accelerator upon project completion. In Project I.D. #J-7941-07, the applicant was conforming to this criterion. The applicant proposes no changes in the current application that would affect that determination. Therefore, the application is conforming to this criterion.

- (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

The applicant, DUHS, proposes a cost overrun for Project I.D. # J-7941-07 to acquire a linear accelerator. The original project was approved for a total capital cost of \$4,336,603, and was scheduled to be complete by June 24, 2011. There is no material change in scope from the originally approved project in this application; the applicant states in Section II.1, page 5, that it proposes to acquire and install the BrainLab ExacTrac system with the linear accelerator to ensure optimum care. The applicant states, on page 6, *“The system can automatically adjust the patient’s position so that the tumor and radiation beam are correctly oriented prior to treatment and allows the treatment team to visualize and correct any deviation in position during a treatment session.”* The applicant states, on page 5, that the addition of this system and the increased cost of the linear accelerator itself due to inflation and advances in technology, are the reasons for the increased costs. In Section VI.4, page 24, the applicant states that the project will now cost \$5,981,036, an increase of \$1,644,433 or 38.4%

[(5,981,036/ \$4,336,603) – 1 = 0.384 or 38.4%]. The applicant states, in Section X, page 42, that the project will be complete by January 1, 2017.

Population to be Served

On page 44, the 2016 SMFP defines the service area for licensed acute care hospitals as the county where the hospital is located, with the exception of any multicounty planning areas. Thus, in this application, the service area is Wake County. Hospitals may serve residents of counties not included in their service area.

In supplemental information, the applicant states that the projected patient origin for the project has not changed from what was proposed in its original application, Project I.D. #J-7941-07. Therefore, the applicant has adequately identified the population to be served.

Analysis of Need

In Section II.4, pages 5-7, the applicant discusses the need for the BrainLab ExacTrac imaging system and the selection of a different linear accelerator than originally proposed. The applicant states that the BrainLab ExacTrac system complements the accuracy of the linear accelerator by providing a unique position verification tool and allows Duke to meet its institutional standard of care. The cost of the BrainLab ExacTrac system, technological advances, and inflation during the intervening years since the original project was issued a CON, have increased the cost of the project more than 15% of the original approved cost.

The following table compares the previously approved capital cost and the proposed capital cost in this application, as reported in Section VI.4, pages 23-24:

DUHS			
Previously Approved and Proposed Capital Costs			
Category	Original Approved Cost	Proposed Cost	Difference
Site Costs	\$85,500	\$0	(\$85,500)
Construction Costs	\$625,670	\$1,167,463	\$541,793
Miscellaneous Costs			
Fixed Equipment Purchase/Lease	\$2,905,173	\$4,283,168	\$1,377,995
Movable Equipment Purchase/Lease	\$117,700	\$281,905	\$164,205
Furniture	\$0	\$20,000	\$20,000
Consultant Fees			
Architect/Engineering Fees	\$73,861	\$0	(\$73,861)
Legal	\$25,000	\$0	(\$25,000)
Other (Contractor's fee, Physics, Contingency, Impact, Regulatory fees)	\$129,384	\$228,500	\$99,116
Other (Financing, Interest, Other not specified)	\$206,717	\$0	(\$206,717)
Subtotal Miscellaneous Project Costs	\$3,457,835	\$4,813,573	\$1,355,738
Total Capital Costs	\$4,169,005	\$5,981,036	\$1,812,031

As illustrated in the table above, the total capital costs proposed in the original application for Project I.D. #J-7941-07 were \$4,169,005. The proposed total capital costs for the project are now \$5,981,036. The difference between the original and current capital costs is \$1,812,031. As shown in the table above, the cost overrun is largely due to an increase in fixed equipment costs.

Due to delays encountered due to litigation, the capital costs of the project at settlement were increased to \$4,336,603. Therefore, the CON issued for the original project, Project I.D. #J-7941-07, was for \$4,336,603. Therefore, the cost overrun is for an increase in capital costs from the adjusted total capital costs of \$4,336,603 to \$5,981,036, and is therefore equal to \$1,644,433.

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

Projected Utilization

In supplemental information, the applicant provides the projected utilization of its linear accelerator for interim operating year, FY2017, and for the first three years of operation, FY2018 – FY2020, as follows:

**Duke Raleigh Hospital
Projected Utilization of Linear Accelerator**

Total Procedures	Interim Year FY2017*	OY1 FY2018	OY2 FY2019	OY3 FY2020
Projected Utilization	2,951	6,133	6,222	6,312

*FY2017 is for the period, July 1, 2017 – December 31, 2017, only.

The applicant provides its assumptions and methodology for its projected utilization in Section III.2, pages 11-13. The utilization projections are a change from those projected in the original application. In Section III.2, pages 11-13, the applicant discusses the reasons for the change, primarily due to projected population increases in Wake County and historical growth in linear accelerator utilization.

The applicant adequately demonstrates that the utilization projections are based on reasonable and adequately supported assumptions.

Access

In Section IV.2, pages 14-15, the applicant states that access to its proposed services will not change from what it stated in its original application, that low income and medically underserved persons will continue to have access to all oncology services provided by Duke Raleigh Hospital. In Section IV.6, page 16, the applicant provides its projected payor mix for the cost overrun and for the original application, stating that some changes have resulted due to changes in the patient population in the service area and changes in healthcare coverage. The applicant anticipates that 57.1% of its proposed services will be paid by Medicare and/or Medicaid.

Conclusion

In the original application, the applicant adequately identified the population to be served, demonstrated the need for the linear accelerator and the extent to which all residents of the service area, including underserved groups, are likely to have access to its services. However, due to delays from litigation, a change in ownership, and a site change, costs for the project have increased during the intervening years. 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.

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.4 and II.5, page 7, the applicant discusses one alternative it considered, summarized as follows:

1. Developing the Project without the BrainLab ExacTrac system - the applicant states that this would not be optimal for patient care because the BrainLab ExacTrac system will enhance quality, lesson errors, and improve patient outcomes for stereotactic radiosurgical procedures (SRS). Therefore, developing the project without this system would not be an effective alternative.

Furthermore, in Project I.D. #J-7941-07, the application was conforming to all other applicable statutory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative. The applicant adequately demonstrates that its proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

- 1. Duke University Health System, Inc. d/b/a Duke Raleigh Hospital shall materially comply with all conditions of approval on the certificate of need for Project I.D. # J-7941-07 except as specifically modified by the conditions of approval for this application, Project I.D. # J-11185-16.**
 - 2. The total approved capital expenditure for Project I.D. # J-7941-07 and Project I.D. # J-11185-16 combined shall be \$5,981,036.**
 - 3. Duke University Health System, Inc. d/b/a Duke Raleigh Hospital 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 that would otherwise require a certificate of need.**
 - 4. Prior to issuance of the certificate of need, Duke University Health System, Inc. d/b/a Duke Raleigh Hospital 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. # J-7941-07. The total capital cost is now expected to be \$5,981,036, an increase of \$1,664,433 or 0.384% [$(\$5,981,036 / \$4,336,603) - 1 = 0.384$ or 38.4%] of the approved capital cost. See Section VI, pages 23-24.

Availability of Funds

In Section VI.5, page 25, the applicant states the total capital cost of the project will be funded with accumulated reserves. In Exhibit 6, the applicant provides a letter dated June 15, 2016 and signed by the Senior Vice President, Chief Financial Officer and Treasurer, DUHS, which documents the availability and intended use of existing accumulated cash reserves to finance the cost overrun. The amount of accumulated cash reserves to be used for the project is \$6,000,000.

In Exhibit 7, the applicant provides the audited financial statements for DUHS for the years ending June 30, 2014 and June 30, 2015. As of June 30, 2015, DUHS had cash and cash equivalents totaling \$434,336,000 with \$5,039,776,000 in total assets and \$3,182,882,000 in net assets (total assets less total liabilities).

Financial Feasibility

In supplemental information that replaces Form C of the applicant’s pro forma financial statements, the applicant projects that revenues will exceed operating expenses in each of the first three operating years of the project, as illustrated in the table below:

Linear Accelerator Revenue and Expenses			
	OY 1 FY2018	OY 2 FY2019	OY 3 FY2020
Gross Patient Revenue	\$10,710,040	\$10,892,614	\$11,079,863
Deductions from Gross Patient Revenue	\$7,979,468	\$8,101,084	\$8,225,621
Net Patient Revenue	\$2,730,572	\$2,791,530	\$2,854,242
Total Expenses	\$2,432,403	\$2,705,995	\$2,759,318
Net Income	\$298,169	\$85,535	\$94,924

In addition, in Form B of the pro forma financial statements, the applicant projects that DUHS’ revenues will exceed operating expenses in each of the first three operating years of the project. The assumptions used by the applicant in preparation of supplemental information and Forms A and B of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See supplemental information and the Financials section of the application for the assumptions used regarding costs and charges.

The discussion regarding utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

Conclusion

The applicant adequately demonstrates the availability of sufficient funds for the capital expenses of the project. The applicant also adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. 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

On page 44, the 2016 SMFP defines the service area for licensed acute care hospitals as the county where the hospital is located, with the exception of any multicounty planning areas. Thus, in this application, the service area is Wake County. Hospitals may serve residents of counties not included in their service area.

In Project I.D. # J-7941-07, the application was conforming to this criterion and no changes are proposed in this application to 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 the original application, Project I.D. #J-7941-07, the application was conforming to this criterion. The applicant proposes no changes in the current application that would affect that determination. In addition, in Section V.2, page 17, the applicant states that it is already operating a linear accelerator on a temporary basis and has sufficient staffing. Furthermore, the applicant states, on page 17, that the addition of the BrainLab ExacTrac system “*will not necessitate the addition of any staff.*” Consequently, the cost overrun application is conforming to this criterion.

Consequently, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Project I.D. # J-7941-07, 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.

NA

- (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-7941-07, 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. # J-7941-07, 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

C

In Section IV.6, page 16, the applicant provides a revised projected payor mix from its original application, Project I.D. #J-7941-07, illustrated as follows:

**Duke Raleigh Hospital
Linear Accelerator Projected Payor Mix**

Payor	Original Application Percentages	Cost Overrun Percentages
Self Pay/Indigent/Charity	1.7%	3.3%
Medicare/ Medicare Managed Care	50.4%	52.0%
Medicaid	4.3%	5.1%
Commercial Insurance	4.9%	1.2%
Managed Care	38.7%	36.3%
Other	0.0%	2.1%
Total	100.0%	100.0%

The applicant states, on page 16, that the changes in payor mix are attributed to changes in the patient population in the service area, changes in healthcare coverage, and the significant percentages of self-pay, Medicare and Medicaid reimbursement that DUHS receives for all of its services. In addition, the applicant's original application, Project I.D. #J-7941-07, 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.

C

In Project I.D. # J-7941-07, 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.

- (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 Section VI.3, pages 17-18, the applicant lists the educational institutions and training programs that utilize DRH as a training site. Consequently, the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.

(18) Repealed effective July 1, 1987.

(18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

On page 44, the 2016 SMFP defines the service area for licensed acute care hospitals as the county where the hospital is located, with the exception of any multicounty planning areas. Thus, in this application, the service area is Wake County. Hospitals may serve residents of counties not included in their service area.

Project I.D. # J-7941-07 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

According to the files in the Acute and Home Care Licensure and Certification Section, DHRS, one of DUHS' three hospitals that it owns or operates in the State of North Carolina was out of compliance with the Medicare Conditions of Participation within the eighteen months immediately preceding submission of the application through the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State. The facility is now back in compliance. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section, and considering the quality of care provided at all three facilities, the applicant provided sufficient evidence that quality care has been provided in the past. 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