

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 15, 2020

Findings Date: April 15, 2020

Project Analyst: Mike McKillip

Team Leader: Gloria C. Hale

Project ID #: J-11850-20

Facility: Duke Radiology Holly Springs

FID #: 160156

County: Wake

Applicant: Duke University Health System, Inc.

Project: Change of scope for Project I.D. # J-11167-16 (Acquire one fixed MRI scanner and develop a new diagnostic center) to add one unit of mammography equipment

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

Duke University Health System, Inc. (DUHS) proposes a change of scope (COS) to a previously approved project, Project I.D. # J-11167-16 (Acquire one fixed MRI scanner and develop a new diagnostic center) to add one unit of mammography equipment. Specifically, the applicant proposes to acquire one unit of 3D tomosynthesis mammography equipment to be located in upfitted space within the previously approved diagnostic center, Duke Radiology Holly Springs.

The proposed project does not involve the addition of any new health service facility beds, services or equipment for which there is a need determination in the 2020 State Medical Facilities Plan (2020 SMFP). Also, there are no policies in the 2020 SMFP applicable to this review. Therefore, Criterion (1) 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- (2) Repealed effective July 1, 1987.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

DUHS proposes a change of scope (COS) to a previously approved project, Project I.D. # J-11167-16 (Acquire one fixed MRI scanner and develop a new diagnostic center) to add one unit of mammography equipment. Specifically, the applicant proposes to acquire one unit of 3D tomosynthesis mammography equipment to be located in upfitted space within the previously approved diagnostic center, Duke Radiology Holly Springs. In Section C.13, page 26, the applicant describes the project as follows:

“DUHS is acquiring one unit of 3D tomosynthesis mammography equipment and upfitting space within the previously approved diagnostic center. This change is necessary to provide access to critical mammography screening services in this part of the county. Combining these services with other imaging in a single diagnostic center provides economies created by shared support staff, services, and other overhead.”

Patient Origin

N.C. Gen. Stat. §131E-176(24a) states, “Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.” The 2020 SMFP does not define a service area for diagnostic centers nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant. Facilities may also serve residents not included in their service area. In Section C.3, page 15, the applicant provides the projected patient origin for the proposed mammography services in the first three full fiscal years (July-June) of operation (FY2022-FY2024), as shown in the table below.

Duke Radiology Holly Springs Projected Patient Origin for Mammography Services						
ZIP Code Areas	FY 1 – FY2022		FY 2 – FY2023		FY 3 – FY2024	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
27502 Apex	196	22%	284	23%	345	23%
27526 Fuquay-Varina	221	25%	310	25%	384	25%
27540 Holly Springs	198	22%	281	22%	336	22%
27539 Apex	119	13%	167	13%	204	13%
27592 Willow Spring	67	8%	93	7%	116	8%
27562 New Hill	16	2%	23	2%	27	2%
All other ZIP Codes/In-migration	65	7%	92	7%	113	7%
Totals*	882	100.0%	1,250	100.0%	1,525	100.0%

*May not foot due to rounding.
 Source: Section C.3, page 15

In Section C.3, page 16, the applicant states, “*DUHS anticipates that the primary service area for mammography services will be the zip codes within a 10 to 20-minute drive time of the proposed location, reflecting the typically local nature of this service and DUHS’s experience at other imaging locations.*” The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 16-20, the applicant explains why it believes the population projected to utilize the proposed mammography equipment included in the COS application needs the proposed services, including:

- The historical growth in utilization of mammography services at DUHS sites in Wake and Durham counties from 2016 to 2019 (page 17).
- The projected growth in the population of the proposed service area (pages 17-19).
- The project will support the DUHS strategic plan to expand access to primary care and specialty care services to the growing Wake County service area (page 19).
- The project will expand access to mammography services for the proposed service area in a lower cost, non-hospital setting (page 20).

The information provided by the applicant in the pages referenced above is reasonable and adequately supported for the following reasons:

- The applicant’s assumptions are based on its historical experience operating similar services.
- The applicant provides information regarding the current and projected population by county for its proposed service area from Truven.

Projected Utilization

In Section Q, Form C, the applicant provides projected utilization for the proposed mammography equipment proposed in this COS application through the first three full fiscal years of operation of the proposed project (FY2022-FY2024) as summarized in the following table.

Mammography Services Utilization			
	Year 1 FY2022	Year 2 FY2023	Year 3 FY2024
Mammography procedures	882	1,250	1,525

Source: Form C, Section Q of the application.

The applicant provides its assumptions and methodology for projecting utilization for its proposed services in Section Q, Form C, pages 58-61, which is summarized as follows:

Step 1: Identify the geographic area and population to be served - The applicant states it identified the service area population for the mammography services as the six ZIP Code Areas within a ten-minute drive time of the diagnostic center's location based on an analysis of existing drive time patterns for DUHS imaging services. See page 58 of the application.

Step 2: Identify the total mammography utilization at six existing DUHS sites that will shift - The applicant states it summarized the total mammography utilization at six existing DUHS sites for FY2019 for patients in the six ZIP Code Areas identified above, and projected the percentage of mammography volumes at existing DUHS sites expected to shift to the proposed mammography services based on several factors. On page 58, the applicant states:

“This shift is anticipated due to the following factors:

- *Convenient geographic location, the first for Duke mammography services in this part of Wake County*
- *Preference of payors and patients for IDTF over hospital-based services*
- *Growth in referring provider network, including Duke primary care and OB/GYN providers in the same medical office building*
- *New Medicaid reimbursement for IDTF services instead of limiting reimbursement to hospital-based providers*
- *Backlog/capacity constraints at existing sites”*

Step 3: Project the additional mammography utilization from the proposed service area - The applicant states it projected additional mammography utilization will originate from the proposed service areas based on several factors, including the increasing population in the service area, growth in the DUHS physician network through the planned recruitment of primary and specialty care physicians, the increased geographic access and patient convenience that the proposed location will offer, and the attractiveness and benefits of a lower cost, non-hospital setting for both patients and payors. See pages 59-60 of the application.

Step 4: Project mammography volumes from in-migration - Based on the applicant's experience operating mammography services at other DUHS locations, it projected an additional 7.5 percent of mammography patients would originate from outside the service area. See pages 60-61 of the application.

In Section Q, page 61, the applicant provides a table showing the projected mammography utilization at the Duke Radiology Holly Springs location, as summarized below:

Duke Radiology Holly Springs Projected Mammography Services Utilization			
	Year 1 FY2022	Year 2 FY2023	Year 3 FY2024
Shift from other DUHS locations	207	318	328
Incremental share from ZIP Code Areas	610	840	1,083
In-migration from outside ZIP Code Areas	65	93	113
Total mammography procedures	882	1,250	1,525

Source: Section Q, page 61 of the application.

Projected utilization is reasonable and adequately supported for the following reasons:

- Projected utilization is based on the applicant's historical mammography utilization data from existing DUHS sites that provide outpatient mammography services to the service area population.
- The applicant projects reasonable market shares and market share growth rates based on the number of existing mammography service providers in the identified service area, and projections provided by a market research firm. Also, in Exhibit C.4(b), the applicant provides copies of letters from physicians expressing their support for the project and their intention to refer patients to the proposed mammography services.
- The applicant provides reasonable and adequately supported information to justify the need for the mammography equipment.

Access

In Section L.6, page 51, the applicant projects the following payor mix for mammography services during the second year of operation (FY2023) following completion of the project, as shown in the following table.

Payment Source	Mammography Services Percent of Total Procedures
Self Pay	0.36%
Charity Care	1.64%
Medicare	28.40%
Medicaid	1.70%
Insurance	66.80%
TRICARE	1.10%
Total*	100.00%

Source: Table on page 51 of the application.

*Totals may not foot due to rounding.

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

- (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

The applicant does not propose the reduction or elimination of a service. Therefore, Criterion (3a) is not applicable to this review

- (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

DUHS proposes a change of scope (COS) to a previously approved project, Project I.D. # J-11167-16 (Acquire one fixed MRI scanner and develop a new diagnostic center) to add one unit of mammography equipment.

In Section E.2, page 31, 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. The alternatives considered were:

- Maintain the status quo – The applicant states this was not an effective alternative due to the fact that it would not take advantage of the potential increased patient convenience and efficiencies of providing expanded imaging services at the site.
- Develop mammography services at another location – The applicant states this was not an effective alternative because co-locating mammography services with MRI scanner services is a more effective alternative in terms of resource-sharing and proximity to other related DUHS healthcare services.
- Relocate existing mammography equipment from another site – The applicant states this alternative is not effective because the existing equipment at other sites is already well-utilized, and the expense of relocating existing equipment would outweigh the benefits.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory review criteria.
- The alternative will meet the need for mammography services in a cost-effective manner.
- The alternative is more cost-effective and convenient for both patients and medical staff.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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. Duke University Health System, Inc. shall materially comply with all representations made in the certificate of need application.**

2. **Duke University Health System, Inc. shall acquire no more than one unit of mammography equipment.**
 3. **Duke University Health System, Inc. as part of this project, shall not acquire any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
 4. **No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Duke University Health System, Inc. shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
 - a. **Payor mix for the services authorized in this certificate of need.**
 - b. **Utilization of the services authorized in this certificate of need.**
 - c. **Revenues and operating costs for the services authorized in this certificate of need.**
 - d. **Average gross revenue per unit of service.**
 - e. **Average net revenue per unit of service.**
 - f. **Average operating cost per unit of service.**
 5. **Duke University Health System, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to insurance 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

DUHS proposes a change of scope (COS) to a previously approved project, Project I.D. # J-11167-16 (Acquire one fixed MRI scanner and develop a new diagnostic center) to add one unit of mammography equipment. Specifically, the applicant proposes to acquire one unit of 3D tomosynthesis mammography equipment to be located in upfitted space within the previously approved diagnostic center, Duke Radiology Holly Springs.

Capital and Working Capital Costs

In Section Q, Form F.1b, the applicant projects the total capital cost of this COS project as shown in the table below.

	Original Costs (Project ID # J-11167-16)*	Additional Costs for COS Equipment	Total
Construction		\$50,000	\$50,000
Medical Equipment		\$348,019	\$348,019
Nonmedical Equipment		\$72,450	\$72,450
Miscellaneous Costs		\$19,531	\$19,531
Total	\$6,155,880	\$490,000	\$6,645,880

*Applicant states total approved capital cost for Project I.D. # J-11167-16 reflects the Agency’s cost inflation adjustment for the time between the application submittal and issuance of the CON.

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

In Section F.3, the applicant projects no additional start-up costs or initial operating expense for associated with the COS application.

Availability of Funds

In Section F.2, page 32, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing		
Type	DUHS	Total
Loans	\$ 0	\$0
Accumulated reserves or OE *	\$490,000	\$490,000
Bonds	\$0	\$0
Other (Equipment Leases)	\$0	\$0
Other (Facility Lease)	\$0	\$0
Total Financing	\$490,000	\$490,000

* OE = Owner’s Equity

Exhibit F.2(a) contains a letter dated January 31, 2020 from the Senior Vice President, Chief Financial Officer and Treasurer DUHS documenting its intention to provide accumulated reserves for the capital needs of the proposed project. Exhibit F.2(b) contains the consolidated financial statements from DUHS documenting that the applicant has sufficient funds in accumulated reserves to finance the proposed project.

Financial Feasibility

The applicant provided pro forma financial statements for Duke Radiology Holly Springs for the first three full fiscal years of operation following completion of the project. In Form F.2, the applicant projects that revenues will exceed operating expenses in the first three operating years of the diagnostic center as a whole, as shown in the table below.

Duke Radiology Holly Springs

	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
Total Gross Revenues (Charges)	\$4,867,719	\$4,954,436	\$5,023,195
Total Net Revenue	\$2,468,309	\$2,511,541	\$2,545,706
Total Operating Expenses (Costs)	\$1,964,797	\$2,013,059	\$2,051,890
Net Income	\$503,512	\$498,481	\$493,816

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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 costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the 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

DUHS proposes a change of scope (COS) to a previously approved project, Project I.D. # J-11167-16 (Acquire one fixed MRI scanner and develop a new diagnostic center) to add one unit of mammography equipment. Specifically, the applicant proposes to acquire one unit of 3D tomosynthesis mammography equipment to be located in upfitted space within the previously approved diagnostic center, Duke Radiology Holly Springs.

N.C. Gen. Stat. §131E-176(24a) states, “Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.” The 2020 SMFP does not define a service area for diagnostic centers nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by

the applicant. Facilities may also serve residents not included in their service area. In Section C.3, page 15, the applicant provides the projected patient origin for the proposed mammography services in the first three full fiscal years (July-June) of operation (FY2022-FY2024).

In Section G.3, page 38, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved diagnostic services in the service area. The applicant states:

“The population in Holly Springs and surrounding areas is growing quickly and the demand for imaging services is growing with it, as set forth in response to Section C.

...

As the population grows and ages, and as that population also faces insurance network limitations, providing access to cost-effective services. This project will therefore not unnecessarily duplicate any existing imaging services in the service area but will instead provide, for the first time, choice for patients in that area. Letters from providers supporting the project are attached at Exhibit C.4(b).”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the applicant adequately demonstrates that the proposed diagnostic equipment is needed in addition to the existing or approved services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 Q, Form H, the applicant provides the projected full-time equivalent (FTE) staffing for the proposed mammography services, as illustrated in the following table.

Position	Projected FTE
	Mammography Staff
	2nd Full Fiscal Year
	(FY2023)
Radiologist Technologist	1.00
Patient Service Associate	0.25
TOTAL	1.25

The assumptions and methodology used to project staffing are provided in Section Q, Form H, and in Section H.4, page 41. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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-11167-16, the applicant was found conforming to this Criterion. The applicant proposes no changes in the current COS application that would affect that determination.

- (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

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to HSA IV where the services will be offered. Furthermore, the applicant does not project to provide the proposed

services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (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

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

In Project I.D. # J-11167-16, the application was found conforming to this criterion. In Section K.5, pages 46-47, the applicant states that there are no changes proposed in this COS application except an updated line drawing to show the upfitted space to accommodate the mammography equipment. The updated line drawing is provided in Exhibit K.5.

- (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-11167-16, the applicant was found conforming to this Criterion. The applicant proposes no changes in the current COS application that would affect that determination.

- (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-11167-16, the applicant was found conforming to this Criterion. The applicant proposes no changes in the current COS application that would affect that determination.

- (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 L.6, page 51, the applicant projects the following payor mix for mammography services during the second year of operation (FY2023) following completion of the project, as shown in the following table.

Payment Source	Mammography Services Percent of Total Procedures
Self Pay	0.36%
Charity Care	1.64%
Medicare	28.40%
Medicaid	1.70%
Insurance	66.80%
TRICARE	1.10%
Total*	100.00%

Source: Table on page 51 of the application.

*Totals may not foot due to rounding.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 0.36% of total services will be provided to self-pay patients, 1.64% to charity care patients, 28.40% to Medicare patients and 1.7% to Medicaid patients.

In Section L.6, pages 50-51, and Section Q, Form F.2, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the applicant's experience.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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-11167-16, the applicant was found conforming to this Criterion. The applicant proposes no changes in the current COS application that would affect that determination.

- (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-11167-16, the applicant was found conforming to this Criterion. The applicant proposes no changes in the current COS application that would affect that determination.

- (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. #J-11167-16, the applicant was found conforming to this Criterion. The applicant proposes no changes in the current COS application that would affect that determination.

- (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 Q, Form A, the applicant identifies Duke Health Heritage Radiology and Duke Imaging Services at Cary Parkway as diagnostic centers that are owned or managed by DUHS.

In Section O.3, page 54, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care occurred at and DUHS facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at the DUHS 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

DUHS proposes a change of scope (COS) to a previously approved project, Project I.D. # J-11167-16 (Acquire one fixed MRI scanner and develop a new diagnostic center) to add one unit of mammography equipment. Specifically, the applicant proposes to acquire one unit of 3D tomosynthesis mammography equipment to be located in upfitted space within the previously approved diagnostic center, Duke Radiology Holly Springs. There are no administrative rules that are applicable to this proposed COS project.