

ATTACHMENT – REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming
CA – Conditional
NC – Nonconforming
NA = Not Applicable

Decision Date: November 13, 2015
Findings Date: November 13, 2015

Project Analyst: Tanya S. Rupp
Team Leader: Lisa Pittman

Project ID #: J-11057-15
Facility: Duke Cancer Center Macon Pond
FID #: 050382
County: Wake
Applicant(s): Duke University Health System, Inc.
Project: Renovate patient care space and acquire imaging equipment

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

Duke University Health System, Inc. (“DUHS”) operates several facilities in Durham and Wake counties, and provides acute care, surgical, emergency, oncology, hospice, therapeutic and rehabilitation services. In 1998 DUHS acquired Duke Raleigh Hospital (“DRH”) in Wake County, and based its Wake County oncology services at that facility. DRH is the site for the Duke Cancer Center in Wake County. In 2014, DUHS acquired existing oncology sites at Macon Pond Road and in Cary that were previously operated by Cancer Centers of North Carolina, P.C. DRH now operates this site as a hospital provider-based outpatient department and provides comprehensive radiology services at its main hospital location.

In this application, DUHS proposes to renovate existing clinic space in the Macon Pond facility, and acquire one ultrasound machine and one mammography unit for radiology

procedures, and two ultrasound machines for image-guided needle biopsy procedures, thereby allowing DRH to provide radiation oncology services as well as outpatient procedures.

There are no need determinations in the 2015 State Medical Facilities Plan (SMFP) that are applicable to this review.

Policies

There is one policy in the 2015 SMFP that applies to this review:

- Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities (page 39, 2015 SMFP)

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, the Certificate of Need Section shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”

The Duke Cancer Center Macon Pond is an existing facility. In Section XI.7, page 78, the applicant states the renovation project will not materially affect energy operations or utility usage. The applicant states energy efficient plans will be part of the renovation design. Additionally, in Exhibit 14 the applicant provides a July 29, 2015 letter from the project architect that further details the applicant’s energy efficiency and water conservation plan.

The applicant adequately demonstrates the proposal includes a plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4 subject to Condition # 3 in Criterion (4).

Conclusion

In summary, the applicant adequately demonstrates that the proposal to renovate existing clinic space and acquire imaging equipment is consistent with Policy GEN-4 in the 2015 SMFP. Therefore, the application is conforming to this criterion as conditioned.

- (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

Duke University Health System d/b/a Duke Raleigh Hospital (“DRH”) currently operates the Macon Pond facility as a hospital provider-based outpatient department. DRH intends to locate its breast and women’s cancer outpatient services primarily at the Macon Pond location. As part of the project, DRH proposes to renovate 15,954 square feet of existing clinic space at Duke Cancer Center Macon Pond (“Macon Pond”), and acquire ultrasound and mammography equipment.

Population to be Served

On page 48, the 2015 SMFP defines the service area for acute care services by county (or multicounty service area for counties without a hospital). Macon Pond is located in Wake County. Thus, the service area for this hospital is Wake County. Facilities may also serve residents of counties not included in their service area.

In Section III.4(a), page 20, the applicant states that DUHS acquired the Macon Pond facility in November 2014, and began operating it as a hospital clinic in February 2015; therefore, DUHS does not have a full year of historical data for Macon Pond for oncology visits. On page 20 the applicant provides patient origin based on discharges for DRH for FY 2015, summarized in the following table:

**Duke Raleigh Hospital
 Patient Discharges FY 2015**

COUNTY	% OF TOTAL
Wake	68.6%
Franklin	5.6%
Johnston	4.0%
Harnett	1.6%
Nash	2.1%
Durham	1.4%
Virginia	1.1%
Other	15.0%
Total	100.0%

In Section III.4(b), page 21, the applicant provides historical patient origin for DRH per service component for FY 2015, as shown in the following table:

**Duke Raleigh Hospital FY 2015
 % of Total Visits per Service Component**

COUNTY	MAMMOGRAPHY	ULTRASOUND	ONCOLOGY
Wake	86.5%	83.6%	67.8%
Franklin	2.7%	2.7%	4.2%
Johnston	3.2%	2.6%	5.6%
Harnett	0.9%	0.6%	2.5%
Nash	1.1%	1.3%	2.1%
Durham	1.6%	1.6%	2.5%
Other	4.0%	7.6%	15.3%
Total	100.0%	100.0%	100.0%

In Section III.5(a), page 21, the applicant states the service area for DRH’s oncology services will be Wake County, as well as Franklin, Johnston, Harnett, Nash and Durham counties. The applicant states it will continue to serve patients throughout the state who seek oncology services.

The applicant adequately identifies the population proposed to be served.

Analysis of Need

In Section II.1(a), page 8, the applicant states the primary purpose of the project is to renovate existing clinic space for patient exams and clinical procedures, indicating that the exam rooms are too small to accommodate the equipment and personnel needed for the oncology services to be provided at Macon Pond. In Section III.1(a), pages 14 – 16, the applicant describes the need the population has for the renovation and acquisition of radiology equipment; and in Section III.1(b), pages 16 – 19, the applicant provides assumptions and methodology to support its stated need.

In Section III.1(a), page 14, the applicant states Duke Medicine is affiliated with Tolnitch Surgical Associates, a breast surgery practice located near Macon Pond. According to the applicant, two surgical oncologists practice at Macon Pond, and a new recruit has committed

to join the practice in 2016. As a result of the growth of the practice and the new surgical oncologists, DUHS states it will move the clinic site to Macon Pond, so that the surgical oncologists will practice in a hospital-based setting with radiation and medical oncologists. The applicant states on page 14 that the hiring of four additional physicians who practice various oncology modalities, combined with the co-location of these oncology modalities at the Macon Pond location will allow for *“the optimal coordination of care of breast cancer patients in a single convenient location, which provides for the easiest and least stressful environment possible for patients.”*

On pages 14 – 15, the applicant explains that the existing clinic rooms at Macon Pond are too small to accommodate the equipment needed for image-guided mammography and ultrasound procedures that are routinely performed in the detection of breast cancer.

The applicant proposes to acquire a 3D Tomosynthesis mammography unit that will detect 41% more invasive breast cancers and reduce false positives by up to 40%. This will benefit early breast cancer detection and, according to the applicant, will allow physicians to see masses and distortions more clearly than with the existing 2D mammography units.

The applicant states ultrasound is another critical diagnostic tool for breast and other cancers, and often an ultrasound is warranted in addition to a mammography to provide a more accurate diagnosis. According to the applicant on page 15, the existing ultrasound equipment is heavily utilized and *“there is a significant scheduling backlog.”* The Macon Pond location needs additional ultrasound capacity to accommodate its patients’ needs, and to be able to offer needle versus surgical biopsy if warranted.

In Section III.1(b), pages 16 – 19, the applicant provides the assumptions and methodology to demonstrate its stated need for additional ultrasound and mammography equipment, as well as facility renovation. The applicant states on page 16 that from FY 2012 to FY 2014, cancer treatment volume at DRH has increased by 42%. Furthermore, since DRH acquired the Macon Pond site in late 2014 and recruited several physicians, the same treatment volume has increased by an additional 38% between FY 2014 and FY 2015.

Similarly, on page 17, the applicant states its mammography volume on two machines increased 20% from FY 2014 to FY 2015, and 67% since Fall 2011. Furthermore, DRH operates three ultrasound machines whose volume in FY 2015 was 9,508 procedures per year, thus exceeding *“typical capacity”* of 6,000 annual procedures on three machines. From FY 2011 through FY 2015, the ultrasound volume increased 17.3% $[(9,508 / 8,105) - 1 = 0.173]$. The applicant states its patients typically encounter a three week waiting period for ultrasound procedures. The renovation of clinic space and acquisition of new imaging equipment will allow DRH to more efficiently accommodate its patients’ needs. On page 17, the applicant states:

“Macon Pond already has a highly utilized linear accelerator and significant other cancer services, including infusion. Duke Raleigh Hospital's high utilization on the main campus limits further growth of services in that location. Therefore,

Duke has determined that it could best meet the needs of patients going forward by coordinating breast and women's cancer specialties at Macon Pond, where there is space to accommodate growing demand for these critical services in an efficient and convenient setting and provide the benefits of coordination of care for specific diagnoses across treatment modalities.” [emphasis in original]

On pages 18 – 19, the applicant cites Truven Analytics data to show that the population of Wake County is projected to grow by a compound annual growth rate (CAGR) of 1.7% from 2015 to 2020. Similarly, the population growth of Franklin, Harnett, Johnston and Nash counties is projected to be among the highest in the state. The applicant cites similar statistics for cancer incidence, stating that in those counties from which its projected population originates, Truven Analytics projects a 17.8% overall growth in new cancer cases over the next five years [17.8 / 5 = 3.56% per year]. On page 18 the applicant states *“The need for Duke to continue to provide operationally efficient and convenient breast and other cancer services in Wake County is clear. This project will best enable Duke to meet that need.”*

Projected Utilization

In Section IV.1, pages 28 – 37, the applicant provides the historical and projected utilization for surgical oncology, mammography and ultrasound services at Macon Pond through the first three years of operation following completion of the project, which is summarized below. The applicant acquired the Macon Pond facility in November 2014, and began operating it as a hospital provider-based outpatient facility in February of 2015; therefore, the historical utilization is scant.

TYPE OF SERVICE	LAST FY	INTERIM FY	FIRST FY	SECOND FY	THIRD FY
	7/2014 – 6/2015	7/2015 – 6/2016	7/2016 – 6/2017	7/2017 – 6/2018	7/2018 – 6/2019
Diagnostic Imaging					
Mammography					
# Units	--	--	1	1	1
# Procedures	--	--	1,607	1,785	1,899
Ultrasound					
# Imaging Units	--	--	1	1	1
# Procedures	--	--	1,102	1,188	1,248
# Surgical Procedure Units	--	--	2	2	2
# Procedures	--	--	1,085	1,196	1,265
Other Service Components – Oncology					
# Surgical Procedures	--	--	1,286	1,418	1,500
Total # Oncology Visits	7,701	9,622	16,796	18,678	19,885

As shown in the table above, the applicant projects 19,885 total oncology visits in the third year of operation.

On pages 29 – 35, the applicant describes the assumptions and methodology it used to project utilization in each of the oncology modalities listed. On pages 29 – 30, the applicant provides assumptions for the projected growth in the number of breast needle biopsies (surgical

oncological clinic procedures) to be performed at Macon Pond. On page 31, the applicant provides assumptions for the projected growth in the number of hematology oncology, radiation oncology, and gynecological oncology visits the practice will experience. On page 33, the applicant provides assumptions for projected growth in the number of mammography procedures to be performed at Macon Pond; and on page 35, the applicant provides assumptions for the projected growth in the number of ultrasound procedures to be performed. In its assumptions for each modality, the applicant relies on the following:

- Projected population growth in the service area;
- Projected growth in the incidence of cancer in the service area;
- Historical experience of Duke's oncology services in Wake and surrounding counties;
- Physician recruitment in FY 2014, combined with commitments from additional physicians for FY 2016 and FY 2017.
- Referral numbers and pattern of the surgical oncologists at Tolnitch Surgical Associates, since they will join the physicians at Duke Macon Pond
- The applicant's efforts to combine all of its Wake County breast and gynecological oncology services in one location to more efficiently serve its patients and reduce the stress many cancer patients are already burdened with.

In Section III.6, page 25, the applicant states the need for this renovation project as proposed is unique to the needs of its patients and the services it provides to those patients. There are no Regulatory Review Criteria that are applicable to this project; therefore, there are no performance standards for utilization that must be met. The applicant's projections of the oncology patients and procedures to be served at Macon Pond following the renovation and acquisition of additional radiation and ultrasound equipment is based on reasonable and adequately supported assumptions. Therefore, the applicant adequately demonstrates the need to renovate existing clinic space at Macon Pond, and to acquire additional radiation and ultrasound equipment to serve breast and gynecological oncology patients.

Access

In Section VI.2, pages 44 - 45, the applicant states Macon Pond will continue to provide services to all patients regardless of their income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or other factor that would classify a patient as underserved. The applicant adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served by the proposed project, demonstrates the need the population has for the services proposed, and demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. 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 III.3, pages 19 - 20, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo –The applicant states that maintaining the status quo is not an effective alternative because it would not allow for the close coordination of care between breast surgical oncologists and other oncology treatment providers, particularly since the existing exam rooms are too small to accommodate patients.
- Do Not Include Imaging Equipment or Relocate Existing Imaging Equipment from the Hospital Campus to Macon Pond – The applicant states this is not an effective alternative because it is critical to have onsite imaging to support its breast cancer program. In addition, the applicant states the existing imaging equipment at the hospital is highly utilized and current hospital volumes could not be accommodated with fewer machines.
- A New Clinic Location – The applicant states a different clinic location other than the existing Macon Pond site is not an effective alternative, because developing a new clinic would not be a cost-effective alternative to renovating existing space. Furthermore, the Macon Pond location has a linear accelerator that could not be easily relocated.

After considering those alternatives, the applicant states the alternative represented in the application is the most effective alternative to meet the identified need.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that the 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 d/b/a Duke Raleigh Hospital shall materially comply with all representations made in the certificate of need application.**
 2. **Duke University Health System 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 expenditures in Section VIII of the application and that would otherwise require a certificate of need.**
 3. **Duke University Health System d/b/a/ Duke Raleigh Hospital shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.**
 4. **Duke University Health System 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

Duke University Health System d/b/a Duke Raleigh Hospital proposes to renovate existing clinic space and acquire imaging equipment to be installed in the Macon Pond facility.

Capital and Working Capital Costs

In Section VIII.1, page 66, the applicant projects the total capital cost will be \$4,257,903, as shown in the following table:

Item	Cost
Construction Materials	\$761,724
Construction Labor	\$1,142,585
Fixed Equipment	\$1,485,868
Architect/Engineering/Permit Fees	\$405,720
Contingency Fund	\$462,006
Total	\$4,257,903

In Section IX.1, page 71, the applicant states there will be no start-up expenses or initial operating expenses associated with the proposed project.

In Section VIII.10, page 69, the applicant lists all DUHS projects which are currently under review by the certificate of need section.

Availability of Funds

In Section VIII.3, page 67, the applicant states the cost of the project will be financed with DUHS accumulated reserves. In Exhibit 16, the applicant provides an August 14, 2015 letter from the Chief Financial Officer and Treasurer for Duke University Health System which confirms sufficient funds are available for and will be applied toward this project.

In Exhibit 7, the applicant provides the consolidated financial statements for DUHS which show that, as of June 30, 2014, DUHS had total assets in the amount of \$4,873,711,000, including \$167,190,000 in cash and cash equivalents. The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

Financial Feasibility

In Form C, on page 84, the applicant shows a net loss for the first three operating years of the Macon Pond facility. However, Macon Pond is operated by DUHS, which has total assets as stated above. In addition, in supplemental information provided to the Agency, the applicant states:

“Duke Raleigh Hospital is operated as a part of the Duke University Health System. As a not-for-profit provider Duke can, and regularly does, operate certain critical patient services at a loss, which may be offset by other revenues. The system’s pro formas and audited financial statements make it clear that the system can support the proposed critical cancer services at the projected level of costs and revenues.”

In Section XII, page 81, the applicant provided pro forma financial statements for DUHS for the first three operating years of the project. In the pro forma financial statement (Form B), the applicant projects that revenues will exceed operating expenses in each of the first three years of operation of the project, as shown in the table below.

DUHS			
	FY 2017	FY 2018	FY 2019
Total Operating Revenue	\$3,130,608,000	\$3,215,874,000	\$3,281,044,000
Total Operating Expense	\$2,957,226,000	\$3,050,802,000	\$3,112,711,000
Operating Income	\$ 173,382,000	\$ 165,072,000	\$ 168,332,000

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the financial section 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. The applicant adequately demonstrates that the financial feasibility of this 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

The 2015 SMFP, on page 48, defines the service area for acute care services by county (or multicounty service area for counties without a hospital). DRH and Macon Pond are located in Wake County. Thus, the service area for DRH is Wake County. Facilities may also serve residents of counties not included in their service area. DRH intends to renovate the Macon Pond facility and locate its breast and women’s cancer outpatient services primarily at that site to more efficiently coordinate patient care for patients with breast and gynecological cancers and to accommodate breast surgical consultations and clinic procedures. The applicant acquired the Macon Pond location in 2014, began operating it in February 2015, and does not have a full year of patient origin data to report. It defines its service area as Wake County, as well as Franklin, Harnett, Nash, Johnston and Durham counties.

In Section III.6, page 24, the applicant states DRH and Rex Hospital are the only comprehensive cancer treatment centers in the proposed service area. Furthermore, non-hospital providers of mammography and ultrasound services are not required to report annual volumes to the State. Utilizing data from the 2015 Hospital License Renewal Applications, the applicant provides the ultrasound and mammography volumes from the area hospitals, as shown in the following table:

FY 2014 Ultrasound and Mammography Utilization

PROVIDER	ULTRASOUND VOLUME	AVERAGE PER UNIT	MAMMOGRAPHY VOLUME	AVERAGE PER UNIT
Duke Raleigh Hospital	9,037 (3 units)	3,012	4,156 (2 units)	2,078
Rex Hospital	17,390 (25 units)	696	24,505 (10 units)	2,451
WakeMed	24,409 (9 units)	2,712	7,182 (4 units)	1,796
WakeMed Cary	8,069 (7 units)	1,152	3,556 (3 units)	1,185
Total	58,905 (44 units)	1,338	36,199 (19 units)	1,905

As shown in the table above, DRH currently operates three ultrasound machines, each of which provided 3,012 procedures in FFY 2014, which is 150% of DRH’s stated capacity. In addition, DRH’s mammography and ultrasound equipment performed more procedures per unit of all the equipment listed by the applicant in the table above.

On page 25, the applicant states that since the need to renovate existing clinic space and install mammography and ultrasound equipment is a need that is internal to DRH to support its own volume at Macon Pond, other providers in the area would not be able to meet that need. Moreover, the applicant states the historical volumes show that capacity in other locations as noted in the table above has not affected DRH Macon Pond’s increasing volumes; and with

the renovation, projected population growth, projected growth in the incidence of cancer, and addition of surgical oncologists, the demand for the oncology services proposed in this application will remain high. Furthermore, the applicant's capacity for ultrasound is 2,000 procedures, and the capacity for mammography is 4,000 procedures. If the applicant relocated an ultrasound or mammography unit from DRH, DRH would be left with utilization in excess of 100% on the remaining equipment. The capacity of the other providers is unknown, since capacity of this type of equipment is defined by the provider. There are no capacity definitions or performance standards in Certificate of Need Law or in the Rules that apply to this application.

The applicant adequately demonstrates the need to renovate existing clinic space and acquire ultrasound and mammography equipment for the provision of breast and gynecological oncology services. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference. Therefore, the applicant adequately demonstrates that the proposal would not result in unnecessary duplication of existing or approved breast and gynecological oncology mammography and ultrasound services. 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 VII.1, pages 56 - 57, the applicant provides the current and projected staffing in Full Time Equivalent (FTEs) for Macon Pond, as shown in the tables below.

Macon Pond Current Staffing, FY 2015

POSITION	# CURRENT FTEs
Administrative	
Nurse Manager	0.33
Clinical	
Registered Nurse	2.67
Licensed Practical Nurse	0.67
Certified Medical Assistant	2.00
Clinical Team Lead	0.67
Support	
Patient Services Associate	1.33
Service Access Team Lead	0.17
Financial Care Counselor	0.67
Total FTEs	8.51

Proposed Staffing FY 2018

POSITION	# FTEs
Administrative	
Nurse Manager	1.00
Clinical	
Registered Nurse	9.50
Licensed Practical Nurse	1.00
Certified Medical Assistant	6.00
Clinical Team Lead	1.00
Mammography Technologist	1.13
Ultrasonographer	1.13
Support	
Patient Service Associate	5.75
Service Access Team Lead	0.25
Financial Care Counselor	1.60
Social Worker	1.00
Dietician	1.00
Patient Navigator	2.00
Tumor Registrar	2.00
Total FTEs	34.36

The applicant states on page 57 and in supplemental information provided at the Agency’s request that *“the 34.36 FTEs include 6.51 incremental staffing for the new services. The remaining FTEs are based on additional growth.”* In Section VII.3, page 58, and Section VII.6, page 59, the applicant describes its experience and process for recruiting and retaining staff. In Section VII.8, page 60, the applicant identifies Michael Spiritos, M.D., as the Medical Director for the facility. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. 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.

C

In Section II.2, page 10, the applicant states that, as a current provider of mammography, ultrasound and comprehensive oncology services, it already provides the necessary ancillary and support services. In Section V.2, pages 39 - 40, the applicant identifies facilities in its proposed service area with which it currently has transfer agreements. Exhibit 9 of the application contains copies of the existing transfer agreements.

In Exhibit 18, the applicant provides letters from physicians, other healthcare providers, and current oncology patients who receive their care at Macon Pond, expressing support for the proposed project. The applicant adequately demonstrates that necessary ancillary and support services are available and that the proposed services will continue to be coordinated with the existing healthcare system. 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:
- (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 Section VI.13, page 50 - 51, the applicant provides the payor mix during FY 2015 for the mammography, ultrasound, and total oncology visits to Duke Raleigh Hospital, as shown in the table below. DRH does not have a full year at the Macon Pond location to show.

PAYOR CATEGORY	MAMMOGRAPHY	ULTRASOUND	ONCOLOGY
Self Pay/Indigent/Charity	2.2%	10.7%	3.8%
Medicare/Medicare Managed Care	35.0%	27.1%	36.7%
Medicaid	3.1%	11.3%	6.3%
Commercial Insurance	1.2%	1.2%	1.3%
Managed Care	57.8%	48.6%	49.9%
Other	0.7%	1.1%	2.0%
Total	100.0%	100.0%	100.0%

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. More current data, particularly with regard to the estimated uninsured percentages, was not available. The following counties comprise the projected counties of residence for the patients to be served at Macon Pond:

	Total # of Medicaid Eligibles as % of Total Population June 2010	Total # of Medicaid Eligibles Age 21 and older as % of Total Population June 2010	% Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center)
County			
Wake	10%	3.3%	18.4%
Durham	16%	5.7%	20.1%
Franklin	18%	7.4%	19.7%
Nash	20%	8.7%	19.7%
Johnston	17%	6.7%	20.0%
Statewide	17%	6.7%	19.7%

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the ultrasound and mammography oncology services proposed in this application.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website

includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicants' current payer mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicant demonstrates that medically underserved populations currently have adequate access to the applicant's existing services and 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

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 49, the applicant states:

“Duke Raleigh Hospital is not obligated under federal regulations to provide uncompensated care, community service, or access by minorities or handicapped persons. For example, Duke Raleigh Hospital does not have any Hill-Burton uncompensated care requirements. However, as previously stated, Duke Raleigh Hospital does not discriminate based on race, ethnicity, creed, color, sex, age, religion, national origin, handicap, or ability to pay. Duke Raleigh Hospital will continue to provide healthcare service and access for all persons, without federal obligation.”

In Section VI.10 (a), page 49, the applicant describes two Office of Civil Rights complaints filed against DUHS facilities in last five years. The applicant states both of the complaints have been fully resolved. 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

C

In Section VI.15, pages 53 - 54, the applicant provides the projected payor mix for the second full fiscal year following completion of the proposed project (FY 2018) for the mammography, ultrasound, and surgical oncology visits to Macon Pond, as shown in the table below.

PAYOR CATEGORY	MAMMOGRAPHY	ULTRASOUND	ONCOLOGY
Self Pay/Indigent/Charity	2.4%	6.6%	0.7%
Medicare/Medicare Managed Care	37.6%	28.4%	32.0%
Medicaid	4.1%	8.9%	1.6%
Commercial Insurance	0.8%	1.2%	1.1%
Managed Care	54.2%	54.0%	63.4%
Other	0.9%	1.0%	1.2%
Total	100.0%	100.0%	100.0%

In Section VI.15(b), page 55, the applicant describes its assumptions.

The applicant demonstrates that medically underserved populations will 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.

C

In Section VI.9(a), page 48, the applicant states access to radiation therapy services will typically be through referral to one of the radiation oncologists with privileges at DRH. The information provided is reasonable and credible and supports a finding of conformity 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 V.1, pages 38 - 39, the applicant lists the existing health professional training programs, both locally and nationally, with which Duke University Hospital (DUH) has

established relationships. The information provided in Section V.1 is reasonable and credible and supports a finding of conformity 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

Macon Pond proposes to renovate 33,785 square feet of existing clinic space in the women's cancer center, and acquire radiation and ultrasound equipment.

In Section V.7, page 42, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The applicant states:

“The proposed project will improve the quality of oncology services, access to services and the cost effectiveness of radiation therapy services at Duke Raleigh. Duke Raleigh is a valued and highly utilized provider in the service area, and ensuring continued capacity is necessary to provide patients a choice of providers.”

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition in the service area include a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- ◆ The applicant adequately demonstrates the need to renovate existing clinic space at the Macon Pond location and acquire radiation and ultrasound equipment, and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criterion (3) and (4), respectively, are incorporated herein by reference.
- ◆ The applicant adequately demonstrates that it will continue to provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.

- ◆ The applicant demonstrates that it will continue to provide adequate access to medically underserved populations. The discussion regarding access found in Criterion (13) is incorporated herein by reference.

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

DUHS is certified by CMS for Medicare and Medicaid participation, and licensed by the NC Department of Health and Human Services. According to files in the Acute and Home Care Licensure and Certification Section in the Division of Health Service Regulation, no incidents have occurred at DUHS within the eighteen months immediately preceding the date of the decision for which any sanctions or penalties related to quality of care were imposed by the State. 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