

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: February 28, 2013

PROJECT ANALYST: Michael J. McKillip

SECTION CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: J-10062-12 / Duke University Health System d/b/a Durham Regional Hospital / Replace two nuclear medicine SPECT cameras and renovate the nuclear medicine department / Durham County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

NA

Duke University Health System d/b/a Durham Regional Hospital [**Durham Regional Hospital**] proposes to replace two nuclear medicine SPECT cameras and renovate the nuclear medicine department. 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 2012 SMFP. There are no policies in the 2012 SMFP that are applicable to this review. Therefore, this criterion is not applicable.

- (2) Repealed effective July 1, 1987.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, Durham Regional Hospital, proposes to replace two nuclear medicine SPECT cameras and renovate the nuclear medicine department. In Section II.1, page 8, the applicant describes the project as follows:

“This application proposes the replacement and upgrade of two Nuclear Medicine Single Photon Emission Computerized Tomography (SPECT) cameras and the renovation of Durham Regional Hospital’s Nuclear Medicine Department. ...

1) Durham Regional currently owns and operates three pieces of nuclear medicine equipment: two SPECT cameras and one single-head/planar camera. The two SPECT cameras are experiencing extensive downtime (approximately one service call per camera per month) that exceeds the vendor’s contractual agreement for service. Both cameras are greater than 12 years old and have reached their end of life. The potential for failure is great and cameras are in need of replacement at this time. The proposed replacement equipment consists of one SPECT unit and one SPECT/CT unit. The new equipment contains new and improved technology that provides enhanced image quality for the patient’s benefit.

2) The Nuclear Medicine Department is original to the hospital and has not been changed significantly in layout over the years as it has evolved to accommodate new equipment. The department’s infrastructure is outdated and the layout is disjointed. The need to grow has fragmented the department throughout the second floor of the hospital and created inefficient workflows and barriers to future advancements. The proposed construction provides a finished Nuclear Medicine Department that will house all patient care activities in one area, allowing for operational efficiencies and a better patient experience.”

In Section III.1(a), page 13, the applicant states:

“After the proposed replacement, Durham Regional Hospital’s Nuclear Medicine Department will consist of one new SPECT/CT camera, one new SPECT camera, and the existing single-head/planar camera.

Additionally, renovation of the current space – in use since 1976 – will allow for including all Nuclear Medicine patient care areas in one cohesive suite to:

- Address patient safety concerns which arise from the current absence of injection rooms.*
- Improve patient experience by creating a dedicated patient waiting room; currently patient must wait in areas dispersed throughout the hospital.*
- Improve efficiency of hospital staff in the provision of care and ancillary services by reformatting patient flow.*
- Ensure appropriate egress in the event of emergencies.”*

In Section III. 4, the applicant provides projected patient origin for Durham Regional Hospital’s nuclear medicine services in the first two years of operation (FY2015 and FY2016), as shown in the table below.

County	Percent of Total
Durham	60.5%
Person	11.5%
Granville	8.8%
Orange	6.6%
Wake	4.0%
Other NC Counties*	6.8%
Other States	1.8%
TOTAL	100.0%

*The applicant provides a complete list of the counties included in the “Other” category in Exhibit III.4b of the application.

On page 17 of the application, the applicant states, “We do not anticipate any change in patient origin for Nuclear Medicine services following completion of the project.” The applicant adequately identified the population proposed to be served.

Need for the Project

In Section IV.1, page 22, the applicant provides a table showing the historical and projected utilization for the nuclear medicine department at Durham Regional Hospital (DRH) through the first three years of operation for the proposed project, which is summarized below:

Durham Regional Hospital Nuclear Medicine Utilization

Year	Nuclear Medicine Camera Units*	Total Nuclear Medicine Procedures**	Percent Change
FY2011 – Actual	3	3,202	---
FY2012 – Actual	3	3,161	-1.3%
FY2013 – Projected	3	3,169	0.3%
FY2014 – Projected	3	3,212	1.4%
FY2015 – Year 1	3	3,256	1.4%
FY2016 – Year 2	3	3,300	1.4%
FY2017 – Year 3	3	3,345	1.4%

*DRH’s nuclear medicine department currently operates two SPECT cameras and one single-head/planar camera. Following completion of the project in FY2015, the DRH nuclear medicine department will operate one SPECT camera, one SPECT/CT camera, and one single-head/planar camera.

**Applicant states that nuclear medicine procedure totals include both SPECT and Gamma procedures.

On pages 13-14 of the application, the applicant describes its assumptions and methodology for projecting utilization of the nuclear medicine department at Durham Regional Hospital as follows:

“The two SPECT cameras together performed 82% of the total nuclear medicine imaging volumes during FY 2012 (with the single head camera performing the remaining 18%). ... The combined utilization of all three Nuclear Medicine cameras for FY 2012 was 71.5% (3161 procedures at 1.6 hours/procedure, divided by 7076 total available hours). In addition to the high utilization of the existing equipment which is reaching the end of their useful life, the need for the project proposed in this application is supported by two more primary factors: 1) Population growth with the Hospital’s primary service area and 2) Growth from additional clinical applications of SPECT technology. The conservative projection outlined within this application demonstrates the need based exclusively on the population growth projected for the DRH primary service area (PSA).

- 1) **Population growth and aging:** The population in Durham Regional Hospital’s primary service area (PSA) is projected to grow 6.8% over the next five years, compared to 7.0% for North Carolina as a whole, based on projections provided by Truven Analytics. While the total population in the PSA is growing, most of the growth is attributed to an increase in people over 45 years of age. The 45-64 year old population is projected to increase 8.7% and the 65+ population is projected to increase 23.5%.*
- 2) **Additional clinical applications:** Nuclear Medicine (Planar and SPECT) is primarily used in cardiology, cancer, neurosciences, and general medicine service lines. In calendar year 2011, over half of all nuclear medicine procedures were cardiac SPECT. However, SPECT/CT technology is increasing, and expanding from cardiology to include applications in oncology, orthopedics, and neurosciences. In cancer, neurosciences, and general medicine, the emergence of more targeted tracers and the development of hybrid cameras will increase utilization for these service lines as standard nuclear imaging is widely available. To determine potential growth in the service area in individual service lines, Duke University Health System utilizes Sg2’s localized Impact of Change (IoC) tool to forecast demand for health care services over the next decade, examining the cumulative effects and interdependencies of key factors driving change in utilization. It supports program development, innovation adoption, facility design and system-wide planning. DUHS’s forecast is built using both DUHS’s institution data as well as North Carolina Hospital Association data for the market forecast. The IoC forecasting methodology allows organizations to forecast future demand using a payment-based model (MS-*

DRGs) as well a disease based classification system, Sg2 CARE (Clinical Alignment and Resource Effectiveness) Families and Groups. This approach assists organizations in managing patients efficiently in the most appropriate, cost-effective care settings across the outpatient and inpatient CARE continuum. ... As illustrated in the graph [shown on page 15 of the application], based on Sg2's forecasting tool, Nuclear Medicine/SPECT overall volume is expected to grow 12.8% between 2011 and 2020 within DRH's primary service area."

The applicant projects utilization will grow by 1.4 percent per year from FY2013 to FY2017, or by approximately 5.6 percent over the four-year period, based only on projected population growth for the primary service area. Exhibit V.3 of the application contains letters from physicians expressing support for the proposed project. Based on the projected population growth in the applicant's service area and the historical utilization of the applicant's nuclear medicine services, the applicant's utilization projections are reasonable. Therefore, the applicant adequately demonstrated the need to replace two nuclear medicine SPECT cameras and renovate the nuclear medicine department at Durham Regional Hospital.

Access

The applicant projects 51% of its patients will be covered by Medicare and Medicaid. The applicant demonstrates adequate access for the underserved to its services.

In summary, the applicant adequately demonstrated the need the population projected to be served has for the proposed project, and demonstrated all residents of the area, and, in particular, underserved groups are likely to have access to the services proposed. 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, page 16, the applicant describes the alternatives considered, including maintaining the status quo and replacing the nuclear medicine cameras without renovating the nuclear medicine department.

- The applicant states it rejected the status quo alternative due to high rates of equipment malfunction for the existing nuclear medicine cameras, which have reached the end of their useful lives, and are nearing the end of the contracts for service by the vendor.
- The applicant considered the alternative of replacing the nuclear medicine cameras, but without renovating the nuclear medicine department, but rejected it because this alternative would leave the department disjointed and outdated, and create an even larger workflow problem than currently exists. It also does not address the egress issues identified under the Life Safety Code.

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

- 1. Duke University Health System d/b/a Durham Regional Hospital shall materially comply with all representations made in the certificate of need application.**
 - 2. Duke University Health System d/b/a Durham Regional Hospital shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application or that would otherwise require a certificate of need.**
 - 3. Duke University Health System d/b/a Durham Regional Hospital shall acknowledge acceptance of and agree to comply with all conditions stated herein to the 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.

In Section VIII.1, the applicant projects its capital cost for the project to be \$3,314,985. In Section VIII.3, the applicant states the capital cost will be financed with accumulated reserves. In Section IX.1, the applicant projects no start-up expenses or initial operating expenses. In Exhibit VIII.6 of the application, the applicant provides a letter from the Senior Vice President and Chief Financial Officer for Duke University Health System, which states

“This will certify that Duke University Health System has as much as \$4 million in accumulated reserves to devote to the acquisition of nuclear medicine equipment and related construction at Durham Regional Hospital.”

Exhibit VIII.9 of the application contains audited financial statements for Duke University Health System, Inc. and Affiliates (DUHS) for the year ended June 30, 2012, which documents that DUHS had \$243 million in cash and cash equivalents as of June 30, 2012. The applicant adequately demonstrated the availability of funds for the projected capital costs described in the application.

In pro forma financial statements for DRH’s nuclear medicine department (Form C), the applicant projects expenses will exceed revenues in each of the first three operating years, as shown below:

Durham Regional Hospital Nuclear Medicine Department

	FY2015 Year 1	FY2016 Year 2	FY2017 Year 3
Total Net Revenue	\$1,994,340	\$2,050,991	\$2,111,592
Total Expenses	\$2,795,098	\$2,891,783	\$2,973,314
Net Income (Loss)	(\$800,758)	(\$840,792)	(\$861,722)

However, in pro forma financial statements for DUHS (Form B), the applicant projects revenue will exceed operating costs (expenses) in each of the first three operating years, as shown below:

Duke University Health System

(All \$ are in 000’s)

	FY2015 Year 1	FY2016 Year 2	FY2017 Year 3
Total Net Revenue	\$2,805,065	\$2,881,395	\$2,968,149
Total Expenses	\$2,516,544	\$2,597,409	\$2,685,021
Net Income (Loss)	\$288,521	\$283,986	\$283,128

Operating costs and revenues are based on reasonable assumptions including projected utilization. See the pro forma financial statements in the application and Criterion (3) for utilization assumptions. The applicant adequately demonstrated that the financial feasibility of the proposal is based upon reasonable projections of operating costs and revenues, and the application is conforming with 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 applicant, Durham Regional Hospital (DRH), proposes to replace two nuclear medicine SPECT cameras and renovate the nuclear medicine department. The following table shows the nuclear medicine service utilization for other providers in the applicant’s primary service area:

Utilization of Existing Nuclear Medicine Providers in DRH’s Primary Service Area

	Total # of SPECT and Gamma Camera Units	Inpatient SPECT & Gamma Procedures	Outpatient SPECT & Gamma Procedures	Total SPECT & Gamma Procedures
Duke University Hospital	10	2,777	10,417	13,194
Granville Medical Center*	1	175	610	785
Person Memorial Hospital**	1	10	110	120
UNC Hospitals-Chapel Hill	16	1,553	6,995	8,548

Source: 2012 Renewal Application for Hospital (FY2011 data).

*Granville Medical Center does not operate a SPECT camera. Utilization data is for a Gamma camera only.

**Person Memorial Hospital does not operate a Gamma camera. Utilization data is for a SPECT camera only.

In Section IV.1, page 22, the applicant provides a table showing the historical and projected utilization for the nuclear medicine department at Durham Regional Hospital (DRH) through the first three years of operation for the proposed project, which is summarized below:

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*DRH’s nuclear medicine department currently operates two SPECT cameras and one single-head/planar camera. Following completion of the project in FY2015, the DRH nuclear medicine department will operate one SPECT camera, one SPECT/CT camera, and one single-head/planar camera.

**Applicant states that nuclear medicine procedure totals include both SPECT and Gamma procedures.

As indicated in the above table, the applicant projects to perform 3,345 procedures on the nuclear medicine cameras in DRH’s nuclear medicine department in the third operating year of the proposed project (FY2017). Based on the utilization standards defined by the applicant in Section IV.2, the three nuclear medicine cameras have a total annual capacity of 4,422 procedures. Therefore, the applicant projects the three nuclear medicine cameras will be

operating at 76 percent of capacity in the third year of operation following completion of the project [$3,345/4.422 = 0.76$].

DRH projected utilization for the nuclear medicine cameras, and demonstrated the need to replace two existing SPECT cameras with one new SPECT/CT camera and one new SPECT camera. The applicant proposes to replace two existing nuclear medicine cameras, and does not propose to add to the total number of nuclear medicine cameras in the applicant's service area. Consequently, the applicant adequately demonstrates the proposed project would not result in the unnecessary duplication of existing or approved health service capabilities or facilities in the applicant's service area. Therefore, the application is conforming with 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 37-38, the applicant provides the current staffing for DRH's nuclear medicine department, as shown in the table below.

DRH Nuclear Medicine Staffing	FTEs
Radiology Technologists	7.39
Clerical	0.81
Total	8.20

The applicant states the proposed project will not result in the addition of any staff to the hospital. In Section VII.8, page 41, the applicant identifies Barbara Griffith, M.D. as the Chief Medical Officer for Durham Regional Hospital. Exhibit V.3 contains copies of letters of support from the Chairperson of the Department of Medicine and the Department of Nuclear Medicine at Durham Regional Hospital. 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 of the application, the applicant states that all of the necessary ancillary and support services for the proposed services are currently provided at Durham Regional Hospital, including anesthesiology, laboratory, and pharmacy. In Exhibit V.2 of the application, the applicant provides a list of facilities with which DRH has transfer agreements. In Exhibit V.3 of the application, the applicant provides letters from physicians supporting the proposed project.

The applicant adequately demonstrates that the proposed project will be coordinated with the existing health care system. Therefore, the application is conforming with 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 34, the applicant provides the payer mix during FY2012 for the Nuclear Medicine department at Durham Regional Hospital, as shown in the table below.

DRH Nuclear Medicine Department Payer Category	Procedures as % of Total
Self Pay/Indigent/Charity	7.4%
Medicare/Medicare Managed Care	47.3%
Medicaid	8.4%
Commercial Insurance	0.8%
Managed Care	34.9%
Other	1.2%
Total	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. The following table illustrates those percentages as of June 2010 and CY2008-2009, respectively. The data in the table was obtained on February 7, 2013. More current data, particularly with regard to the estimated uninsured percentages, was not available.

	Total # of Medicaid Eligibles as % of Total Population	Total # of Medicaid Eligibles Age 21 and older as % of Total Population	% Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center)
County			
Durham	16%	5.7%	20.1%
Granville	15%	6.3%	18.4%
Orange	9%	3.5%	18.9%
Person	18%	8.3%	18.0%
Wake	10%	3.3%	18.4%
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 services offered by the applicant.

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. On page 33, the applicant states:

“Duke University Health System hospitals have now satisfied the requirements of Federal regulations to provide, on a annual basis, a certain amount of uncompensated care in return for Hill Burton funds previously received. ... They have no special obligation under applicable Federal regulations to provide uncompensated care, community service, or access by minorities and handicapped person other than those obligations that apply to private, non-profit, acute care hospitals which participate in the Medicare, Medicaid and Title V programs. ... DRH will continue to provide charity care and other community services as previously described in Section VI.”

In Section VI.10 (a), page 33, the applicant states there have been no civil rights access complaints filed within the last five years. 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, page 36, the applicant provides the projected payer mix for second full fiscal year following completion of the proposed project (FY2016) for the Nuclear Medicine department at Durham Regional Hospital, as shown in the table below.

DRH Nuclear Medicine Department Payer Category	Procedures as % of Total
Self Pay/Indigent/Charity	2.5%
Medicare/Medicare Managed Care	49.3%
Medicaid	9.5%
Commercial Insurance	0.8%
Managed Care	36.7%
Other	1.2%
Total	100.0%

On page 36, the applicant states, *“These projections reflect the aging of the North Carolina population forecast in the tables provided by the State Office of Management and Budget, and an assumed shift from Self-Pay to Medicaid and Managed Care reflecting the impact of the health reform legislation that is to take effect in 2014.”* 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 32, the applicant describes the range of means by which a person will have access to its services. Therefore, the application is conforming with 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, page 24, the applicant states Durham Regional Hospital (DRH) has established relationships with area health professional training programs. Exhibit V.1 contains a list of programs with which DRH has these arrangements. The information

provided in Section V.1 and Exhibit 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

In Section V.7, page 26, the applicant states the proposed project will foster competition by promoting the cost-effectiveness, quality and access to services at Durham Regional Hospital. 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 include a positive impact on cost-effectiveness, quality and access to nuclear medicine services in the applicant's service area. This determination is based on the information in the application, and the following analysis:

- The applicant adequately demonstrates the need for the proposed project, and that it is a cost-effective alternative to meet that need;
- The applicant adequately demonstrated it will continue to provide quality services; and
- The applicant adequately demonstrated it will continue to provide adequate access to medically underserved populations.

Therefore, 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

Durham Regional Hospital 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 Durham Regional Hospital or Duke University Hospital 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