

DEPARTMENT OF HEALTH AND HUMAN SERVICES DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER GOVERNOR MANDY COHEN, MD, MPH

SECRETARY

MARK PAYNE DIRECTOR

January 10, 2018

Catharine W. Cummer 3100 Tower Blvd, Suite 1300 Durham, NC 27707

Exempt from Review - Replacement Equipment

Record #:

2467

Facility Name:

Duke Regional Hospital

FID #:

923142

Business Name:

Duke University Health System

Business #:

640

Project Description:

Replace existing magnetic resonance imaging (MRI) equipment

County:

Durham

Dear Ms. Cummer:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of December 26, 2017, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(f). Therefore, you may proceed to acquire without a certificate of need the GE SIGNA Artist MRI scanner to replace the existing GE Twinspeed Excite MRI scanner. This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

Moreover, you need to contact the Agency's Construction and Acute and Home Care Licensure and Certification Sections to determine if they have any requirements for development of the proposed project.

It should be noted that the Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this office and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Bernetta Thorne-Williams

Project Analyst

Martha J. Frisone

Chief, Healthcare Planning and Certificate of Need Section

cc:

Construction Section, DHSR

Sharetta Blackwell, Program Assistant, Healthcare Planning, DHSR Acute and Home Care Licensure and Certification Section, DHSR

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

WWW.NCDHHS.GOV TELEPHONE 919-855-3873

LOCATION: EDGERTON BUILDING • 809 RUGGLES DRIVE • RALEIGH, NC 27603 MAILING ADDRESS: 2704 MAIL SERVICE CENTER •RALEIGH, NC 27699-2704 AN EQUAL OPPORTUNITY/ AFFIRMATIVE ACTION EMPLOYER



Catharine W. Cummer
Regulatory Counsel, Strategic Planning

December 26, 2017

Via Electronic Mail

Martha Frisone Chief, Healthcare Planning and Certificate of Need Section Division of Health Service Regulation 2704 Mail Service Center Raleigh, NC 27699-2704

Re: Equipment Replacement Project at Duke Regional Hospital

Dear Ms. Frisone:

On behalf of the Duke University Health System, I am writing to provide prior written notice of an equipment replacement project for an MRI scanner at Duke Regional Hospital and to request the Section's written confirmation that the project is exempt from certificate of need review.

This project satisfies the requirements under N.C.G.S. 131E-184(f) for "replacement equipment that exceeds the two million dollar (\$2,000,000) threshold set forth in G.S. 131E-176(22) if all of the following conditions are met:

- (1) The equipment being replaced is located on the main campus.
- (2) The Department has previously issued a certificate of need for the equipment being replaced. This subdivision does not apply if a certificate of need was not required at the time the equipment being replaced was initially purchased by the licensed health service facility.
- (3) The licensed health service facility proposing to purchase the replacement equipment shall provide prior written notice to the Department, along with supporting documentation to demonstrate that it meets the exemption criteria of this subsection."

Main campus

The existing and replacement MRI scanner (designated as MRI 2) are/will be located in the main Duke Regional Hospital building. This is on the "main campus" of the facility, as defined in 131E-176(14n), as "[t]he site of the main building from which a licensed health service facility provides clinical patient services and exercises financial and administrative control over the entire facility, including the buildings and grounds adjacent to that main building" and "[o]ther



Martha Frisone December 26, 2017

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areas and structures that are not strictly contiguous to the main building but are located within 250 yards of the main building." Duke Regional Hospital is a licensed health service facility, and the main hospital building from which Duke Regional Hospital provides its inpatient clinical services and exercises financial and administrative control over all hospital is located at 3643 North Roxboro Road in Durham. Floor plans for the replacement project and the hospital's license are enclosed:

Previous Certificate of Need

The existing MRI scanner was originally acquired pursuant to a certificate of need issued for Project J-6207-00, and upgraded pursuant to a May 13, 2008, letter of no review from the state. The Certificate of Need and letter is enclosed.

Replacement Equipment

The equipment qualifies as replacement equipment pursuant to the existing statutory and regulatory definition. A completed Equipment Comparison form is enclosed. Both the existing equipment and the replacement equipment are magnetic resonance imaging scanners used for diagnostic imaging procedures. The existing machine is currently in service and will remain so until the replacement equipment is operational, at which time it will be removed from service within the state, unless the Certificate of Need Section otherwise approves its continued use in the state. A copy of the equipment quotation for the proposed new scanner is available upon request. Duke will not acquire any other major medical equipment or develop any other new institutional health services other than those described in Section 131E-176(16)(b).

We would appreciate your confirmation that this project is exempt from CON review. Thank you for your attention to this request. If you have questions, please let me know.

Very truly yours,

Catharine W. Cummer

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Enclosures

State of Anth Carolina Bepartment of Health and Human Services Division of Health Service Regulation

Effective January 01, 2017, this license is issued to Duke University Health System, Inc.

to operate a hospital known as

Duke Regional Hospital
located in Durham, North Carolina, Durham County.

This license is issued subject to the statutes of the State of North Carolina, is not transferable and shall remain in effect until amended by the issuing agency.

Facility ID: 923142 License Number: H0233

Bed Capacity: 369

General Acute 316, Rehabilitation 30, Psych 23,

Dedicated Inpatient Surgical Operating Rooms:

Dedicated Ambulatory Surgical Operating Rooms:

Shared Surgical Operating Rooms:

Dedicated Endoscopy Rooms:

Authorized, by:

Secretary, N.C. Department of Health and Human Services

Director, Division of Health Service Regulation

STATE OF NORTH CAROLINA

Department of Health and Human Services Division of Facility Services

CERTIFICATE OF NEED

Project Identification Number J-6207-00

FID #923142

ISSUED TO: Duke University Health System

3000 Erwin Road Durham, NC 27710

Pursuant to N.C. Gen. Stat. § 131E-175, et. seq., the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the "certificate holder") to develop the certificate of need project identified above. The certificate holder shall develop the project in a manner consistent with the representations in the project application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by N.C. Gen. Stat. § 131E-176(16)e. The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. § 131E-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to N.C. Gen. Stat. § 131E-189 for any of the reasons provided in that law.

SCOPE:

Acquire a magnetic resonance imaging (MRI) scanner to be located at Durham. Regional Hospital for a total of two MRI scanners at Durham Regional Hospital/Durham County

- CONDITIONS: 1.
- Duke University Health System, Inc. shall materially comply with all representations made in the certificate of need application and the supplemental information submitted to the Agency dated February 19, 2001. In those instances in which any of these representations conflict, Duke University Health Sitemaps, Inc. shall materially comply with the last made representations.
- Duke University Health System, Inc. shall not acquire, as part of this 2. project, equipment that is not included in the capital expenditure in Section VIII of the application and that would otherwise require a certificate of

PHYSICAL LOCATION:

Durham Regional Hospital 3643 North Roxboro Road Durham, NC 27704

MAXIMUM CAPITAL EXPENDITURE:

\$2,700,850

TIMETABLE:

See Reverse Side

FIRST PROGRESS REPORT DUE: August 1, 2001

This certificate is effective as of the 2nd day of April, 2001.

Chief, Certificate of Feed Section Division of Facility Co.

Division of Facility Services

TIMETABLE

Completion of preliminary drawings	
Completion of final drawings and specifications	April 30, 2001
Approval of final drawings and specifications by	May 31, 2001
Construction Section, DFS	Y 40
Approval of Site by Construction Section, DFS	June 30, 2001
Contract Award	June 30, 2001
25% completion of construction	August 31, 2001
50% completion of construction	October 31, 2001
75% completion of construction	November 30, 2001
Completion of construction	January 31, 2002
Occupancy/offering of service(s)	March 31, 2001
Ordering of equipment	May 1, 2002
Arrival of equipment	September 30, 2001
Operation of equipment	April 1, 2002
operation of equipment	May 1, 2002



North Carolina Department of Health and Human Services Division of Health Service Regulation Certificate of Need Section

2704 Mail Service Center Raleigh, North Carolina 27699-2704

Michael F. Easley, Governor Dempsey Benton, Secretary

www.ncdhhs.gov/dhsr

Lee Hoffman, Section Chief Phone: 919-855-3873 Fax: 919-733-8139

May 13, 2008

Catharine Cummer 149 Cedar Hills Cir. Chapel Hill NC 27514

RE:

No Review/Duke University Health System d/b/a Durham Regional Hospital/Upgrade MRI scanner in Room #2/Durham County
FID # 923142

Dear Ms. Cummer:

The Certificate of Need (CON) Section received your letter of February 11, 2008 regarding the above referenced proposal. Based on the CON law in effect on the date of this response to your request, the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Certificate of Need Section. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

In addition, you should contact the Acute and Home Care Licensure and Certification Section to determine if they have any requirements for development of the proposed project. Please contact the CON Section if you have any questions.

Sincerely,

Michael J. McKillip

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Project Analyst

Lee B. Hoffman, Chief Certificate of Need Section

cc:

Construction Section, DHSR

Acute and Home Care Licensure and Certification Section, DHSR



Location: 701 Barbour Drive & Dorothea Dix Hospital Campus & Raleigh, N.C. 27603

An Equal Opportunity / Affirmative Action Employer



EQUIPMENT COMPARISON

	EXISTING	REPLACEMENT
	EQUIPMENT	EQUIPMENT
Type of Equipment (List Each Component)	MRI Scanner	MRI Scanner
Manufacturer of Equipment	GE	GE
Tesla Rating for MRIs	1.5T	1.5 T
Model Number	Twinspeed Excite	SIGNA Artist
Serial Number		TBD
Provider's Method of Identifying Equipment	MRI 2	MRI 2
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #	NA	NA
Mobile Tractor Serial Number/VIN #	NA	AN
Date of Acquisition of Each Component	July 2005	TBD
Does Provider Hold Title to Equipment or Have a Capital Lease?	Holds Title	TBD
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <use attached="" form=""></use>		2,906,000
Total Cost of Equipment		1.490.456 (after trade-in)
Fair Market Value of Equipment		(III) anni rama (III)
Net Purchase Price of Equipment		
Locations Where Operated	Duke Regional MRI	Duke Regional MRI
Number Days In Use/To be Used in N.C. Per Year	365	365
Percent of Change in Patient Charges (by Procedure)	NA	0
Percent of Change in Per Procedure Operating Expenses (by Procedure)	NA	0
Type of Procedures Currently Performed on Existing Equipment	MRI	NA
Type of Procedures New Equipment is Capable of Performing	NA	MRI



DRAWING SHEET LIST

FRAMING PLAN, SECTION & DETAILS

Duke University Health System

Duke Regional Hospital MRI # 2 Replacement Renovation

3643 North Roxboro Road, Durham, North Carolina

FPDC #3751 HSDR

Owner:

Duke University Health System FPDC # HSDR

Durham, North Carolina

Architect:

RND Architects, PA

Durham, North Carolina Phone: 919-490-1266 David B. Daniel, AIA david@RNDarchitects.com

PM&E Engineer:

Spring Stoops McCullen Engineers, PA

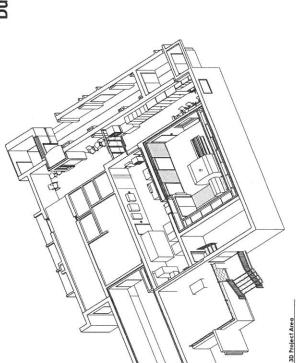
FPDC# 3751 HSDR Duke Regional Hospital MRI#2 Replacement Renovation DukeHealth

> smccullen@ssmepa.com Durham, North Carolina Phone: 919-544-1936 Steven McCullen, PE

Structural Engineer:

Consulting Engineers, PA Gardner & McDaniel

Durham, North Carolina Phone: 919-544-1936 Steve McDaniel, PE steve@gmengrs.com







Project Location







DESIGN DEVELOPMENT PRICING SET

A001

