



DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

September 27, 2017

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

Exempt from Review – Replacement Equipment

Record #: 2396
Facility Name: Duke University Hospital
FID #: 943138
Business Name: Duke University Health System
Business #: 640
Project Description: Replace existing electrophysiology lab equipment
County: Durham

Dear Ms. Cumber:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of September 1, 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 electrophysiology lab equipment, FlashPoint FDI0 to replace the electrophysiology lab equipment, Integris 5000 located on the 7th floor of Duke North. 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
Shareta 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



Williams, Bernetta

From: Catharine Cummer <catharine.cummer@duke.edu>
Sent: Monday, September 25, 2017 11:09 AM
To: Williams, Bernetta
Subject: RE: DUH equipment replacement

This email will confirm that the equipment to be replaced will be sold or otherwise disposed of upon replacement. If you need further information, please let mw know. Thank you.

Catharine

Catharine Cummer
Regulatory Counsel, Strategic Planning
Duke University Health System
3100 Tower Blvd, Suite 1300
Durham NC 27707
(919) 668-0857 (office)
(919) 423-6928 (cell)

From: Williams, Bernetta [mailto:bernetta.williams@dhhs.nc.gov]
Sent: Monday, September 25, 2017 11:01 AM
To: Catharine Cummer
Subject: RE: DUH equipment replacement

Catharine,

I need the following statement concerning the replacement equipment:

Documentation that the equipment proposed to be replaced will be sold or otherwise disposed of once the proposed replacement equipment is installed and operational. See the definition of "replacement equipment" in N.C. Gen. Stat. §131E-176(22a) and the rule at 10 NCAC 14C .0303.

Thank you,

Bernetta Thorne-Williams

Project Analyst
Division Health Service Regulation, Healthcare Planning and Certificate of Need Section
North Carolina Department of Health and Human Services

919 855 3873 office
bernetta.williams@dhhs.nc.gov

809 Ruggles Drive
2704 Mail Service Center
Raleigh, NC 27699-2704

From: Catharine Cummer [<mailto:catharine.cummer@duke.edu>]
Sent: Friday, September 01, 2017 2:36 PM
To: Frisone, Martha; Moore, Veronica M; Williams, Bernetta
Subject: DUH equipment replacement

Attached please find a notice of exempt replacement of an EP lab at Duke University Hospital. Thanks!

Catharine

Catharine W. Cummer
Regulatory Counsel, Strategic Planning
Duke University Health System
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Record # 2396
FID# 090108
943138

Duke University Health System

Catharine W. Cummer
Regulatory Counsel, Strategic Planning

September 1, 2017

Via Electronic Mail



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

Re: Exempt Replacement Project at Duke University Hospital

Dear Ms. Frisone:

The purpose of this letter is to request the CON Section's written confirmation that the acquisition of replacement electrophysiology lab equipment 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.

As set forth below, we believe that Duke University Hospital's project meets these requirements and is exempt from certificate of need review.

(1) Main Campus

The purpose of this project is to replace existing electrophysiology equipment located on the 7th floor of Duke North, which is part of the main building of Duke University Hospital. The "main campus" of the facility is defined in N.C.G.S. 131E-176(14n) to include both "[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 areas and structures that are not strictly contiguous to the main building but are located within 250 yards of the main building.”

In this case, Duke University Hospital is a licensed health service facility, and the main hospital building from which Duke University Hospital provides its clinical services and exercises financial and administrative control is the physically contiguous structure that includes Duke South, Duke North, the Duke Children’s Hospital, the Duke Medicine Pavilion, the Morris Clinic, the Duke Cancer Center, the Wadsworth Building, and the Hudson Building. A floor plan showing the site of this replacement on the 7th floor of Duke North is enclosed. The hospital’s license and campus map have been previously provided to the CON Section.

(2) Previous Certificate of Need

The existing equipment was acquired and put into service in 2000, pursuant to the attached CON that included authorization for replacement electrophysiology equipment.

(3) Replacement equipment

The equipment qualifies as replacement equipment pursuant to the existing statutory and regulatory definitions. A completed Equipment Comparison form is enclosed. Both the existing equipment and the replacement equipment provide cardiac catheterization procedures. The total project cost exceeds \$2,000,000 reflecting major medical equipment, related equipment, and renovation/installation expenses. Copies of the equipment quotations are 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).

Thank you for your attention to this request. If you have questions about this information, please let me know.

Very truly yours,



Catharine W. Cummer

Enclosures

Effective May 30, 2017, this license is issued to

Duke University Health System, Inc.

to operate a hospital known as

Duke University 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: 943138

License Number: H0015

Bed Capacity: 957

General Acute 938, Psych 19,

Dedicated Inpatient Surgical Operating Rooms: 6

Dedicated Ambulatory Surgical Operating Rooms: 9

Shared Surgical Operating Rooms: 50

Dedicated Endoscopy Rooms: 11

State Of North Carolina

Department Of Human Resources Division Of Facility Services

Certificate Of Need

Project Identification Number J-5327-96 Effective Date July 16, 1996

Issued to: Duke University
3000 Erwin Road
Durham, NC 27710

The North Carolina Department of Human Resources, pursuant to the North Carolina Health Planning and Resource Development Act of 1978, G.S. § 131-175, et seq., as amended and recodified, G.S. § 131E-175, et seq., hereby finds and certifies that the new institutional health service proposed by the person listed above is consistent with, or as conditioned is consistent with the plans, standards, and criteria prescribed by the Act and the rules and regulations promulgated thereunder. The findings of the Department are attached hereto and incorporated by reference.

This Certificate affords the person listed above the opportunity to proceed with development of the proposed new institutional health service in a manner consistent with the plans, standards, and criteria prescribed by the Act and the rules and regulations promulgated thereunder. This Certificate includes and is limited to:

SCOPE: See Reverse Side

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: 3000 Erwin Road
Durham, NC 27710

MAXIMUM CAPITAL EXPENDITURE: \$9,434,000

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: January 6, 1997

This Certificate is limited to the person listed above and is not transferable or assignable. This Certificate may be withdrawn as provided in G.S. § 131E-189, and the rules and regulations promulgated thereunder.

Issuance of this Certificate does not supplant provisions or requirements embodied in codes, ordinances, statutes other than G.S. § 131E-175, et seq., rules regulations or guidelines administered or enforced by municipal, state or federal agencies or the agent thereof.

Ben A. Harshbarger

Duke University will consolidate eight existing cardiac catheterization laboratories and two existing electrophysiology laboratories at Duke Hospital into a single suite with eight cardiac catheterization rooms on the seventh floor of Duke North Hospital. The suite will accommodate four interventional cardiology laboratories, three adult cardiac catheterization (diagnostic) laboratories; one pediatric cardiac catheterization laboratory providing diagnostic, therapeutic and electrophysiology services; and, essential support facilities, including a 16 bed holding area for patients and a family waiting area. Duke will also purchase two (2) bi-plane and two (2) single-plane cardiac imaging systems to replace existing equipment used in the interventional labs.

CONDITIONS

1. Duke University shall materially comply with all representations made in the certificate of need application.
2. Duke University shall dispose of the existing cardiac catheterization equipment that is being replaced as part of this project.
3. Duke University shall acknowledge acceptance and compliance with all conditions stated herein to the Certificate of Need Section in writing prior to the issuance of the certificate of need.

Applicant acknowledged acceptance of and compliance with all applicable conditions with correspondence received by the Certificate of Need Section on June 19, 1996.

TIMETABLE

Completion of preliminary drawings _____	March 8, 1996 - June 7, 1996
Completion of final drawings and specifications _____	June 14, 1996 - October 11, 1996
Approval of final drawings and specifications by Construction Section, DFS _____	July 26, 1996 - November 22, 1996
Contract Award _____	August 9, 1996 - December 9, 1996
25% completion of construction _____	September 6, 1996 - June 26, 1998
50% completion of construction _____	October 4, 1996 - July 17, 1998
75% completion of construction _____	November 1, 1996 - August 7, 1998
Completion of construction _____	November 29, 1996 - August 28, 1998
Occupancy/offering of service _____	December 9, 1996 - October 26, 1998
Ordering equipment _____	December, 1997
Arrival of equipment _____	June, 1998 - August, 1998
Operation of equipment _____	July, 1998 - September, 1998

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	Electrophysiology Lab Equipment	Electrophysiology Lab Equipment
Manufacturer of Equipment	Philips	Philips
Tesla Rating for MRIs		
Model Number	Integris 5000	FlashPoint FD10
Serial Number	Asset # 121808	
Provider's Method of Identifying Equipment	EP Lab No. 1	EP Lab No. 1
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #		
Mobile Tractor Serial Number/VIN #		
Date of Acquisition of Each Component		
Does Provider Hold Title to Equipment or Have a Capital Lease?	Hold Title	Hold Title
Specify if Equipment Was/Is New or Used When Acquired	Used	New
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>		\$ 3,329,000
Total Cost of Equipment	1,446,299	\$ 910,322
Fair Market Value of Equipment		
Net Purchase Price of Equipment		\$ 910,322
Locations Where Operated	Rm 7424 Duke North	Rm 7424 Duke North
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	Pacemakers	N/A
Type of Procedures New Equipment is Capable of Performing	NA	Pacemakers, Simple Ablations, Tilt Studies, ICD implants