

NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**
Division of Health Service Regulation

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director

July 18, 2018

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

Exempt from Review – Replacement Equipment

Record #: 2655
Facility Name: Duke University Hospital
FID #: 943138
Business Name: Duke University Health System, Inc.
Business #: 640
Project Description: Replace existing vascular lab equipment
County: Durham

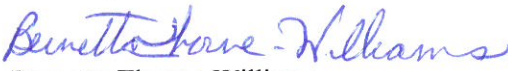
Dear Ms. Cummer:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of July 9, 2018, 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 IGS 740 vascular lab equipment to replace the Allura Xper FD20 vascular lab equipment. 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
Amy Craddock, Assistant Chief, Healthcare Planning, DHSR
Acute and Home Care Licensure and Certification Section, DHSR

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION
HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
MAILING ADDRESS: 2704 Mail Service Center, Raleigh, NC 27699-2704
www.ncdhhs.gov/dhsr/ • TEL: 919-855-3873

Williams, Bernetta

From: Catharine Cumber <catharine.cummer@duke.edu>
Sent: Monday, July 16, 2018 2:30 PM
To: Williams, Bernetta
Cc: Gilbert Pope
Subject: RE: [External] FW: Equipment replacement

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It will be removed from service. I apologize for not making that clear. Thanks.

From: Williams, Bernetta [mailto:bernetta.williams@dhhs.nc.gov]
Sent: Monday, July 16, 2018 2:18 PM
To: Catharine Cumber
Subject: RE: [External] FW: Equipment replacement

Good afternoon Catharine,

What will happen to the existing vascular equipment?

From: Catharine Cumber [mailto:catharine.cummer@duke.edu]
Sent: Friday, July 13, 2018 11:21 AM
To: Williams, Bernetta
Subject: [External] FW: Equipment replacement

CAUTION: External email. Do not click links or open attachments unless verified. Send all suspicious email as an attachment to [Report Spam](#).

Bernetta,
I was just informed internally that there is some urgency in moving forward with the attached project as soon as possible. Would it be possible to request that the response to this be expedited (or at least to let me know if you have identified any red flags that would slow it down)? I am hopeful that it is very straightforward as a replacement. Thanks very much!

Catharine

Catharine Cumber
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: Catharine Cumber
Sent: Monday, July 09, 2018 2:11 PM
To: 'martha.frisone@dhhs.nc.gov'; Bernetta.Williams@dhhs.nc.gov
Cc: Lara Orgain
Subject: Equipment replacement

Martha and Bernetta,
I hope you all are doing well. Attached is an equipment replacement notice with floor plans showing the site of the replacement in Duke University Hospital. Please let me know if you have any questions. Thanks very much.

Catharine

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 **Duke University Health System**

Catharine W. Cummer
Regulatory Counsel, Strategic Planning

July 9, 2018

Via Electronic Mail

Ms. Martha Frisone
Chief
Ms. Bernetta Thorne-Williams
Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704



Re: Exempt Replacement Project at Duke University Hospital

Dear Ms. Frisone and Ms. Thorne-Williams:

The purpose of this letter is to request the CON Section's written confirmation that the acquisition of replacement vascular 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

Ms. Martha Frisone
Ms. Bernetta Thorne-Williams
July 9, 2018
Page 2

The purpose of this project is to replace vascular laboratory equipment located in Room 1548K5 on the first 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 is enclosed. The hospital's license and campus map have been previously provided to the CON Section and are available upon request.

(2) Previous Certificate of Need

The existing equipment was acquired and put into service in 2005, pursuant to a CON issued for Project J-7024-04.

(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 vascular 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. Cumber

Enclosures

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	Vascular Special Procedure Mono-plane	Vascular Special Procedure Mono-plane
Manufacturer of Equipment	Philips	GE
Tesla Rating for MRIs	N/A	N/A
Model Number	Allura Xper FD20	IGS 740
Serial Number	9896-001-85651	TBD
Provider's Method of Identifying Equipment	Asset no. 139282	TBD
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #	N/A	N/A
Mobile Tractor Serial Number/VIN #	N/A	N/A
Date of Acquisition of Each Component	04/29/2005	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>	\$910,000	\$2,470,000
Total Cost of Equipment	\$650,000	\$1,158,927
Fair Market Value of Equipment	N/A	\$1,158,927
Net Purchase Price of Equipment	N/A	\$1,158,927
Locations Where Operated	Durham, NC	Durham, NC
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	Vascular Intervention	NA
Type of Procedures New Equipment is Capable of Performing	NA	Vascular Intervention

STATE OF NORTH CAROLINA

Department of Health and Human Services

Division of Facility Services

CERTIFICATE OF NEED

for

Project Identification Number J-7024-04

FID# 943138

ISSUED TO: Duke University Health System, Inc.
d/b/a Duke University Hospital
3100 Tower Boulevard, Suite 600, Box 80
Durham, NC 27707

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: Duke University Health System, Inc. shall acquire an angiography system, install it in Duke University Hospital's Radiology Intervention suite and use it for neuro and vascular radiology procedures and occasional peripheral intervention procedures/Durham County

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: Duke University Health System d/b/a Duke University Hospital
3000 Erwin Road, Durham, NC 27710

MAXIMUM CAPITAL EXPENDITURE: \$877,000

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: February 1, 2005

This certificate is effective as of the 17th day of August, 2004.

Lee B. Hoffmann
Chief, Certificate of Need Section
Division of Facility Services

