



NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

May 5, 2021

Catharine Cummer
catharine.cummer@duke.edu

Exempt from Review – Replacement Equipment

Record #: 3552
Date of Request: April 30, 2021
Facility Name: Duke University Hospital
Type of Facility: Hospital
FID #: 943138
Business Name: Duke University Health System, Inc.
Business #: 640
Project Description: Replace existing CT scanner
County: Durham

Dear Ms. Cummer:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the above referenced project is exempt from certificate of need review in accordance with G.S. 131E-184(a)(f). Therefore, you may proceed to acquire without a certificate of need the Siemens Somatom Force MDCT scanner to replace the GE Discovery 750 HD CT scanner. The replacement equipment will be used exclusively for research purposes initially and will then transition to clinical use upon FDA approval. There will be no increase in the number of CT scanners operated by DUH. 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.

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,

Handwritten signature of Kim Meymandi

Kim Meymandi
Project Analyst

Handwritten signature of Lisa Pittman for

Lisa Pittman
Acting Chief, Certificate of Need

cc: Radiation Protection Section, DHSR
Construction 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: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704
https://info.ncdhhs.gov/dhsr/ • TEL: 919-855-3873



Catharine W. Cummer
Regulatory Counsel, Strategic Planning

April 30, 2021

Via Electronic Mail

Ms. Lisa Pittman
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

Re: Exempt CT Project at Duke University Hospital

Dear Ms. Frisone:

I am writing to notify the Agency of the acquisition of a CT scanner at the Duke University Hospital (DUH) and to seek confirmation that this acquisition is exempt from CON requirements.

DUH intends to acquire a newly developed state-of-the-art CT scanner from Siemens (a Somatom Force MDCT). The scanner would be used exclusively for research purposes pending FDA approval of the equipment. At that time, DUH plans to transition it to clinical use when the equipment receives FDA approval as a replacement for existing equipment. We would note that this is a similar arrangement to one previously approved by the state on July 24, 2015.

Research use

We believe the initial acquisition is exempt from CON requirements under NCGS Section 131E-179. DUH will be acquiring for research use a CT scanner for use on the hospital campus. The project will not affect the hospital's charges for the provision of medical or other patient care services other than those included in the research; will not change the bed capacity of the facility, or substantially change the medical or other patient care services of the facility. While the equipment is designated for research only, DUH will not bill patients or payors for services on this equipment. A research exemption form is included.

Conversion to clinical use/replacement of existing clinical scanner

Upon FDA approval and the conclusion of research activities, DUH intends to replace an existing clinical CT scanner with this new equipment. As the net effect will be no increase in the number of clinical CT scanners operated at DUH, we understand that this conversion from

Notice of Proposed Research Activity

N.C. Gen. Stat. §131E-179 allows a health service facility to offer a new institutional health service to be used solely for research without a certificate of need, if the Department grants an exemption. To request an exemption to offer a new institutional health service to be used solely for research, please respond to the following:

1. Facility Information:

Duke University Hospital	943138
(Name)	(FID #)

2. Facility Address:

2301 Erwin Road	Durham	Durham
(Street)	(City)	(County)

3. Project Description:

DUH intends to acquire a newly developed state-of-the-art CT scanner, Siemens Force MDCT, and install it into an existing bay in the main hospital. The scanner will be used for research purposes by Duke and Siemens for approximately 6 months.

4. Document that the proposed project will not:

- a. Affect the charges of the health service facility for the provision of medical or other patient care services other than services which are included in the research;
- b. Substantially change the bed capacity of the facility; or
- c. Substantially change the medical or other patient care services of the facility.

DUH attests that the project will meet these requirements.

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotripter, MRI, PET, Simulator, CT Scanner, Other Major Medical Equipment)	CT Scanner	CT Scanner
Manufacturer	GE	Siemens
Model number	Discovery 750 HD	Somatom Force MDCT
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	CC CT 1N57	DUH B5
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	2012	2021
Was the existing equipment new or used when acquired? / Is the replacement equipment new or used?	New	New
Total projected capital cost of the project <Attach a signed Projected Capital Cost form>		\$3.5M
Total cost of the equipment		\$2.2M
Location of the equipment <Attach a separate sheet for mobile equipment if necessary>	CC- 1N57	DUH- B5
Document that the existing equipment is currently in use	Yes	
Will the replacement equipment result in any increase in the average charge per procedure ?		No
If so, provide the increase as a percent of the current average charge per procedure		
Will the replacement equipment result in any increase in the average operating expense per procedure ?		No
If so, provide the increase as a percent of the current average operating expense per procedure		
Type of procedures performed on the existing equipment <Attach a separate sheet if necessary>	CT	
Type of procedures the replacement equipment will perform <Attach a separate sheet if necessary>		CT

research to clinical use would be exempt as the acquisition of replacement equipment under NCGS Section 131E-184(f), as set forth below:

(1) Main Campus

Upon implementation of the new scanner for clinical use, it will be placed into service in the DUH Duke North tower, which is on the main campus of the hospital. The existing equipment is currently in operation in the DUH Cancer Center, also on the main campus. 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. 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.

(2) Previous Certificate of Need

The existing equipment was acquired and put into service in 2012 as one of three incremental CT scanners approved pursuant to CON Project J-8275-08.

(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 CT scanning procedures. The total project cost exceeds \$2,000,000 reflecting major medical equipment, related equipment, and renovation/installation expenses. The equipment quotation 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).

Upon putting the new equipment into clinical service, DUH will take the existing equipment out of clinical use in the state, unless it first receives approval from the Agency for any alternative proposal.

Ms. Lisa Pittman
April 30, 2021
Page 3

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

Catharine W. Cummer

Enclosures