



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor

KODY H. KINSLEY • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

March 11, 2024

Catharine Cummer
catharine.cummer@duke.edu

Exempt from Review – Replacement Equipment

Record #: 4381
Date of Request: February 7, 2024
Facility Name: Duke Raleigh Hospital
FID #: 923421
Business Name: Duke University Health System, Inc.
Business #: 640
Project Description: Replace two CT scanners
County: Wake

Dear Catharine 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(f). Therefore, you may proceed to acquire without a certificate of need the two Siemens CT scanners to replace the two GE CT scanners. This determination is based on your representations that the existing units 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,

Crystal Kearney
Project Analyst

Micheala Mitchell
Chief

cc: Acute and Home Care Licensure and Certification Section, DHSR
Radiation Protection 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

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER



Catharine W. Cummer
Regulatory Counsel, Strategic Planning

February 7, 2024

Via Electronic Mail

Ms. Micheala Mitchell, Chief
Ms. Lisa Pittman, Assistant Chief
Mr. Michael McKillip, Project Analyst
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 Raleigh Hospital

Dear Ms. Mitchell, Ms. Pittman, and Mr. McKillip:

On behalf of the Duke University Health System, I am writing to provide prior written notice of an equipment replacement project and to request the Section's written confirmation that the project is exempt from certificate of need review. The project involves the replacement of two CT scanners at Duke Raleigh Hospital.

This equipment replacement project satisfies the requirements under N.C.G.S. 131E-184(f) for replacement equipment that exceeds the applicable cost 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 equipment are/will be located in the main Duke Raleigh 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 areas and structures that are not strictly contiguous to the main building but are located within 250 yards of the main building.”

Duke Raleigh Hospital is a licensed health service facility (license available upon request), and the main hospital building from which Duke Raleigh Hospital provides its inpatient clinical services and exercises financial and administrative control over all Duke Raleigh Hospital services is located at 3400 Wake Forest Road in Raleigh.

Certificate of Need

As set forth in Project J-8708-11, Duke Raleigh Hospital was approved for the acquisition of an additional CT scanner for a total of three on the hospital campus (it has since received approval for a fourth scanner which is under development). This project is intended to replace two of those three total scanners. Duke represents that the equipment was appropriately originally developed pursuant to all required regulatory approvals.

Replacement Equipment

The equipment qualifies as replacement equipment pursuant to the existing statutory and regulatory definition. Completed Equipment Comparison forms for both pieces of equipment are enclosed. Both the existing equipment and the replacement equipment are equipment capable of providing CT imaging procedures.

A copy 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).

Disposition of Existing Equipment

The vendor of the replacement equipment is removing the existing equipment from operation.

Conclusion

Even if this project did not meet the requirements of Section 131E-184(f), we would note that this project also meets the exemption criteria of Section 131E-184(a)(7) as replacement equipment under the updated cost threshold.

February 7, 2024

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

Very truly yours,

Catharine W. Cummer

Catharine W. Cummer

Enclosures

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	CT
Manufacturer	GE	Siemens
Model number	750 HD	X.Ceed
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	1610A	1610A
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	5/2016	2024
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>		\$2.36M
Total cost of the equipment		\$1.34
Location of the equipment <Attach a separate sheet for mobile equipment if necessary>	Duke Raleigh Hospital	Duke Raleigh Hospital
Document that the existing equipment is currently in use	In Use	N/A
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>	Diagnostic Scan	N/A
Type of procedures the replacement equipment will perform <Attach a separate sheet if necessary>	N/A	Diagnostic Scan

	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	CT
Manufacturer	GE	Siemens
Model number	750 HD	X.Ceed
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	1610B	1610B
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	10/2013	2024
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>		\$2.3M
Total cost of the equipment		\$1.16
Location of the equipment <Attach a separate sheet for mobile equipment if necessary>	Duke Raleigh Hospital	Duke Raleigh Hospital
Document that the existing equipment is currently in use	In Use	N/A
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>	Diagnostic Scans	N/A
Type of procedures the replacement equipment will perform <Attach a separate sheet if necessary>	N/A	Diagnostic Scans

From: [Catharine Cumber](#)
To: [Stancil, Tiffany C](#)
Cc: [Lara Orgain](#)
Subject: [External] Exemption notice
Date: Wednesday, February 7, 2024 1:43:01 PM
Attachments: [To State Exemption Notice DRAH CT replacements 2024.docx](#)
[Replacement Equipment Comparison Form DRAH CTs.docx](#)

CAUTION: External email. Do not click links or open attachments unless verified. Report suspicious emails with the Report Message button located on your Outlook menu bar on the Home tab.

Tiffany,

Please see the attached exemption notice for CT replacements on the Duke Raleigh Hospital campus. I am happy to answer any questions you may have. Thank you,
Catharine

Catharine W. Cumber
Regulatory Counsel, Strategic Planning, Duke University Health System
Office 919-668-0857 | Cell 919-423-6928