

North Carolina Department of Health and Human Services Division of Health Service Regulation

Pat McCrory Governor Richard O. Brajer Secretary DHHS

Drexdal Pratt Division Director

August 31, 2015

Catharine Cummer, Regulatory Counsel, Strategic Planning Duke University Health System 3100 Tower Boulevard, Suite 1300 Durham NC 27707

Exempt from Review - Replacement Equipment

Record #:

1698

Facility Name:

Duke University Hospital

FID #:

943138

Business Name:

Duke University Health System

Business #:

639

Project Description:

Replace CT scanner in the emergency department

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 August 24, 2015, the above referenced proposal 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 Siemens Force CT scanner. This determination is based on your representations that the unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need.

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,

Michael J. McKillip

Project Analyst

Martha J. Frisone!

Assistant Chief, Certificate of Need

cc:

Construction Section, DHSR

Assistant Chief, Healthcare Planning

Acute and Home Care Licensure and Certification Section, DHSR

AMS.

Healthcare Planning and Certificate of Need Section

www.ncdhhs.gov Telephone: 919-855-3873 • Fax: 919-715-4413 Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603 Mailing Address: 2704 Mail Service Center •Raleigh, NC 27699-2704

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Catharine W. Cummer
Regulatory Counsel, Strategic Planning

August 24, 2015

Via Electronic Mail

Martha Frisone 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:

The purpose of this letter is to request the Section's written confirmation that the acquisition of a CT scanner 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.

Received by the CON Section

AUG 2 4 2015

(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 is now exempt from certificate of need review.

(1) Main Campus

The purpose of this project is to replace an existing CT scanner that is currently operated in the Duke University Hospital emergency department in Duke North, and that, after replacement, will be located in the Duke Medical Pavilion, which is located on the main campus

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Martha Frisone August 24, 2015 Page 2

of Duke University Hospital. (At the same time, an existing CT scanner currently located in the Duke Medical Pavilion will be relocated to the vacated CT room in the ED; all costs for this relocation are included in the project costs.) 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 Medical Pavilion, the Morris Clinic, the Duke Cancer Center, the Wadsworth Building, and the new Hudson Building.

(2) Previous Certificate of Need

Duke received a certificate of need for an emergency department renovation project including the acquisition of the equipment to be replaced pursuant to project ID # J-7072-04 approving the renovation of the emergency department and acquisition of the CT scanner.

(3) Replacement equipment

The equipment qualifies as replacement equipment pursuant to the existing statutory and regulatory definitions. A completed Equipment Comparison form and capital cost form are enclosed. Both the existing equipment and the replacement equipment provide CT imaging procedures. The total project cost exceeds \$2,000,000 reflecting equipment and installation expenses. A copy of the equipment quotation 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).

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

EQUIPMENT COMPARISON DUH CT ED Replacement

| | EXISTING | REPLACEMENT |
|--|--------------------------|--------------------------|
| | EQUIPMENT | EQUIPMENT |
| Type of Equipment (List Each Component) | CT | CŢ |
| Manufacturer of Equipment | GE Medical Systems | Siemens Medical Systems |
| Tesla Rating for MRIs | n/a | n/a |
| Model Number | GE LightSpeed VCT | Force CT |
| Serial Number | 371128CN0 | To be determined |
| Provider's Method of Identifying Equipment | Asset #140865 | To be determined |
| 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 | 2005 | To be determined - 2015 |
| Does Provider Hold Title to Equipment or Have a Capital Lease? | Title | Title |
| Specify if Equipment Was/Is New or Used When Acquired | New | New |
| Total Capital Cost of Project (Including Construction, etc.) <use attached="" form=""></use> | \$1,162,698.30 | \$ 3,169,527 |
| Total Cost of Equipment | \$1,132,698.30 | |
| Fair Market Value of Equipment | \$ 105,000.00 | |
| Net Purchase Price of Equipment | \$1,132,698.30 | \$ 2,302,882 |
| Locations Where Operated | Duke University Hospital | Duke University Hospital |
| | Emergency Department | Duke Medicine Pavilion |
| 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 | CT procedures | NA |
| Type of Procedures New Equipment is Capable of Performing | NA | CT procedures |

PROPOSED TOTAL CAPITAL COST OF PROJECT

| Project Name: | | | | |
|--|---|---------------------|-------------------------------------|---|
| Provider/Company: | | | | |
| A. Site Costs (1) Full purphase price of land | | e | | |
| (1) Full purchase price of land Acres Price per Acre \$ | | \$ | | |
| (2) Closing costs | \$ | | | |
| (3) Site Inspection and Survey | Φ | \$ | | |
| (4) Legal fees and subsoil investigation | | \$ \$ | | |
| (5) Site Preparation Costs | | Φ | | |
| Soil Borings | \$ | | | |
| Clearing-Earthwork | · - | | | |
| Fine Grade For Slab | ф | | | |
| Roads-Paving | \$ | | | |
| Concrete Sidewalks | φ | | | |
| Water and Sewer | \$ | | | |
| Footing Excavation | \$ | | | |
| Footing Backfill | \$ | | | |
| Termite Treatment | \$ | | | |
| Other (Specify) | \$ | | | |
| Sub-Total Site Preparation Costs | Ψ | \$ | | |
| (6) Other (Specify) | | \$ | | |
| (7) Sub-Total Site Costs | | Ψ | \$ 0 | |
| B. Construction Contract | | | <u> </u> | |
| (8) Cost of Materials | | | | |
| General Requirements | \$ | | | |
| Concrete/Masonry | \$ | | | |
| Woods/Doors & Windows/Finishes | \$ | | | |
| Thermal & Moisture Protection | \$ | | | |
| Equipment/Specialty Items | \$ | | | |
| Mechanical/Electrical | \$ | | | |
| Other (Specify) | \$ | | | |
| Sub-Total Cost of Materials | *************************************** | \$ 210,000 | | |
| (9) Cost of Labor | | \$ 315,000 | | |
| (10) Other (Contingency) | | \$98,500 | | |
| (11) Sub-Total Construction Contract | | | \$ <u>623,500</u> | |
| C. Miscellaneous Project Costs | | | | |
| (12) Building Purchase | | \$ | | |
| (13) Fixed Equipment Purchase/Lease | 1 | \$ <u>2,307,782</u> | | |
| (14) Movable Equipment Purchase/Lease | | \$25.000 | | |
| (15) Furniture | | \$ <u>15,000</u> | | |
| (16) Landscaping | | \$ | | |
| (17) Consultant Fees | | | | |
| Architect and Engineering Fees | \$ <u>78.600</u> | | | |
| Legal Fees | \$ | | | |
| Market Analysis | \$ | | | |
| Other (CON/Permit/DHSR) | \$ <u>6,500</u> | | | |
| Other (Specify) | \$ | • | | |
| Sub-Total Consultant Fees | | \$ | | |
| (18) Financing Costs (e.g. Bond, Loan, etc.). (19) Interest During Construction. | | \$ | | |
| ` ' | | . \$ | | |
| (20) Other (Technology/Training/Moving/Storage) | | \$ <u>113,145</u> | 8 2 546 02H | |
| (21) Sub-Total Miscellaneous | | | \$ <u>2,546,027</u> | |
| (22) Total Capital Cost of Project (Sum A-C above) | | | \$ <u>3,169,527</u> | |
| certify that, to the best of my knowledge, the costs of the promote | d project named abo | | | |
| (AVA) I have | 7 | Date Cer | tified: 7-6-15 | |
| Signatur of Litenser Architect of Engineer) | | Date Cel | inieu, | - |
| ordinant or remained cupition of pittinger) | | | | |
| assure that, to the best of my knowledge, the above costs for the put the proposed project as described. | proposed project are | complete and corre | et and that it is my intent to care | У |
| | | D : 5' | • | |
| Signature and Title of Officer Authorized to Represent Provider/C | (MDABA) | Date Sign | sa: | |
| organism and this or Chitco Authorized to Nepresell F104Idel/C | OUIDARY / | | | |