



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

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Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt
Division Director

October 11, 2013

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

No Review

Facility or Business: Duke University Health System d/b/a Duke University Hospital
Project Description: Acquisition of portable intra-operative CT scanner
County: Durham
FID #: 943138

Dear Ms. Cummer:

The Certificate of Need Section (CON Section) received your letter of October 9, 2013 regarding the above referenced proposal. Based on the CON law **in effect on the date of this response to your request**, the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Certificate of Need Section. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

Please contact the CON Section if you have any questions. Also, in all future correspondence you should reference the Facility I.D. # (FID) if the facility is licensed.



Certificate of Need Section

www.ncdhhs.gov

Telephone: 919-855-3873 • Fax: 919-733-8139

Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

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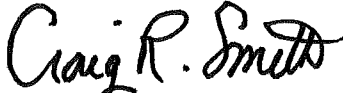


Ms. Cummer
October 10, 2013
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Sincerely,



Michael J. McKillip, Project Analyst



Craig R. Smith, Chief
Certificate of Need Section

cc: Medical Facilities Planning Section, DHSR



Catharine W. Cummer
Regulatory Counsel, Strategic Planning

Via Electronic Delivery

October 9, 2013

Mr. Michael McKillip
Analyst
Certificate of Need Section
Division of Health Service Regulation
North Carolina Department of Health and Human Services
2704 Mail Service Center
Raleigh, NC 27699-2704

Re: Duke University Hospital Project # J-8030-07
Request for Material Compliance Determination

Dear Mr. McKillip:

On behalf of the Duke University Health System, I am writing to notify the CON Section of our intent to acquire a CT scanner that can be moved for use at a variety of locations within Duke University Hospital. Duke has the opportunity to purchase a Portable Intra-Operative CT which has just received FDA 510(k) clearance. This equipment is a mobile 32-slice helical CT system with a large 107cm (42") bore and a field of view of 50cm x 100cm, ensuring flexibility of patient positioning and the ability to image the entire spine in a single acquisition. While the name of the equipment indicates its utility as intra-operative equipment due to its ability to be moved in and out of operating rooms, it is not limited to intra-operative and operating room use.

The total cost of the equipment, which requires no construction or installation as it can be moved from room to room, is less than \$750,000. We have previously made the quote for this equipment available to you for your review, and the quote reflects that all costs for delivery and training are included in that cost. Because this equipment is less than \$750,000, it is our understanding that it does not constitute major medical equipment subject to certificate of need review.

We would note that Duke was expressly approved for 5 additional CT scanners as part of Project J-8030-07 and has not yet purchased and installed all of the approved scanners. However, unless otherwise instructed by the CON Section, we would not consider this "mobile" CT scanner as part of the DMP project because it would not be limited to use at the DMP and in

Mr. Michael McKillip
October 9, 2013

fact could be moved throughout the DMP, Duke North, Duke South, and any other contiguous areas at the Duke University Hospital. If necessary, however, Duke would be willing to consider this new CT scanner as one of the five scanners approved as part of Project J-8030-07. (This would not be the designated "intra-operative" fixed CT scanner already installed as part of the operating room suite in the DMP.)

We would appreciate your confirmation that this acquisition does not require any further certificate of need review, and furthermore that it is in compliance with Project ID J-8030-07. Please let us know if you consider this scanner as one of the approved scanners under that project, or if you have any other questions. Thank you for your attention to this request.

Very truly yours,

Catharine W. Cummer