



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

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt
Division Director

July 23, 2013

Dee Jay Zerman
UNC Health Care
211 Friday Center Drive, Suite G015
Chapel Hill NC 27517

No Review

Facility or Business: Rex Hospital
Project Description: Temporary software upgrade to vascular lab
County: Wake
FID #: 953429

Dear Ms. Zerman:

The Certificate of Need Section (CON Section) received your letter of July 10, 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.

Moreover, you need to contact the Acute and Home Care Licensure and Certification Section of the Division of Health Service Regulation to determine if they have any requirements for development of the proposed project.

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.



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. Zerman
July 23, 2013
Page 2

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.

Sincerely,



Michael J. McKillip, Project Analyst



Craig R. Smith, Chief
Certificate of Need Section

cc: Medical Facilities Planning Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR



zerman



Dee Jay Zerman
UNC HCS
James T. Hedrick Building
211 Friday Center Drive
Suite G015
Chapel Hill, NC 27517

July 10, 2013

Mr. Michael J. McKillip
Certificate of Need Section
Division of Health Service Regulation, DHHS
2704 Mail Services Center
Raleigh, NC 27699-2704

RE: Request for No Review / Temporary use of vendor installed software in vascular room during previously approved cardiac catheterization lab replacement / Rex Hospital, Inc. / Wake County

Dear Mr. McKillip:

On June 12, 2013, the CON Section determined that a proposed replacement of the existing Philips Allura cardiac catheterization equipment with a new Philips FD 10 cardiac catheterization unit was Exempt from Review. A copy of this determination is attached as Exhibit 1. The vendor, Philips, has suggested it can temporarily install software into one of Rex's existing vascular rooms during the time the cardiac catheterization lab will be out-of-service. This software will allow the performance of some basic cardiac catheterization procedures in this room. We are requesting confirmation from the CON Section that this proposed temporary installation of software into an existing vascular room would not require CON review.

The temporary use of the vascular room with the added software will better allow Rex to meet patient needs during the period of time that one cardiac catheterization lab will not be operational. The temporary use of this vascular room as a cardiac catheterization lab during the replacement time period will not result in an additional cardiac catheterization lab, as the total CON approved number of operational cardiac catheterization labs at Rex will not increase. The vendor will de-install the software from the vascular lab upon completion of the replacement cardiac catheterization lab's installation and commissioning. A recent discussion with Martha Frisone, Assistant Section Chief, confirmed that this

type of temporary use of vendor installed software has previously been requested by another entity and authorized by the CON Section.

Rex's existing cardiac catheterization labs are used on a daily basis. A reduction in the number of operational cardiac catheterization labs will complicate the provision of appropriate patient care. However, the existing Philips Allura equipment requires replacement due to its age and declining image quality. The ability to temporarily use an existing vascular room with software installed by the vendor, will allow Rex to maintain the current level of care to our patients, without encountering significant operational delays, and patient, staff and physician dissatisfaction.

Should you require any additional information regarding this request, please do not hesitate to contact me at 919-966-1129.

Sincerely,

A handwritten signature in cursive script that reads "Dee Jay Zerman".

Dee Jay Zerman, Director of Regulatory Planning
UNC HCS
919-966-1129
dzerman@unch.unc.edu



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Division of Health Service Regulation**

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt
Division Director

June 12, 2013

Dee Jay Zerman, Director of Regulatory Planning
UNC HCS, Hedrick Building
211 Friday Center Drive, Suite 1068
Chapel Hill NC 27517

Exempt from Review - Replacement Equipment

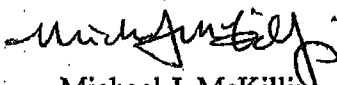
Facility: Rex Hospital
Project Description: Replace existing Philips Allura cardiac catheterization unit with a new Philips FD10 cardiac catheterization unit
County: Wake
FID #: 953429

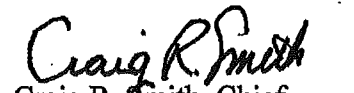
Dear Ms. Zerman:

In response to your letter of June 5, 2013, the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, the Philips FD10 cardiac catheterization equipment to replace the existing Philips Allura cardiac catheterization equipment [Serial # 2933]. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need. Further please be advised that as soon as the replacement equipment is acquired, you must provide the CON Section and the Medical Facilities Planning Section with the serial number of the new equipment to update the inventory, if not already provided.

It should be noted that this 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 Agency 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


Craig R. Smith, Chief
Certificate of Need Section

Certificate of Need Section

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