



DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

April 19, 2017

Marcus C. Hewitt
Smith Moore Leatherwood, LLP
434 Fayetteville St, Suite 2800
Raleigh NC 27601

Exempt from Review – Replacement Equipment

Record #: 2238
Facility Name: WakeMed Cary Hospital
FID #: 990332
Business Name: WakeMed
Business #: 2025
Project Description: Temporary replacement of the cardiac catheterization lab
County: Wake

Dear Mr. Hewitt:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of April 7, 2017, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(a)(7). Therefore, you may proceed to modify without a certificate of need the vascular lab equipment to perform cardiac catheterization procedures on a temporary basis while the cardiac catheterization equipment is being repaired.

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

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

WWW.NCDHHS.GOV

TELEPHONE 919-855-3873

LOCATION: EDGERTON BUILDING • 809 RUGGLES DRIVE • RALEIGH, NC 27603

MAILING ADDRESS: 2704 MAIL SERVICE CENTER • RALEIGH, NC 27699-2704

AN EQUAL OPPORTUNITY/ AFFIRMATIVE ACTION EMPLOYER



SMITHMOORE
LEATHERWOOD
ATTORNEYS AT LAW

April 7, 2017

Via E-mail

Martha Frisone
Assistant Chief, Certificate of Need
N.C. Department of Health & Human Services
Division of Health Service Regulation
Healthcare Planning and Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704



Re: Notice of Exemption for Temporary Replacement Equipment - WakeMed
Cardiac Catheterization Lab at WakeMed Cary, Wake County

Dear Ms. Frisone:

We submit this notice on behalf of WakeMed regarding the temporary replacement of the existing cardiac catheterization lab located at WakeMed Cary Hospital in Cary, Wake County, North Carolina ("Cath Lab"). The pertinent facts supporting this request are outlined below.

WakeMed operates and holds a certificate of need for one cardiac catheterization lab at WakeMed Cary. This morning, the Cath Lab experienced a malfunction that took the machine out of service and which will require replacement of parts estimated to take two to three weeks. Without provision for temporary cardiac catheterization service, patients at WakeMed Cary (including inpatients) who require cardiac catheterization procedures would require transfer to another facility.

However, WakeMed Cary has a vascular lab that can be converted via a software modification that would allow it to perform cardiac catheterization procedures while the Cath Lab is being repaired. Accordingly, WakeMed plans to modify its vascular lab and use it to temporarily replace the Cath Lab. Once the Cath Lab is repaired, it will be returned to service and it will replace the modified vascular lab. When the Cath Lab is returned to service, the software modification to the vascular lab will be reversed and it will resume service as a vascular lab only.

Neither the software modification nor either replacement will require any capital expenditure, and WakeMed Cary will not at any time operate more than one cardiac

SMITHMOORE
LEATHERWOOD
ATTORNEYS AT LAW

Martha Frisone

April 7, 2017

Page 2

catheterization lab. Further, the replacement of the Cath Lab will have no effect on patient charges or operating expenses, consistent with 10A N.C.A.C. 14C.0303(d)(3). Accordingly, the replacement of Unit S1336M with Unit G1251A is exempt from review under N.C. Gen. Stat. § 131E-184(a)(7).

As set forth above, we request the Agency's confirmation that the temporary replacement of the Cath Lab, and the subsequent replacement of the temporary equipment with the Cath Lab once it is repaired, are exempt from CON review pursuant to N.C. Gen. Stat. § 131E-184(a)(7) and do not require CON review or approval.

Please let us know if you have any questions or need additional information from us.

Sincerely,

SMITH MOORE LEATHERWOOD LLP



Marcus C. Hewitt