



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

August 5, 2015

Barbara L. Freedy
Novant Health, Inc.
2085 Frontis Plaza Boulevard
Winston-Salem, North Carolina 27103

Exempt from Review

Record #: 1666
Facility Name: Novant Health Matthews Medical Center
FID #: 945076
Business Name: Novant Health, Inc.
Business #: 1341
Project Description: Temporary utilization of an existing vascular lab for both peripheral vascular procedures and cardiac catheterization procedures, thereby replacing cardiac catheterization equipment currently provided by DLP Healthcare, while a replacement cardiac catheterization lab is relocated and installed from Novant Health Presbyterian Medical Center (NHPMC)
County: Mecklenburg

Dear Ms. Freedy:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of July 15, 2015, the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-184(a)(7). Therefore, you may proceed to offer, develop or establish the above referenced project without a certificate of need.

However, you need to contact the Acute and Home Care Licensure and Certification Section 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 Agency. 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;



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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(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.

If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,



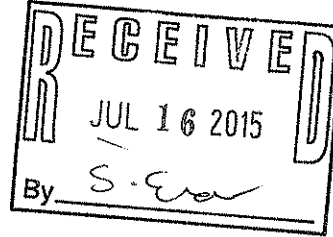
Gloria C. Hale
Project Analyst



Martha J. Frisone, Assistant Chief
Certificate of Need

cc: Acute and Home Care Licensure and Certification Section, DHSR
Assistant Chief, Healthcare Planning

July 15, 2015

**VIA HAND DELIVERY**

Martha J. Frisone, Assistant Chief
Healthcare Planning and Certificate of Need Section
North Carolina Department of Health & Human Services
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, NC 27603

RE: No Review Request for Temporary Use of Novant Health Matthews Medical Center's Vascular Lab Unit During Replacement of Cardiac Catheterization Unit/ Mecklenburg County/HSA III

Dear Ms. Frisone:

This letter seeks the CON Section's written confirmation that Novant Health Matthews Medical Center's (NHMMC) request to temporarily use NHMMC's newest vascular lab unit (the Vascular Lab) does not require CON review.¹ The Vascular Lab is capable of performing both peripheral vascular procedures and cardiac catheterization procedures. NHMMC proposes to use the Vascular Lab for both peripheral vascular procedures and cardiac catheterization procedures while the proposed NHMMC replacement cardiac cath unit² is being installed. This approach would avoid harmful disruption to NHMMC's established cardiac cath program (the Program).

The Program has been in operation since the early 2000s. The Program began offering percutaneous coronary interventions (PCI) in 2010. The Program is staffed primarily by two board-certified cardiologists who practice with the Novant Health Heart & Vascular Institute-Matthews physician group.

During the 12-month period from April 2014-March 2015, NHMMC performed almost 600 diagnostic cardiac cath and almost 300 PCIs. NHMMC is also a STEMI Center serving four

¹ The Vascular Lab is the subject of the Replacement Equipment Exemption Request that was submitted to the CON Section on July 14, 2015.

² Simultaneous with this request, Novant Health, Inc., NHMMC and Novant Health Presbyterian Medical Center (NHPMC) have filed: (1) a Replacement Equipment Exemption Request to replace one of NHPMC's four existing cardiac cath units; (2) a No Review Request seeking Agency confirmation that the transfer of one of NHPMC's cath units to NHMMC is not subject to CON review; and (3) a letter from the Medical Director of the NHMMC cath lab confirming that NHMMC can safely perform interventional cath procedures without open heart surgery on site.

counties. STEMI is an acronym that means ST segment elevation myocardial infarction. A STEMI heart attack is a deadly type of heart attack that is caused by a prolonged blockage of blood supply in the heart.


The cardiologists recommended and have confirmed that using the cardiac cath functionality of the Vascular Lab will allow them to provide uninterrupted cardiac catheterization procedures while the NHMMC replacement cath unit is being installed in the existing cath lab space at NHMMC. Once the installation and testing of the NHMMC replacement cardiac cath unit is completed and that cath unit is operational, NHMMC will cease using the Vascular Lab for cardiac catheterization cases. Thus, there will never be a time when more than one cath lab is in operation at NHMMC. This scenario was discussed with the Assistant Chief of the CON Section in May 2015 and she indicated that it was feasible.

There will be no additional cost for the temporary use of the Vascular Lab to perform cardiac cath procedures as it will already exist and be in operation at NHMMC.

We do not believe that any of the definitions of "new institutional health service" in N.C. Gen. Stat. § 131E-176(16) apply to the temporary use of the Vascular Lab for cardiac cath procedures. Accordingly, we respectfully request that the CON Section confirm in writing that the CON Law does not apply to the facts presented here.

Thank you for your prompt consideration of this request. Please do not hesitate to contract me at 336-718-4483 or blfreedy@novanthealth.org if you have questions.

Sincerely,



Barbara L. Freedy
Novant Health, Inc.
Director, Certificate of Need

cc: Roland Bibeau, President, Novant Health Matthews Medical Center
Regina Hartung, VP, Cardiac Services, NH Presbyterian Medical Center
Laura MacFadden, VP, Design & Construction, Novant Health
Lisa Griffin, Manager, CON Novant Health, Inc.

File: TempUseMMCVascUnitForCathFINAL.07.15.2015.docx