



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

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Division Director

August 22, 2013

Gary S. Qualls
K&L Gates, LLP
430 Davis Drive, Suite 400
Morrisville, North Carolina 27560

No Review

Facility or Business: Carolinas Medical Center - Union
Project Description: Interim designation of interventional radiology unit as cardiac catheterization unit and cardiac catheterization unit as interventional radiology unit

County: Union
FID #: 923515

Dear Mr. Qualls:

The Certificate of Need Section (CON Section) received your letter of August 20, 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.

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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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,

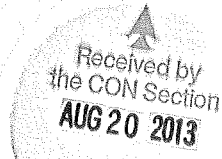


Gloria C. Hale, Project Analyst



Craig R. Smith, Chief
Certificate of Need Section

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



August 20, 2013

Via Hand Delivery

Craig R. Smith, Chief
N.C. Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section
809 Ruggles Drive
Raleigh, NC 27603

Re: No Review Letter Regarding Cardiac Catheterization Unit

Dear Mr. Smith:

Our client, The Charlotte-Mecklenburg Hospital Authority ("CMHA") d/b/a CMC-Union, is requesting a "No Review" determination that CMC-Union may, on an interim basis:

1. designate its current interventional radiology unit ("IR Unit") as the cardiac catheterization ("Cardiac Cath") Unit and,
2. designate the Cardiac Cath Unit as the dedicated non-cardiac cath IR Unit.

At all times during this process, CMC-Union would operate only one Cardiac Cath Unit as defined in N.C. Gen. Stat. § 131E-176(16)(2f) which would provide cardiac catheterization services as defined in N.C. Gen. Stat. § 131E-176(16)(2g) ("Cardiac Cath Services"). Switching the designation of the two rooms is not reviewable as a new institutional health service under the North Carolina Certificate of Need ("CON") law, and does not otherwise trigger CON review.

By way of background, CMC-Union's Cardiovascular Center is comprised of one IR Unit and one Cardiac Cath Unit. The IR Unit was replaced in May 2013 at a total cost of \$1.3 million and has the capability to perform cardiac cath procedures. However, the IR Unit has not performed cardiac catheterization services as defined in N.C. Gen. Stat. § 131E-176(16)(2g) because that IR Unit is not CMC-Union's approved unit for that purpose. CMC-Union's Cardiac Cath Unit was installed in January 2000, over 13 years ago. Plans call to replace this Cardiac Cath Unit in the 4th quarter of 2013 or the first quarter of 2014 with a "Replacement Cath Unit" at a cost of less than \$2 million.

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Until the Cardiac Cath Unit is replaced, CMC-Union would like to designate the current IR Unit as the unit on which CMC-Union would temporarily perform Cardiac Cath Services until the Replacement Cath Unit is purchased, installed and operational. After the new Replacement Cath Unit is operational, CMC-Union would like to switch the unit designations back to their original designations.

The temporary unit designation switch does not trigger any of the definitions of a “new institutional health service,” which would implicate CON review. N.C. Gen. Stat. § 131E-178 provides that no person shall offer or develop a “new institutional health service” without first obtaining a CON. The term “new institutional health service” is defined in over fifteen different ways at N.C. Gen. Stat. § 131E-176(16). Among these definitions is N.C. Gen. Stat. § 131E-176(16)b, which defines a “new institutional health service” to include:

. . . [T]he obligation by any person of a capital expenditure exceeding two million dollars (\$2,000,000) to develop or expand a health service or a health service facility, or which relates to the provision of a health service. The cost of any studies, surveys, designs, plans, working drawings, specifications, and other activities, including staff effort and consulting and other services, essential to the acquisition, improvement, expansion, or replacement of any plant or equipment with respect to which an expenditure is made shall be included in determining if the expenditure exceeds two million dollars (\$2,000,000).

See N.C. Gen. Stat. § 131E-176(16)b.

The switch in room designation does not constitute a “new institutional health service” under N.C. Gen. Stat. § 131E-176(16)b because the proposal does not exceed the \$2,000,000 threshold. Moreover, the switch in room designation is not the development or offering of cardiac catheterization services, pursuant to N.C. Gen. Stat. § 131E-176(16)f because these services are already offered at CMC-Union. Moreover, because the IR Unit is merely temporarily taking the place of the Cardiac Cath Unit (and thus operating under the Cardiac Cath Unit’s CON), the unique circumstances of this situation do not warrant treating this as the acquisition of cardiac catheterization equipment under N.C. Gen. Stat. § 131E-176(16)f1. The Agency has frequently authorized the temporary substitution of regulated equipment without requiring a CON. Accordingly, the proposed temporary unit designation switch does not require CMC-Union to obtain a CON pursuant to N.C. Gen. Stat. § 131E-176(16)b, or any other provision of the CON statutes.

Once the Agency has confirmed that CMC-Union can temporarily use the IR Unit for Cardiac Cath Services until the Replacement Cath Unit is operational, CMC-Union will file an

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Exemption Notice seeking confirmation that the Replacement Cath Unit is exempt from CON review pursuant to N.C. Gen. Stat. § 131E-184.

Based upon the foregoing information, CMC-Union hereby requests that the Agency provide a written response confirming that the switch in unit designation does not require a CON pursuant to N.C. Gen. Stat. § 131E-176(16), or any other provision of the CON statutes.

Please let us know if you need additional information. We thank you for your consideration of this submission.

Sincerely,



Gary S. Qualls