



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

April 30, 2014

Greg Bass  
201 East Grover Street  
Shelby, NC 28150

**No Review**

Facility or Business: Cleveland Regional Medical Center

Project Description: Temporarily designate existing angiography unit as the cardiac catheterization unit and designate existing cardiac catheterization unit as the angiography unit

County: Cleveland

FID #: 953106

Dear Mr. Bass:

The Certificate of Need Section (CON Section) received your letter of March 21, 2014, 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 it has 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](http://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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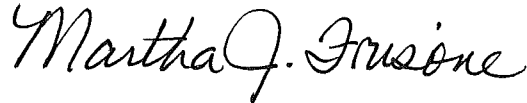
Greg Bass  
April 30, 2014  
Page 2

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,



Julie Halatek  
Project Analyst



Martha J. Frisone, Interim Chief  
Certificate of Need Section

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



*Julie*

## Carolinan HealthCare System

*Edward J. Brown III*  
Chairman

*Michael C. Tarwater, FACHE*  
Chief Executive Officer

Received by  
the CON Section  
MAR 24 2014

*Joseph G. Piemont*  
President & COO  
March 21, 2014

Ms. Martha J. Frisone, Interim Chief  
Certificate of Need Section  
Division of Health Service Regulation  
Department of Health and Human Services  
809 Ruggles Drive  
Raleigh, North Carolina 27603-0530

RE: No Review Letter Regarding Cardiac Catheterization Unit at Cleveland Regional Medical Center

Dear Ms. Frisone:

Cleveland Regional Medical Center (CRMC) is requesting a "No Review" determination that CRMC may, on an interim basis:

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

At all times during this process CRMC would operate only one Cardiac Cath Unit as defined in N.C. Gen. Stat. § 131E-176(16)(2f) which would provide cardiac catheterization services ("Cardiac Cath Services") as defined in N.C. Gen. Stat. § 131E-176(16)(2g). 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, CRMC's Cardiac Cath Unit and Angio Unit are adjacent to each other and operated jointly as part of the Cardiovascular Center. The Angio Unit is a General Electric Innova 4100 model that was placed in service in June 2005. The General Electric Innova 4100 series has been used in cardiac cath labs nationally, and is capable of imaging during cardiac cath procedures.

On February 11, 2014 CRMC received approval from the CON Section to replace its existing Cardiac Cath Unit (a nine year-old GE Innova 2000 System) with new, technologically comparable equipment. While the Cardiac Cath Unit is being replaced, CRMC would like to designate the current Angio Unit as the unit on which CRMC would temporarily perform Cardiac Cath Services. After the new Cardiac Cath Unit is operational, CRMC 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 switch in room designation does not constitute a “new institutional health service” because the proposal does not exceed \$2,000,000 and does not result in the development or offering of cardiac catheterization services because the services are already offered at CRMC. Moreover, because the Angio 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 CON Section has frequently authorized temporary substitution of regulated equipment without requiring a CON. Accordingly, the proposed temporary unit designation switch does not require CRMC to obtain a CON pursuant to any provision of the CON statutes.

We would appreciate your written concurrence that this switch in unit designation does not require a CON pursuant to any provision of the CON statutes. If you have any questions or require further information regarding this project, please contact me at 704-355-0314.

Sincerely,

A handwritten signature in cursive script that reads "Greg Bass".

Greg Bass, Director  
CHS Management Company