

Georgia Department of Community Health

Rhonda M. Medows, MD, Commissioner

Sonny Perdue, Governor

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WRITER'S DIRECT DIAL 404-657-7198

June 25, 2008

Travis Roose Manager of Cardiac Services Meadows Regional Medical Center 1703 Meadows Lane Vidalia, GA 30475

RE: Senate Bill 433 Clarification Regarding C-PORT and Therapeutic Cardiac Catheterization

Dear Mr. Roose:

The Georgia Department of Community Health, Division of Health Planning (the Department) is in receipt of your request, dated May 20, 2008, seeking clarification of the C-PORT Study and therapeutic cardiac catheterization provisions contained in Senate Bill 433. Specifically, your request concerns open heart surgical backup in elective and acute angioplasty procedures. Your request was submitted in response to the Department's invitation to submit questions regarding the impact and applicability of Senate Bill (SB) 433, a Certificate of Need (CON) reform bill passed during the 2008 session of the Georgia General Assembly.

Your letter is submitted on behalf of Meadows Regional Medical Center (Meadows Regional) in Vidalia, Toombs County, Georgia. You are the manager of the cardiac catheterization lab at Meadows Regional. The hospital has one full-time interventional cardiologist with trained staff. The hospital would like to recruit another interventional cardiologist. You ask whether, as a result of the content of SB 433, Meadows Regional would be allowed to begin performing therapeutic cardiac catheterizations on an emergency basis in the existing cardiac catheterization lab.

The CON reform changes contained within SB 433 are effective on July 1, 2008. One of the new exemptions from prior CON review and approval in the legislation is for therapeutic cardiac catheterization in hospitals selected by the Department prior to July 1, 2008, to participate in the Atlantic Cardiovascular Patient Outcomes Research Team (C-Port) Study and therapeutic cardiac catheterization in hospitals, that, as determined by the Department on an annual basis, meet the criteria to participate in the C-Port Study but have not been selected for participation; provided, however, that if the criteria requires a transfer agreement to another hospital, no hospital shall unreasonably deny a transfer agreement to another hospital. O.C.G.A. § 31-6-47(a)(22). {Note: all citations referenced are effective July 1, 2008}.

Please be advised that Section 3-1 of SB 433 provides that the CON changes in Part I of the bill shall become effective on July 1, 2008, and shall only apply to applications submitted on or after July 1, 2008. As a result, on and after July 1, 2008, an existing participant in the C-Port Study, chosen by the Department to participate in the study before July 1, 2008, will no longer require prior CON review and approval to perform therapeutic cardiac catheterization procedures. Also, at some point in the fall of 2008, after the new and amended administrative rules to implement SB 433 in its entirety are promulgated and in effect, the Department will, on a date certain to be re-issued annually, publish standards for hospitals who are not current participants in the C-Port Study to avail themselves of this exemption and to perform therapeutic cardiac catheterization procedures in its existing cardiac catheterization lab pursuant to the provisions of SB 433 unless and until it received authorization through the published standards referenced herein.

A party wishing to avail itself of this exemption on or after July 1, 2008, pursuant to the published standards provided for in the second clause of the exemption language, must submit a specific and factual determination request to the Department on the existing published Determination Form, along with the proper filing fee. The Department will respond as appropriate, and the Department response shall be the written confirmation of exemption required in SB 433. This letter is not the official written exemption required under SB 433. The Department will annually re-publish standards to implement this particular exemption, and those hospitals who receive confirmation of exemption pursuant to these published standards, will be required to show compliance with the standards on a continuing annual basis, notwithstanding the year in which they received initial confirmation of compliance with the published standards.

I hope this letter is responsive to your request. If there are any further questions or concerns, please feel free to contact me at the Department.

Sincerely,

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Clyde L. Reese, III General Counsel