



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 30, 2008

Robert M. Trimm
President & Chief Executive Officer
Satilla Regional Medical Center
410 Darling Avenue
Waycross, GA 31501

RE: Senate Bill 433 Clarification Regarding Adult Therapeutic Cardiac
Catheterization and Atlantic C-PORT Trial Participation

Dear Mr. Trimm:

The Georgia Department of Community Health, Division of Health Planning (the Department) is in receipt of your request, dated May 30, 2008, seeking clarification with respect to the therapeutic cardiac catheterization provisions contained in Senate Bill 433. You also inquired about Satilla Regional Medical Center's (Satilla) qualification for participation in the current Atlantic C-PORT Trial. 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.

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).

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 without prior CON review and approval.

A party wishing to avail itself of this exemption on or after July 1, 2008, pursuant to the published standards, 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 an official written confirmation of any activity to be undertaken on or after July 1, 2008 pursuant to SB 433. A hospital may not begin to perform adult therapeutic cardiac catheterization procedures pursuant to the SB 433 exemption referenced above prior to receipt of a determination from the Department indicating compliance with the standards to be published.

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.

The Department recognizes, as outlined in your letter, that Satilla was one of the alternate sites chosen for the Georgia C-Port participants in October of 2005. The Department is also aware that two of the ten participants in Georgia chosen at that time are now, essentially, not active study participants. The Department does intend to examine the possibility of officially deleting one or more of the inactive participants in the study, and inserting one or more of the alternates. That decision, when and if it is made, does not impact the analysis outlined above in this letter.

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,



Clyde L. Reese, III
General Counsel