



GEORGIA DEPARTMENT OF
COMMUNITY HEALTH

Rhonda M. Medows, MD, Commissioner

Sonny Perdue, Governor

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WRITER'S DIRECT DIAL
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May 29, 2008

Mr. Bob Bigley
Chief Executive Officer
East Georgia Regional Medical Center
1499 Fair Road, Hwy. 67, P.O. Box 1048
Statesboro, GA 30459

RE: Senate Bill 433 Clarification Regarding Therapeutic Cardiac Catheterization and
Adult Diagnostic Cardiac Catheterization

Dear Mr. Bigley:

The Georgia Department of Community Health, Division of Health Planning (the Department) is in receipt of your request, dated May 1, 2008, seeking clarification with respect to the therapeutic and adult diagnostic cardiac catheterization provisions contained in Senate Bill 433. This 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 request asks two basic questions. The first involves the criteria and process the Department will use to advise hospitals if they can proceed with providing adult therapeutic cardiac catheterization services. You also ask, on the same subject, whether there will be ongoing monitoring and/or reporting required. 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}.

The second set of questions in your request involve the applicability of the statutory dollar thresholds for capital expenditures and the acquisition of major medical equipment contained in SB 433 and the new exemption for adult diagnostic cardiac catheterization. SB 433 provides that the new capital expenditure threshold will be \$2.5 million as of July

1, 2008, and the new major medical equipment threshold, for equipment to be utilized in a hospital setting or in physicians' offices, will be \$1 million. O.C.G.A. § 31-6-2(14)(A)(B). The legislation also provides that, effective July 1, 2008, diagnostic cardiac catheterization in a hospital setting on patients 15 years of age and older, is not subject to prior CON review and approval. You ask whether the costs thresholds apply to the acquisition of additional diagnostic cardiac catheterization equipment, or a capital expenditure to offer the service.

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 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.

In response to your second set of questions, one of the new exemptions from prior CON review and approval in the legislation is for diagnostic cardiac catheterization services offered in a hospital setting on patients 15 years of age and older. O.C.G.A. § 31-6-47(a)(21). If a proposed service, or expansion of an existing service, meets this statutory exemption on or after July 1, 2008, it will be exempt from the other provisions of the health planning statute, and the exemption will apply regardless of the dollar expenditure involved, whether a capital expenditure or for major medical equipment, i.e., cardiac catheterization equipment.

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,

A handwritten signature in cursive script that reads "Clyde L. Reese, III". The signature is written in black ink and is positioned above the printed name.

Clyde L. Reese, III
General Counsel