



North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section

2704 Mail Service Center • Raleigh, North Carolina 27699-2704
<http://www.ncdhhs.gov/dhsr/>

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February 27, 2012

Maureen Demarest Murray
Smith, Moore, Leatherwood
300 N. Greene Street, Suite 1400
Greensboro, NC 27401

RE: No Review / WakeMed / Acquisition of ownership interests of CSA-1, owners of five heart-lung bypass machines located at WakeMed / Wake County
FID #: 943528

Dear Ms. Murray:

The Certificate of Need (CON) Section received your letter of February 8, 2012 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.

Please contact the CON Section if you have any questions.

Sincerely,

Michael J. McKillip
Project Analyst

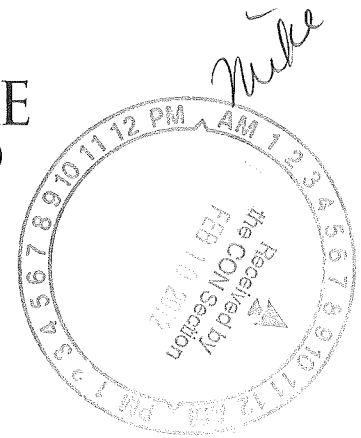
Craig R. Smith, Chief
Certificate of Need Section





SMITH MOORE LEATHERWOOD

February 8, 2012



Via E-Mail and U.S. Mail

Mr. Craig R. Smith, Chief
Ms. Martha Frisone, Assistant Chief
North Carolina Department of Health
Service Regulation
Certificate of Need Section
2704 Mail Service Center
Raleigh, North Carolina 27696-2704

Re: WakeMed Acquisition of Ownership Interests in CSA-1

Dear Mr. Smith and Ms. Frisone:

We represent WakeMed. The purpose of this letter is to provide notice to the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Certificate of Need Section (the "Agency") and confirm that WakeMed's acquisition of the ownership interests of CSA-1 is not reviewable as a new institutional health service under the North Carolina Certificate of Need ("CON") law. CSA-1 is a wholly owned sub of CSA Medical, LLC ("CSA") and owns five (5) heart lung bypass ("HLB") machines that have been and are operated at WakeMed. WakeMed would acquire the membership interests in CSA-1, which would continue to exist as a legal entity and to own the five (5) HLB machines that would remain located and operated at WakeMed.

The Agency has issued numerous declaratory rulings and no review letters that acknowledge that acquisition of ownership interests in a legal entity does not constitute a reviewable acquisition of the medical equipment owned by that legal entity. For example, in a declaratory ruling issued to New Hanover Perfusionists, Inc., the Agency determined that the purchase of stock did not constitute the acquisition of a heart-lung bypass machine because ownership of the regulated heart-lung bypass equipment would not change. The Agency also determined that the transaction was not an obligation to develop or expand a health service or health service facility because the equipment company was not a health service facility. The stock purchase transaction proposed also was not "a capital expenditure . . . which relates to the provision of a health service" within the meaning of N.C. Gen. Stat. § 131E-176(16)(b). The definition of "health service" specifically "does not include administrative and other activities that are not integral to clinical management." Stock or membership interest ownership is not integral to clinical management. *In re: Request for Declaratory Ruling by New Hanover Perfusionists, Inc., January 24, 2008.*


Mr. Craig R. Smith, Chief
Ms. Martha Frisone, Assistant Chief
February 8, 2012
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Similarly, the Department approved the sale of 100% of the issued and outstanding stock of a company that owned a linear accelerator to another entity. Linear accelerators are regulated in the same manner as heart-lung bypass equipment. The Department held that certificate of need review was not required for the stock purchase transaction. *See Declaratory Ruling, In re: Request for Declaratory Ruling by Radiation Therapy Services, Inc. and North Carolina Radiation Therapy Management Services, Inc.*, September 14, 2007.

We would appreciate written confirmation from you that the anticipated transaction does not require CON review. If you require additional information to consider this request, please contact us. We appreciate your consideration.

Sincerely yours,

SMITH MOORE LEATHERWOOD LLP

A handwritten signature in cursive script that reads "Maureen Demarest Murray".

Maureen Demarest Murray

cc: Stan Taylor, WakeMed