



North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt
Division Director

August 7, 2015

Dr. Bruce Schroeder
Carolina Breast Imaging Specialists, PLLC
990 Johns Hopkins Drive
Greenville, North Carolina 27834

Exempt from Review – Proposed Research Activity


Record #: 1679
Facility Name: Carolina Breast Imaging Specialists, PLLC
Type of Facility: Diagnostic Center
FID #: N/A
Business Name: Carolina Breast Imaging Specialists, PLLC
Business #: 2139
Project Description: Research project using an investigational medical imaging device
County: Pitt

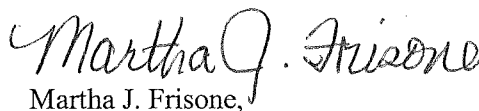
Dear Dr. Schroeder:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) determined that based on your letter of August 4, 2015, the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-179. Therefore, you may proceed to offer, develop or establish the above referenced project without a certificate of need.

However, you need to contact the Agency's Construction and Acute and Home Care Licensure and Certification Sections to determine if they have any requirements for development of the proposed project.

It should be noted that this Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this Agency and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Jane Rhoe-Jones
Project Analyst


Martha J. Frisone,
Assistant Chief, Certificate of Need

cc: Construction Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR
Assistant Chief, Healthcare Planning



Healthcare Planning and Certificate of Need Section

www.ncdhhs.gov

Telephone: 919-855-3873 • Fax: 919-715-4413

Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

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Bruce F. Schroeder, M.D.

August 4, 2015

North Carolina Division of Health Services Regulation

To whom it may concern:

This letter serves as notification of our plan to conduct a research project using an investigational medical imaging device at our office at Johns Hopkins Drive in Greenville.

We will not incur any capital expenditure related to this equipment and neither patients nor their insurance companies will be charged for any examination(s) performed on this device.

We believe this activity to be exempt from CON regulation pursuant to NC Statute 131E-179, which reads:

"Research activities.

(a) Notwithstanding any other provisions of this Article, a health service facility may offer new institutional health services to be used solely for research, or incur the obligation of a capital expenditure solely for research, without a certificate of need, if the Department grants an exemption. The Department shall grant an exemption if the health service facility files a notice of intent with the Department in accordance with rules promulgated by the Department and if the Department finds that the offering or obligation will not:

(1) Affect the charges of the health service facility for the provision of medical or other patient care services other than services which are included in the research;


(2) Substantially change the bed capacity of the facility; or

(3) Substantially change the medical or other patient care services of the facility.

(b) After a health service facility has received an exemption pursuant to subsection (a) of this section, it shall not offer the new institutional health services, or use a facility acquired through the capital expenditure, in a manner which affects the charges of the facility for the provision of medical or other patient care services, other than the services which are included in the research and shall not charge patients for the use of the service for which an exemption has been granted, without first obtaining a certificate of need from the Department; provided, however, that any facility or service acquired or developed under the exemption provided by this section shall not be subject to the foregoing restrictions on its use if the facility or service could otherwise be offered or developed without a certificate of need.

(c) Any of the activities described in subsection (a) of this section shall be deemed to be solely for research even if they include patient care provided on an occasional and irregular basis and not as a part of the research program. (1983, c. 775, s. 1; 1987, c. 511, s. 1; 1991, c. 692, s. 4.)"

Thank you for your attention to this matter.


Bruce F. Schroeder, M.D. 8/4/15



Bruce F. Schroeder, M.D.

Notice of Proposed Research Activity

N.C.G.S. §131E-179 allows a health service facility to offer a new institutional health service to be used solely for research without a certificate of need, if the Department grants an exemption. To request an exemption to offer a new institutional health service to be used solely for research, please respond to the following:

1. Facility Information:

Carolina Breast Imaging Specialists 2139
(Name) Business ID

2. Facility Address:

990 Johns Hopkins Dr. Greenville Pitt
(Street) (City) (County)

3. Project Description:

This study is being conducted to determine the image quality using a new investigational medical imaging device, in accordance with the United States Food and Drug Administration (FDA) requirements.

4. Document that the proposed project will not:

- a. Affect the charges of the health service facility for the provision of medical or other patient care services other than services which are included in the research;
i. There will be no charges to patients or their insurance companies related to this project
b. Substantially change the bed capacity of the facility; or
i. Not applicable
c. Substantially change the medical or other patient care services of the facility.
i. This project will not substantially affect care or services

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