



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

September 15, 2014

Bruce Schroeder, MD
Carolina Breast Imaging LLC
990 Johns Hopkins Drive
Greenville, North Carolina 27834

No Review

Facility or Business: Carolina Breast Imaging LLC (CBI)
Project Description: Acquisition of Diagnostic Equipment
County: Pitt

Dear Dr. Schroeder:

The Certificate of Need Section (CON Section) received your letter of September 3, 2014 regarding the above referenced proposal. According to the information that you provided, the cost of the proposed Tomosynthesis Adapter is \$78,619.32 (including taxes). Thus, the total cost of all medical diagnostic equipment which includes mammography equipment [1 diagnostic and 1 screening] - \$270,407.91; stereotactic biopsy accessory - \$25,000.00; DEXA bone density device - \$23,884.00; and ultrasound equipment - \$56,213.00 is \$487,070.81. 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.

Moreover, you need to contact the Radiation Protection Section of the Division of Health Service Regulation (DHSR) to determine if they have any requirements for development of the proposed project.

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



Certificate of Need Section

www.ncdhhs.gov

Telephone: 919-855-3873 • Fax: 919-733-8139

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

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

An Equal Opportunity/ Affirmative Action Employer

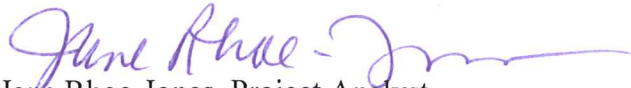


Bruce Schroeder
September 15, 2014
Page 2

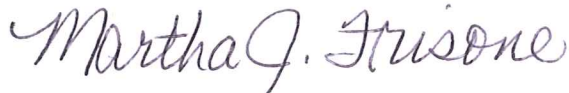
original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

Please contact the CON Section if you have any questions. Also, in all future correspondence you should reference the Facility I.D. # (FID) if the facility is licensed.

Sincerely,



Jane Rhoe-Jones, Project Analyst



Martha J. Frisone, Interim Chief
Certificate of Need Section

cc: Radiation Protection Section, DHSR



Bruce F. Schroeder, M.D.

September 3, 2014

Via Email and FedEx

Martha Frisone
Interim Chief, CON Section
2704 Mail Service Center
Raleigh, NC 27699-2704

Dear Ms. Frisone:

I am writing to inform you of my plan to acquire an additional accessory for our digital mammography equipment and to request a no review determination related to this acquisition.

The current standard for breast cancer screening is two dimensional digital mammography. This tool has been studied extensively and proven to be an essential part of early detection and has resulted in significant impact on breast cancer mortality rates. However, like every medical device or test, it is imperfect. Recent evidence has shown that acquiring the mammogram images from multiple angles to produce image "slices" (akin to a CT scan) can improve cancer detection and significantly lower the rate of false positive results. In keeping with my mission to provide the women of Eastern North Carolina with the most advanced breast cancer detection available, I am planning to purchase and install this accessory on one of my existing mammography systems.

The actual device is a mechanical system that holds the breast in the necessary position so the mammography X-ray tube can move along an arc to create the multiple mammographic images that comprise the "Tomosynthesis" data set. The images are created and processed on the same computer that controls the mammogram unit and processes the standard digital mammogram images. There is no other equipment necessary to make this accessory function for its intended purpose.

The cost of this accessory (quote from GE Healthcare attached) is \$80,119.32 inclusive of delivery, installation, training, physicist certification and sales tax.

This practice was opened in November 2013 after the issuance of a no-review determination based on "diagnostic medical equipment" as defined in N.C. Gen. Stat. § 131E-176(9b) with a total value of \$408,451 (See attached "Value of Diagnostic Equipment".) No new "diagnostic equipment" has been acquired since opening the practice.

The new total value of all "diagnostic medical equipment" is \$488,570.81 and thus below the statutory cap of \$500,000.

We would like to make this exciting new tool available to our patients as soon as possible and so respectfully ask that, based upon the information provided in this letter, you give this request your earliest possible attention. We look forward to your written confirmation that the proposal described herein does not require a certificate of need.

Sincerely,


Bruce F. Schroeder M.D.



Bruce F. Schroeder, M.D.

VALUE OF DIAGNOSTIC EQUIPMENT

EXISTING EQUIPMENT

Mammo 1	\$112,636.00
Mammo 2	\$106,071.91
Stereotactic Biopsy Device	\$25,000.00
CESM	\$45,000.00
Injector	\$6,700.00
DEXA	\$23,884.00
Ultrasound	\$56,213.00
Taxes	\$25,346.58
Miscellaneous	\$7,600.00
<i>Total Existing</i>	<i>\$408,451.49</i>

PROPOSED EQUIPMENT

Tomosynthesis Adapter	\$73,476.00
Taxes	\$5,143.32
Physicist	\$1,500.00
<i>TOTAL PROPOSED</i>	<i>\$80,119.32</i>
TOTAL INCLUDING PROPOSED	\$488,570.81

Quotation Number: PR2-C32659 V 2

Carolina Breast Imaging LLC
990 Johns Hopkins Dr
Greenville NC 27834-7224

Attn: Bruce Schroeder
990 Johns Hopkins Dr Greenville
NC 27834-7224

Date: 09-03-2014

This Agreement (as defined below) is by and between the Customer and the GE Healthcare business ("GE Healthcare"), each as identified herein. GE Healthcare agrees to provide and Customer agrees to pay for the Products listed in this GE Healthcare Quotation ("Quotation"). "Agreement" is defined as this Quotation and the terms and conditions set forth in either (i) the Governing Agreement identified below or (ii) if no Governing Agreement is identified, the following documents:

- 1) This Quotation that identifies the Product offerings purchased or licensed by Customer;
- 2) The following documents, as applicable, if attached to this Quotation: (i) GE Healthcare Warranty(ies); (ii) GE Healthcare Additional Terms and Conditions; (iii) GE Healthcare Product Terms and Conditions; and (iv) GE Healthcare General Terms and Conditions.

In the event of conflict among the foregoing items, the order of precedence is as listed above.

This Quotation is subject to withdrawal by GE Healthcare at any time before acceptance. Customer accepts by signing and returning this Quotation or by otherwise providing evidence of acceptance satisfactory to GE Healthcare. Upon acceptance, this Quotation and the related terms and conditions listed above (or the Governing Agreement, if any) shall constitute the complete and final agreement of the parties relating to the Products identified in this Quotation. The parties agree that they have not relied on any oral or written terms, conditions, representations or warranties outside those expressly stated or incorporated by reference in this Agreement in making their decisions to enter into this Agreement. No agreement or understanding, oral or written, in any way purporting to modify this Agreement, whether contained in Customer's purchase order or shipping release forms, or elsewhere, shall be binding unless hereafter agreed to in writing by authorized representatives of both parties. Each party objects to any terms inconsistent with this Agreement proposed by either party unless agreed to in writing and signed by authorized representatives of both parties, and neither the subsequent lack of objection to any such terms, nor the delivery of the Products, shall constitute an agreement by either party to any such terms.

By signing below, each party certifies that it has not made any handwritten modifications. Manual changes or mark-ups on this Agreement (except signatures in the signature blocks and an indication in the form of payment section below) will be void.

- Terms of Delivery: FOB Destination
- Quotation Expiration Date: 09-28-2014
- Billing Terms: 80% delivery / 20% Installation
- Payment Terms: Due ON Receipt - 30 Days
- Governing Agreement: None

Each party has caused this agreement to be signed by an authorized representative on the date set forth below. Please submit purchase orders to GE Healthcare
Please submit Purchase Orders to: General Electric Company, GE Healthcare, 3000 N. Grandview Blvd., Mail Code WT-897, Waukesha, WI 53188

GE HEALTHCARE

Kimberly Allen
09-03-2014
Vaso Healthcare - Authorized Manufacturer Rep

CUSTOMER

Authorized Customer _____ Date _____
Print Name and Title _____
PO # _____
Desired Equipment First Use Date _____

GE Healthcare will use reasonable efforts to meet Customer's desired equipment first use date. The actual delivery date will be mutually agreed upon by the parties.

INDICATE FORM OF PAYMENT:

If "GE HFS Loan" or "GE HFS Lease" is NOT selected at the time of signature, then you may NOT elect to seek financing with GE Healthcare Financial Services (GE HFS) to fund this arrangement after shipment.

- Cash/Third Party Loan
- GE HFS Lease
- GE HFS Loan
- Third Party Lease (please identify financing company) _____



Quotation Number: PR2-C32659 V 2

Item No.	Qty	Catalog No.	Description
	1		Senographe Essential IB Options
1	1	S30361AD	DBT License The SenoClaire license is required only in France, Germany, Netherlands, Japan and USA.
2	1	S30331CL	SENOCLAIRE LLH1 PREMIUM V Enhancement of the Premium View software to display dark and bright images, such as implants
3	1	S30361AR	SENOCLAIRE FOR USA CAN SENOCLAIRE FOR USA CAN
4	1	W0203MM	TiP 2 Day MM Accreditation Program Onsite Training TiP 2 Day MM Accreditation Program Onsite Training TiP Onsite program designed to prepare the technologist for performing the requirements of ACR Accreditation on GE MM Systems. Training is delivered Monday through Friday between 8AM and 5PM. T&L expenses are included. This training program must be scheduled and completed within 12 months after the date of product delivery.

Quote Summary:

Customer Loyalty Discount for NEW SenoCl	(\$25,000.00)
Total Quote Net Selling Price	\$73,476.00

(Quoted prices do not reflect state and local taxes if applicable. Total Net Selling Price Includes Trade In allowance, if applicable.)





Bruce F. Schroeder, M.D.

September 3, 2014

Via Email and FedEx

Martha Frisone
Interim Chief, CON Section
2704 Mail Service Center
Raleigh, NC 27699-2704



Dear Ms. Frisone:

I am writing to inform you of my plan to acquire an additional accessory for our digital mammography equipment and to request a no review determination related to this acquisition.

The current standard for breast cancer screening is two dimensional digital mammography. This tool has been studied extensively and proven to be an essential part of early detection and has resulted in significant impact on breast cancer mortality rates. However, like every medical device or test, it is imperfect. Recent evidence has shown that acquiring the mammogram images from multiple angles to produce image "slices" (akin to a CT scan) can improve cancer detection and significantly lower the rate of false positive results. In keeping with my mission to provide the women of Eastern North Carolina with the most advanced breast cancer detection available, I am planning to purchase and install this accessory on one of my existing mammography systems.

The actual device is a mechanical system that holds the breast in the necessary position so the mammography X-ray tube can move along an arc to create the multiple mammographic images that comprise the "Tomosynthesis" data set. The images are created and processed on the same computer that controls the mammogram unit and processes the standard digital mammogram images. There is no other equipment necessary to make this accessory function for its intended purpose.

The cost of this accessory (quote from GE Healthcare attached) is \$80,119.32 inclusive of delivery, installation, training, physicist certification and sales tax.

This practice was opened in November 2013 after the issuance of a no-review determination based on "diagnostic medical equipment" as defined in N.C. Gen. Stat. § 131E-176(9b) with a total value of \$408,451 (See attached "Value of Diagnostic Equipment".) No new "diagnostic equipment" has been acquired since opening the practice.

The new total value of all "diagnostic medical equipment" is \$488,570.81 and thus below the statutory cap of \$500,000.

We would like to make this exciting new tool available to our patients as soon as possible and so respectfully ask that, based upon the information provided in this letter, you give this request your earliest possible attention. We look forward to your written confirmation that the proposal described herein does not require a certificate of need.

Sincerely,

Bruce F. Schroeder M.D.



Bruce F. Schroeder, M.D.

VALUE OF DIAGNOSTIC EQUIPMENT

EXISTING EQUIPMENT

Mammo 1	\$112,636.00
Mammo 2	\$106,071.91
Stereotactic Biopsy Device	\$25,000.00
CESM	\$45,000.00
Injector	\$6,700.00
DEXA	\$23,884.00
Ultrasound	\$56,213.00
Taxes	\$25,346.58
Miscellaneous	\$7,600.00
<i>Total Existing</i>	<i>\$408,451.49</i>

PROPOSED EQUIPMENT

Tomosynthesis Adapter	\$73,476.00
Taxes	\$5,143.32
Physicist	\$1,500.00
<i>TOTAL PROPOSED</i>	<i>\$80,119.32</i>
TOTAL INCLUDING PROPOSED	\$488,570.81

Quotation Number: PR2-C32659 V 2

Carolina Breast Imaging LLC
990 Johns Hopkins Dr
Greenville NC 27834-7224

Attn: Bruce Schroeder
990 Johns Hopkins Dr Greenville
NC 27834-7224

Date: 09-03-2014

This Agreement (as defined below) is by and between the Customer and the GE Healthcare business ("GE Healthcare"), each as identified herein. GE Healthcare agrees to provide and Customer agrees to pay for the Products listed in this GE Healthcare Quotation ("Quotation"). "Agreement" is defined as this Quotation and the terms and conditions set forth in either (i) the Governing Agreement identified below or (ii) if no Governing Agreement is identified, the following documents:

- 1) This Quotation that identifies the Product offerings purchased or licensed by Customer;
- 2) The following documents, as applicable, if attached to this Quotation: (i) GE Healthcare Warranties; (ii) GE Healthcare Additional Terms and Conditions; (iii) GE Healthcare Product Terms and Conditions; and (iv) GE Healthcare General Terms and Conditions.

In the event of conflict among the foregoing items, the order of precedence is as listed above.

This Quotation is subject to withdrawal by GE Healthcare at any time before acceptance. Customer accepts by signing and returning this Quotation or by otherwise providing evidence of acceptance satisfactory to GE Healthcare. Upon acceptance, this Quotation and the related terms and conditions listed above for the Governing Agreement, if any, shall constitute the complete and final agreement of the parties relating to the Products identified in this Quotation. The parties agree that they have not relied on any oral or written terms, conditions, representations or warranties outside those expressly stated or incorporated by reference in this Agreement in making their decisions to enter into this Agreement. No agreement or understanding, oral or written, in any way purporting to modify this Agreement, whether contained in Customer's purchase order or shipping release forms, or elsewhere, shall be binding unless hereafter agreed to in writing by authorized representatives of both parties. Each party objects to any terms inconsistent with this Agreement proposed by either party unless agreed to in writing and signed by authorized representatives of both parties, and neither the subsequent lack of objection to any such terms, nor the delivery of the Products, shall constitute an agreement by either party to any such terms.

By signing below, each party certifies that it has not made any handwritten modifications. Manual changes or mark-ups on this Agreement (except signatures in the signature blocks and an indication in the form of payment section below) will be void.

- Terms of Delivery: FOB Destination
- Quotation Expiration Date: 09-28-2014
- Billing Terms: 80% delivery / 20% Installation
- Payment Terms: Due ON Receipt - 30 Days
- Governing Agreement: None

Each party has caused this agreement to be signed by an authorized representative on the date set forth below. Please submit purchase orders to GE Healthcare

Please submit Purchase Orders to: General Electric Company, GE Healthcare, 3000 N. Grandview Blvd., Mail Code WT-897, Waukesha, WI 53188

GE HEALTHCARE

Kimberly Allen
09-03-2014
Vaso Healthcare - Authorized Manufacturer Rep

CUSTOMER

Authorized Customer _____ Date _____

Print Name and Title _____

PO # _____

Desired Equipment First Use Date _____

GE Healthcare will use reasonable efforts to meet Customer's desired equipment first use date. The actual delivery date will be mutually agreed upon by the parties.

INDICATE FORM OF PAYMENT:

If "GE HFS Loan" or "GE HFS Lease" is NOT selected at the time of signature, then you may NOT elect to seek financing with GE Healthcare Financial Services (GE HFS) to fund this arrangement after shipment.

Cash/Third Party Loan

GE HFS Lease

GE HFS Loan

Third Party Lease (please identify financing company) _____



Quotation Number: PR2-C32659 V 2

Item No.	Qty	Catalog No.	Description
	1		Senographe Essential IB Options
1	1	S30361AD	DBT License The SenoClaire license is required only in France, Germany, Netherlands, Japan and USA.
2	1	S30331CL	SENOCLAIRE LLH1 PREMIUM V Enhancement of the Premium View software to display dark and bright images, such as implants
3	1	S30361AR	SENOCLAIRE FOR USA CAN SENOCLAIRE FOR USA CAN
4	1	W0203MM	TiP 2 Day MM Accreditation Program Onsite Training TiP 2 Day MM Accreditation Program Onsite Training TiP Onsite program designed to prepare the technologist for performing the requirements of ACR Accreditation on GE MM Systems. Training is delivered Monday through Friday between 8AM and 5PM. T&L expenses are included. This training program must be scheduled and completed within 12 months after the date of product delivery.

Quote Summary:

Customer Loyalty Discount for NEW SenoCl	(\$25,000.00)
Total Quote Net Selling Price	\$73,476.00

(Quoted prices do not reflect state and local taxes if applicable. Total Net Selling Price Includes Trade In allowance, if applicable.)



rhoe-jones, jane e

From: Bruce Schroeder <schroeder@cbispecialists.com>
Sent: Thursday, September 04, 2014 8:49 AM
To: rhoe-jones, jane e
Subject: No review letter
Attachments: CBIS No Review.pdf; ATT00001.htm; PastedGraphic-3.tiff; ATT00002.htm

Jane:

Attached is the “No-review” request we spoke about this morning. Please confirm receipt and let me know if you have any questions or if there is any additional information I can provide.

Thank you for your time and attention to this matter.