



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor

MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

October 31, 2018

Kristy Hubard
2131 South 17th Street
Wilmington, NC 28402

Exempt from Review – Replacement Equipment

Record #: 2754
Facility Name: South Atlantic Radiation Oncology, LLC
FID #: 050139
Project Description: Replace existing CT simulator owned by South Atlantic Radiation Oncology, LLC and managed by New Hanover Regional Medical Center
County: Brunswick

Dear Ms. Hubard:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter dated October 16, 2018 and received October 24, 2018, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the Philips 10110 Diamond Select Big Bore CT Simulator to replace the existing Varian ACU831C07 CT Simulator located at South Atlantic Radiation Oncology, LLC in Supply. This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

Moreover, you need to contact the Agency's Construction, Radiation Protection 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 the 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 office and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Tanya S. Rupp
Project Analyst

Martha J. Frisone
Chief, Healthcare Planning and
Certificate of Need Section

cc: Construction Section, DHSR
Radiation Protection Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR
Melinda Boyette, Administrative Assistant, Healthcare Planning, DHSR

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
MAILING ADDRESS: 2701 Mail Service Center, Raleigh, NC 27699-2701
www.ncdhhs.gov/dhsr/ • TEL: 919-855-3750 • FAX: 919-733-2757

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER



October 16, 2018

Ms. Martha Frisone, Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
NC Department of Health and Human Services
2704 Mail Service Center
Raleigh, North Carolina 27699-2704

RE: Request for No Review Determination for Replacement of Equipment / Brunswick County

Dear Ms. Frisone:

Pursuant to 10A NCAC 14C.0202, New Hanover Regional Medical Center (“NHRMC”) intends to replace one CT simulator and requests a determination that such replacement is exempt from review because it falls within the definition of NCGS § 131E-184 (a)(7) and the regulations set out in 10A NCAC 14C.0303.

CT Simulator Replacement

| Site | Equipment to be Replaced | Trade-in of Existing | Total Project Cost |
|--------------------------------------|--------------------------|----------------------|--------------------|
| NHRMC Radiation Oncology - Brunswick | Varian Simulator | Yes | \$498,628 |

Exemption from Review

Pursuant to NCGS § 131E-184(a): “The department shall exempt from certificate of need review a new institutional health service if it receives prior written notice from the entity proposing the new institutional health service, when notice includes an explanation of why the new institutional health service is required, for any of the following: ... (7) To provide replacement equipment.”

NCGS § 131E-176(22a) defines “replacement equipment” as equipment that costs less than \$2,000,000 and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced.

Applicable Regulations

10A NCAC 14C.0303 defines “comparable medical equipment” as equipment that “is functionally similar and which is used for the same diagnostic or treatment purposes.” Replacement equipment is comparable if:

- (1) it has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements; and
- (2) it is functionally similar and is used for the same diagnostic or treatment purposes as the equipment currently in use and is not used to provide a new health service; and
- (3) the acquisition of the equipment does not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.

Replacement equipment is not comparable to the equipment being replaced if the replacement equipment is capable of performing procedures that could result in the provision of a new health service or type of procedure that has not been provided with the existing equipment.

Compliance

NHRMC hereby certifies that:

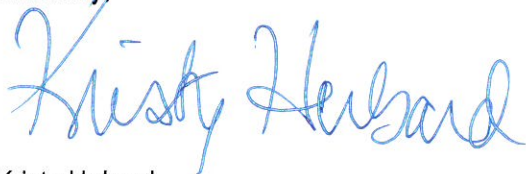
1. The estimated project costs for the replacement of the CT simulator is less than \$2,000,000.
2. The replacement equipment will be purchased for the sole purpose of replacing comparable equipment currently in use, which will be traded in for disposal and removed from North Carolina. A comparison of the existing and replacement equipment is provided in Exhibit A.
3. The replacement equipment is functionally similar to existing equipment and will be used for the same diagnostic and/or treatment procedures as the equipment currently in use.
4. No increase in charges will occur within the first twelve months after the replacement equipment is acquired.
5. The average cost per CT simulation will not increase as a result of the equipment replacement.

Determination Requested

NHRMC requests that the Division of Health Service Regulation make a determination that the replacement of the CT simulator, as proposed herein does not constitute new institutional health services and is thus exempt from certificate of need review.

If you require additional information concerning this request, please contact me at 910-815-5908.

Sincerely,



Kristy Hubbard
Chief Strategy Officer
New Hanover Regional Medical Center

Exhibit A - Existing/Replacement Equipment Comparison

- Bus id 1308
- NR 2754

EQUIPMENT COMPARISON

Exhibit A

| | EXISTING EQUIPMENT | REPLACEMENT EQUIPMENT |
|--|--------------------------------------|--------------------------------------|
| Equipment Location | NHRMC Radiation Oncology - Brunswick | NHRMC Radiation Oncology - Brunswick |
| Type of Equipment | Standard Acuity Simulator | CT Simulator |
| Manufacturer | Varian | Philips |
| Model | ACU831C07 | 100110 Diamond Select Big Bore |
| Serial Number | H770254 | TBD at purchase |
| Date of Acquisition | 11/01/2007 | November 2018 |
| Specify if Equipment Was/Is New or Used When Acquired | New | New |
| Total Capital Cost of Project (Including Construction, etc.) | N/A | \$498,628 |
| Total Cost of Equipment | N/A | \$403,628 |
| Percent of Change in Patient Charges (by Procedure) | N/A | 0% |
| Type of Procedures Currently Performed on Existing Equipment | CT simulation | CT simulation |