



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

January 10, 2020

Kristy Hubard
2131 S. 17th Street
Wilmington, NC 28401

Exempt from Review – Replacement Equipment

Record #: 3183
Facility Name: New Hanover Regional Medical Center
FID #: 943372
Business Name: New Hanover Regional Medical Center
Business #: 1308
Project Description: Replace ceiling-mounted C-arm in OR #25
County: New Hanover

Dear Ms. Hubard:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter dated January 3, 2020 and received by the Agency on January 6, 2020, 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 ARTIS Q to replace the RS AXIOM ARTIS TA SILVER, Serial # 1495. 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 M. Saporito
Project Analyst

Martha J. Frisone
Chief

cc: Construction Section, DHSR
Radiation Protection Section, DHSR
Acute and Home Care Licensure and Certification Section, 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: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704
<https://info.ncdhhs.gov/dhsr/> • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

943372
1308 B²
3183 NR

Received by Healthcare
JAN - 6 2020
Planning & CON Section

January 3, 2020

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 / New Hanover County

Dear Ms. Frisone:

Pursuant to 10A NCAC 14C.0202, New Hanover Regional Medical Center ("NHRMC") intends to replace its ceiling-mounted c-arm in Operating Room 25 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.

Ceiling-Mounted C-Arm Replacement

Site	Equipment to be Replaced	Trade-in of Existing	Total Project Cost
NHRMC 17 th Street	Siemens RS Axion Artis TA Silver	Yes	\$1,347,476

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:

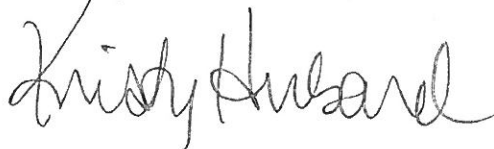
1. The estimated project costs for the replacement of the existing ceiling-mounted c-arm is less than \$2,000,000. Please refer to Exhibit A.
2. The replacement equipment will be purchased for the sole purpose of replacing comparable equipment currently in use, which will be traded in for disposal and removed from North Carolina. A comparison of the existing and replacement equipment is provided in Exhibit B.
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 vascular case 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 ceiling-mounted c-arm, 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 910-667-5908.

Sincerely,



Kristy Hubard
Chief Strategy Officer
New Hanover Regional Medical Center

Exhibit A – Project Capital Costs
Exhibit B -- Existing/Replacement Equipment Comparison

PROJECT CAPITAL COSTS

Exhibit A

New Hanover Regional Medical Center

Building Purchase Price	
Purchase Price of Land	
Closing Costs	
Site Preparation	
Construction/Renovation Contract(s)	\$104,000
Landscaping	
Architect / Engineering Fees	
Medical Equipment	\$1,243,476
Non-Medical Equipment	
Furniture	
Consultant Fees (specify)	
Financing Costs	
Interest during Construction	
Other (specify)	
Total Capital Cost	\$1,347,476

EQUIPMENT COMPARISON

Exhibit B

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	Ceiling Mounted Imaging	Ceiling Mounted Imaging
Manufacturer of Equipment	Axiom	Siemens
Tesla Rating for MRIs	N/A	N/A
Model Number	RS AXIOM ARTIS TA SILVER	ARTIS Q
Serial Number	1495	TBD
Provider's Method of Identifying Equipment	NHRMC Tag #38421	TBD
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #	N/A	N/A
Mobile Tractor Serial Number/VIN #	N/A	N/A
Date of Acquisition of Each Component	2008	TBD
Dues Provider Hold Title to Equipment or Have a Capital Lease?	Title	Title
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.)	Part of 2006 Master Plan	\$1,347,476
Total Cost of Equipment	\$656,268	\$1,243,476
Fair Market Value of Equipment	\$0	\$1,243,476
Net Purchase Price of Equipment	N/A	\$1,243,476
Locations Where Operated	OR 25 of NHRMC	OR 25 of NHRMC
Number Days In Use/To Be Used in N.C. Per Year	365	365
Percent of Change in Patient Charges (by Procedure)	N/A	0%
Percent of Change in Per Procedure Operating Expenses (by Procedure)	N/A	0%
Type of Procedures Currently Performed on Existing Equipment	Vascular surgery	Vascular surgery
Type of Procedures New Equipment is Capable of Performing	N/A	N/A

Waller, Martha K

From: dlegarth@nc.rr.com
Sent: Monday, January 6, 2020 12:25 PM
To: Tanya, Saporito; Waller, Martha K
Cc: 'Nancy O'Dacre'
Subject: [External] Letter of CON Exemption
Attachments: NHRMC OR Replacement.pdf

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to report.spam@nc.gov

Hi Tanya,

Attached please find a Letter of CON Exemption for replacement equipment.

David Legarth



Mail Address:
P.O. Box 1936
Apex, NC 27502

FedEx/UPS Address:
108 Curely Maple Court
Apex, NC 27502

Phone:
(919)244-7609