



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**
Division of Health Service Regulation

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director

July 16, 2018

Tim Ludwig
CarolinaEast Health System
PO Box 12157
New Bern, NC 28561

Exempt from Review – Replacement Equipment


Record #: 2653
Facility Name: CarolinaEast Medical Center
FID #: 923126
Business Name: CarolinaEast Health System
Business #: 2722
Project Description: Temporarily use a mobile cardiac catheterization unit while one of the fixed units is offline for software upgrades
County: Craven

Dear Mr. Ludwig:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of July 12, 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 temporarily place into service without a certificate of need the Philips Allura FD10 to temporarily replace the fixed Philips Allura Xper FD20 while software upgrades are occurring. This determination is based on your representations that the temporary unit will be removed from the state once the software upgrades are completed.

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,


Jane Rhoe-Jones
Project Analyst


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

cc: Amy Craddock, Assistant Chief, 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: 2704 Mail Service Center, Raleigh, NC 27699-2704
www.ncdhhs.gov/dhsr/ • TEL: 919-855-3873

rhoe-jones, jane e

From: Daniel Carter <DanielCarter@ascendient.com>
Sent: Thursday, July 12, 2018 12:34 PM
To: rhoe-jones, jane e
Subject: RE: [External] Temporary Replacement Exemption for CarolinaEast

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Jane,

No problem. And just to clarify, we are not asking for confirmation that the transaction meets the definition of "replacement equipment." CEMC is not actually replacing equipment, at least not permanently. It just wants to use the CON approval for one of its fixed labs for a mobile temporarily. I just didn't want you to think that we're asking you to determine whether it meets the requirements of "replacement equipment" in the rules. I should also note that they're not asking for a determination of reviewability (or no review) for the upgrade. You may certainly determine that, but they are comfortable proceeding with the upgrade without such a determination, if that helps.

The existing equipment is a Philips Allura Xper FD20 (Serial # 2200). As noted, it will not be replaced, so the make and model will remain the same. The software is being upgraded from version 7.2 to 8.1.

The temporary mobile equipment is Philips Allura FD10 (Serial # 300025738). It will only be used during the software upgrades and then will go back out of state.

Thanks. Feel free to ask anything else—I'm happy to give you the information you need.

Daniel

From: rhoe-jones, jane e <jane.rhoe-jones@dhhs.nc.gov>
Sent: Thursday, July 12, 2018 12:26 PM
To: Daniel Carter <DanielCarter@ascendient.com>
Subject: RE: [External] Temporary Replacement Exemption for CarolinaEast

Daniel,
Thanks. I apologize, but I failed to ask the make and model of the equipment being replaced as well as the make and model of the replacement equipment.

Jane

From: Daniel Carter [<mailto:DanielCarter@ascendient.com>]
Sent: Thursday, July 12, 2018 12:19 PM
To: rhoe-jones, jane e
Subject: RE: [External] Temporary Replacement Exemption for CarolinaEast

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Jane,

The cost is \$294,439.50. That's just software; no physical changes to the equipment are being performed.

Thank you.

Daniel

From: rhoe-jones, jane e <jane.rhoe-jones@dhhs.nc.gov>
Sent: Thursday, July 12, 2018 11:40 AM
To: Daniel Carter <DanielCarter@ascendient.com>
Subject: RE: [External] Temporary Replacement Exemption for CarolinaEast

Hi Daniel,
Thank you and the same to you. However, the summer is moving along pretty fast.

I do have one question. Tim mentioned that the, "cost of the software upgrades will not exceed the capital thresholds that constitute a new institutional health service." However, what is the cost of the software upgrades for the cardiac cath unit?

Thanks,
Jane

From: Daniel Carter [<mailto:DanielCarter@ascendient.com>]
Sent: Thursday, July 12, 2018 9:45 AM
To: rhoe-jones, jane e
Cc: Blackmon, Erica N
Subject: [External] Temporary Replacement Exemption for CarolinaEast

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Jane,

Good morning. I hope your summer is going well. I have another exemption letter for a temporary replacement—please see the attached. If you need any more information, please let me know.

Thank you.

Daniel

Daniel R. Carter, MBA
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July 12, 2018

- CarolinaEast Medical Center
- CarolinaEast Diagnostic Center
- CarolinaEast Surgery Center
- CarolinaEast Rehabilitation Hospital
- CarolinaEast Heart Center
- CarolinaEast Urology Center
- CarolinaEast Internal Medicine
- CarolinaEast Pediatrics
- CarolinaEast Gastroenterology
- CarolinaEast Cardiac, Thoracic & Vascular Surgery
- CarolinaEast Ear, Nose & Throat
- CarolinaEast Radiation Oncology
- CarolinaEast Physical Medicine & Rehabilitation
- CarolinaEast Home Care
- CarolinaEast Foundation
- CarolinaEast Wound Healing & Hyperbaric Services
- Crossroads Mental Health

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

RE: Temporary Replacement Equipment for CarolinaEast Medical Center's Fixed Cardiac Catheterization Equipment

Dear Ms. Frisone:

The purpose of this letter is to request that CarolinaEast Medical Center ("CEMC") be permitted to temporarily utilize a mobile cardiac catheterization unit in place of one of its existing fixed cardiac catheterization units while it undergoes software upgrades. These upgrades will enhance patient care by providing better visualization for the physicians during the case and radiation dose structured reporting. CEMC estimates the upgrades will take approximately two to three weeks during August 2018. During that time, the laboratory being upgraded will be closed and unavailable for patient treatment. Please note that the cost of the upgrades does not exceed the capital thresholds that constitute a new institutional health service, nor will any additional types of procedures be able to be performed on the equipment that are not currently being performed. The upgrades will not result in an increase to patient charges.

As one of only three tertiary care hospitals located east of I-95, and with only two existing and operational fixed cardiac catheterization labs, CEMC needs to ensure that sufficient capacity is available for both scheduled and emergency patients. As such, CEMC intends to contract with Modular Devices, Inc. to bring a mobile cardiac catheterization unit to CEMC from out of state. CEMC already has a mobile pad in place that will accommodate the mobile unit, so no construction will be necessary to provide the temporary service. Upon completion of the necessary upgrades, the vendor will remove the mobile cardiac catheterization unit from the state. The serial number of the equipment to be upgraded is #2200 and the serial number of the mobile equipment to be used temporarily is #300025738. At no time during this process will CEMC diagnose or treat patients using more than two cardiac catheterization units.

Ms. Martha Frisone, Chief
July 12, 2018
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CEMC hopes to commence this work within the next few weeks, so please let me know if I can provide any additional information to expedite our request.

Sincerely,

A handwritten signature in black ink, appearing to read 'TL' followed by a long, sweeping horizontal stroke that ends in a small loop.

Tim Ludwig
Vice President, Ancillary Services
CarolinaEast Health System