



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor

KODY H. KINSLEY • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

April 26, 2023

Sandy T. Godwin

stgodwin@capefearvalley.com

Exempt from Review – Replacement Equipment

Record #: 4182
Date of Request: April 17, 2023
Facility Name: Cape Fear Valley Medical Center
FID #: 943057
Business Name: Cumberland County Hospital System, Inc.
Business #: 578
Project Description: Replacement of cardiac catheterization equipment
County: Cumberland

Dear Ms. Godwin:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the above referenced project is exempt from certificate of need review in accordance with G.S. 131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the Siemens cardiac catheterization equipment to replace the Siemens cardiac catheterization equipment (Serial # SR3940). 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.

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

Micheala Mitchell
Chief

cc: Acute and Home Care Licensure and Certification Section, DHSR
Radiation Protection 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



CAPE FEAR VALLEY HEALTH

BEHAVIORAL HEALTH CARE
BLADEN COUNTY HOSPITAL
CAPE FEAR VALLEY MEDICAL CENTER
CAPE FEAR VALLEY REHABILITATION CENTER
HEALTH PAVILION NORTH
HIGHSMITH-RAINEY SPECIALTY HOSPITAL
HOKE HOSPITAL

April 17, 2023

Ms. Tanya Saporito
Project Analyst, Healthcare Planning and Certificate of Need Section
Ms. Tanya Saporito
Project Analyst, Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
2704 Mail Center Service
Raleigh, NC 27699-2704

BLOOD DONOR CENTER
BREAST CARE CENTER
CANCER CENTER
CAPE FEAR VALLEY MEDICAL GROUP
CARELINK
CAPE FEAR VALLEY HOMECARE & HOSPICE, LLC
CUMBERLAND COUNTY EMS
FAMILY BIRTH CENTER
HEART & VASCULAR CENTER
HEALTHPLEX
LIFELINK CRITICAL CARE TRANSPORT
SLEEP CENTER

RE: Replacement of Cardiac Catheterization Equipment at Cape Fear Valley Medical Center / Cumberland County

Dear Ms. Saporito:

The purpose of this letter is to notify the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (the "Agency") that Cape Fear Valley Medical Center ("CFVMC") plans to replace cardiac catheterization equipment located in the hospital facility. CFVMC requests a determination that the respective 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.

The existing cardiac catheterization equipment is situated in the Heart Center on the second floor at CFVMC and has been in service for over 14 years. The equipment has exceeded its useful life. CFVMC intends to replace the existing cardiac catheterization equipment in the CFVMC 2nd Floor Heart Center with a new Siemens cardiac catheterization equipment. The existing equipment will be removed from CFVMC when the replacement equipment is installed.

Pursuant to NCGS § 131 E-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.

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



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HOKE HOSPITAL

- (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.

As set forth below, we believe that Cape Fear Valley Medical Center’s project meets these requirements and is exempt from certificate of need review.

BLOOD DONOR CENTER
BREAST CARE CENTER
CANCER CENTER
CAPE FEAR VALLEY MEDICAL GROUP
CARELINK
CAPE FEAR VALLEY HOMECARE & HOSPICE, LLC
CUMBERLAND COUNTY EMS
FAMILY BIRTH CENTER
HEART & VASCULAR CENTER
HEALTHPLEX
LIFELINK CRITICAL CARE TRANSPORT
SLEEP CENTER

- (1) The equipment being replaced is located on the main campus.
- (2) The total estimated cost to acquire and install the replacement equipment is less than \$2,000,000. See **Attachment A**.
- (3) 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.
- (4) 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.
- (5) CFVMC will not acquire any other major medical equipment or develop any other new institutional health services described in N.C. General Statute 131-E176(16) as part of this project.
- (6) The project will not increase patient charges or per procedure operating expenses more than 10% within 12 months of the replacement equipment being acquired.

A copy of the equipment comparison table is included in **Attachment B**.

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

Please contact me at 910.615.6852 or stgodwin@capefearvalley.com regarding any questions concerning this request.

Sincerely,

Sandy T. Godwin
Vice President, Planning
Cape Fear Valley Health System

Attachments

Projected Capital Cost Form	
Building Purchase Price	\$ -
Purchase Price of Land	\$ -
Closing Costs	\$ -
Site Preparation	\$ -
Construction / Renovation Contract (s)	\$ 598,657
Landscaping	\$ -
Architect / Engineering Fees	\$ -
Medical Equipment	\$ 669,135
Non-Medical Equipment	\$ -
Furniture	\$ -
Consultant Fees (specify)	\$ -
Financing Costs	\$ -
Interest during Construction	\$ -
Other (Contingency)	\$ -
TOTAL CAPITAL COSTS	\$ 1,267,792

[Signature]
10 APR. '23

[Signature]
10 APRIL 2023
NORTH CAROLINA
CONCORD, N.C.

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment	Cath Lab (Original CON # M-5804-98 and replaced under CON M-7069-04 with completion October 2008)	Cath Lab
Manufacturer of Equipment	Siemens	Siemens
Tesla Rating for MRIs	NA	NA
Model Number	7555126	
Serial Number	SR3940	
Provider's Method of Identifying Equipment	Cardiac Cath	Cardiac Cath
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number / VIN #	NA	NA
Mobile Tractor Serial Number / VIN #	NA	NA
Date Acquired	10/1/2008	NA
Does Provider Hold Title to Equipment or Have a Capital Lease?	Own	Will Own
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>		\$1,267,792
Construction & renovation cost	\$1,492,770	\$598,657
Total Cost of Equipment		\$669,135
Fair market Value of Equipment	NA	\$669,135
Net Purchase Price of Equipment	NA	\$669,135
Locations Where Operated	Cape Fear Valley Medical Center	Cape Fear Valley Medical Center
Number of Times Equipment was Used to Provide a Health Service during the 12 months prior to the Date of the Written Notice	1,075	NA
Type of Procedures Currently Performed on Existing Equipment	R/L Heart Caths, Coronary Angiography and Stents, Biopsy, Peripheral Arteriogram, Peripheral Artery Angioplasty and Stents, IABP	NA
Type of Procedures New Equipment is Capable of Performing	NA	R/L Heart Caths, Coronary Angiography and Stents, Biopsy, Peripheral Arteriogram, Peripheral Artery Angioplasty and Stents, IABP

CERTIFICATION BY A LICENSED ARCHITECT OR ENGINEER

I certify that, to the best of my knowledge, the projected total construction capital cost for the proposed project is complete and correct and that it is our intent to carry out the proposed project as described.

Signature of Licensed Architect or Engineer

Date Signed

10 APRIL 2023

From: [Tanya, Saporito](#)
To: [Stancil, Tiffany C](#)
Subject: FW: [External] Cape Fear Valley Medical Center"s Cath Lab Exemption request
Date: Monday, April 17, 2023 2:47:50 PM
Attachments: [CFVMC Cath Lab #2 Replacement Exemption 4.17.2023 DHSR Package.pdf](#)

Oops. 😞

Thank you Tiffany,

I miss you

Tanya Saporito, J.D. *I work from home and in the office. Email is the best way to contact me.*

Project Analyst

[Division of Health Service Regulation](#), Certificate of Need
[NC Department of Health and Human Services](#)

Office: 919-855-3873

Tanya.saporito@dhhs.nc.gov

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2704 Mail Service Center
Raleigh, NC 27699-2704

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From: Sandy Godwin <stgodwin@capefearvalley.com>
Sent: Monday, April 17, 2023 2:10 PM
To: Tanya, Saporito <tanya.saporito@dhhs.nc.gov>
Subject: [External] Cape Fear Valley Medical Center's Cath Lab Exemption request

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Good afternoon,

I hope you are doing very well.

Attached is Cape Fear Valley Medical Center's request for an exemption of a Cath Lab.

Please let me know if you need any additional information.

Have a great day!

Sandy

Sandy T Godwin
Vice President of Planning
Cape Fear Valley Health System
910-615-6852 office
stgodwin@capefearvalley.com

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