

ROY COOPER • Governor

KODY H. KINSLEY • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

December 29, 2022

Denise M. Gunter

Denise.gunter@nelsonmullins.com

Exempt from Review - Replacement Equipment

Record #: 4103

Date of Request: November 16, 2022

Facility Name: Onslow Memorial Hospital, Inc.

FID #: 923383

Business Name: Onslow Memorial Hospital, Inc.

Business #: 1354

Project Description: Replace existing CT Simulator

County: Onslow

Dear Ms. Gunter:

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 GE Healthcare CT Scanner Catalog #S7891AN to replace the Siemens CT Scanner Serial # hxa5006481. 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,

Gregory F. Yakaboski

Micheala Mitchell

Project Analyst

Micheala Mitchell

Chief

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

Radiation Protection Section, DHSR

Construction 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



Denise M. Gunter T: 336.774.3322 F: 336.774.3372 denise.gunter@nelsonmullins.com

NELSON MULLINS RILEY & SCARBOROUGH LLP ATTORNEYS AND COUNSELORS AT LAW

The Knollwood, 380 Knollwood Street Suite 530 Winston-Salem, North Carolina 27103 T: 336.774.3300 F: 336.774.3299 nelsonmullins.com

November 16, 2022

VIA EMAIL ONLY

Micheala Mitchell. Chief North Carolina Department of Health and Human Services Division of Health Service Regulation Healthcare Planning and Certificate of Need Section 809 Ruggles Drive Raleigh, North Carolina 27603

Replacement Equipment Exemption Request

Onslow County Hospital Authority/Onslow Memorial Hospital (H0048)

Onslow County FID #: 923383 Business #: 1354

Health Service Area VI

Dear Ms. Mitchell:

On behalf of Onslow County Hospital Authority ("OCHA"), the governing body of Onslow Memorial Hospital ("OMH") in Jacksonville, North Carolina, I am providing prior written notice of OMH's intention to replace an existing CT Simulator at a projected capital cost of \$650,930.91. The equipment comparison form is attached as **Exhibit A**, and the signed capital cost form is attached as **Exhibit B**¹. OMH's existing CT Simulator is approximately 12 years old and has reached the end of its useful life.

N.C. Gen. Stat. § 131E-184(a)(7) exempts from CON review the provision of replacement equipment. N.C. Gen. Stat. § 131E-176(22a) defines "replacement equipment" as:

Equipment that costs less than two million dollars (\$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

¹ The services of an architect or engineer are not necessary for this project, so the capital cost form is signed by an officer of OMH.

Micheala Mitchell November 16, 2022 Page 2

of when replaced. In determining whether the replacement equipment costs less than two million dollars (\$2,000,000), the costs of equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the replacement equipment shall be included. The capital cost for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater.

N.C. Gen. Stat. § 131E-176(22a).

In addition, 10A NCAC 14C.0303(b) requires that the equipment to be replaced has been used by the person requesting the exemption at least 10 times to provide a health service within the 12 months prior to the date of the exemption letter. Subpart (c) of this rule contains two exclusions:

- (1) the replacement equipment is capable of providing a health service that the equipment being replaced cannot provide; and
- (2) the equipment to be replaced was acquired less than 12 months prior to the date the exemption notice is submitted and it was refurbished or reconditioned when it was acquired

Each requirement of the statute and the rule is met here. The replacement CT Simulator, including all costs essential to acquiring and making the equipment operational, costs less than \$2 million. When the replacement CT Simulator is ready to be used, the existing CT Simulator will be decommissioned and removed. It will not be brought back into North Carolina for use without appropriate CON approval. OMH further represents that it has used the existing CT Simulator at least 10 times in the last 12 months to treat patients. Neither of the exclusions in 10A NCAC 14C.0303(c)(1) or (2) applies here. As shown in **Exhibit A**, the replacement CT Simulator will perform procedures in CPT code 77290 (management of radiation therapy, simulation, complex), which is the same as the existing CT Simulator. The replacement CT Simulator will also be capable of performing procedures in CPT code 77293 (respiratory motion management simulation) which is not a regulated health service.

Accordingly, we respectfully request the Agency's prompt written confirmation that the proposed acquisition of a replacement CT Simulator is exempt from CON review.

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Thank you for your time and consideration.

Sincerely,

Denise M. Gunter

Enclosures

cc: Lisa Pittman Derek Hunter

(all via email, with enclosures)

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotriptor, MRI, PET, Simulator, CT Scanner, Other Major Medical Equipment)	CT Scanner	CT Scanner
Manufacturer	Siemens	GE Healthcare
Model number	1029 3050	S7891an discovery rt gen 3 el
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	Serial#hxa5006481	Catalog# S7891AN
Is the equipment mobile or fixed?	Fixed	Fixed
Date of acquisition	August 31, 2010	pending
Was the existing equipment new or used when acquired? / Is the replacement equipment new or used?	New	New
Total projected capital cost of the project <attach a="" capital="" cost="" form="" projected="" signed=""></attach>	n/a	\$650,930.91
Total cost of the equipment	\$681,056.00	\$630,930.91
Location of the equipment <attach a="" equipment="" for="" if="" mobile="" necessary="" separate="" sheet=""></attach>	ORO CT Room	ORO CT Room
Document that the existing equipment is currently in use	Yes	n/a
Will the replacement equipment result in any increase in the average charge per procedure?	n/a	no
If so, provide the increase as a percent of the current average charge per procedure	n/a	n/a
Will the replacement equipment result in any increase in the average operating expense per procedure?	n/a	Not anticipated
If so, provide the increase as a percent of the current average operating expense per procedure	n/a	n/a
Type of procedures performed on the existing equipment <attach a="" if="" necessary="" separate="" sheet=""></attach>	77290 CPT Management of radiation therapy, simulation, complex	n/a
Type of procedures the replacement equipment will perform <attach a="" if="" necessary="" separate="" sheet=""></attach>	n/a	77290, 77293 Respiratory motion management simulation

Date of last revision: 5/17/19

Projected Capital Cost Form

Building Purchase Price	\$0
Purchase Price of Land	\$0
Closing Costs	\$0
Site Preparation	\$0
Construction/Renovation Contract(s)	\$0
Landscaping	\$0
Architect / Engineering Fees	\$0
Medical Equipment	\$630,930.91
Non-Medical Equipment	\$0
Furniture	\$0
Consultant Fees (specify)	\$0
Financing Costs	\$0
Interest during Construction	\$0
Other (specify) FLOORING	\$20,000
Total Capital Cost	\$650,930.91

CERTIFICATION BY A LICENSED ARCHITECT OR ENGINEER

I certify that, to the best of my knowledge, the projected ca complete and correct.	apital cost for the proposed project is
Signature of Licensed Architect or Engineer	Date Signed:
CERTIFICATION BY AN OFFICER OR AGENT FOR THE PROPO	ONENT
I certify that, to the best of my knowledge, the projected total is complete and correct and that it is our intent to carry out the	l capital cost for the proposed project ne proposed project as described.
Signature of Officer/Agent	Date Signed:h
Title of Officer/Agent	

Date of Last Revision: 5.17.19

From: Denise Gunter
To: Stancil, Tiffany C

Subject: [External] FW: Replacement Equipment Exemption Request for Onslow Memorial Hospital

Date: Wednesday, November 16, 2022 12:39:32 PM

Attachments: Notice of Replacement Equipment 4874-2930-0030 v.1.docx

Replacement CT Simulator Comparison OMH.docx Exhibit B-CT Sim Projected Capital Cost Form.pdf

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to Report Spam.

First batch – one more to follow. Thanks.

From: Denise Gunter

Sent: Wednesday, November 16, 2022 11:56 AM

To: Yakaboski, Greg <greg.yakaboski@dhhs.nc.gov>; tiffany.c.hunt@dhhs.nc.gov

Cc: Mitchell, Micheala L < micheala.mitchell@dhhs.nc.gov>; Pittman, Lisa

lisa.pittman@dhhs.nc.gov>; Derek L. Hunter (dhunter@ncdoj.gov) <dhunter@ncdoj.gov>

Subject: Replacement Equipment Exemption Request for Onslow Memorial Hospital

Good morning, Greg and Tiffany,

I understand Martha may be out, so I am taking the liberty of copying Tiffany on this correspondence.

I hope all is well with everyone. Attached is a replacement equipment exemption request for Onslow Memorial Hospital with attachments. Could you please let me know that you have received this?

Thanks and best regards.



Confidentiality Notice

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