



NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

VIA EMAIL ONLY

May 18, 2021

Denise M. Gunter
Denise.gunter@nelsonmullins.com

Exempt from Review – Replacement Equipment

Record #: 3561
Date of Request: May 14, 2021
Facility Name: Columbus Regional Diagnostics
FID #: 050908
Business Name: Columbus Regional Healthcare System
Business #: 519
Project Description: Replace existing mobile MRI scanner
County: Columbus

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 Signa Voyager G2 VX28 1.5T to replace the GE 1.5T Signa LX mobile MRI scanner. 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,

[Handwritten signature of Tanya M. Saporito]

Tanya M. Saporito
Project Analyst

[Handwritten signature of Lisa Pittman] for

Lisa Pittman
Acting Chief, Certificate of Need

cc: Acute 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

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May 14, 2021

**VIA EMAIL**

Lisa Pittman, Acting 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

Re: Replacement Equipment Exemption Request and Addition of Host Sites for  
Mobile MRI Scanner, Project I.D. No. O-7340-05

Dear Ms. Pittman:

On behalf of Columbus Regional Diagnostics (“CRD”), an affiliate of Columbus Regional Health System (“CRHS”), I am writing to inform the CON Section of CRD’s intention to replace a mobile MRI scanner (the “Existing Scanner”) and to add host sites to the route for the scanner once it is replaced. The history of the Existing Scanner is described in the declaratory ruling attached hereto as **Exhibit A**.

**Replacement MRI Scanner**

The Existing Scanner was originally acquired more than a decade ago and has reached the end of its useful life. In fact, within the last month, CRD decided to temporarily suspend service on the Existing Scanner due to its age. CRD does not believe it is in the best interest of patient care to use the Existing Scanner which does not offer the image quality physicians and patients expect today. Additionally, CRD’s service vendor for the Existing Unit declined to enter into a service contract extension due to the unit’s age, as the vendor cannot guarantee its ongoing operational integrity. The Existing Scanner has, however, been used at least 10 times in the last 12 months, as required by 10A N.C.A.C. 14C.0303(b).

CRD has decided to replace the Existing Scanner with a new GE Signa Voyager (the "Replacement Scanner"). Information about the scanner is linked here: <https://www.gehealthcare.com/products/magnetic-resonance-imaging/1-5t/signa-voyager>. The capital costs to acquire the Replacement Scanner are \$1,592,302.20, which includes all costs essential to acquiring the Replacement Scanner and making it operational, including the trailer used to transport the mobile scanner. The capital cost form and the replacement equipment comparison form are attached hereto as **Exhibits B and C**, respectively. As these documents illustrate, the project meets the requirements of N.C. Gen. Stat. § 131E-176(22a) and 10A NCAC 14C.0303. Accordingly, and pursuant to N.C. Gen. Stat. § 131E-184(a)(7), CRD respectfully requests that it be allowed to acquire the Replacement Scanner without obtaining a CON.

### Host Sites

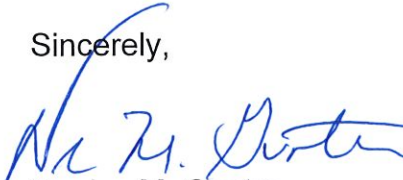
Once the Replacement Scanner is in service, CRD intends to serve the following host sites, which are all within the scope of the 2008 settlement agreement (the "Settlement Agreement") described on page 2 of **Exhibit A**.

Host Site	Address	Days of Service
Columbus County Site	619 Jefferson Street, Whiteville, NC	Two days/week during the week, Monday-Friday
Brunswick County Site	509 Old Waterford Way, Suite 104, Leland, NC	Three days/week during the week, Monday-Friday
Robeson County Site	404 Hatfield Court, Lumberton, NC	Sundays

The costs and charges to the public will not increase due to the addition of these host sites, and the scope of services historically offered by the Existing Scanner will not change as a result of allowing the Replacement Scanner to serve these host sites. Accordingly, and pursuant to N.C. Gen. Stat. § 131E-181, CRD respectfully asks that it be allowed to serve these host sites once the Replacement Scanner is operational.

Please let me know if you have any questions or need further information. Thank you for your time and prompt attention to this request.

Sincerely,



Denise M. Gunter

Enclosures



**NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES  
DIVISION OF HEALTH SERVICE REGULATION  
RALEIGH, NORTH CAROLINA**

**IN RE: REQUEST FOR DECLARATORY )  
RULING BY COLUMBUS REGIONAL ) DECLARATORY RULING  
DIAGNOSTICS )  
Project I.D. No. O-7340-05 )**

I, Drexdal Pratt, as Director of the Division of Health Service Regulation, North Carolina Department of Health and Human Services (“Department”), do hereby issue this Declaratory Ruling pursuant to North Carolina General Statute § 150B-4 and 10A N.C.A.C. 14A .0103 under the authority granted me by the Secretary of the Department of Health and Human Services.

In 2013, Columbus Regional Diagnostics (“Columbus” or “Petitioner”) acquired the assets of Waccamaw Ultrasound & Diagnostics (“Waccamaw”), including a mobile MRI scanner acquired pursuant to the Certificate of Need (“CON”) issued for Project I.D. # O-7340-05. Columbus is now requesting to add two (2) host sites for the mobile MRI at Orthopaedic Specialists, PA, 509 Olde Waterford Way (“Olde Waterford Way Site”), Suite 103, Leland, NC; and Rocky Point Medical Center (“Rocky Point Medical Center Site”), 27 Commerce Drive, Rocky Point, NC. This ruling pertains only to the matters referenced herein. Except as provided by N.C.G.S. § 150B-4, the Department expressly reserves the right to make a prospective change in the interpretation of the statutes and regulations at issue in this Declaratory Ruling. Susan Fradenburg and Justin Mark Puleo of Smith Moore Leatherwood LLP have requested this ruling on behalf of Petitioner and have provided the material facts upon which this ruling is based.

## **STATEMENT OF THE FACTS**

On January 27, 2006 Waccamaw was approved to acquire a mobile MRI scanner pursuant to a settlement agreement in Project I.D. # O-7340-05. The original host sites for the mobile MRI scanner were 619 Jefferson Street, Whiteville and 604 North Madison Street, Whiteville.

A settlement agreement (“the 2008 settlement agreement”) dated October 23, 2008 established that the service area for the Waccamaw Mobile MRI scanner included the counties of Columbus, Robeson Bladen, Pender, Brunswick, and New Hanover. According to the 2008 settlement agreement, the Agency also agreed to permit Waccamaw to use its scanner and trailer at the locations in Wilmington, New Hanover County and Rocky Point, Pender County as proposed in Waccamaw’s Requests for Declaratory Rulings.

Pursuant to subsequent declaratory rulings and the 2008 settlement agreement Waccamaw also served the following sites with its mobile MRI scanner: 1414 30th Street, Wilmington; 404 Hatfield Court, Lumberton; 27 Commerce Drive, Rocky Point, and 1515 Medical Center Drive, Wilmington.

Columbus no longer serves the sites located at 1414 30th Street, Wilmington; 515 Medical Center Drive, Wilmington, and 604 North Madison Street, Whiteville. Columbus is proposing to serve the additional host site at the Olde Waterford Way Site with mobile MRI services one day per week. Further, Columbus proposes to reactivate the previously approved site at the Rocky Point Medical Center Site which was deactivated pursuant to Waccamaw’s request in 2011.

## **ANALYSIS**

N.C.G.S. §131E-181(a) provides that “[a] certificate of need shall be valid only for the defined scope, physical location, and person named in the application.” The recipient of the CON must also materially comply with the representations made in the CON application. N.C.G.S. §131E-181(b).

If Petitioner's proposal were to represent a material change in the physical location or scope of the project, the CON law would require a full review of Petitioner's proposal. N.C.G.S. § 131E-181(a).

Petitioner states there will be no change in the scope of services originally proposed for the mobile MRI scanner and the two new sites will not create any increases in charges to the public. Petitioner also states it will not incur any capital costs to serve these two new locations because each site already has a pad for a mobile MRI scanner.

Based on the facts as presented by Petitioner, Petitioner's proposal does not constitute a material change in the physical location or scope of the project and is allowable. The proposed host sites are within the approved service areas. The addition of the proposed host sites will not change the population served by the mobile MRI scanner, will not negatively impact the quality, scope, or availability of services provided by the mobile diagnostic program, and will not increase costs or charges. Petitioner agrees to materially comply with all the requirements and representations made in its original CON application, subsequent declaratory rulings, and settlement agreement.

N.C.G.S. § 131E-189(b) allows the Agency to withdraw Petitioner's CON if Petitioner either fails to develop the service in a manner consistent with the representations made in the Petitioner's application or with any conditions that were placed on the CON. Petitioner will not be developing its project in a manner that is materially different from the representations made in its application, declaratory rulings, and settlement agreement nor will it be developing its project in a manner that is inconsistent with any of the conditions that were placed on its CON.

### **CONCLUSION**

For the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that Petitioner's request for a declaratory ruling to add two new host sites for the mobile MRI scanner at Orthopaedic Specialists, PA, 509 Olde Waterford Way, Suite 103, Leland; and

Rocky Point Medical Center, 27 Commerce Drive, Rocky Point, will not constitute a material change in the physical location or scope of the project, will not violate N.C.G.S. § 131E-181, and will not constitute a failure to satisfy a condition of the certificate of need in violation of N.C.G.S. § 131E-189(b).

This the \_\_\_\_\_ day of December, 2014.

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Drexdal Pratt, Director  
Division of Health Service Regulation  
N.C. Department of Health and Human Services

**CERTIFICATE OF SERVICE**

I certify that a copy of the foregoing Declaratory Ruling has been served upon the nonagency party by certified mail, return receipt requested, by depositing the copy in an official depository of the United States Postal Service in first-class, postage pre-paid envelope addressed as follows:

**CERTIFIED MAIL**

Susan Fradenburg  
Justin Mark Puleo  
Smith Moore Leatherwood LLP  
434 Fayetteville Street, Suite 2800  
Raleigh, North Carolina 27601

This the \_\_\_\_\_ day of December, 2014.

\_\_\_\_\_  
Cheryl Ouimet  
Chief Operating Officer



**Projected Capital Cost Form**

Building Purchase Price	
Purchase Price of Land	
Closing Costs	
Site Preparation	
Construction/Renovation Contract(s)	
Landscaping	
Architect / Engineering Fees	
Medical Equipment	\$1,592,302.20
Non-Medical Equipment	
Furniture	
Consultant Fees (specify)	
Financing Costs	
Interest during Construction	
Other (specify)	
<b>Total Capital Cost</b>	<b>\$1,592,302.20</b>

**CERTIFICATION BY A LICENSED ARCHITECT OR ENGINEER**

I certify that, to the best of my knowledge, the projected capital cost for the proposed project is complete and correct.

N/A \_\_\_\_\_  
Signature of Licensed Architect or Engineer

Date Signed: \_\_\_\_\_

**CERTIFICATION BY AN OFFICER OR AGENT FOR THE PROPONENT**

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

DocuSigned by:  
*Jason Beck*  
\_\_\_\_\_  
Signature of Officer/Agent

Date Signed: 5/13/2021

Chief Operating Officer

\_\_\_\_\_  
Title of Officer/Agent

## EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type (e.g., Cardiac Catheterization, Gamma Knife®, Heart-lung bypass machine, Linear Accelerator, Lithotripter, MRI, PET, Simulator, CT Scanner, Other Major Medical Equipment)	MRI	MRI
Manufacturer	GE	GE
Model number	1.5T Signa LX	Signa Voyager G2 VX28 1.5T
Other method of identifying the equipment (e.g., Room #, Serial Number, VIN #)	SN: 216724MR5	
Is the equipment mobile or fixed?	Mobile	Mobile
Date of acquisition	2013 (by CRD) Exact date of purchase by original owner is unknown	TBD
Was the existing equipment new or used when acquired? / Is the replacement equipment new or used?	Used	New
Total projected capital cost of the project <Attach a signed Projected Capital Cost form>	NA	1,592,302.20
Total cost of the equipment	We believe it was \$1.7 million, but we were not the original purchaser	1,592,302.20
Location of the equipment <Attach a separate sheet for mobile equipment if necessary>	619 Jefferson Street, Whiteville NC 28472	Mobile unit
Document that the existing equipment is currently in use	See accompanying letter	NA
Will the replacement equipment result in any increase in the average charge per procedure?	NA	no
If so, provide the increase as a percent of the current average charge per procedure	NA	N/A

Will the replacement equipment result in any increase in the average operating expense per procedure?	NA	no
If so, provide the increase as a percent of the current average operating expense per procedure	NA	N/A
Type of procedures performed on the existing equipment <Attach a separate sheet if necessary>	Non-contrast MRI exams	NA
Type of procedures the replacement equipment will perform <Attach a separate sheet if necessary>	NA	All MRI exams, contrast and non-contrast

Date of last revision: 5/17/19

**From:** [Denise Gunter](#)  
**To:** [Tanya, Saporito](#)  
**Subject:** [External] RE: Follow up  
**Date:** Tuesday, May 18, 2021 4:05:20 PM

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

Hi, Tanya,  
Yes, I can confirm that.  
Thanks.



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**DENISE M. GUNTER PARTNER**  
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**From:** Tanya, Saporito <[tanya.saporito@dhhs.nc.gov](mailto:tanya.saporito@dhhs.nc.gov)>  
**Sent:** Tuesday, May 18, 2021 3:59 PM  
**To:** Denise Gunter <[denise.gunter@nelsonmullins.com](mailto:denise.gunter@nelsonmullins.com)>  
**Subject:** Follow up

◀**External Email**▶ - From: [tanya.saporito@dhhs.nc.gov](mailto:tanya.saporito@dhhs.nc.gov)

Hello Denise,

I have one question regarding the request to replace the existing mobile MRI scanner at Columbus Regional Diagnostics, submitted on May 14, 2021. Will you please confirm that the existing unit, once replaced, will be sold or disposed of and will not be used again in the State without first obtaining a certificate of need if one is required?

Thank you in advance.

**Tanya Saporito, J.D.**

Project Analyst

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

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Office: 919-855-3873

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