

ROY COOPER • Governor

KODY H. KINSLEY • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

March 3, 2022

Karin Sandlin

ksandlin@claritysservices.com

Exempt from Review – Replacement Equipment

Record #: 3831

Date of Request: February 18, 2022

Facility Name: AdventHealth Hendersonville

FID #: 943388

Business Name: Fletcher Hospital, Inc.

Business #: 745

Project Description: Replace existing MRI scanner

County: Henderson

Dear Ms. Sandlin:

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(f). Therefore, you may proceed to acquire without a certificate of need the GE 1.5T Voyager MRI scanner to replace the GE 1.5T Signa HDx, Serial #41744WH4, 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,

Ena Lightbourne Project Analyst

Micheala Mitchell

Micheala Mitchell

Chief

cc: Acute & Home Care Licensure and Certification 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



February 17, 2022

Via Electronic Mail

Ms. Micheala Mitchell
Ms. Ena Lightbourne
Division of Health Service Regulation
N.C. Department of Health and Human Services
809 Ruggles Drive
Raleigh, NC 27626-0530

RE: Replacement of MRI Equipment at AdventHealth Hendersonville

Dear Ms. Mitchell:

The purpose of this letter is to inform the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (the "Agency") that AdventHealth Hendersonville (AdventHealth) intends to replace a magnetic resonance imaging (MRI) scanner located in the hospital facility. The capital cost for the replacement MRI scanner project exceeds \$2M. See Attachment A. AdventHealth requests a determination that the respective replacement is exempt from review because it satisfies the requirements of NCGS § 131E-184(f) and the regulations set out in 10A NCAC 14C .0303.

The existing GE 1.5T MRI scanner has been in service for 13 years and it has exceeded its useful life. AdventHealth intends to replace the existing MRI scanner in the same location with a GE 1.5T Voyager MRI scanner. The existing MRI scanner will be removed from AdventHealth and returned to the vendor when the replacement MRI scanner 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."

Pursuant to NCGS § 131E-184(f): "The Department shall exempt from certificate of need review the purchase of any replacement equipment that exceeds the two million dollar (\$2,000,000) threshold set forth in G.S. 131E- 176(22a) if all of the following conditions are met:

- (1) The equipment being replaced is located on the main campus.
- (2) The Department has previously issued a certificate of need for the equipment being replaced. This subdivision does not apply if a certificate of need was not required at

- the time the equipment being replaced was initially purchased by the licensed health service facility.
- (3) The licensed health service facility proposing to purchase the replacement equipment shall provide prior written notice to the Department, along with supporting documentation to demonstrate that it meets the exemption criteria of this subsection.

The replacement of the MRI scanner at AdventHealth falls within the parameters of this exemption. Specifically:

(1) Main Campus

The "main campus" of the facility is defined in N.C.G.S. 131E-176(14n) includes "[t]he site of the main building from which a licensed health service facility provides clinical patient services and exercises financial and administrative control over the entire facility, including the buildings and grounds adjacent to that main building" and "[o]ther areas and structures that are not strictly contiguous to the main building but are located within 250 yards of the main building."

AdventHealth Hendersonville is an existing licensed health service facility, and the main campus hospital facility provides clinical patient services and exercises financial and administrative control over the entire facility, including the buildings and grounds adjacent to the main building. The existing fixed MRI scanner and proposed fixed MRI scanner are and will be located in the hospital facility, respectively.

(2) <u>CON</u>

The CON for Project ID B-7384-05 documents that AdventHealth was previously approved to operate a fixed MRI scanner.

(3) Prior Written Notice

This letter serves as prior written notice to the Agency of AdventHealth's intent to acquire replacement equipment.

The proposed MRI scanner qualifies as replacement equipment pursuant to the existing statutory and regulatory definitions.

- (1) The existing MRI scanner is currently in use, as documented on AdventHealth's 2022 License Renewal Application included in Attachment B.
- (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.

- (3) The replacement equipment is functionally similar to existing equipment and will be used for the same diagnostic MRI procedures as the equipment currently in use.
- (4) AdventHealth will not acquire any other major medical equipment or develop any other new institutional health services described in N.C. Gen. Stat. §131E-176 (16) as part of this project.
- (5) 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 C.

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

Please contact me at 828.681.2102 or scott.miller@adventhealth.com regarding any questions concerning this request.

Sincerely,

Signature: Scatt Miller (Feb 17, 2022 20:40 EST)

Email: scott.miller@adventhealth.com

Scott Miller
Vice President Operations | COO
AdventHealth Hendersonville

Attachments

Attachment A:
Capital Cost Table

AdventHealth Hendersonville Projected Capital Cost Forn	n: MRI Replacement
Building Purchase Price	
Purchase Price of Land	
Closing Costs	
Site Preparation	
Construction / Renovation Contract (s)	\$548,002
Landscaping	
Architect / Engineering Fees	\$36,708
Medical Equipment	\$1,689,819
Non-Medical Equipment	
Furniture	
Consultant Fees (specify)	
Financing Costs	
Interest during Construction	
Other (Temporary MRI Rental)	\$102,459
TOTAL CAPITAL COSTS	\$2,376,988

Attachment B:

2022 LRA Excerpt

License No: <u>H0019</u> Facility ID: <u>943388</u>

Instructions for Hospitals with multiple campuses: For MRI Services, (Sections 10b-10e, pp 17-18), do not provide cumulative/combined data for all campuses. Provide data for individual campuses only.

b. MRI Procedures

Indicate the number of procedures performed on MRI scanners (units) operated during the 12-month reporting period at your facility. For hospitals that use equipment at multiple sites/campuses, please copy the MRI pages and provide separate data for each site/campus. Campus – if multiple sites: Main Campus, 100 Hospital Drive, Hendersonville

	Inpatient Procedures*			Outpatient Procedures*			
Procedures	With Contrast or Sedation	Without Contrast or Sedation	TOTAL Inpatient	With Contrast or Sedation	Without Contrast or Sedation	TOTAL Outpatient	TOTAL Procedures
Fixed	203	611	814	1,298	432	1,730	2,544
Mobile (performed only at this site)							
TOTAL**	203	611	814	1,298	432	1,730	2,544

^{*} An MRI procedure is defined as a single discrete MRI study of one patient (single CPT-coded procedure). An MRI study means one or more scans relative to a single diagnosis or symptom.

Note: Healthcare Planning and Certificate of Need may request CPT codes for MRI procedures if further clarification is needed.

c. Fixed MRI Scanners

Indicate the number of MRI scanners (units) operated during the 12-month reporting period at your facility. For hospitals that operate medical equipment at multiple sites/campuses, please copy the MRI pages and provide separate data for each site/campus. Campus – if multiple sites: Main Campus, 100 Hospital Drive, Hendersonville

Fixed Scanners	Number of Units
Number of fixed MRI scanners-closed, including open-bore scanners (do not include any Policy AC-3 scanners)	1
Number of fixed MRI scanners-open (do not include any Policy AC-3 scanners)	
Number of Policy AC-3 MRI scanners used for general clinical purposes	
Total Fixed MRI Scanners	1

Number of grandfathered fixed MRI scanners on this campus:	
For questions, please contact Healthcare Planning and Certificate of Need at 919-855-3873.	
CON Project ID numbers for all other fixed MRI scanners on this campus:	_

^{**} Totals must be greater than or equal to the totals in the MRI Patient Origin Table on page 30 of this application.

Attachment C: Equipment Comparison Table

AdventHealth Hendersonville MRI Replacement	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment	MRI Scanner	MRI Scanner
Manufacturer of Equipment	GE	GE
Tesla Rating for MRI	1.5T	1.5T
Model Number	Signa HDx	Voyager
Serial Number	41744WH4	TBD
Specifiy 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 Acquired	Manufactured 9/2008; Acquired 7/1/2009	TBD
Does Provider Hold Title to Equipment or Have a Capital Lease?	Owned	N/A
Specifiy if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <see a="" attachment=""></see>	N/A	\$2,376,988
Total Cost of Equipment	\$795,045	\$1,689,819
Fair market Value of Equipment	N/A	\$1,689,819
Net Purchase Price of Equipment	N/A	\$1,689,819
Location Where Operated	Main Campus	Main Campus
Number of Times Equipment was Used to Provide a Health Service during the 12 months prior to the Date of the Written Notice	2,500+	N/A
Type of Procedures Currently Performed on Existing Equipment	MRI Procedures	N/A
Type of Procedures New Equipment is Capable of Performing	N/A	MRI Procedures

Signature: Scat Nilluv

Scott Miller (Feb 17, 2022 20:40 EST)

Email: scott.miller@adventhealth.com

From: <u>Lightbourne, Ena</u>
To: <u>"Karin Sandlin"</u>

Cc: Murrill, Mark; Waller, Martha K

Subject: RE: [External] AdventHealth Hendersonville Exemption Request

Date: Friday, February 18, 2022 11:56:54 AM

Received. Thank you.

From: Karin Sandlin < ksandlin@claritysservices.com>

Sent: Friday, February 18, 2022 11:55 AM

To: Lightbourne, Ena <ena.lightbourne@dhhs.nc.gov> **Cc:** Murrill, Mark <MARK.MURRILL@AdventHealth.com>

Subject: [External] AdventHealth Hendersonville Exemption Request

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

Ena,

Attached please find an Exemption Request from AdventHealth Hendersonville regarding the replacement of an existing fixed MRI scanner at the hospital main campus.

Please feel free to contact me if you have any questions or desire additional information.

Thank you,

Karin

Karin Sandlin

President, Clarity Strategic Services

4208 Six Forks Road, Suite 1000, Raleigh, 27609

Mobile: 919-271-8200

ksandlin@claritysservices.com www.claritystrategicservices.com

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