

ROY COOPER • Governor

KODY H. KINSLEY • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

April 17, 2023

Tina Hair Hinshaw, Alliance Healthcare thinshaw@allianceradiology-us.com

Exempt from Review – Replacement Equipment

Record #: 4179

Date of Request: April 12, 2023

Business Name: Alliance Healthcare Services, Inc.

Business #: 60

Project Description: Temporarily replace mobile MRI scanners while they undergo repairs

County: Chatham, Durham and Wake

Dear Ms. Hinshaw:

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 mobile MRI scanner ESP66 to temporarily replace the two mobile MRI scanners, ESP43 and Signa294, while those mobile MRI scanners undergo repairs. This determination is based on your representations that the temporary replacement unit will be removed following completion of the repairs 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,

Michael J. McKillip

Team Leader

Micheala Mitchell

Micheala Mitchell

Chief

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



April 12, 2023

Mr. Mike McKillip, CON Analyst
Ms. Micheala Mitchell, Chief
Health Planning and Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Alliance Healthcare Services - Written Notice for Exemption from CON Review for the Temporary Replacement of MRI Scanners ESP43 and Signa 294

Dear Mrs. McKillip and Ms. Mitchell:

I am writing regarding the urgent need to temporarily replace MRI scanners ESP43 and Signa294 such that maintenance and repairs can be completed. Please accept this notice of exemption to temporarily replace ESP43 and Signa294 with ESP66, VIN# 1M9A3A823AH022453 which is an existing mobile MRI scanner owned by Alliance and will be utilized as the interim temporary MRI for this scanner. When ESP66 is no longer needed to serve as a temporary replacement for ESP43 and Signa294, it will return to its normal route.

The legacy Alliance MRIs ESP43 (Serial# 1M9A3A82XCH022811) and Signa294 (serial #1S9FA482231182634) are scanners that have properly been reported in the 2023 NC MRI Equipment Inventory. The sites impacted during this two week maintenance period and thus will utilize the coverage unit are:

- Chatham Hospital, 475 Progress Blvd, Siler City, NC 27344 (Chatham)
- Raleigh Radiology Oberlin, 505 Oberlin Rd, Raleigh, NC 97605 (Wake)
- Duke Regional Hospital, 3643 N. Roxboro Rd, Durham, NC 27704 (Durham)

This letter provides justification and written notice regarding the replacement equipment in accordance with NCGS 131 E-184. Alliance Healthcare Services also provides documentation that the equipment conforms to the Certificate of Need Laws and Administrative rules: GS 131E-184(a) (7) Exemptions from review to provide replacement equipment 10A NCAC 14C.0303 Replacement Equipment Administrative Rules.

Overview

This existing MRI scanner requires temporary replacement due to:

- HVAC parts failure
- Service to the existing host site is disrupted if temporary replacement MRI is not provided
- Alliance has no available capacity on other MRI scanners in North Carolina to provide coverage for the unit that needs to be repaired.

Compliance Documentation

Compliance with G.S. 131E-176 (22a) Replacement Equipment Definition is evident because the temporary replacement scanner has a fair market value of \$350,000 to \$400,000 which is far less than the \$2,000,000 threshold.

The replacement MRI equipment will be used for the same diagnostic purposes as the existing equipment. In addition, Alliance is providing written notice to the Department in accordance with G.S. 131E-184 (a) (7) Exemption from Review to provide replacement equipment.

Applicability and Conformance with Administrative Rule 10A NCAC 14C.0303 Replacement Equipment Alliance Healthcare Services plans to use an existing mobile MRI as a temporary replacement. No equipment will be purchased. The temporary replacement equipment conforms to the rules as follows:

10A NCAC 14C .0303 REPLACEMENT EQUIPMENT

- (a) This Rule defines the terms used in the definition of "replacement equipment" set forth in G.S. 131E-176(22a). Alliance Healthcare Services has reviewed this rule definition.
- (b) "Currently in use" means that the equipment to be replaced has been used by the person requesting the exemption at least 10 times to provide a health service during the 12 months prior to the date the written notice required by G.S. 131E-184(a) is submitted to the CON Section.

Alliance Healthcare Services confirms that ESP21 meets the definition of "currently in use" because the MRI scanner provides service during the previous 12 months prior to the date of this written notice.

(c) Replacement equipment is not "comparable" if: (1) the replacement equipment to be acquired is capable of providing a health service that the equipment to be replaced cannot provide; or (2) the equipment to be replaced was acquired less than 12 months prior to the date the written notice required by G.S. 131E-184(a) is submitted to the CON Section and it was refurbished or reconditioned when it was acquired by the person requesting the exemption.

The replacement MRI scanner is comparable to the equipment being replaced because the temporary replacement equipment will be used to acquire the same types of MRI images and data. Alliance Healthcare Services certifies that the replacement mobile MRI equipment will be used for the same diagnostic purposes as the existing MRI unit.

The existing equipment, ESP43 and Signa294, will be temporarily replaced by ESP66, which will return to its normal location once repairs are completed. The temporary use of replacement ESP66 will be discontinued in approximately 12 days (in April 2023) when the repairs of ESP43 and Signa294 have been completed and returned to service.

Thank you for your review and consideration of this information. Please call me at 805.325.3078 if you have any questions.

Sincerely,

Tina Hair Hinshaw, MBA

RVP, Mobile Operations Southeast Region

805.325.3078

thinshaw@allianceradiology-us.com or tina.hinshaw@akumin.com

CC: Jennifer Freeman, Manager of Operations Alliance Healthcare Services/Alliance Radiology/Akumin Rodney Skelding, Manager of Operations Alliance Healthcare Services/Alliance Radiology/Akumin

 From:
 Mckillip, Mike

 To:
 Stancil, Tiffany C

 Cc:
 Mitchell, Micheala L

Subject: FW: [External] Notice of Exemption-Temp Replacement-MRI repairs ESP43 and SIGNA294

Date: Thursday, April 13, 2023 9:59:25 AM

Attachments: AR NCCON ESP43 and Signa294 Temp Coverage 2asets April 2023.pdf

Hi Tiffany,

Exemption request for your records. I can do this one. Thanks.

Mike

Michael McKillip

Team Leader, Certificate of Need Division of Health Service Regulation, Healthcare Planning and Certificate of Need NC Department of Health and Human Services

Office: 919-855-3877 (I am in the office on Wednesday and Friday, and can best be reached by email on Monday, Tuesday and Thursday.)

mike.mckillip@dhhs.nc.gov

809 Ruggles Drive, Edgerton 2704 Mail Service Center Raleigh, NC 27699

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From: Tina Hinshaw <Tina.Hinshaw@akumin.com>

Sent: Wednesday, April 12, 2023 5:42 PM

To: Mckillip, Mike <mike.mckillip@dhhs.nc.gov>; Mitchell, Micheala L

<Micheala.Mitchell@dhhs.nc.gov>

Cc: Rodney Skelding < rodney.skelding@akumin.com>; Jenny Freeman

<jennifer.freeman@akumin.com>; Tina Hinshaw <tina.hinshaw@akumin.com>

Subject: [External] Notice of Exemption-Temp Replacement-MRI repairs ESP43 and SIGNA294

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

Please see attached written notice of temp replacement of ESP43 and SIGNA294 while HVAC repairs are taking place.

Please call/text/email if you have any questions or concerns. Regards,

Tina

Tina Hair Hinshaw
RVP Mobile Operations, Southeast
805.325.3078 (cell)
Tina.Hinshaw@Akumin.com

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