

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

December 9, 2021

David French, Consultant to Alliance Healthcare Djfrench45@gmail.com

Exempt from Review – Replacement Equipment		
Record #:	3752	
Date of Request:	December 1, 2021	
Business Name:	Alliance Healthcare Services, Inc.	
Business #:	60	
Project Description:	Temporary replacement of mobile MRI scanner	
Counties:	Buncombe, Orange and Wake	

Dear Mr. French:

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 Espree 1.5T mobile MRI scanner (Unit # ESP 52) to temporarily replace the Siemens Espree 1.5T mobile MRI scanner (Unit # ESP 43). This determination is based on your representations that, following repairs to the existing unit (Unit # ESP 43), it will be returned to service and the replacement unit (Unit # ESP 52) will be removed and 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 Project Analyst

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

ALLIANCE HEALTHCARE SERVICES

December 1, 2021

Ms. Micheala Mitchell, Chief Mr. Mike Mckillip, CON Analyst 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 Emergency Temporary Replacement of Mobile MRI Scanner ESP 43

Dear Ms. Mitchell and Mr. Mckillip:

I am writing on behalf of my client, Alliance Healthcare Services (Alliance), regarding the urgent need to temporarily replace mobile MRI scanner ESP 43 (Legacy Unit). Repairs are needed to the frame of the trailer of this unit. The ESP 43 mobile MRI was brought into North Carolina earlier this year as the permanent replacement for SIGNA 480. Alliance obtained the equipment replacement exemption on April 29, 2021 as seen in the attached correspondence.

Please accept this notice of exemption to temporarily replace the above unit with ESP 52 Serial # 1M9A3A826CH022806, which is an existing mobile MRI scanner owned by Alliance and will be utilized as an interim temporary unit at this location. When ESP 52 is no longer needed to serve as a temporary replacement for ESP 43 it will be removed from North Carolina.

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 replacement equipment conforms to the Certificate of Need laws and Administrative rules: G.S. 131E-184 (a) (7) Exemptions from review to provide replacement equipment 10A NCAC 14C.0303 Replacement Equipment Administrative Rules

Overview

The existing mobile MRI scanner requires temporary replacement for several reasons:

- The existing ESP 43 requires repairs that are estimated to take approximately three weeks
- Service to the existing host sites will be disrupted if a temporary replacement mobile MRI scanner 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.

The host sites that will be served by the replacement mobile MRI scanner are:

Raleigh Radiology 505 Oberlin Road, Suite 110, Raleigh, NC 27605 Wake County UNC Eastowne Medical Office Building 100 Eastowne Drive Chapel Hill, NC 27514 Orange County

Margaret R Pardee Memorial Hospital Southeastern Sports Medicine 21 Turtle Creek Drive Asheville, NC 28803 Buncombe County

Compliance Documentation

Compliance with G.S. 131E-176 (22a) Replacement Equipment Definition is evident because the temporary replacement mobile MRI scanner has a fair market value of \$400,000 which is far less than the \$2,000,000 threshold. Since the ESP 52 MRI equipment is already owned by Alliance no capital cost will be incurred for its short-term use.

The replacement MRI equipment will be used for the same diagnostic purposes as the existing equipment. In addition, Alliance is providing prior 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 ESP 43 meets the definition of "currently in use" because the MRI scanner currently serves Raleigh Radiology, UNC Eastowne and Southeastern Sports Medicine.

(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 to be temporarily replaced was acquired in 2011. The temporary replacement unit will be removed from North Carolina.

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	TEMPORARY REPLACEMENT
Type of Equipment (List Each Component)	MRI	MRI
Manufacturer of Equipment	Siemens	Siemens
Tesla Rating for MRIs	1.5T	1.5T
Model Number	ESPREE	ESPREE
Serial Number	1M93A82XCH022811	1M9A3A826CH022806
Provider's Method of Identifying Equipment	ESP 43	ESP 52
Specify if Mobile or Fixed	Mobile	Mobile
Mobile Trailer Serial Number/VIN #	1M93A82XCH022811	1M9A3A826CH022806
Mobile Tractor Serial Number/VIN #	NA – No changes	NA – No changes
Date of Acquisition of Each Component	2011	2012
Hold Title or Lease	Holds Title	Holds Title
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (no construction involved)	NA	\$400,000 FMV Already owned by Alliance
Total Cost of Equipment	NA	NA
Fair Market Value of Equipment	NA	NA
Net Purchase Price of Equipment	NA	NA
Locations Where Operated Currently	Raleigh Radiology, UNC Eastowne, Southeastern Sports Medicine	Raleigh Radiology, UNC Eastowne, Southeastern Sports Medicine
Number Days In Use/To be Used in N.C. Per Year	Up to 365	Short Term Replacement
Percent of Change in Patient Charges (by Procedure)	NA	0%
Percent of Change in Per Procedure Operating Expenses (by Procedure)	NA	0%
Type of Procedures Currently Performed on Existing Equipment	MRI Procedures	MRI Procedures
Type of Procedures New Equipment is Capable of Performing	NA	MRI Procedures

The temporary use of replacement ESP 52 will be discontinued in approximately three weeks when the repair of ESP 43 has been completed and returned to service.

Thank you for your review and consideration of this information. Please call me at 336 432-8308 if you have any questions.

Sincerely,

Aland Jamh

David J. French Consultant to Alliance Healthcare Services

P.O. Box 2154 Reidsville, NC 27023 djfrench45@gmail.com

Cc: Rodney Skelding Manager of Operations Alliance Healthcare Services



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

April 29, 2021

David French, Consultant to Alliance Healthcare Services, Inc. djfrench45@gmail.com

Exempt from Review - Replacement Equipment Record #: 3538

Record #:	3538
Date of Request:	April 22, 2021
Facility Name:	Alliance Healthcare Services, Inc.
FID #:	040553
Business Name:	Alliance Healthcare Services, Inc.
Business #:	60
Project Description:	Replace existing mobile MRI scanner
County:	Forsyth

Dear Mr. French:

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 ESPREE ESP 43, Serial # 1M9A3A82XCH022811, mobile MRI scanner to be used in place of the GE SIGNA 480, Serial # 1S9FA4826X1182271 mobile MRI scanner while the GE SIGNA 480 is being temporarily used at Wake Forest Baptist Hospital-Kernersville (Material compliance approval, Project ID #G-11798-19 dated March 29, 2021). This determination is based on your representations that the existing unit, GE SIGNA 480, will be sold or otherwise disposed of after its temporary use at Wake Forest Baptist Hospital-Kernersville 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,

Celia C. Unman Celia C. Inman

Project Analyst

Gloria C. Hale

for Lisa Pittman Acting Chief, Certificate of Need

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

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION
 From:
 Mckillip, Mike

 To:
 Waller, Martha K

 Subject:
 FW: [External] Alliance Equipment Replacement Exemption

 Date:
 Wednesday, December 1, 2021 9:44:41 AM

 Attachments:
 ALLIANCE Temporary Replacement ESP 43 with ESP 52.pdf

FYI

Michael McKillip

Project Analyst Division of Health Service Regulation, Healthcare Planning and Certificate of Need <u>NC Department of Health and Human Services</u>

Office: 919-855-3877 mike.mckillip@dhhs.nc.gov

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

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From: David French <djfrench45@gmail.com>
Sent: Wednesday, December 1, 2021 8:20 AM
To: Mckillip, Mike <mike.mckillip@dhhs.nc.gov>
Cc: Rodney Skelding <rskelding@allianceradiology-us.com>; Tina Hinshaw
<thinshaw@allianceradiology-us.com>
Subject: [External] Alliance Equipment Replacement Exemption

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Hi Mike,

Please confirm that you have received the attached Equipment Replacement Exemption request for the Alliance MRI scanner. This is a temporary replacement while ESP 43 is being repaired. Please call or email me if you have any questions.

Thank you,

David French 336 432-8308