



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

July 8, 2020

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

Exempt from Review – Replacement Equipment

Record #: 3315
Business Name: Alliance Healthcare Services, Inc.
Business #: 60
Project Description: Temporarily replace mobile MRI scanner at Duke Raleigh Hospital
County: Wake

Dear Mr. French:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of July 3, 2020, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(a)(7). Therefore, you may proceed to temporarily replace without a certificate of need the Siemens MRI Scanner SYM 43 (Serial # 1M9A3A8216H022412) that requires repairs with a rental MRI scanner (ESP 400-622907). This determination is based on your representations that the rental unit will be removed when repairs are completed 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 Michael J. McKillip]

Michael J. McKillip
Project Analyst

[Handwritten signature of Martha J. Frisone]

Martha J. Frisone
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

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

## ALLIANCE HEALTHCARE SERVICES

July 3, 2020

Ms. Martha Frisone, Chief  
Health Care 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 Temporary Replacement of Mobile MRI Scanner SYM 43 Serial # 1M9A3A8216H022412 (grandfathered unit), in Wake County

Dear Ms. Frisone:

Alliance Healthcare Services (Alliance) has an urgent need to temporarily replace mobile MRI scanner SYM 43 Serial # 1M9A3A8216H022412 (grandfathered unit). This MRI scanner is owned by Alliance and leased to Duke University Health System (Duke Raleigh) and has been properly reported to DHSR Healthcare Planning.

Please accept this notice of exemption to temporarily replace the above SYM 43 unit with Siemens Rental ESP 400-622907. When this Siemens rental unit is no longer needed to serve as a temporary replacement for SYM 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 and 10A NCAC 14C.0303 Replacement Equipment Administrative Rules.

### **Overview**

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

- 1) The existing SYM 43 urgently requires repairs.
- 2) Service to the existing host site will be disrupted if a temporary replacement mobile MRI scanner is not provided.
- 3) Patient diagnosis and treatment at the host sites will be disrupted without access to MRI.
- 4) Alliance has no available capacity on other MRI scanners in North Carolina to provide coverage for the unit that needs to be repaired.

Alliance recognizes the need to provide high quality, cost effective, and reliable mobile MRI scanner service. The host site that will be served by the replacement mobile MRI scanner is:

Duke Raleigh Hospital - Cary  
3700 NW Cary Parkway  
Cary NC 27609  
Wake County

### **Compliance Documentation**

Compliance with G.S. 131E-176 (22a) Replacement Equipment Definition is demonstrated because the temporary replacement MRI scanner has a current fair market value of \$450,000.

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 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 NCSC 14C. 0303 Replacement Equipment*

*(a) The purpose of this Rule is to define 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) “Activities essential to acquiring and making operational the replacement equipment” means those activities which are indispensable and requisite, absent which the replacement equipment could not be acquired or made operational.*

Alliance Healthcare Services has reviewed this rule definition.

*(c) “Comparable medical equipment” means equipment which is functionally similar and which is used for the same diagnostic or treatment purposes.*

Alliance Healthcare Services has reviewed this rule definition.

*(d) Replacement equipment is comparable to the equipment being replaced if:*

*(1) it has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements; and*

The replacement MRI scanner is comparable to the equipment being replaced because the temporary replacement equipment will also obtain MRI images and data. The proposed replacement mobile MRI scanner will be used to acquire the same types of MRI images and data.

*(2) it is functionally similar and is used for the same diagnostic or treatment purposes as the equipment in use and is not used to provide a new health service; and*

Alliance Healthcare Services certifies that the replacement mobile MRI equipment will be used for the same diagnostic purposes as the existing MRI unit.

*(3) The acquisition of the equipment does not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.*

The host site will utilize the temporary replacement MRI scanner and shall be notified by Alliance Imaging that no increases in costs or patient charges will result from the temporary replacement.

*(e) Replacement equipment is not comparable to the equipment being replaced if:*

*(1) the replacement equipment is new or reconditioned, the existing equipment was purchased second hand and the replacement equipment is purchased less than three years after the acquisition of the existing equipment.*

Not applicable. This notice involves a temporary replacement MRI scanner. Following completion of the repairs the existing equipment will be brought back into service and the temporary replacement unit will be removed from North Carolina.

*(2) The replacement equipment is new, the existing equipment was reconditioned when purchased, and the replacement equipment is purchased less than three years after the acquisition of the existing equipment; or*

Not applicable. See the explanation above.

*(3) The replacement equipment is capable of performing procedures that could result in the provision of a new health service or type of procedure that has not been provided with the existing equipment; or*

Not applicable. The replacement equipment is functionally similar to the existing equipment and will be used for the same diagnostic procedures as the existing equipment. The existing equipment will be brought back into service and the temporary replacement unit will be removed from North Carolina.

*(4) The replacement equipment is purchased and the existing equipment is leased, unless the lease is a capital lease;*

Not applicable. The existing equipment is not leased.

*(5) The replacement equipment is a dedicated PET scanner and the existing equipment is:*

*(A) a gamma camera with coincidence capability; or*

*(B) nuclear medicine equipment that was designed, built, modified to detect only the single photon emitted from nuclear events other than positron annihilation.*

Not applicable. The existing equipment is an MRI scanner and not a gamma camera or nuclear medicine equipment.

## EQUIPMENT COMPARISON

	<b>EXISTING EQUIPMENT</b>	<b>TEMPORARY REPLACEMENT</b>
Type of Equipment (List Each Component)	<b>MRI</b>	<b>MRI</b>
Manufacturer of Equipment	<b>Siemens</b>	<b>Siemens</b>
Tesla Rating for MRIs	<b>1.5T</b>	<b>1.5T</b>
Model Number	<b>Symphony</b>	<b>Espreo</b>
Serial Number	<b>1M9A3A8216H022412</b>	<b>400-622907</b>
Provider's Method of Identifying Equipment	<b>SYM 43</b>	<b>ESP 400-622907</b>
Specify if Mobile or Fixed	<b>Mobile</b>	<b>Mobile</b>
Mobile Trailer Serial Number/VIN #	<b>1M9A3A8216H022412</b>	<b>400-622907</b>
Mobile Tractor Serial Number/VIN #	<b>NA – No changes</b>	<b>NA – No changes</b>
Date of Acquisition of Each Component	<b>2009</b>	<b>2010</b>
Hold Title or Lease	<b>Holds Title</b>	<b>Short Term Rental</b>
Specify if Equipment Was/Is New or Used When Acquired	<b>New</b>	<b>Rental</b>
Total Capital Cost of Project (no construction involved)	<b>NA</b>	<b>NA</b>
Total Cost of Equipment	<b>NA</b>	<b>NA</b>
Fair Market Value of Equipment	<b>NA</b>	<b>Rental Temporary</b>
Net Purchase Price of Equipment	<b>NA</b>	<b>NA</b>
Locations Where Operated Currently	<b>Please see list</b>	<b>Please see list</b>
Number Days In Use/To be Used in N.C. Per Year	<b>Up to 365</b>	<b>Temporary</b>
Percent of Change in Patient Charges (by Procedure)	<b>NA</b>	<b>0%</b>
Percent of Change in Per Procedure Operating Expenses (by Procedure)	<b>NA</b>	<b>0%</b>
Type of Procedures Currently Performed on Existing Equipment	<b>MRI Procedures</b>	<b>MRI Procedures</b>
Type of Procedures New Equipment is Capable of Performing	<b>NA</b>	<b>MRI procedures</b>

The temporary use of replacement unit to serve the host sites will be discontinued when the repair of SYM 43 has been completed and the scanner has been returned to service.

Thank you for your review and consideration of this information. Please call me at the office at 336 432-8308 (cell phone) if you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "David French", written in a cursive style.

David French  
Consultant to Alliance Healthcare Services  
P.O. Box 2154  
Reidsville, NC 27023  
djfrench45@gmail.com

Cc: Jennifer Freeman and Rodney Skelding  
Managers of Operations  
Alliance Healthcare Services

**ALLIANCE HEALTHCARE SERVICES**

June 30, 2019

Ms. Martha Frisone, Chief  
Health Planning and Certificate of Need Section  
2704 Mail Service Center  
Raleigh, NC 27699-2704

RE: Temporary Equipment Replacement for MRI Scanner SYM 43 Serial #  
1M9A3A8216H022412 (grandfathered unit)

Dear Ms. Frisone,

**Alliance Healthcare Services intends to temporarily replace its existing mobile MRI SYM 43 Serial (grandfathered unit) with a replacement unit Siemens Rental # 400-622907.**

In accordance with 10A NCAC 14C.030 Replacement Equipment Administrative Rules, Alliance agrees that the replacement MRI scanner equipment will not result in more than a 10 percent increase in expense or charges to any MRI host sites. This is a temporary replacement and no changes to the current agreements or charges will result.

Thank you for your consideration. Please call me if you have any questions.

Sincerely,

*Jennifer Freeman*

Jennifer Freeman  
Manager of Operations  
Alliance Radiology  
**704-957-9900**



**From:** [David French](#)  
**To:** [Waller, Martha K](#); [Mckillip, Mike](#)  
**Cc:** [Jennifer Freeman](#); [Rodney Skelding](#)  
**Subject:** [External] Alliance Temporary Replacement for SYM 43 in Wake County  
**Date:** Friday, July 3, 2020 9:06:56 AM  
**Attachments:** [Alliance Temporary Replacement SYM 43 final.pdf](#)

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Good morning,

Please see the attached temporary replacement exemption for Alliance MRI Scanner SYM 43..

David French  
336 432-8308 cell