



NC DEPARTMENT OF  
**HEALTH AND  
HUMAN SERVICES**

ROY COOPER • Governor

MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

December 10, 2019

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

**Exempt from Review – Replacement Equipment**

**Record #:** 3148  
**Business Name:** Alliance Healthcare Services, Inc.  
**Business #:** 60  
**Project Description:** Temporarily replace an existing mobile MRI scanner  
**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 November 25, 2019, 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 acquire without a certificate of need the SIGNA 492 mobile MRI scanner (Serial # 1KKVA482BJL226990) to temporarily replace the existing SIGNA 457 mobile MRI scanner (Serial # 1S9FA821181183197). 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,

Michael J. McKillip  
Project Analyst

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

## Waller, Martha K

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**From:** David French <dj french45@gmail.com>  
**Sent:** Monday, November 25, 2019 10:21 AM  
**To:** Mckillip, Mike; Waller, Martha K  
**Cc:** Aaron Dunn; Cale G. Arnold; Jamie Faison  
**Subject:** [External] Raleigh Orthopedic Clinic and Alliance MRI Temporary Replacement Exemption  
**Attachments:** SIGNA 457 Alliance Temporary Equipment Replacement Exemption 11\_25\_19.pdf

**CAUTION:** External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to [report.spam@nc.gov](mailto:report.spam@nc.gov)

Good morning,

Please confirm that you have received the attached temporary replacement exemption for SIGNA 457. If you have questions, please call or email me.

Thanks

David French  
336 432-8308 cell

ALLIANCE HEALTHCARE SERVICES



November 25, 2019

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

RE: Raleigh Orthopaedic Clinic and Alliance Healthcare Services - Written Notice for Exemption from CON Review for Temporary Replacement of Mobile MRI Scanner SIGNA 457 Serial # 1S9FA821181183197 (CON Project ID# J-7757-06)

Dear Ms. Frisone:

I am writing on behalf of my clients, Raleigh Orthopaedic Clinic (ROC) and Alliance Healthcare Services (Alliance), regarding the urgent need to temporarily replace mobile MRI scanner SIGNA 457 Serial # 1S9FA821181183197 (CON # J-7756-06). A copy of the Inventory Form for SIGNA 457 is attached. Please accept this notice of exemption to temporarily replace the above unit with SIGNA 492 GE 1.5 T MRI that is owned by Alliance and utilized in other states or as an approved interim temporary unit. When this unit is no longer needed to serve as a temporary replacement for SIGNA 457 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:

- 1) The existing SIGNA 457 requires repairs that are estimated to take approximately 4 days.
- 2) Service to the existing host sites 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.

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

Raleigh Orthopaedic Clinic 3001 Edwards Mill Rd Raleigh, NC 27612 Wake	Raleigh Orthopaedic Clinic 222 Asheville Cary, NC 27511 Wake	Raleigh Orthopaedic Clinic 10880 Durant Road Raleigh, NC 27614 Wake
Raleigh Orthopaedic Clinic 1305 Timber Drive Garner, NC 27529 Wake		

### **Compliance Documentation**

Compliance with G.S. 131E-176 (22a) Replacement Equipment Definition is demonstrated in Attachment 1 which shows that the temporary replacement scanner is a unit owned by Alliance with a current fair market value of \$350,000.

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**

ROC and Alliance plan 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).*

ROC and Alliance have 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.*

ROC and Alliance have 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.*

ROC and Alliance have 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*

ROC and Alliance certify 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 certify 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. 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.

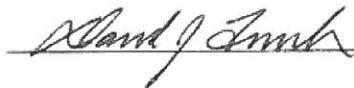
**EQUIPMENT COMPARISON**

	<b>EXISTING EQUIPMENT</b>	<b>TEMPORARY REPLACEMENT</b>
Type of Equipment (List Each Component)	MRI	MRI
Manufacturer of Equipment	GE	GE
Tesla Rating for MRIs	1.5T	1.5T
Model Number	Signa HDx	Signa Hdx
Serial Number	1S9FA821181183197	1KKVA482B.JL226990
Provider's Method of Identifying Equipment	SIGNA 457	SIGNA 492
Specify if Mobile or Fixed	Mobile	Mobile
Mobile Trailer Serial Number/VIN #	1S9FA821181183197	1KKVA482B.JL226990
Mobile Tractor Serial Number/VIN #	NA – No changes	NA – No changes
Date of Acquisition of Each Component	2006	2004
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 (2006)	\$350,000 (FMV)
Total Cost of Equipment	NA	NA
Fair Market Value of Equipment	NA	NA
Net Purchase Price of Equipment	NA	NA
Locations Where Operated Currently	Please see list	Please see list
Number Days In Use/To be Used in N.C. Per Year	Up to 365	4 days
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 SIGNA 492 GE 1.5T scanner to serve the host sites will be discontinued on approximately November 30, 2019, 2019 when the repair of SIGNA 457 has been completed and returned to service. At that time SIGNA 492 will be removed from North Carolina.

Thank you for your review and consideration of this information. Please call me at the office at 336 349-6250 or 336 432-8308 (cell phone) if you have any questions.

Sincerely,

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

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

Cc: Aaron Dunn  
Manager of Operations  
Alliance Healthcare Services

**ALLIANCE HEALTHCARE SERVICES**

November 24, 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 SIGNA 457

Dear Ms. Frisone,

Raleigh Orthopaedic Clinic and Alliance Healthcare Services intend to temporarily replace its existing mobile SIGNA 457 with a replacement unit, SIGNA 492

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 at if you have any questions.

Sincerely,

**Aaron Dunn**

Aaron Dunn RT(R)(MR)  
Manager of Operations  
Alliance Radiology  
(Cell) 919-270-5751