



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

March 21, 2019

David French
djfrench45@gmail.com

Exempt from Review – Replacement Equipment

Record #: 2902
Business Name: Alliance Healthcare Services, Inc.
Business #: 60
Project Description: Temporary replacement of SIGNA 432 Mobile MRI scanner
County: Multiple

Dear Mr. French:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of March 15, 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 416, Serial # .159FAU862651182803 mobile MRI scanner to temporarily replace the SIGNA 432, Serial # 1S9FA482061182880, grandfathered mobile MRI unit. This determination is based on your representations that upon repair of the original unit, the replacement 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,

Celia C. Inman
Project Analyst

Martha J. Frisone
Chief, Healthcare Planning and
Certificate of Need Section

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

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704
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Rec'd by Email
3/15/19

ALLIANCE HEALTHCARE SERVICES

March 15, 2019

Ms. Martha Frisone, 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 Emergency
Temporary Replacement of Mobile MRI Scanner SIGNA 432 Serial No. 1S9FA482061182880

Dear Ms. Frisone:

I am writing on behalf of my client, Alliance Healthcare Services, regarding the urgent need to temporarily replace mobile MRI scanner SIGNA 432 Serial Number 1S9FA482061182880 (grandfathered unit). Please accept this notice of exemption to temporarily replace the above unit with Sig 416 Serial No. .159FAU862651182803 which is an existing mobile MRI scanner 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 432 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 432 requires repairs that are estimated to take approximately four 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 seriously disrupted without access to MRI.
- 4) Alliance does not have 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 OrthoCarolina host sites that will be served by the replacement grandfathered mobile MRI scanner are:

OrthoCarolina-Shelby
101 Delta Park Drive
Shelby, NC 28150
Cleveland County

OrthoCarolina-Mooresville
124 Welton Way
Mooresville, NC 28117
Iredell County

OrthoCarolina P.A.
1604 Medical Drive
Laurinburg, NC 28352
Scotland County

OrthoCarolina- Monroe
703 Comfort Lane
Monroe, NC 28112
Union County

OrthoCarolina – Gastonia
870 Summit Crossing Place
Gastonia, NC 28040
Gaston County

OrthoCarolina- Spine Center
2001 Randolph Road
Charlotte, NC 28207
Mecklenburg County

Compliance Documentation

Compliance with G.S. 131E-176 (22a) Replacement Equipment Definition is demonstrated in Attachment 1 which shows that the temporary replacement scanner has an actual cost of less than \$2,000,000.

No additional shipping or installation costs are expected. The actual purchase for the MRI scanner (2015) is reflected in the attached table

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) *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 is 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. 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

	EXISTING EQUIPMENT (To be temporarily removed from service for repairs.)	TEMPORARY REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	MRI	MRI
Manufacturer of Equipment	GE	GE
Tesla Rating for MRIs	NA	NA
Model Number	GE 1.5T	GE 1.5T
Serial Number	1S9FA482061182880	159FAU862651182803
Provider's Method of Identifying Equipment	SIGNA 432	SIGNA 416
Specify if Mobile or Fixed	Mobile	Mobile
Mobile Trailer Serial Number/VIN #	1S9FA482061182880	159FAU862651182803
Mobile Tractor Serial Number/VIN #	NA – No changes	NA - No changes
Date of Acquisition of Each Component	2015	2015
Does Provider Hold Title to Equipment or Have a Capital Lease?	Holds Title	Holds Title
Specify if Equipment Was/Is New or Used When Acquired	New when acquired	New when acquired
Total Capital Cost of Project (no construction involved)	NA	Existing equipment
Total Cost of Equipment	NA	Already owned by Alliance
Fair Market Value of Equipment	NA	\$1,818,200 (2015)
Net Purchase Price of Equipment	NA	NA
Locations Where Operated	OrthoCarolina sites –see list	Same OrthoCarolina sites
Number Days In Use/To be Used in N.C. Per Year	365	Specified days for temporary replacement
Percent of Change in Patient Charges (by Procedure)	NA	No increase will result
Percent of Change in Per Procedure Operating Expenses (by Procedure)	NA	No increase will result
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 416 to serve the OrthoCarolina host sites will be discontinued on approximately March 23, 2019 when the repair of Signa 432 has been completed and returned to service.

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 black ink, appearing to read "David French". The signature is written in a cursive style with a horizontal line underneath.

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

Cc: Arron Dunn
Manager of Operations
Alliance Healthcare Services
Phone: 919-270-5751

ALLIANCE HEALTHCARE SERVICES

March 15, 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 432

Dear Ms. Frisone,

Alliance Imaging intends to temporarily replace its existing mobile MRI Scanner Signa 432, serial number 1S9FA482061182880, with a replacement unit, Signa 416.

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 336 580-9061 if you have any questions.

Sincerely,

Aaron Dunn

Aaron Dunn RT(R)(MR)
Manager of Operations
Alliance Radiology
(Cell) 919-270-5751
adunn@allianceradiology-us.com

