



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, 2020

David French
djfrench45@gmail.com

Exempt from Review – Replacement Equipment

Record #: 3445
Date of Request: December 1, 2020
Facility Name: Piedmont HealthCare
FID #: 031129
Business Name: Alliance Healthcare Services, Inc.
Business #: 60
Project Description: Temporarily replace existing fixed MRI scanner
County: Iredell

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 VOYA 1 MRI scanner (serial number 1S9AC4824FS834446) to replace the SIGNA 456 MRI scanner (serial number 1SF9FA8248183226). This determination is based on your representations that the VOYA 1 MRI scanner will not be used again in the State without first obtaining a certificate of need if one is required after it is no longer needed to serve as a temporary replacement.

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 Misty L. Piekaar-McWilliams]

Misty L. Piekaar-McWilliams
Project Analyst

[Handwritten signature of Martha J. Frisone]

for

Lisa Pittman
Assistant Chief, Certificate of Need

cc: Radiation Protection Section, DHSR
Construction 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
https://info.ncdhhs.gov/dhsr/ • TEL: 919-855-3873

ALLIANCE HEALTHCARE SERVICES

December 1, 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 and Piedmont HealthCare - Written Notice for Exemption from CON Review for Temporary Replacement of Fixed MRI Scanner SIGNA 456 Serial # 1SF9FA8248183226, CON # F-6957-03 (Iredell County)

Dear Ms. Frisone:

Alliance Healthcare Services (Alliance) and Piedmont HealthCare need to temporarily replace fixed MRI scanner SIGNA 456 Serial # 1SF9FA8248183226 that requires repairs. This MRI scanner is currently utilized at Piedmont Healthcare in Iredell County. This MRI scanner has been properly reported in the 2020 MRI Inventory Forms to DHSR Healthcare Planning.

Please accept this notice of exemption to temporarily replace the above unit with VOYA 1, Serial Number 1S9AC4824FS834446. This replacement MRI unit is already owned by Alliance and is typically used to serve host sites in other states. When this temporary replacement unit (VOYA 1) is no longer needed to serve as a temporary replacement for SIGNA 456 it will be removed from service in 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 SIGNA 456 requires repairs and maintenance due to high utilization.
- 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 full time coverage for the unit that needs to be repaired.

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

Piedmont HealthCare
700 Sullivan Rd.
Statesville NC 28677

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.

Piedmont HealthCare 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 fixed MRI will be back in 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	TEMPORARY REPLACEMENT
Type of Equipment (List Each Component)	MRI	MRI
Manufacturer of Equipment	GE	GE
Tesla Rating for MRIs	1.5T	1.5T
Model Number	SIGNA	VOYAGER
Serial Number	1SF9FA8248183226	1S9AC4824FS834446
Provider's Method of Identifying Equipment	SIGNA 456	VOYA 1
Specify if Mobile or Fixed	Mobile	Mobile
Mobile Trailer Serial Number/VIN #	1SF9FA8248183226	1S9AC4824FS834446
Mobile Tractor Serial Number/VIN #	NA – No changes	NA – No changes
Date of Acquisition of Each Component	2004	2017
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	NA
Total Cost of Equipment	NA	NA
Fair Market Value of Equipment	NA	\$950,000
Net Purchase Price of Equipment	NA	NA
Locations Where Operated Currently	Piedmont HealthCare Statesville	Piedmont HealthCare Statesville
Number Days In Use/To be Used in N.C. Per Year	Up to 365	Temporary
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 the replacement unit, VOYA 1, to serve at the designated host site will be discontinued when the repair of SIGNA 456 has been completed and the scanner has been returned to service.

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

Sincerely,

A handwritten signature in cursive script, appearing to read "David French", written in black ink on a white background.

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

Cc: Rodney Skelding
rskelding@allianceradiology-us.com

ALLIANCE HEALTHCARE SERVICES

December 1, 2020

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 456 Serial
CON # F-6957-03

Dear Ms. Frisone,

Alliance Healthcare Services intends to temporarily replace its existing fixed MRI scanner SIGNA 456 with a temporary replacement unit VOYA 1.

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 email me if you have any questions.

Sincerely,

Rodney Skelding

Manager of Operations
Alliance Radiology
Rodney Skelding
rskelding@allianceradiology-us.com

From: [David French](#)
To: [Piekaar, Misty L](#); [Waller, Martha K](#); [Flores, Disraeliza](#)
Cc: [Rodney Skelding](#)
Subject: [External] Alliance Temporary Equipment Replacement for MRI
Date: Tuesday, December 1, 2020 2:49:25 PM
Attachments: [Alliance SIGNA 456 Temporary Replacement 12_1_20.pdf](#)

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Hi,

Please confirm that you have received the attached.

Alliance Healthcare Services and Piedmont HealthCare - Written Notice for Exemption from CON Review for Temporary Replacement of Fixed MRI Scanner SIGNA 456 Serial # 1SF9FA8248183226, CON # F-6957-03 (Iredell County)

Thanks

David French
336 432-8308