

ROY COOPER • Governor

MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director

VIA EMAIL ONLY

July 10, 2018

David French
David French djfrench45@gmail.com

Exempt from Review - Replacement Equipment

Record #:

2642

Facility Name:

Alliance Imaging, Inc.

FID#:

001325

Business Name:

Alliance Healthcare Services, Inc.

Business #:

60

Project Description:

Temporary replacement of SIGNA 447 MRI scanner

County:

Guilford

Dear Mr. French:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of June 29, 2018, received on July 2, 2018, 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 445, Serial #1S9FA4821183120 MRI scanner to replace the SIGNA 447, Serial #1S9FA482171183120 MRI scanner. 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:

Amy Craddock, Assistant Chief, Healthcare Planning, DHSR

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: 2704 Mail Service Center, Raleigh, NC 27699-2704 www.ncdhhs.gov/dhsr/ • TEL: 919-855-3873

Rech by mail

Strategic Healthcare Consultants P.O. Box 2154 Reidsville NC 27323

June 29, 2018

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

RE: Alliance Imaging Inc. - Written Notice for Exemption from CON Review for **Emergency Temporary**Replacement MRI Scanner (Guilford County)

Dear Ms. Frisone:

I am writing on behalf of my client, Alliance Imaging Inc., regarding the urgent need to temporarily replace the mobile MRI Scanner SIGNA 447, serial number 1S9FA482171183120 (grandfathered unit). The air conditioning system on the unit requires immediate repairs.

Please accept this notice of exemption to temporarily replace the above unit with SIGNA 445, serial #1S9FA4821183120. This unit is owned by Alliance Imaging and is utilized in Virginia. When this unit is no longer needed to serve as a temporary replacement for SIGNA 447 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 Imaging Inc. also provides documentation that the replacement equipment conforms to the Certificate of Need laws and Administrative rules:

G.S. 131E-176 (22a) Replacement equipment definition 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 447 requires repairs.
- 2) Service to the existing host sites will be disrupted if a temporary replacement mobile MRI scanner cannot be 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 Imaging recognizes the need to provide high quality, cost effective, and reliable mobile MRI scanner service.

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

SE Orthopaedic Specialists, PA 1130 N. Church St Suite 100 Greensboro, NC 27401

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 Fair Market Value of less than \$2,000,000.

No additional shipping or installation costs are expected. The fair market value for the MRI scanner is reflected in the attached quotes.

The replacement MRI equipment will be used for the same diagnostic purposes as the existing equipment.

In addition, Alliance Imaging 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 Imaging Inc. 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 Imaging Inc. 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 Imaging Inc. 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 Imaging Inc. 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 Imaging Inc. 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 sites 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

Type of Equipment (List Each Component) Manufacturer of Equipment Tesla Rating for MRIs Model Number GE Serial Number	(To be temporarily removed from NC for repairs.) MRI GE NA GE1.5 T Horizon ES LX 1S9FA482171183120 SIGNA 447	TEMPORARY REPLACEMENT EQUIPMENT MRI GE
	from NC for repairs.) MRI GE NA GE1.5 T Horizon ES LX 1S9FA482171183120 SIGNA 447	TEMPORARY REPLACEMENT EQUIPMENT MRI
	from NC for repairs.) MRI GE NA GE1.5 T Horizon ES LX 1S9FA482171183120 SIGNA 447	REPLACEMENT EQUIPMENT MRI GE
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	MRI GE NA GE1.5 T Horizon ES LX 1S9FA482171183120 SIGNA 447	MRI GE
f Equipment	GE NA GE1.5 T Horizon ES LX 1S9FA482171183120 SIGNA 447	GE
r MRIs	NA GE1.5 T Horizon ES LX 1S9FA482171183120 SIGNA 447	
	GE1.5 T Horizon ES LX 1S9FA482171183120 SIGNA 447	NA
	1S9FA482171183120 SIGNA 447	GE 1.5T
	SIGNA 447	1S9FA4821183120
Provider's Method of Identifying Equipment		SIGNA 445
Specify if Mobile or Fixed	Mobile	Mobile
Mobile Trailer Serial Number/VIN #	1S9FA482171183120	1S9FA4821183120
Mobile Tractor Serial Number/VIN #	NA – No changes	NA - No changes
Date of Acquisition of Each Component		
Does Provider Hold Title to Equipment or Have a Capital Lease?	Holds Title	Holds Title
red	New when acquired	New when acquired
lect (no construction involved)	NA	Existing equipment
Total Cost of Equipment	NA	Already owned by Alliance
Fair Market Value of Equipment	NA	See attached FMV
Net Purchase Price of Equipment	NA	See attached FMV
Locations Where Operated SE Orth	SE Orthopaedic Specialists, PA	SE Orthopaedic Specialists, PA
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
nt	MRI Procedures	MRI Procedures
Type of Procedures New Equipment is Capable of Performing	NA	MRI procedures

The temporary use of replacement SIGNA 445 to serve CON-approved host sites in North Carolina will be discontinued when the repair of SIGNA 447 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,

David French

Consultant to Alliance Radiology

Dand J Truch

P.O. Box 2154

Reidsville, NC 27323

djfrench45@gmail.com

Cc:

Rodney Skelding

Manager of Operations

Alliance Healthcare Services

Phone: 910-340-1494

Andre' D. Kellogg, Sr., MPA Director of Operations

Alliance Healthcare Services

Phone: 404-317-7800

August 4, 2016

Cathy Weinhold Asset Manager Alliance Healthcare Radiology Newport Beach, CA 92660

Re: Value of Imaging Equipment

Cathy

As requested, the following is the estimated "Fair Market Value" for imaging equipment described below:

GE 1.5T Excite 8 Channel 11X Mobile MRI housed in a Mobile Trailer

Fair Market Value: \$325,000 to \$350,000

Market value is based on system and trailer in good to excellent condition and appearance.

Please contact me if I can be of further assistance.

Sincerely,

Matthew Pac