

North Carolina Department of Health and Human Services Division of Health Service Regulation

Pat McCrory Governor Aldona Z. Wos, M.D. Ambassador (Ret.) Secretary DHHS

> Drexdal Pratt Division Director

January 7, 2014

Alliance Imaging, Inc. 913 Aquaview Drive Kernersville, NC 27284

Exempt from Review - Replacement Equipment

Facility:

Alliance Imaging, Inc.

Project Description:

Temporarily replace a mobile MRI scanner while it is being repaired

County:

Guilford

FID #: 001325

Dear Ms. Crawford:

In response to your letter of December 20, 2013, the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(7). Therefore, you may proceed to utilize, without a certificate of need, the temporary replacement GE Mobile MRI 1.5T Signa, serial number 1JJ482W9L515090 (Signa 98) to replace the existing GE Mobile MRI 1.5T Signa Horizon ES, serial number 1S9FA482171183120 (Signa 447) at Southeastern Orthopedic Specialists in Greensboro during the Signa 447's repair. Once the Signa 447 is repaired, the Signa 98 temporary replacement mobile MRI scanner will be removed from the state and not brought back into North Carolina without CON approval. This determination is based on your representation that the existing temporary replacement Signa 98 MRI scanner will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need.

It should be noted that this 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 Agency and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

cc:

Kim Randolph Project Analyst

Medical Facilities Planning, DHSR

Martha J. Frisone, Interim Chief Certificate of Need Section



ALLIANCE HEALTHCARE SERVICES

913 Aquaview Drive Kernersville, NC. 27284

December 20, 2013

Mr. Craig Smith Chief, Certificate of Need Section 2704 Mail Service Center Raleigh, NC 27699-2704



RE: Written Notice for Exemption from CON Review for Temporary Replacement Equipment, Alliance Imaging Inc. MRI Scanner Serial Number 1S9FA482171183120 (Signa 447)

Existing Grandfathered MRI FID # 001325 (Alliance Imaging Inc. Mobile MRI Diagnostic Program)

Dear Mr. Smith:

Alliance Imaging intends to temporarily replace its existing 1.5 Tesla mobile MRI scanner, serial number 1S9FA482171183120 (Signa 447), with a used mobile MRI scanner from Alliance's inventory from outside North Carolina. In accordance with NCGS 131 E-184, this letter provides justification and written notice regarding the replacement equipment. 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, # 1S9FA482171183120 (Signa 447), requires temporary replacement for several reasons:

- 1) Maintenance and repairs at the GE Service Center are required due to the age and condition of the MRI scanner and the extent of required repairs to the exterior trailer.
- 2) Service to the existing host site will be disrupted if a temporary replacement mobile MRI unit cannot be provided.
- 3) Alliance does not have sufficient available capacity on other grandfathered units in North Carolina to provide consecutive days of 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 that is consistent with the equipment capabilities of community hospitals and imaging centers.

This specific MRI scanner, # 1S9FA482171183120 (Signa 447), that is being replaced is a "grandfathered unit" that was properly reported in the 2013 Mobile MRI Equipment Inventory forms.

Alliance Imaging has identified serial number 1JJ482W9L515090 (Signa 98), as the temporary replacement mobile MRI scanner that will be brought to North Carolinas in four to eight weeks. The host site that will be served by the replacement mobile MRI scanner is:

Southeastern Orthopaedic Specialists 1130 North Church Street Greensboro, NC 27405

Once the 1S9FA482171183120 (Signa 447) unit is repaired, the temporary unit, Signa 98 will be removed from North Carolina.

Compliance Documentation

Compliance with G.S. 131E-176 (22a) Replacement Equipment Definition is demonstrated in Attachment 3 which shows that the replacement MRI scanner and coach will cost less than \$2,000,000.

Both of the equipment units described above have original purchase prices that are far less than \$2,000,000; the current fair market values of the equipment are also less.

As seen in the attached letter, the replacement MRI equipment will be used for the same diagnostic purposes as the existing mobile MRI scanner. Once the replacement MRI becomes available for use, the existing mobile MRI scanner will be removed from North Carolina.

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 provide a mobile MRI scanner as temporary replacement equipment for its existing mobile MRI scanner in accordance with the following *regulatory requirements:*

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 temporary replacement MRI scanner is comparable to the equipment being replaced because the replacement equipment will also obtain MRI images. The proposed replacement mobile MRI scanner is not an extremity MRI or a dedicated breast MRI unit.

(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

As seen in the attached letter, Alliance Imaging Inc. certifies that the temporary replacement mobile MRI equipment will be used for the same diagnostic purposes as the existing MRI scanner.

(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.

As seen in the attached letter, the host site that will utilize the replacement MRI scanner has certified that the replacement of the MRI equipment will 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.

Alliance Imaging expects that the projected operating expenses for the replacement MRI scanner will not increase in the first year following the exchange.

- (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. The MRI unit Signa 447 being temporarily replaced was purchased new in 2011. The temporary replacement equipment is already owned by Alliance and no purchase of a replacement unit is involved.

(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. The temporary replacement equipment is not new and the existing equipment was not a reconditioned unit when it was acquired.

(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 replacement equipment is a full- featured MRI scanner. These features do not change the basic technology or result in the provision of a new health service or type of procedure.

(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 not a dedicated PET scanner, gamma camera or nuclear medicine equipment.

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EQUIPMENT COMPARISON

	EXISTING	TEMPORARY
	EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	Mobile MRI	Mobile MRI
Manufacturer of Equipment	GE	GE
Tesla Rating for MRIs	1.5T	1.5T
Model Number	Signa Horizon ES	Signa
Serial Number	1S9FA482171183120	1JJ482W9L515090
Provider's Method of Identifying Equipment	Signa 447	Signa 98
Specify if Mobile or Fixed	Mobile	Mobile
Mobile Trailer Serial Number/VIN #	1S9FA482171183120	1JJ482W9L515090
Date of Acquisition of Each Component	2011	Not applicable for temporary unit
		Irom outside Ive acquired in 2003
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	Alliance Existing Inventory
Total Capital Cost of Project (no construction involved)	NA	No additional cost equipment
		already owned
Total Cost of Equipment	NA	\$1.9 million original purchase cost
Fair Market Value of Equipment	See above	\$475,000
Net Purchase Price of Equipment	NA	NA – equipment owned
Locations Where Operated	"Grandfathered Unit"	"Grandfathered Unit" status
	status at host sites	Southeastern Orthopaedic Specialists
		1130 North Church Street Greensboro, NC 27405
Number Days In Use/To be Used in N.C. Per Year	365	Temporary unit 12 to 14 days
Percent of Change in Patient Charges (by Procedure)	NA	NA
Percent of Change in Per Procedure Operating Expenses (by Procedure)	NA	NA
Type of Procedures Currently Performed on Existing Equipment	MRI Procedures	MRI Procedures
Type of Procedures New Equipment is Capable of Performing	MRI procedures	MRI procedures

Thank you for your review and consideration of this information. Please call me at 336-207-5613 if you have any questions.

Sincerely,

Trida I Crawford

Freda Crawford
Manager of Operations
Alliance Imaging
fcrawford@allianceimaging.com
Alliance Healthcare Services
336 207 5613

Attachments:

Letter from Alliance Imaging Inc. regarding use of replacement MRI scanner, charges to host site and operating costs

ALLIANCE HEALTHCARE SERVICES

913 Aquaview Drive Kernersville, NC. 27284

Mr. Craig Smith Chief, Certificate of Need Section 2704 Mail Service Center Raleigh, NC 27699-2704

RE:

Replacement of Existing MRI Scanner

Unit Serial Number #

Grandfathered Mobile MRI Scanner

FID # 001325 (Alliance Imaging Inc. Mobile MRI Diagnostic Program)

Dear Mr. Smith:

Please review the following information regarding the equipment replacement exemption notice:

Alliance Imaging Inc. certifies that the replacement mobile MRI equipment will be used for the same diagnostic purposes as the existing MRI scanner. In addition the acquisition of the temporary replacement MRI scanner will not result in Alliance increasing charges to the host site. Furthermore, the host site, Southeastern Orthopaedic Specialists, has no plans to increase MRI charges to patients as the replacement MRI unit is only temporary.

As Director of Operations of Alliance Imaging Inc., please accept this letter as certification that the temporary replacement mobile MRI scanner, serial number 1JJ482W9L515090 (Signa 98), will promptly be removed from North Carolina once the original unit Signa 447 is repaired. The expected delivery of the temporary replacement unit and repairs to the existing grandfathered unit is in the next two to four weeks.

The temporary replacement unit is owned by Alliance and had an original purchase cost of \$1.9 million and a current estimated FMV of \$475,000. No capital costs or equipment purchase is involved in the use of the temporary replacement equipment. Alliance Imaging will use its existing tractor and driver to transport remove the grandfathered mobile MRI unit Signa 447 to the repair facility and also to transport the temporary replacement unit Signa 98.

Thank you for your review and consideration of this information. Please call me at 336 207 5613 if you have any questions.

Sincerely,

Freda Crawford

Manager of Operations

Freda & Crawford

Alliance Imaging

fcrawford@allianceimaging.com

Alliance Healthcare Services