



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

Roy Cooper
Governor

Dempsey E. Benton
Interim Secretary DHHS

Mark Payne, Director
Health Service Regulation

January 12, 2017

David French, Consultant
Alliance Healthcare Services
1233 Front Street, Suite A
Raleigh, NC 27612

Exempt from Review – Replacement Equipment

Record #: 2134
Business Name: Alliance Imaging, Inc.
Business #: 60
Project Description: Replace mobile MRI scanner
County: Pitt

Dear Mr. French:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of January 4, 2016 [2017], the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-184(a)(7). Therefore, you may proceed to replace without a certificate of need the GE 1.5T Horizon (SIGNA 438) mobile MRI scanner with the GE 1.5T Horizon Infinity ES LX (SIGNA 406) mobile MRI scanner (which you already own). This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need.

Moreover, you need to contact the Agency’s Acute and Home Care Licensure and Certification Section, to determine if they have any requirements for development of the proposed project.

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,

Jane Rhoe-Jones
Jane Rhoe-Jones
Project Analyst

Martha J. Frisone
Martha J. Frisone
Assistant Chief, Certificate of Need

cc: Paige Bennett, Assistant Chief, Healthcare Planning, DHSR
Acute and Home Care Licensure and Certification Section, DHSR

Healthcare Planning and Certificate of Need Section

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Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704
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ALLIANCE HEALTHCARE SERVICES
1233 Front Street, Suite A
Raleigh, NC 27612



January 4, 2016

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

RE: Written Notice for Exemption from Review for Replacement Equipment,
Alliance Imaging Inc. MRI Scanner Serial Number 1S9FA482061182958 Signa 438:
Grandfathered MRI Scanner with a Host Site in Pitt County

Dear Ms.Frisone:

Alliance Imaging intends to replace its existing mobile MRI scanner, serial number 1S9FA482061182958 (Signa 438) which was acquired in 2005 with a similar unit that is already owned by Alliance Healthcare Services, unit Signa 406 serial number 1S9FA482851182740, which was recently upgraded.

Signa 438 is to be removed from North Carolina. The replacement unit is already owned by Alliance and was removed from North Carolina to have repairs and upgrades; it was replaced by ESP 61 earlier this year. This previous exemption request was submitted and approved in August 2016.

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 serial number 1S9FA482061182958 Signa 438 was acquired in 2005 and will be replaced in North Carolina and reassigned to host sites in other states.

- 1) The MRI scanner SIGNA 438 is a grandfathered MRI scanner with limited software applications and scanning capabilities.
- 2) The replacement SIGNA 406 has been upgraded and will be better suited to serve the scanning needs of the host site.
- 3) Healthcare providers in North Carolina have demand for mobile MRI service with current imaging technology and capabilities to supplement their existing services and to improve access.

Alliance Imaging recognizes the need to provide a high quality, cost effective, and reliable mobile MRI scanner service that is consistent with the equipment capabilities of community hospitals.

This specific MRI scanner, serial number 1S9FA482061182958 Signa 438, that is being replaced is a grandfathered MRI scanner that has properly been reported in the attached 2016 Mobile MRI Equipment Inventory form.

The host site that will be served by the replacement mobile MRI scanner is:

Orthopaedics East
810 WH Smith Blvd
Greenville, NC 27834
Pit County

Once the replacement unit is operational, the existing MRI 1S9FA482061182958 Signa 438 will be removed from North Carolina.

Compliance Documentation

Compliance with G.S. 131E-176 (22a) Replacement Equipment Definition is demonstrated in Attachment 1 which shows that the replacement MRI scanner and coach will cost less than \$2,000,000.

The FMV of SIGNA 406 is \$350,000 as seen in Attachment 1.

As seen in Attachment 2, the Alliance Operations Manager documents that the replacement MRI equipment will be used for the same diagnostic purposes as the existing mobile MRI scanner. 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 bring in a mobile MRI scanner as 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 replacement MRI scanner is comparable to the equipment being replaced because the new 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*

Alliance Imaging Inc. certifies that the 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.*

The host site that will utilize the replacement MRI scanner certifies that the acquisition of the replacement equipment will not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months.

Included in Exhibit 2 is documentation from Alliance Imaging that it will not increase charges by more than 10% to its host site during the first twelve months of the replacement scanner operation. Alliance Imaging expects that the projected operating expenses for the replacement MRI scanner will not increase.

- (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. As seen in the table on page 5, the equipment being replaced was purchased more than three years ago.

- (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 replacement equipment is new and will be purchased more than three years after the acquisition of the existing equipment.

(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.

EQUIPMENT COMPARISON

	EXISTING 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	Horizon	Horizon Infinity ES LX
Serial Number	1S9FA482061182958	1S9FA482851182740
Provider's Method of Identifying Equipment	SIGNA 438	SIGNA 406
Specify if Mobile or Fixed	Mobile	Mobile
Mobile Trailer Serial Number/VIN #		
Mobile Tractor Serial Number/VIN #	NA - No changes	Same as above
Date of Acquisition of Each Component	2005	2004 upgraded in 2016
Does Provider Hold Title to Equipment or Have a Capital Lease?	Hold Title	Hold Title
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (no construction involved)	NA	Owned by Alliance
Total Cost of Equipment	NA	Owned by Alliance
Fair Market Value of Equipment	NA	\$350,000
Net Purchase Price of Equipment	NA	NA
Locations Where Operated Currently	"Grandfathered Unit" Orthopaedic East	"Grandfathered Unit" Status Continuing at Host Site
Number Days In Use/To be Used in N.C. Per Year	365	365
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

Thank you for your review and consideration of this information.
Please call me at 336 449-6250 if you have any questions.

Sincerely,

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

David French
Consultant to Alliance Healthcare Services

Attachments:

- 1) MRI scanner and coach fair market value
- 2) Letter from Alliance regarding replacement MRI scanner and charges to host site

AMERICAN MEDICAL RESOURCES
MEDICAL ASSETS MANAGEMENT GROUP, INC. 17015 S. HAWAII DR. SUITE 200
DUBLIN, CA 94568

July 29, 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:

2004 GE 1.5 tesla Excite 8 Channel 11x MRI system housed in an A.K. Associates Trailer

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

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

Please contact me if I can be of further assistance.

Sincerely,

Matthew Pac
Vice President

ALLIANCE HEALTHCARE SERVICES
1233 Front Street, Suite A
Raleigh, NC 27612

December 22, 2016, 2016

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

RE: Alliance HealthCare Replacement MRI Equipment,
Serial Number

Dear Ms. Frisone,

Alliance Imaging intends to replace its existing mobile MRI scanner, serial number 1S9FA482061182958 Signa 438 which was acquired in 2005, with a similar unit that is already owned by Alliance Healthcare Services and was recently upgraded unit Signa 406. The replacement MRI scanner will be used for the same diagnostic purposes as the existing unit.

In accordance with 10A NCAC 14C.030 Replacement Equipment Administrative Rules, we agree that the replacement MRI equipment will not result in more than a 10 percent increase in charges to the host site within the first twelve months after the equipment is acquired.

Thank you for your consideration. Please call me at (910) 340-1494 if you have any questions.

Sincerely,

Melissa VanOostrom

Melissa VanOostrom, Manager of Operations
Alliance HealthCare Radiology
Mobile: (910) 340-1494
Email: mvanoostrom@allianceradiology-us.com

3 January 2017

Martha Frisone
Assistant Chief
Health Planning and Certificate of Need Section
2704 Mail Service Center
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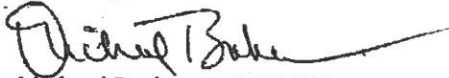
RE: Equipment Exemption for Replacement MRI Scanner

Dear Ms. Frisone,

Please accept this letter as certification that replacement of the Alliance MRI equipment provided to Orthopaedics East & Sports Medicine Center, Inc. will not result in more than a 10 percent increase in patient charges or per procedure operating expenses within the first twelve months following replacement.

Please let me know if you have any questions.

Sincerely,



Michael Brohawn, FACMPE
Practice Administrator