



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

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Division Director

January 12, 2015

Freda Crawford, Manager of Operations
Alliance Imaging
1136 Southern Meadows Drive
Raleigh NC 27603

Exempt from Review - Replacement Equipment

Facility: Alliance Imaging
Project Description: Replace grandfathered mobile MRI scanner
County: Cabarrus and Guilford

Dear Ms. Crawford:

In response to your letter of December 22, 2014, 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 acquire, without a certificate of need, the GE Signa HDxt mobile MRI scanner to replace the existing GE Signa Horizon ES LX mobile MRI scanner. 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.

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,

Michael J. McKinnip
Project Analyst

Martha J. Frisone, Assistant Chief
Certificate of Need

cc: Assistant Chief, Healthcare Planning



Healthcare Planning and Certificate of Need Section

www.ncdhhs.gov

Telephone: 919-855-3873 • Fax: 919-733-8139

Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

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mike

**ALLIANCE HEALTHCARE SERVICES
1136 Southern Meadows Drive
Raleigh, NC 27603**



December 22, 2014,

Ms. Martha Frisone
Interim Chief
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 1S9FA482331182609
Grandfathered MRI Unit

Dear Ms Frisone:

Alliance Imaging intends to replace its existing mobile MRI scanner, serial number 1S9FA482331182609, which was acquired in 2001, with a newer refurbished unit that is already owned by Alliance Healthcare Services. The replacement unit is SIGNA 1.5 Tesla Signa HDxt serial number 1S9FA482431182635 (Magnet # R2936) and has been utilized in other states in the Southeast but not in 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 was acquired in 2001 and will need to be replaced very soon for several reasons:

- 1) The MRI scanner has older software applications that are difficult to maintain.
- 2) Costly maintenance and repairs are required due to the age and condition of the scanner
- 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 high quality, cost effective, and reliable mobile MRI scanner service. This specific MRI scanner, serial number 1S9FA482331182609 (Signa 280), that is being replaced is a grandfathered unit that has properly been reported in the 2014 Mobile MRI Equipment Inventory forms.

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

Carolina Neurosurgery and Spine Associates
110 Lake Concord Road NE
Concord, NC 28025

Carolina Neurosurgery & Spine Associates
1130 North Church Street, #200
Greensboro NC 27401

The replacement unit serial number 1S9FA482431182635 (Magnet # R2936) will be delivered in the next few weeks. Once the replacement unit is operational, the existing MRI scanner 1S9FA482X11182426 will be permanently 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 attached worksheet shows that the MRI equipment and mobile unit with upgrades have a fair market value of **\$750,000**. No additional shipping or installation costs are expected.

As seen in Attachment 2 (letter from Freda Crawford Operations Manager), the replacement MRI equipment will be used for the same diagnostic purposes as the existing mobile MRI scanner. Once the new 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 transfer one of its existing out-of-state mobile MRI scanner 1S9FA482431182635 (Magnet # R2936), into North Carolina as replacement equipment for its existing mobile MRI scanner 1S9FA482331182609 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. The replacement scanner will be used to perform the same types of procedures as the current mobile MRI scanner.

(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. The proposed replacement mobile MRI scanner will be utilized in accordance with same accreditation standards as the existing 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 Attachment 2 letter, 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.

As seen in Attachment 3, the host sites that will utilize the replacement MRI scanner have certified that the acquisition of the 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. Included in Exhibit 2 is documentation from Alliance Imaging that it will not increase charges by more than 10% to its host sites during the first twelve months of operation of the replacement scanner.

Alliance Imaging expects that the projected operating expenses for the replacement MRI scanner will increase by less than 5 percent over the existing scanner due to the increase in the depreciation expense. The MRI equipment is already owned by Alliance and is covered by a maintenance service agreement.

(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 in 2001 which is more than three years ago. The replacement equipment was originally manufactured and acquired in 2003 by Alliance.

(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 an existing out-of-state unit owned by Alliance and the existing equipment was new when it was purchased in 2001.

(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.

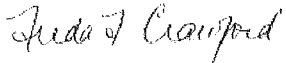
Not applicable. The existing equipment is not a dedicated PET scanner, gamma camera or nuclear medicine equipment.

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 23XX16 Channel
Model Number	Signa Horizon ES LX	Signa HDxt
Serial Number	1S9FA482331182609	Magnet Serial # R2936
Provider's Method of Identifying Equipment	SIGNA 280	Signa 451
Specify if Mobile or Fixed	Mobile	Mobile
Mobile Trailer Serial Number/VIN #	1S9FA482331182609	1S9FA482431182635
Mobile Tractor Serial Number/VIN #	NA - No changes	1S9FA482431182635
Date of Acquisition of Each Component	MRI Acquired October/2001	Currently owned by Alliance outside of NC
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	Used when acquired
Total Capital Cost of Project (existing equipment owned by Alliance)	NA	NA
Total Cost of Equipment	NA	NA
Fair Market Value of Equipment	NA	\$750,000 based on \$575,000 purchase cost plus upgrades
Net Purchase Price of Equipment	NA	NA
Locations Where Operated		Carolina Neurosurgery & Spine in Concord and Carolina Neurosurgery & Spine in Greensboro
Number Days In Use/To be Used in N.C. Per Year	365	365
Percent of Change in Patient Charges (by Procedure)	NA	less than 10%
Percent of Change in Per Procedure Operating Expenses (by Procedure)	NA	Estimated 5%
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 336-207-5613 if you have any questions.

Sincerely,



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

Attachments:

- 1) Letter from Alliance Imaging Inc. regarding use of replacement MRI scanner, charges to host site and operating costs
- 2) Host site certification that MRI charges will not be increased by more than 10 percent during the 12 month period following equipment replacement

ALLIANCE HEALTHCARE SERVICES
913 Aquaview Drive Kernersville, NC. 27284

Ms Martha Frisone
Interim Chief, Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27 699-2704

RE: Replacement of Existing MRI Scanner
Unit Serial # 1S9FA482331182609
Grandfathered Mobile MRI Scanner
FID # 001325 (Alliance Imaging Inc. Mobile MRI Diagnostic Program)

Dear Ms. Frisone:

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 replacement MRI scanner will not result in Alliance increasing charges to the host site by more than 10% during the first twelve months of operation of the replacement scanner.

As Manager of Operations of Alliance Imaging Inc., please accept this letter as certification that the existing mobile MRI scanner, Signa 280, Serial Number 1S9FA482331182609, will promptly be removed from North Carolina once the replacement mobile MRI unit is delivered. The expected delivery of the replacement unit and removal of the existing grandfathered unit is in the next four to eight weeks.

Alliance Imaging will notify the CON section and the Medical Facilities Planning Section of the model and serial number of the replacement equipment.

Alliance Imaging will use its existing tractor and driver to remove the grandfathered mobile MRI unit from North Carolina.

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
Alliance Imaging
fcrawford@allianceimaging.com
Alliance Healthcare Services

CAROLINA
NeuroSurgery & Spine
ASSOCIATES

Neurosurgery

Physical Medicine & Rehabilitation

Physical Therapy

Imaging

Ms. Martha Frisone
Interim Chief, Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27 699-2704

RE: Replacement Equipment for MRI Scanner Unit Serial Number #
1S9FA482331182609

Dear Mr. Frisone:

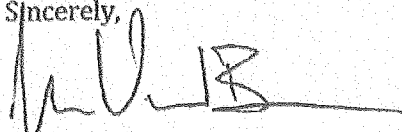
I understand that Alliance Imaging intends to replace its existing "grandfathered" 1.5 Tesla MRI scanner (Serial Number 1S9FA482331182609), with an existing 1.5T MRI scanner that has been upgraded and will originate from Alliance's out-of-state inventory. Please accept this letter as our indication to utilize the replacement MRI scanner at the following addresses, pursuant to a services agreement with Alliance:

Carolina Neurosurgery and Spine Associates
110 Lake Concord Road NE
Concord, NC 28025

Carolina Neurosurgery & Spine Associates
1130 North Church Street, #200
Greensboro NC 27401

In accordance with 10A NCAC 14C.0303 Replacement Equipment Administrative Rules, Carolina Neurosurgery and Spine Associates agree that the replacement MRI equipment will not result in more than a ten percent increase in patient charges at the host sites listed above within the first twelve months after the equipment is acquired,

Sincerely,



Mike Vander Baan
Chief Operating Officer
Carolina NeuroSurgery & Spine Associates

800-344-6716 • CarolinaNeuroSurgery.com

Charlotte • 225 Baldwin Ave., Charlotte, NC 28204 • 704-376-1605, 800-344-6716
Greensboro • 1130 N. Church St., Suite 200, Greensboro, NC 27401 • 336-272-4578
Huntersville • 9735 Kinsey Ave., Suite 300, Huntersville, NC 28078 • 704-831-4100
Concord • 110 Lake Concord Rd. NE, Concord, NC 28025 • 704-792-2672
Rock Hill • 175 Amendment Ave., Suite 104, Rock Hill, SC 29732 • 803-325-1618
Ballantyne • 14135 Ballantyne Corp. Pl., Suite 100, Charlotte, NC 28277 • 704-831-4300
Matthews • 1401 Matthews Township Pkwy., Suite 300, Matthews, NC 28105 • 704-831-4150