



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

Pat McCrory
Governor

Richard O. Brajer
Secretary DHHS

Mark Payne
Assistant Secretary for Audit and
Health Service Regulation

April 28, 2016

Rodney Skelding
1233 Front Street, Suite A
Raleigh, NC 27612

Exempt from Review – Replacement Equipment

Record #: 1930
Business Name: Alliance Healthcare Services
Business #: 2391
Project Description: Replace mobile MRI scanner
Counties: Catawba and Watauga

Dear Mr. Skelding:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter received on April 13, 2016, 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 acquire, without a certificate of need, the General Electric Signa 1.5T mobile MRI scanner. This determination is based on your representations that the 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 Construction and Acute and Home Care Licensure and Certification Sections 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,

Julie Halatek
Project Analyst

Martha J. Frisone,
Assistant Chief, Certificate of Need

cc: Kelli Fisk, Program Assistant, Healthcare Planning, DHSR



Healthcare Planning and Certificate of Need Section

www.ncdhhs.gov

Telephone: 919-855-3873 • Fax: 919-715-4413

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

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



March 13, 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 1S9FA482241182716
Grandfathered MRI Scanner with Host Sites in Catawba and Watauga Counties

Dear Ms. Frisone:

Alliance Imaging intends to replace its existing mobile MRI scanner, serial number 1S9FA482241182716 Signa 405 which was acquired in 2004, with a similar unit that is already owned by Alliance Healthcare Services. The replacement unit is a SIGNA 1.5 Tesla unit 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 serial number 1S9FA482241182716 was acquired in August 2004 and will soon need to be replaced 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 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 1S9FA482241182716, that is being replaced is a grandfathered MRI scanner that has properly been reported in the 2016 Mobile MRI Equipment Inventory forms (Signa 405).

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

OrthoCarolina – Hickory (formerly Hickory Orthopaedic Center)
214 18th Street SE
Hickory, NC 28602
Catawba County

OrthoCarolina-Boone NC
194 Doctors Drive
Boone, NC 28607
Watauga County

Once the replacement unit is operational, the existing MRI scanner serial 1S9FA482241182716 (SIGNA 405) 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 attached worksheet shows that the MRI equipment and mobile unit have a fair market value of \$650,000. No additional shipping or installation costs are expected.

As seen in Attachment 2, Rodney Skelding, 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

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 the replacement scanner operation.

Alliance Imaging expects that the projected operating expenses for the replacement MRI scanner will increase by 5 percent over the existing scanner due to the increase in the depreciation expense. In first year of operation the MRI equipment will be covered by a warranty 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 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	Signa 1.5T Horizon	GE 1.5T 23x 16 channel HDXi MRI
Serial Number		
Provider's Method of Identifying Equipment	SIGNA 405	SIGNA 273
Specify if Mobile or Fixed	Mobile	Mobile
Mobile Trailer Serial Number/VIN #	1S9FA482241182716	1S9FA482X31182591
Mobile Tractor Serial Number/VIN #	NA - No changes	Same as above
Date of Acquisition of Each Component	MRI Acquired August 2004	Purchased in 2003 and upgraded in 2014
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	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	See FMV letter \$650,000
Net Purchase Price of Equipment	NA	
Locations Where Operated Currently	"Grandfathered Unit" OrthoCarolina Boone Hickory Orthopaedic	"Grandfathered Unit" status continuing at host sites
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% (Additional depreciation and maintenance)
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 336 580-9061 if you have any questions.

Sincerely,



Rodney Skelding
Operations Manager

Attachments:

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

AMERICAN RADIOLOGY RESOURCE
MEDICAL IMAGING CONSULTING / EQUIPMENT SALES / MOBILE RENTALS

March 21, 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 23x 16 channel HDxt MRI unit housed in an AK Associates mobile trailer

Fair Market Value: \$600,000 to \$650,000

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

22 W. PADONIA ROAD, SUITE 325B
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OFFICE 410-252-4921 CELL 410-458-0107
E-MAIL MPAC@AMER-RAD.COM

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,
Signa 405 Serial Number 1S9FA482241182716

Dear Ms. Frisone,

Alliance HealthCare intends to replace its existing grandfathered MRI scanner, Signa 405 serial number 1S9FA482241182716, with a newer unit owned by Alliance. 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% increase in charges to the host sites within the first twelve months after the equipment is acquired.

As the Operations Manager of Alliance HealthCare, please accept this letter as certification that the existing mobile MRI scanner 1S9FA482241182716 will be promptly removed from North Carolina once the replacement MRI unit is delivered. Alliance will use its existing tractor and driver to remove the grandfathered MRI scanner from North Carolina.

Thank you for your consideration. Please call me at 336 580-9061 if you have any questions.

Sincerely,

Rodney Skelding
Manager of Operations





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,
Signa 405 Serial Number 1S9FA482241182716

Dear Ms. Frisone,

I understand that Alliance HealthCare intends to replace its existing grandfathered MRI scanner, serial number 1S9FA482241182716, with a newer unit owned by Alliance. Please accept this letter as our indication that we plan to utilize the replacement MRI scanner at

OrthoCarolina-Boone NC
194 Doctors Drive
Boone, NC 28607
Watauga County

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% increase in patient charges within the first twelve months after the equipment is acquired.

Please call me if you have any questions.

Sincerely,

Brent Shear, CFO
OrthoCarolina



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,
Signa 405 Serial Number 1S9FA482241182716

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OrthoCarolina Hickory
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Hickory, NC 28602
Catawba County

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Please call me if you have any questions.

Sincerely,

Brent Shear, CFO
OrthoCarolina