

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 5, 2016

Melissa VanOostrom 1233 Front Street Suite A Raleigh, NC 27612

Exempt from Review - Replacement Equipment

Récord #:

1916

Business Name:

Alliance Imaging Inc.

Business #:

Project Description: Replace mobile MRI scanner

Dear Ms. VanOostrom:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter dated February 29, 2016 and received in our office on March 10, 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 GE Excite HDx 16 Channel mobile MRI, VIN Number 1S9FA4826X1182271. 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.

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,

Tanya S. Rupp Project Analyst

Assistant Chief, Certificate of Need

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 An Equal Opportunity/ Affirmative Action Employer

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cc:

ALLIANCE HEALTHCARE SERVICES

1233 Front Street, Suite A Raleigh, NC 27612

February 29, 2016

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

Equipment, NR 16 1916

Written Notice for Exemption from Review for Replacement Equipment, Alliance Imaging Inc. MRI Scanner Serial Number 1S9FA482231182617

Grandfathered MRI Scanner with Host Sites in Harnett, Johnston and New Hanover Counties

Dear Ms.Frisone:

RE:

Alliance Imaging intends to replace its existing mobile MRI scanner, serial number 1S9FA482231182617 Signa 284 which was acquired in 2001, with a similar newer 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 was acquired in July 2001 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 1S9FA482231182617, that is being replaced is a grandfathered MRI scanner that has properly been reported in the 2016 Mobile MRI Equipment Inventory forms (Signa 284).

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

Carolina Regional Orthopaedics 110 Patrick Court Rocky Mount, NC 27804 Harnett County

Eastern Carolina Medical Center One Medical Dr. Benson, NC 27504 Johnston County

New Hanover Regional Medical Center 102 Military Cutoff Rd. Wilmington, NC 28405 New Hanover County

Once the replacement unit is operational, the existing MRI scanner # 1S9FA482231182617 (SIGNA 284) 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 letter from Matthew Pac with American Radiology Resources shows that the replacement MRI equipment and mobile unit have a fair market value of between \$575,000 and \$625,000. No additional shipping or installation costs are expected because Alliance has tractor trailer to bring the equipment into North Carolina.

As seen in Attachment 2, Melissa VanOostrom, 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 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

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 in 2001 more than three years ago and the replacement MRI scanner was acquired by Alliance in 2013.

(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 already owned by Alliance was purchased in 2013 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 | REPLACEMENT |
|--|--|---------------------------------|
| | EQUIPMENT | EQUIPMENT |
| Type of Equipment (List Each Component) | Mobile MRI | Mobile MRI |
| Manufacturer of Equipment | 3 | GE |
| Tesla Rating for MRIs | 1.51 | ŢS. |
| Model Number | Signa 1.5T Horizon | Excite HDx 16 Channel |
| Serial Number | | R0363 |
| Provider's Method of Identifying Equipment | SIGNA 284 | SIGNA 480 |
| Specify if Mobile or Fixed | Mobile | Mobile |
| Mobile Trailer Serial Number/VIN # | 1S9FA482231182617 | 1S9FA4826X1182271 |
| Mobile Tractor Serial Number/VIN # | NA – No changes | NA – No changes |
| Date of Acquisition of Each Component | MRI Acquired | Acquired in 2013 |
| | 2/12/2001 | |
| 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 | No cost |
| Total Cost of Equipment | NA | Owned by Alliance |
| Fair Market Value of Equipment | NA | \$575,000 to \$625,000 |
| Net Purchase Price of Equipment | NA | |
| Locations Where Operated Currently | "Grandfathered Unit" | "Grandfathered Unit" |
| | Carolina Regional Orthopedics New Hanover Regional Eastern Carolina Medical Center | 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) | ΑΛ | 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 (910) 340-1494 if you have any questions.

Sincerely,

Melissa Van Oostrom

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Attachments:

1) MRI scanner and coach fair market value

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

3) Host site certification that MRI charges will not be increased by more than 10 percent during the 12 month period following equipment replacement

February 8, 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: 2013 GE 1.5 Tesla Excite HDx 16 Channel MRI unit housed in a 2013 Schaffer Mobile Trailer

Options include but not limited to the following:

Software Level16X, ACGD Gradient cabinets, DICOM 3.0, Fiesta 3D, Asset, 3DFRFSE, Asset Plus, Spectroscopy, SGD EchoSpeed, DW EPI, FLAIR EPI, SPECIAL, Smartprep, SSFSE, Three plane localizer, Modality Worklist, iDrive, IDrive Pro, Tricks, Fiesta-c, Breast2, Propeller DWI, 3D Fat Sat Fiesta, Lava, Lava-XV, Brave, Cosmic, HDxKey, Clariview, iDrive ProPlus, SSFSE MRCP, T1 Breathhold, ACGDE Plus, Fluro-Trigger MRA.

Coils:

Shoulder Array (Large & Small), TMJ (Bi-lateral), 8 CH NV Array, 8 Ch Body Array, Extremity Array (Knee) 8 channel HI Res Brain, 8CH CTL Array, QD Head, Breast Array, Hi Res Wrist

Fair Market Value: \$575,000 to \$625,000

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 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 189FA482231182617

Dear Ms. Frisone.

Alliance HealthCare intends to replace its existing grandfathered MRI scanner, serial number 1S9FA482231182617, 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 1S9FA482231182617 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 (910) 340-1494 if you have any questions.

Sincerely,

Melissa VanOostrom

Meliose Van Opotion

Manager of Operations

EASTERN CAROLINA MEDICAL CENTER

I Medical Drive Benson, NC 27594

Ms. Martha Frisone Assistant Chief Health Planning and Certificate of Need Section 2704 Mail Service Center Raleigh, NC 27599-2764

RE:

Alliance HealthCare Replacement MRI Equipment,

Serial Number 1S9FA482231182617

Dear Ms. Frisone.

I understand that Alliance HealthCare intends to replace its existing grandfathered MRI scanner, serial number 1895A482231182617, with a newer unit owned by Alliance. Please accept this letter as our indication that we plan to utilize the replacement MRI scanner at

Eastern Carolina Medical Center One Medical Dr. Benson NC 27504 Johnston 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,

Kellie B. Lee

Eastern Carolina

Medical Center

Disapostic Coordinator

919-207-1019 (direct line)

910-894-7875 (fbx)

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

RE:

Alliance HealthCare Replacement MRI Equipment.

Serial Number 1S9FA482231182617

Dear Ms. Frisone.

I understand that Alliance HealthCare intends to replace its existing grandfathered MRI scanner, serial number 1S9FA482231182617, with a newer unit owned by Alliance. Please accept this letter as our indication that we plan to utilize the replacement MRI scanner at

New Hanover Regional Medical Center 1135Military Cutoff Rd., Suite 101 Wilmington NC 28405 New Hanover County

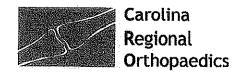
In accordance with 10A NCAC 14C.030 Replacement Equipment Administrative Rules, we agree that the replacement MRI equipment will not result in more than a 10% increase in patient charges within the first twelve months after the equipment is acquired.

Please call me if you have any questions.

Sincerely,

John Jacker

Joshua Tucker New Hanever Regional Medical Director of Radiology



...Improving the health of our communities

Alberto J. d'Empaire, M.D. General orthopaedics

Glenn E. MacNichol, M.D.** Back & neck care, spine injections, pain management

Robert C. Martin, D.O.* Sports medicine, arthroscopic surgery, general orthopaedics

David C. Miller, M.D.*,*** Back & neck care, spine surgery

Mark N. Perlmutter, M.D. Hand and wrist care, general orthopaedics

Thomas J. Galisin, PA-C Sports medicine, spine care, general orthopaedics

Vincent P. Keeney, PA-C Sports medicine, general orthopaedics

Paul N. Lanfranchi, PA-C Back & neck care, general orthopaedics

Laura A. Medlin, PA-C Spine care, pain management 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 1S9FA482231182617

Dear Ms. Frisone,

I understand that Alliance HealthCare intends to replace its existing grandfathered MRI scanner, serial number 1S9FA482231182617, with a newer unit owned by Alliance. Please accept this letter as our indication that we plan to utilize the replacement MRI scanner at

Carolina Regional Orthopedics 110 Patrick Court Rocky Mount NC 27804 Harnett 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,

Deanna Rand

Practice Administrator

Rocky Mount Office: 110 Patrick Court Rocky Mount, NC 27804 P: 252/443-0400

F: 252/443-0572

Tarboro Office: 2906 N. Main Street Tarboro, NC 27886 P: 252/823-7212 F: 252/823-5668

Certified, American Board of Orthopaedic Surgeons; Fellow, American Academy of Orthopaedic Surgeons
Certified, American Board of Anesthesiology; Certified, American Board of Interventional Pain Physicians
Certified, American Board of Spine Surgery; Fellow, American College of Spine Surgery