



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

Pat McCrory
Governor

Richard O. Brajer
Secretary DHHS

Mark Payne, Director
Health Service Regulation

August 19, 2016

Melissa VanOostrom, Operations Manager
Alliance Healthcare Services
1233 Front Street, Suite A
Raleigh, NC 27612

Exempt from Review – Replacement Equipment

Record #: 2028
Business Name: Alliance Imaging, Inc.
Business #: 60
Project Description: Replace mobile MRI scanner
Counties: Duplin, Martin and Pender

Dear Ms. VanOostrom:

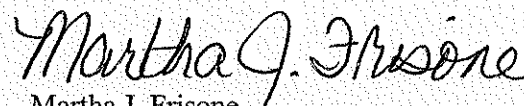
The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of August 15, 2016, the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the Siemens 1.5T Magnetom Espree (ESP 61) mobile MRI scanner to replace the GE 1.5T Horizon Infinity ES LX (SIGNA 406) 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.

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
Project Analyst


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
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



rhoe-jones, jane e

From: Melissa VanOostrom <mvanoostrom@allianceradiology-us.com>
Sent: Thursday, August 18, 2016 11:47 AM
To: rhoe-jones, jane e
Subject: RE: Clarification re: Exemption for Replacement Mobile MRI-eastern NC

Mrs. Rhoe-Jones,
Sorry about the typos. The correct information is
SIGNA 406
CON Project ID Q-6884-03

Please let me know if you need anything further.

Regards,
Melissa

Melissa VanOostrom, Manager of Operations
Alliance HealthCare Radiology
Mobile: (910) 340-1494 | Fax: (480) 212-8558
Email: mvanoostrom@allianceradiology-us.com
www.allianceradiology-us.com



From: rhoe-jones, jane e [mailto:jane.rhoe-jones@dhhs.nc.gov]
Sent: Thursday, August 18, 2016 11:05 AM
To: Melissa VanOostrom
Subject: Clarification re: Exemption for Replacement Mobile MRI-eastern NC

Melissa,
As we discussed, please clarify:

1. Whether the equipment is a SIGNA 406 or SIGNA 460
2. The associated Project ID # Q-6884-03 or Project ID # G-6271-00

Thank you,
Jane

Jane Rhoe-Jones, MSPH
Project Analyst
Health Service Regulation, Healthcare Planning & Certificate of Need Section
North Carolina Department of Health and Human Services

919-855-3873 office
jane.rhoe-jones@dhhs.nc.gov

809 Ruggles Drive
2704 Mail Service Center
Raleigh, NC 27699-2701



Nothing Compares

Email correspondence to and from this address is subject to the North Carolina Public Records Law and may be disclosed to third parties.

[Twitter](#) [YouTube](#)

Unauthorized disclosure of juvenile, health, legally privileged, or otherwise confidential information, including confidential information relating to an ongoing State procurement effort, is prohibited by law. If you have received this e-mail in error, please notify the sender immediately and delete all records of this e-mail.

Email correspondence to and from this address is subject to the North Carolina Public Records Law and may be disclosed to third parties by an authorized State official. Unauthorized disclosure of juvenile, health, legally privileged, or otherwise confidential information, including confidential information relating to an ongoing State procurement effort, is prohibited by law. If you have received this email in error, please notify the sender immediately and delete all records of this email.

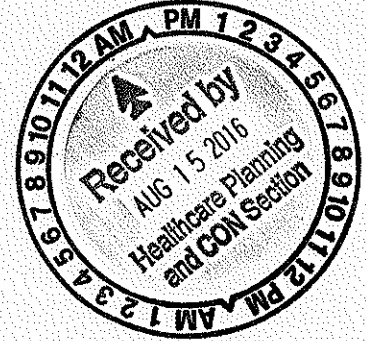
This email has been scanned by the Symantec Email Security.cloud service.
For more information please visit <http://www.symanteccloud.com>

This message contains information which may be confidential and privileged. Unless you are the addressee (or authorized to receive for the addressee), you may not use, copy, or disclose this message or any information contained in this message. If you have received this message in error, please notify the sender by reply e-mail and delete this message. Thank you.

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

August 15, 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 of Existing MRI Equipment
CON Project ID # Q-6884-03

Dear Ms. Frisone,

Alliance Imaging Inc. intends to replace MRI scanner SIGNA 406 (serial # 1S9FA482851182740), a CON-approved mobile MRI, with a newer mobile MRI scanner, ESP 61 Alliance Imaging Inc. and University Health Systems obtained CON approval (Project ID # Q-6884-03) for the mobile MRI scanner that serves multiple mobile host sites in eastern North Carolina. The replacement mobile MRI scanner ESP 61 (serial # 1M9A3A8236H22848) will be assigned to serve the same host sites and SIGNA 406 will be removed from North Carolina.

In accordance with NCGS 131 E-184, this letter provides justification and written notice regarding the replacement equipment. Alliance also provides documentation that the replacement equipment that is being exchanged 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 SIGNA 406 serial number 1S9FA482851182740 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 1S9FA482851182740, that is being replaced, has properly been reported in the 2016 Mobile MRI Equipment Inventory forms (Signa 406).

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

Duplin General Hospital Inc.
401 North Main Street
Kenansville, NC 28349-0278

Martin General Hospital
310 S. McCaskey Road
Williamston, NC 27892

Pender Memorial Hospital
507 East Fremont Street
Burgaw, NC 28425

Once the replacement unit is operational, the existing MRI scanner SIGNA 406 serial will be removed from North Carolina.

Compliance Documentation

Compliance with G.S. 131E-176 (22a) Replacement Equipment Definition is demonstrated because there is no acquisition cost for MRI scanners because two existing MRI scanners are being exchanged.

As seen in Attachment 2, Melissa Van Oostrom, 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 exchange 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 exchange of MRI scanners are comparable because both units obtain MRI images. The exchanged mobile MRI scanner are 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 Healthcare Services certifies that the exchanged of mobile MRI equipment will be used for the same diagnostic purposes. Following the exchange, SIGNA 273 will be utilized in accordance with the conditions for CON (Project ID # G-6271-00) to serve designated host sites that have obtained CON approval or authorization through Declaratory rulings

(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.

Alliance certified that no equipment acquisition is involved. Consequently no increases in operating costs or patient charges will result from the proposed exchange of equipment.

(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 proposed exchange of equipment involves no acquisition of additional MRI scanners.

(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 proposed exchange of equipment involves no acquisition of MRI scanners.

(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 exchange units are full featured MRI scanner with differences in software. 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.

| <u>Equipment Comparison Following the Proposed Exchange</u> | | EXCHANGE EQUIPMENT | EXCHANGE EQUIPMENT |
|--|--|---|---|
| Type of Equipment (List Each Component) | | Mobile MRI | Mobile MRI |
| Manufacturer of Equipment | | GE | Siemens |
| Tesla Rating for MRIs | | 1.5T | 1.5T |
| Model Number | | Horizon Infinity ES LX | Magnetom Espree |
| Serial Number | | | |
| Provider's Method of Identifying Equipment | | SIGNA 406 | ESP 61 |
| Specify if Mobile or Fixed | | Mobile | Mobile |
| Mobile Trailer Serial Number/VIN # | | 1S9FA482851182740 | 1M9A3A8236H22848 |
| Mobile Tractor Serial Number/VIN # | | Same as above | Same as above |
| Date of Acquisition of Each Component | | | |
| 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) | | Owned by Alliance | Owned by Alliance |
| Total Cost of Equipment | | Owned by Alliance | Owned by Alliance |
| Fair Market Value of Equipment | | | |
| Net Purchase Price of Equipment | | | |
| Locations Where Operated Currently | | Martin General Pender Memorial Duplin General | Martin General Pender Memorial Duplin General |
| Number Days In Use/To be Used in N.C. Per Year | | 365 | 365 |
| Percent of Change in Patient Charges (by Procedure) | | No increases | No increases |
| Percent of Change in Per Procedure Operating Expenses (by Procedure) | | No % Change | No % Change |
| 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 336 580-9061 if you have any questions. You may also contact our consultant, David French at (336) 342-6509 if you have questions.

Sincerely,

Melissa VanOostrom

Operations Manager

Attachments:

- 1) MRI scanner and coach purchase cost documentation
- 2) Letter from Alliance Imaging Inc. regarding use of exchanged MRI scanners and charges to host sites



August 15, 2016

Melissa VanOostrom
Alliance Imaging Inc.
1233 Front Street, Suite A
Raleigh, NC 27612

RE: Purchase Cost for ESP 61

Dear Ms. VanOostrom,

The purchase price of ESP 61 was \$1,283,226.00 and includes OEM equipment, injector, coach and graphics. Taxes were 6 percent of the purchase price which is \$76,993.56. Therefore the total capital cost for the MRI scanner is \$1,360,219.56.

If you have any questions please call me.

Cathy H Weinhold, RT

Asset Manager
Alliance HealthCare Radiology
Office: (717) 484-4566 | Mobile: (717) 471-3053
E-mail: cweinhold@allianceimaging.com

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

August 15, 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,
SIGNA 406 Serial Number 1S9FA482851182740

Dear Ms. Frisone,

Alliance HealthCare intends to exchange its existing grandfathered MRI scanner SIGNA 460 with MRI scanner ESP 61. SIGNA 460 is a jointly held CON approved unit CON scanners that serves hospitals sites in eastern North Carolina

In accordance with 10A NCAC 14C.030 Replacement Equipment Administrative Rules, we agree that the exchange MRI equipment will not result in any increase in charges to the host sites 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
Operations Manager