



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

June 24, 2016

David French
PO Box 2154
Reidsville, NC 27323

Exempt from Review – Replacement Equipment

Record #: 1973
Business Name: Alliance Imaging, Inc.
Business #: 2391
Project Description: Temporarily replace mobile MRI scanner which needs repairs
Counties: Catawba & Watauga

Dear Mr. French:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of June 17, 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 SIGMA mobile MRI scanner. This determination is based on your representations that the temporary unit will be removed from North Carolina once the repairs are made.

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: Paige Bennett, Assistant Chief, Healthcare Planning, DHSR

Healthcare Planning and Certificate of Need Section

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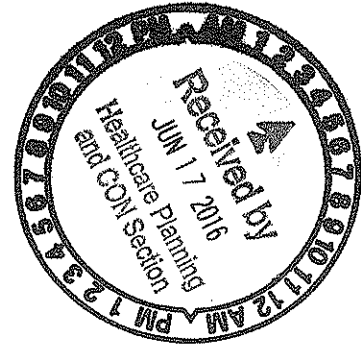
Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

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

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June 17, 2016



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

RE: Alliance Imaging Inc. - Written Notice for Exemption from CON Review for **Emergency Temporary Replacement MRI Scanner**

Dear Ms. Frisone:

I am writing on behalf of my client, Alliance Imaging Inc., regarding the urgent need to temporarily replace the mobile MRI Scanner SIGNA 273, serial number 1S9FA482X31182591 (grandfathered unit). This unit was recently brought into North Carolina as a replacement unit for SIGNA 405. An exemption notice was submitted to the Health Planning and Certificate of Need Section on April 13, 2016.

Please accept this notice of exemption to temporarily replace the above unit with SIGNA 242, serial # is R1512, VIN# - m 1JJV462W91L679090. This unit is owned by Alliance Imaging and is utilized t in other states. When this unit is no longer needed to serve as a temporary replacement for SIGNA 273 it will be removed from North Carolina.

This letter provides justification and written notice regarding the replacement equipment in accordance with NCGS 131 E-184. 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 requires temporary replacement for several reasons:

- 1) The existing SIGNA 273 requires repairs and the completion date is not known at this time.
- 2) Service to the existing host sites will be disrupted if a temporary replacement mobile MRI scanner cannot be provided.
- 3) Patient diagnosis and treatment at the host sites will be seriously disrupted without access to MRI.
- 4) Alliance does not have available capacity on other MRI scanners in North Carolina to provide coverage for the unit that needs to be repaired.

Alliance Imaging recognizes the need to provide high quality, cost effective, and reliable mobile MRI scanner service.

The current host sites that will be served by the replacement grandfathered 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

Compliance Documentation

Compliance with G.S. 131E-176 (22a) Replacement Equipment Definition is demonstrated in Attachment 1 which shows that the temporary replacement scanner has an actual cost of less than \$2,000,000.

No additional shipping or installation costs are expected. The fair market value for the MRI scanner is reflected in the attached quotes.

The replacement MRI equipment will be used for the same diagnostic purposes as the existing equipment.

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 use an existing mobile MRI as a temporary replacement. No equipment will be purchased. The temporary replacement equipment conforms to the rules as follows:

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 temporary replacement equipment will also obtain MRI images and data. The proposed replacement mobile MRI scanner is used to acquire the same types of MRI images and data.

(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 unit.

(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 sites will utilize the temporary replacement MRI scanner and shall be notified by Alliance Imaging that no increases in costs or patient charges will result from the temporary replacement.

(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. This notice involves a temporary replacement MRI scanner. The existing equipment will be brought back into service and the temporary replacement unit will be removed from North Carolina.

(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. See the explanation above.

(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 existing equipment will be brought back into service and the temporary replacement unit will be removed from North Carolina.

(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 an MRI scanner and not a gamma camera or nuclear medicine equipment.

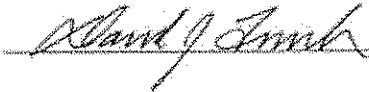
EQUIPMENT COMPARISON

	EXISTING EQUIPMENT (To be temporarily removed from NC for repairs.)	TEMPORARY REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	MRI	MRI
Manufacturer of Equipment	GE	GE
Tesla Rating for MRIs	NA	NA
Model Number	GE 1.5T 23x 16 channel HD Xi	GE 1.5T
Serial Number	1S9FA482X31182591	R 1512
Provider's Method of Identifying Equipment	SIGNA 273	SIGNA 242
Specify if Mobile or Fixed	Mobile	Mobile
Mobile Trailer Serial Number/VIN #	1S9FA482X31182591	1JJV462W91L679090
Mobile Tractor Serial Number/VIN #	NA - No changes	NA - No changes
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 when acquired	New when acquired
Total Capital Cost of Project (no construction involved)	NA	Existing equipment
Total Cost of Equipment	NA	Already owned by Alliance
Fair Market Value of Equipment	NA	\$450,000 FMV
Net Purchase Price of Equipment	NA	\$450,000 FMV
Locations Where Operated	OrthoCarolina Hickory and OrthoCarolina Boone (grandfathered unit)	OrthoCarolina Hickory and OrthoCarolina Boone
Number Days In Use/To be Used in N.C. Per Year	365	Specified days for temporary replacement
Percent of Change in Patient Charges (by Procedure)	NA	No increase will result
Percent of Change in Per Procedure Operating Expenses (by Procedure)	NA	No increase will result
Type of Procedures Currently Performed on Existing Equipment	MRI Procedures	MRI Procedures
Type of Procedures New Equipment is Capable of Performing	NA	MRI procedures

The temporary use of replacement SIGNA 242 to serve CON-approved host sites in North Carolina will be discontinued when the repair of SIGNA 273 has been completed and returned to service.

Thank you for your review and consideration of this information. Please call me at the office at 336 349-6250 or 336 432-8308 (cell phone) if you have any questions.

Sincerely,

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

David French
Consultant to Alliance Radiology
P.O. Box 2154
Reidsville, NC 27323
djfrench45@gmail.com

Cc: Rodney Skelding
Manager of Operations
Alliance Healthcare Services
Phone: 910-340-1494

Andre' D. Kellogg, Sr., MPA
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