



NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

January 19, 2021

Mr. David French
djfrench45@gmail.com

Exempt from Review – Replacement Equipment

Record #: 3459
Date of Request: December 30, 2020
Facility Name: Alliance Imaging, Inc.
FID #: 001325
Business Name: Alliance Healthcare Services, Inc.
Business #: 60
Project Description: Replace existing fixed MRI scanner
County: Iredell

Dear Mr. French:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the above referenced project is exempt from certificate of need review in accordance with G.S. 131E-184(a)(7). Therefore, you may proceed to utilize without a certificate of need the SIGNA 456 MRI scanner to replace the existing SIGNA 413 MRI scanner. The SIGNA 456 MRI scanner is already owned by Alliance and will soon be delivered to the facility once it has been refurbished. This determination is based on your representations that the existing unit will be removed from service in North Carolina and will not be used again in the State without first obtaining a certificate of need if one is required.

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,

[Handwritten signature of Misty L. Piekaar-McWilliams]

Misty L. Piekaar-McWilliams
Project Analyst

[Handwritten signature of Lisa Pittman]

Lisa Pittman
Assistant Chief, Certificate of Need

cc: Construction Section, DHSR

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION
HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704
https://info.ncdhhs.gov/dhsr/ • TEL: 919-855-3873

ALLIANCE HEALTHCARE SERVICES

December 24, 2020

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

RE: Alliance Healthcare Services and Piedmont HealthCare - Written Notice for Exemption from CON Review for Permanent Replacement of Fixed MRI Scanner SIGNA 413 Serial # 1S9FA48245118278 (Iredell County)

Dear Ms. Frisone:

Alliance Healthcare Services (Alliance) is planning to permanently replace fixed MRI scanner SIGNA 413 Serial # 1S9FA482451182783 that will be removed from North Carolina. During the past year, this MRI scanner has been utilized at Piedmont Healthcare in Mooresville, Iredell County. This MRI scanner has been properly reported in the 2020 MRI Inventory Forms to DHSR Healthcare Planning. SIGNA 413 is a “legacy” MRI scanner that was authorized to be used in North Carolina prior to CON regulation. The permanent replacement unit for SIGNA 413 will be SIGNA 456 Serial Number 1SF9FA8248183226.

SIGNA 456 is already owned by Alliance and will soon be delivered to Mooresville once it has been refurbished. This unit was recently removed from service in Statesville and was temporarily replaced by Voya 1; later SIGNA 269 will become its permanent replacement. The SIGNA 269 replacement exemption is documented separately.

This letter provides justification and written notice regarding the replacement equipment in accordance with G.S. 131E-184 (a) (7) Exemptions from Review to provide replacement equipment and 10A NCAC 14C.0303 Replacement Equipment Administrative Rules.

Overview

The existing SIGNA 413 requires extensive repairs and maintenance due to high utilization. SIGNA 413 will be removed from North Carolina. Service to Piedmont Healthcare in Mooresville will be disrupted if a replacement mobile MRI scanner, SIGNA 456, is not provided. Alliance has no available capacity on other MRI scanners in its North Carolina inventory to provide full time coverage for the unit that needs to be removed.

The host site that will be served by the replacement mobile MRI scanner is:

Piedmont HealthCare
128 Medical Park Dr., Suite 102
 Mooresville, NC 28677

Compliance Documentation

Compliance with G.S. 131E-176 (22a) Replacement Equipment Definition is demonstrated because the replacement MRI scanner (SIGNA 456) has a current fair market value of approximately \$400,000. The MRI is already owned by Alliance as it was purchased in 2006.

The replacement MRI equipment will be used for the same diagnostic purposes as the existing equipment. In addition, Alliance 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 plans to use an existing mobile MRI that it owns as the replacement. No equipment will be purchased. The replacement equipment conforms to the rules as follows:

10A NCSC 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 Healthcare Services 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 Healthcare Services 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 Healthcare Services 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 will be 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 Healthcare Services 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.

Piedmont HealthCare and Alliance Imaging confirm 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. The replacement equipment is owned by Alliance and was purchased new.

(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. 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	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	MRI	MRI
Manufacturer of Equipment	GE	GE
Tesla Rating for MRIs	1.5T	1.5T
Model Number	SIGNA	SIGNA
Serial Number	1S9FA48245118278	1SF9FA8248183226
Provider's Method of Identifying Equipment	SIGNA 413	SIGNA 456
Specify if Mobile or Fixed	Mobile	Mobile
Mobile Trailer Serial Number/VIN #	1S9FA482451182783	1SF9FA8248183226
Mobile Tractor Serial Number/VIN #	NA – No changes	No changes
Date of Acquisition of Each Component	02/2006	2004
Hold Title or 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	NA
Total Cost of Equipment	NA	NA
Fair Market Value of Equipment	NA	\$400,000
Net Purchase Price of Equipment	NA	NA
Locations Where Operated Currently	Piedmont HealthCare Mooresville	Piedmont Healthcare Mooresville
Number Days In Use/To be Used in N.C. Per Year	Up to 365	Permanent 365
Percent of Change in Patient Charges (by Procedure)	NA	0%
Percent of Change in Per Procedure Operating Expenses (by Procedure)	NA	0%
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 consideration of this information. Please call me at 336 432-8308 (cell phone) if you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "David French", written over a horizontal line.

David French
Consultant to Alliance Healthcare Services
P.O. Box 2154
Reidsville, NC 27023
djfrench45@gmail.com

Cc: Rodney Skelding
rskelding@allianceradiology-us.com

ALLIANCE HEALTHCARE SERVICES

December 23, 2020

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

RE: Equipment Replacement for MRI Scanner SIGNA 413

Dear Ms. Frisone,

Alliance Healthcare Services intends to permanently replace its existing fixed MRI scanner SIGNA 413 with SIGNA 456.

In accordance with 10A NCAC 14C.030 Replacement Equipment Administrative Rules, Alliance and Piedmont Healthcare agree that the replacement MRI scanner equipment will not result in more than a 10 percent increase in expense or charges.

Thank you for your consideration. Please email me if you have any questions.

Sincerely,

Rodney Skelding

Manager of Operations
Alliance Radiology
Rodney Skelding
rskelding@allianceradiology-us.com

From: [David French](#)
To: [Piekaar, Misty L](#); [Rodney Skelding](#)
Subject: Re: [External] Alliance MRI Equipment Replacement Exemption Notices
Date: Tuesday, January 5, 2021 10:54:05 AM

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to [Report Spam](#).

Based on previous exemption letters for grandfathered MRI scanners these are collectively assigned as follows:

Existing Grandfathered MRI
FID # 001325 (Alliance Imaging Inc. Mobile MRI Diagnostic Program)

On Tue, Jan 5, 2021 at 10:04 AM David French <djfrench45@gmail.com> wrote:
Please see the attached inventory form for SIGNA 413.

Alliance has grandfathered units that have been authorized for use in NC prior to CON regulation.
SIGNA 413 is one of these. Please see the previous temporary replacement exemption for SIGNA 413.

I will look for FID# that is assigned to the Alliance grandfathered mobile diagnostic program and send that to you.

Thanks

David French
336 432-8308

On Tue, Jan 5, 2021 at 9:54 AM Piekaar, Misty L <Misty.Piekaar@dhhs.nc.gov> wrote:

David-

One last question. I looked in our database and didn't see it. I didn't locate it in MFF either (database licensure uses). Do you also have the FID?

Misty L. Piekaar-McWilliams, JD

Certificate of Need Project Analyst

[Division of Health Service Regulation, Healthcare Planning and Certificate of Need](#)

[NC Department of Health and Human Services](#)

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Office: 919-855-3883

Misty.Piekaar@dhhs.nc.gov

809 Ruggles Drive, Edgerton Building

2704 Mail Service Center

Raleigh, NC 27699-2704

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From: David French <djfrench45@gmail.com>

Sent: Tuesday, January 5, 2021 9:51 AM

To: Piekaar, Misty L <Misty.Piekaar@dhhs.nc.gov>

Cc: Rodney Skelding <rskelding@allianceradiology-us.com>

Subject: Re: [External] Alliance MRI Equipment Replacement Exemption Notices

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According to my records the address:

Piedmont HealthCare

128 Medical Park Dr., Suite 102

Mooresville, NC 28677

On Tue, Jan 5, 2021 at 9:40 AM Piekaar, Misty L <Misty.Piekaar@dhhs.nc.gov> wrote:

David/Rodney-

I am currently reviewing the exemptions and wanted to know if someone could provide to me the address for the Piedmont Healthcare Mooresville facility as referenced in your exemption letter for permanent replacement of fixed MRI scanner SIGNA 413? I am pulling up multiple entries in our database but want to be sure I have the correct location with what I show in our database. Thanks!

Misty

Misty L. Piekaar-McWilliams, JD

Certificate of Need Project Analyst

[Division of Health Service Regulation, Healthcare Planning and Certificate of Need](#)

[NC Department of Health and Human Services](#)

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#StayStrongNC and get the latest at nc.gov/covid19.

Office: 919-855-3883

Misty.Piekaar@dhhs.nc.gov

809 Ruggles Drive, Edgerton Building

2704 Mail Service Center

Raleigh, NC 27699-2704

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From: David French <djfrench45@gmail.com>

Sent: Thursday, December 24, 2020 12:26 PM

To: Flores, Disraeliza <Disraeliza.Flores@dhhs.nc.gov>; Piekaar, Misty L <Misty.Piekaar@dhhs.nc.gov>

Cc: Rodney Skelding <rskelding@allianceradiology-us.com>

Subject: [External] Alliance MRI Equipment Replacement Exemption Notices

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Hi,

Please confirm that you have received the two attached MRI replacement exemptions.

Both are for locations in Iredell County.

Thanks

David French

Strategic Healthcare Consultants

336 432-8308

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