



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

June 20, 2019

David French
djfrench45@gmail.com

Exempt from Review – Replacement Equipment

Record #: 2972
Business Name: Alliance Healthcare Services, Inc.
Business #: 60
Project Description: Temporarily replace mobile MRI scanner
County: Alleghany, Avery, Buncombe, Macon

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 18, 2019, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the SYM 72, Serial #1S9FA482942282695 to temporarily replace the ESP 66 mobile MRI scanner Serial #1M9A3A820YH022324, which was approved (Record #2956) as temporary replacement for the mobile MRI SIGNA 67 Serial # 1JJV482W4WL512370 being upgraded to permanently replace the grandfathered mobile MRI scanner SIGNA 404 Serial #1S9FA482141182724 (Record #2885). This determination is based on your representations that the existing unit will be sold or otherwise disposed of 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,

Celia C. Inman
Celia C. Inman
Project Analyst

Martha J. Frisone
Martha J. Frisone
Chief

cc: Acute and Home Care Licensure and Certification 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
www.ncdhhs.gov/dhsr • TEL: 919-855-3873



June 18, 2019

Martha Frisone, Chief
Celia Inman, Project Analyst
Healthcare 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 Healthcare Services
MRI Scanner SIGNA 404 Serial Number 1S9FA482141182724

Dear Ms. Celia Inman and Ms. Frisone:

Alliance Healthcare Services Inc. (Alliance) intends to replace its existing grandfathered MRI scanner, SIGNA 404 Serial Number 1S9FA482141182724 that was acquired in 2004. SIGNA 404 will be removed from North Carolina when its replacement is delivered. Previously the Agency issued the replacement equipment exemption to allow for SIGNA 67 Serial Number 1JJV482W4WL512370 to be brought into North Carolina as the SIGNA 404 replacement. Please see the attached correspondence dated March 29, 2019 included in Attachment 3.

By previous correspondence, Alliance recently informed the Agency that before this can occur, SIGNA 67 will need to have more extensive maintenance and upgrades than was previously known. So in the meanwhile, Alliance obtained authorization to proceed to remove SIGNA 404 from North Carolina and utilize ESP 66, Serial Number 1M9A3A820YH022324 as the interim replacement unit until SIGNA 67 is fully upgraded. Unfortunately, ESP 66, the current interim replacement MRI scanner is not operational. Consequently, Alliance now requests authorization to utilize SYM 72, Serial Number 1S9FA482941182695 as the alternate interim replacement MRI scanner until such time that ESP 66, is functional. SYM 72 will be removed from North Carolina once ESP 66 is available to serve as the approved interim MRI.

In accordance with NCGS 131 E-184, this letter provides justification and written notice regarding the replacement equipment. Alliance Healthcare Services 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

P.O. Box 2154
Reidsville NC 27323

Overview

The existing mobile MRI scanner number SIGNA 404 Serial Number 1S9FA482141182724 was acquired in 2010 and will be replaced in North Carolina and reassigned to host sites in other states.

- 1) The MRI scanner SIGNA 404 is a grandfathered scanner in North Carolina that is planned to be removed from North Carolina.
- 2) The permanent replacement SIGNA 67 need maintenance that will take several months to complete.
- 3) Alliance proposed to have ESP 66 is to be used as a temporary interim replacement unit with SIGNA 404 to leave the State and while SIGNA 67 is being prepared for service as the permanent replacement. However ESP 66 is not operational at this time.
- 4) Alliance now proposes to utilize SYM 72 as the temporary interim unit until ESP 66 is repaired.

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, number SIGNA 404 Serial Number 1S9FA482141182724 that is being replaced is a grandfathered MRI scanner that has properly been reported on the attached 2019 MRI Equipment Inventory form.

The host sites that will be served by the replacement mobile MRI scanner include:

Charles A. Cannon Mem. Hosp.
434 Hospital Drive
Linville, NC 28646

Alleghany Memorial Hospital
233 Doctors Street
Sparta, NC 28675

Duke LifePoint Harris Regional
at Franklin Med 55 Holly Springs Park Drive
Franklin, NC 28734

Margaret R Pardee Memorial Hospital
21 Turtle Creek Drive
Asheville, NC 28803

These locations have existing MRI pads and utilities to support the mobile MRI scanner that will be provided through a services agreement by Alliance. As a grandfathered mobile MRI scanner other additional existing host sites with mobile MRI pads may be served.

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 with a capital cost less than \$2,000,000.

As seen in Attachment 1, the Alliance Operations Manager documents that the replacement MRI equipment will be used for the same diagnostic purposes as the existing mobile MRI scanner.

The previous temporary interim ESP 66 is a refurbished mobile MRI scanner owned by Alliance that was purchased on 1/8/2018 for \$860,000.

The proposed alternate temporary interim SYM 72 is a rmobile MRI scanner owned by Alliance that has a current Fair Market value of \$450,000

The permanent replacement unit SIGNA 67 Serial Number 1JJV482W4WL512370 is a mobile MRI scanner that is owned by Alliance; with a Fair Market Value of \$300,000 as seen in Attachment 2.

Applicability and Conformance with Administrative Rule 10A NCAC 14C.0303 Replacement Equipment

Alliance Healthcare Services will 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 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 temporary and permanent replacement MRI scanners are 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 Healthcare Services certifies that the temporary and permanent 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.

The host sites that will utilize the replacement MRI scanner certify that the acquisition of the replacement equipment will not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months.

Included in Attachment 2 is documentation from Alliance that it will not increase charges by more than 10% to its host sites during the first twelve months of the replacement scanner's operation. Alliance Imaging expects that the projected operating expenses for the replacement MRI scanner will not increase.

(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, SIGNA 67, is existing equipment owned by Alliance that was purchased new more than three years ago..

(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	TEMPORARY REPLACEMENT EQUIPMENT	INTERIM TEMPORARY REPLACEMENT EQUIPMENT	PERMANENT REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	MRI	MRI	MRI	MRI
Manufacturer of Equipment	GE	SEIMENS	SEIMENS	GE
Tesla Rating for MRIs	1.5t	1.5t	1.5T	1.5T
Model Number	SIGNA	ESPREE	SYMPHONY	SIGNA
Serial Number	159FA482141182724	1M9A3A820VH022324	159FA482941182695	1JJV482W4WL512370
Provider's Method of Identifying Equipment	SIGNA 404	ESP 66	SYM 72	SIGNA 67
Specify if Mobile or Fixed	Mobile (Grandfathered)	Mobile (Grandfathered)	Mobile (Grandfathered)	Mobile (Grandfathered)
Mobile Trailer Serial Number/VIN #	159FA482141182724	1M9A3A820VH022324	159FA482941182695	1JJV482W4WL512370
Mobile Tractor Serial Number/VIN #	NA - No changes	NA	NA	NA - No changes
Date of Acquisition of Each Component	2004	2018	2000	1999
Specify if Equipment Was/Is New or Used When Acquired	Hold Title New	Hold Title Used/ Refurbished	Hold Title New	Hold Title New
Total Capital Cost of Project (no construction involved)	NA	\$860,000 Purchase	FMV = \$450,000	FMV = \$ 300,000
Total Cost of Equipment	NA	\$860,000 Purchase		NA
Fair Market Value of Equipment	NA	\$860,000 Purchase	FMV = \$450,000	NA
Net Purchase Price of Equipment	NA	\$860,000 Purchase		NA
Locations Where Operated Currently	Grandfathered Unit See list	Grandfathered Unit See list	Grandfathered Unit See list	Grandfathered Unit See list
Number Days In Use/To be Used in N.C. Per Year	Up to 365	Interim - several months	Interim - several weeks or months	Up to 365
Percent of Change in Patient Charges (by Procedure)	NA	NA	NA	0%
Percent of Change in Per Procedure Operating Expenses (by Procedure)	NA	0%	0%	0%
Type of Procedures Currently Performed on Existing Equipment	MRI Procedures	MRI Procedures	MRI Procedures	MRI Procedures
Type of Procedures New Equipment is Capable of Performing	NA	MRI Procedures	MRI Procedures	MRI Procedures

Thank you for your review and consideration of this information. Please call me at **336 349-6250** if you have any questions.

Sincerely,



djfrench45@gmail.com

David French
Consultant to Alliance Healthcare Services

Cc: Cale Arnold
Rodney Skelding

Attachments:

- 1) CON Capital Cost Form
- 2) Letter from Alliance Regarding Replacement MRI Scanner and Charges to Host Sites
- 3) Copy of Previous Exemption Request and Response

Attachment 1. Fair Market Value for Permanent Replacement



March 21, 2019

Cathy Weinhold
Asset Manager
Alliance HealthCare Services

RE: Fair Market Value of Mobile MRI

Dear Ms. Weinhold:

As requested, the following is the estimated "Fair Market Value" for the imaging equipment described below:

1999 GE 1.5 Tesla 8 CH HDxt MRI System Housed in an Ellis & Watts Trailer

Fair Market Value: \$275,000 to \$300,000

Market value is based on the system and trailer as used and to be in good to very good condition.

Please contact me if I can be of further assistance.

Sincerely,

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

David J French
President

P.O. Box 2154
Reidsville NC 27323

Attachment 2. Compliance Letter 10A NCAC 14C.0303

ALLIANCE HEALTHCARE SERVICES

March 21, 2019

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

RE: Alliance HealthCare Replacement MRI Equipment,
SIGNA 404 Serial Number 1S9FA482141182724

Dear Ms. Frisone,

Alliance Healthcare Services (Alliance) intends to replace its existing grandfathered MRI scanner, SIGNA 404 Serial Number 1S9FA482141182724. The MRI replacement scanner serial number SIGNA 67 Serial Number 1JJV482W4WL512370 is a mobile MRI scanner that is owned by Alliance.

The replacement MRI scanner SIGNA 67 will be used for the same diagnostic purposes as the existing MRI unit.

In accordance with 10A NCAC 14C.0303 Replacement Equipment Administrative Rules, we agree that the replacement MRI equipment will not result in more than a 10 percent increase in charges to the host site within the first twelve months after the equipment is acquired.

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

Sincerely,



Rodney Skelding
Manager Operations
rskelding@alliancera-diology-us.com

Attachment 3. Previous Equipment Replacement Exemption Correspondence



NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

May 30, 2019

David French
P.O. Box 2154
Reidsville, NC 27323

Exempt from Review – Replacement Equipment

Record #: 2956
Business Name: Alliance Healthcare Services Inc.
Business #: 60
Project Description: Temporarily replace mobile MRI scanner
Counties: Alleghany, Avery, Buncombe, Macon

Dear Mr. French:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of May 20, 2019, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the ESP 66 mobile MRI Scanner, Serial # 1M9A3A820YH022324, to temporarily replace the SIGNA 404 mobile MRI Scanner, Serial # 1S9FA482141182724. This determination is based on your representations that the existing unit will be sold or otherwise disposed of 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,

[Signature of Ena Lightbourne]
Ena Lightbourne
Project Analyst

[Signature of Martha J. Frisone]
Martha J. Frisone
Chief, Healthcare Planning and Certificate of Need Section

cc: Acute and Home Care Licensure and Certification Section, DHSR

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HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

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