



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 #: 3458
Project ID #: F-6957-03
Date of Request: December 30, 2020
Facility Name: Piedmont Healthcare
FID #: 031129
Business Name: Alliance Healthcare Services, Inc.
Business #: 60
Project Description: Replace existing fixed MRI scanner at Piedmont HealthCare and discontinue use of the temporary MRI scanner previously approved at this location
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 acquire without a certificate of need the SIGNA 269 MRI scanner to replace the temporary VOYA 1 MRI scanner. The VOYA 1 MRI scanner received approval from the Agency to serve as a temporary replacement MRI scanner on December 1, 2020, for the SIGNA 456 MRI scanner. This determination is based on your representations that the existing unit, VOYA 1, 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 456 Serial # 1SF9FA8248183226, CON # F-6957-03 (Iredell County)

Dear Ms. Frisone:

Alliance Healthcare Services (Alliance) and Piedmont HealthCare are planning to permanently replace fixed MRI scanner SIGNA 456 Serial # 1SF9FA8248183226 that requires repairs. During the past year, this MRI scanner has been utilized at Piedmont Healthcare in Iredell County. This MRI scanner has been properly reported in the 2020 MRI Inventory Forms to DHSR Healthcare Planning. The permanent replacement SIGNA 269 Serial Number 1KKVA48292L208014 will be delivered in several weeks.

On December 1, 2020, Alliance submitted an exemption notice to temporarily replace MRI SIGNA 456 Serial # 1SF9FA8248183226 with VOYA 1, Serial Number 1S9AC4824FS834446. VOYA 1 will continue to serve as a temporary replacement until the permanent replacement SIGNA 269 can be delivered and parked at Piedmont Healthcare as a parked fixed unit. Accordingly, the temporary replacement unit (VOYA 1) will no longer be needed and it will be removed from service in North Carolina.

Once MRI scanner SIGNA 456 Serial # 1SF9FA8248183226 has been repaired it will become a replacement unit for an existing Alliance mobile scanner SIGNA 413 that is documented in separate correspondence.

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 456 requires repairs and maintenance due to high utilization. Service to Piedmont Healthcare in Statesville will be disrupted if a replacement mobile MRI scanner 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 repaired.

Alliance recognizes the need to provide high quality, cost effective, and reliable MRI service. The host site that will be served by the replacement mobile MRI scanner is:

Piedmont HealthCare
700 Sullivan Rd.
Statesville, NC 28677

Compliance Documentation

Compliance with G.S. 131E-176 (22a) Replacement Equipment Definition is demonstrated because the replacement MRI scanner (SIGNA 269) has a current fair market value of \$450,000. Please see the attached FMV letter from Block Imaging.

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 as a temporary replacement. No equipment will be purchased. The temporary 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 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. This notice involves a replacement MRI scanner that is already owned by Alliance and was acquired 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 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	TEMPORARY REPLACEMENT (Previously Submitted)	PERMANENT REPLACEMENT
Type of Equipment (List Each Component)	MRI	MRI	MRI
Manufacturer of Equipment	GE	GE	GE
Tesla Rating for MRIs	1.5T	1.5T	1.5T
Model Number	SIGNA	VOYAGER	SIGNA
Serial Number	1SF9FA8248183226	1S9AC4824FS834446	1KKVA48292L208014
Provider's Method of Identifying Equipment	SIGNA 456	VOYA 1	SIGNA 269
Specify if Mobile or Fixed	FIXED (PARKED)	Mobile	FIXED (PARKED)
Mobile Trailer Serial Number/VIN #	1SF9FA8248183226	1S9AC4824FS834446	1KKVA48292L208014
Mobile Tractor Serial Number/VIN #	NA – No changes	NA – No changes	No changes
Date of Acquisition of Each Component	2004	2017	2003
Hold Title or Lease	Holds Title	Holds Title	Holds Title
Specify if Equipment Was/Is New or Used When Acquired	New	New	New
Total Capital Cost of Project (no construction involved)	NA	NA	NA
Total Cost of Equipment	NA	NA	NA
Fair Market Value of Equipment	NA	\$950,000	\$450,000
Net Purchase Price of Equipment	NA	NA	NA
Locations Where Operated Currently	Piedmont HealthCare Statesville	Piedmont HealthCare Statesville	Piedmont Healthcare Statesville
Number Days In Use/To be Used in N.C. Per Year	Up to 365	Temporary	Permanent 365
Percent of Change in Patient Charges (by Procedure)	NA	0%	0%
Percent of Change in Per Procedure Operating Expenses (by Procedure)	NA	0%	0%
Type of Procedures Currently Performed on Existing Equipment	MRI Procedures	MRI Procedures	MRI Procedures
Type of Procedures New Equipment is Capable of Performing	NA	MRI procedures	MRI Procedures

MRI scanner SIGNA 456 Serial # 1SF9FA8248183226 will be removed from service at the Piedmont location in Statesville. Once has been repaired it will become a replacement unit for an existing Alliance mobile scanner SIGNA 413 (in Mooresville) that is documented in separate replacement exemption correspondence.

The temporary use of the replacement unit, VOYA 1, to serve at the designated host site will be discontinued when SIGNA 269 is delivered and set up. VOYA 1 shall be removed from North Carolina.

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 cursive script, appearing to read "David J. French".

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 456 Serial 1SF9FA8248183226,
CON # F-6957-03

Dear Ms. Frisone,

Alliance Healthcare Services intends to permanently replace its existing fixed MRI scanner SIGNA 456 with SIGNA 269.

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



PHONE 517-668-8800
TOLL-FREE 888-694-6478
FAX 517-668-8899

Fair Market Valuation

Unit Signa 269

Description: 16 CH

Manufacturer: GE

Model: 1.5T Signa HDxt

Date of Manufacture: 2003

Software Version: 23.0

Trailer Manufacturer: Ellis & Watts

Trailer VIN: 1KKVA48292L208014

Fair Market Valuation for system: \$350,000-\$450,000

The Fair Market Value represented is what Block Imaging considers the median range for an "in-place" asset provided the information presented. Other factors must be considered in valuing what the unit is worth to Alliance Healthcare or via orderly liquidation. The replacement value of this unit would include the following items not accounted for in this FMV – site preparation, delivery, installation and service agreements.

Prepared by Block Imaging International 03/04/2020.