

ROY COOPER • Governor

MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

October 14, 2020

David French, Consultant to Alliance Healthcare Services differench45@gmail.com

Exempt from Review - Replacement Equipment

Record #: 3372

Facility: Alliance Healthcare Services, Inc.

FID #: 040553

Business Name: Alliance Healthcare Services, Inc.

Business #: 60

Project Description: Temporarily replace existing mobile MRI scanner

County: Multiple

Dear Mr. French:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of October 2, 2020, 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 Siemens SYM 72, Serial #1S9FA482941182695 mobile MRI scanner to temporarily replace the Siemens ESP 66 Serial # 1M9A3A820YH022324 (CON Project ID # G-7038-04) mobile MRI scanner, serving host sites in Alamance, Chatham and Mecklenburg counties. This determination is based on your representations that this replacement is temporary while the existing unit is undergoing repairs and once the ESP 66 MRI scanner is repaired, the SYM 72, Serial #1S9FA482941182695 MRI scanner will be removed from the State 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 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

https://info.ncdhhs.gov/dhsr/ • TEL: 919-855-3873

ALLIANCE HEALTHCARE SERVICES

October 2, 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 - Written Notice for Exemption from CON Review for Temporary Replacement of Mobile MRI Scanner ESP 66 Serial # 1M9A3A820YH022324 CON Project ID # G-7038-04 (Alamance, Chatham and Mecklenburg Counties)

Dear Ms. Frisone:

Alliance Healthcare Services (Alliance) has an urgent need to again temporarily replace mobile MRI scanner ESP 66 Serial # 1M9A3A820YH022324 that is assigned to CON Project ID # G-7038-04. Unfortunately, ESP 66 requires additional repairs. This MRI scanner is currently utilized at the UNC Burlington, UNC Chatham and CEENTA in Charlotte. This MRI scanner has been properly reported in the 2020 MRI Inventory Forms to DHSR Healthcare Planning.

Please accept this notice of exemption to temporarily replace the above unit with SYM 72, Serial Number 1S9FA482941182695. This replacement MRI unit is already owned by Alliance and is typically used to serve host sites in other states. When this temporary replacement unit (SYM 72) is no longer needed to serve as a temporary replacement for ESP 66 it will be removed from service in North Carolina.

This letter provides justification and written notice regarding the replacement equipment in accordance with NCGS 131 E-184. Alliance Healthcare Services also provides documentation that the replacement equipment conforms to the Certificate of Need laws and Administrative rules: 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 mobile MRI scanner requires temporary replacement for several reasons:

- 1) The existing ESP 66 urgently requires repairs.
- 2) Service to the existing host site will be disrupted if a temporary replacement mobile MRI scanner is not provided.
- 3) Patient diagnosis and treatment at the host sites will be disrupted without access to MRI.
- 4) Alliance has no available capacity on other MRI scanners in North Carolina to provide coverage for the unit that needs to be repaired.

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

University of North Carolina 1225 Huffman Mill Road Burlington, NC 27215 Alamance

UNC Chatham Hospital 475 Progress Blvd. Siler City, NC 27344 Chatham

CEENTA 6035 Fairview Road Charlotte, NC 28210 Mecklenburg

Compliance Documentation

Compliance with G.S. 131E-176 (22a) Replacement Equipment Definition is demonstrated because the temporary replacement MRI scanner has a current fair market value of \$450,000.

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.

The host site 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. Following completion of the repairs 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

	I	
	EXISTING	TEMPORARY
	EQUIPMENT	REPLACEMENT
Type of Equipment (List Each Component)	MRI	MRI
Manufacturer of Equipment	Siemens	Siemens
Tesla Rating for MRIs	1.5T	1.5T
Model Number	ESPREE	SYMPHONY
Serial Number	1M9A3A820YH022324	1S9FA482941182695
Provider's Method of Identifying Equipment	ESP 66	SYM 72
Specify if Mobile or Fixed	Mobile	Mobile
Mobile Trailer Serial Number/VIN #	1M9A3A820YH022324	1S9FA482941182695
Mobile Tractor Serial Number/VIN #	NA – No changes	NA – No changes
Date of Acquisition of Each Component	2018	2000
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	\$450,000
Net Purchase Price of Equipment	NA	NA
Locations Where Operated Currently	UNC Burlington,	UNC Burlington,
	UNC Chatham,	UNC Chatham
	CEENTA Charlotte	CEENTA Charlotte
Number Days In Use/To be Used in N.C. Per Year	Up to 365	Temporary
Percent of Change in Patient Charges (by Procedure)	NA	0%
Percent of Change in Per Procedure Operating Expenses (by	NA	0%
Procedure)		
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 the replacement unit, SYM 72, to serve at the designated host sites will be discontinued when the repair of ESP 66 has been completed and the scanner has been returned to service.

Thank you for your consideration of this information. Please call me at 336 432-8308 (cell phone) if you have any questions.

Sincerely,

David French

Consultant to Alliance Healthcare Services

Dand J Truch

P.O. Box 2154

Reidsville, NC 27023

djfrench45@gmail.com

Cc: Rodney Skelding

rskelding@allianceradiology-us.com

ALLIANCE HEALTHCARE SERVICES

October 2, 2020

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

RE: Temporary Equipment Replacement for MRI Scanner ESP 66 Serial #1M9A3A820YH022324

Dear Ms. Frisone,

Alliance Healthcare Services intends to temporarily replace its existing mobile MRI Scanner ESP 66 with a temporary replacement unit SYM 72.

In accordance with 10A NCAC 14C.030 Replacement Equipment Administrative Rules, Alliance agrees that the replacement MRI scanner equipment will not result in more than a 10 percent increase in expense or charges to any MRI host sites. This is a temporary replacement and no changes to the current agreements or charges will result.

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

Sincerely,

Rodney Skelding

Manager of Operations Alliance Radiology Rodney Skelding rskelding@allianceradiology-us.com From: <u>David French</u>

To: Waller, Martha K; Flores, Disraeliza

Cc: Rodney Skelding

Subject: [External] Alliance Exemption for Temporary Equipment Replacement

Date: Friday, October 2, 2020 8:31:18 AM

Attachments: Alliance Temporary Replacement ESP 66 10 2 2020.pdf

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to report.spam@nc.gov

Good morning,

Please confirm that the CON office has received the attached Alliance exemption notice.

Thank you,

David French 336 432-8308