

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

March 2, 2021

David French Djfrench45@gmail.com

Exempt from Review – Replacement Equipment		
Record #:	3469	
Date of Request:	January 11, 2021	
Business Name:	Alliance Healthcare Services, Inc.	
Business #:	60	
Project Description:	Temporary replacement of existing mobile MRI scanner	
Counties:	Catawba and 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 413 (Serial number 1S9FA482451182783) to replace the SIGNA 407 (Serial number 1S9FA482641182704). 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,

Ena Lightbourne Project Analyst

Lisa Pittman Assistant Chief, Certificate of Need

cc: Radiation Protection Section, DHSR 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

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

ALLIANCE HEALTHCARE SERVICES

January 11, 2021

Ms. Martha Frisone, Chief Health 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 Emergency Temporary Replacement of Mobile MRI Scanner SIGNA 407 Serial # 1S9FA482641182704, CON Project ID # G-6271-00

Dear Ms. Frisone:

I am writing on behalf of my client, Alliance Healthcare Services, regarding the urgent need to temporarily replace mobile MRI scanner SIGNA 407 Serial # 1S9FA482641182704 (Project ID # CON G-6271-00). A copy of the SIGNA 2020 Mobile MRI Inventory Form is attached. Please accept this notice of exemption to temporarily replace the above unit with SIGNA 413 Serial #1S9FA482451182783, which is an existing mobile MRI scanner owned by Alliance and utilized in other states or as an approved interim temporary unit. (SIGNA 413 was previously used in North Carolina but was removed from service when it was replaced in December 2020 by SIGNA 456.)

When SIGNA 413 is no longer needed to serve as a temporary replacement for SIGNA 407 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 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 10A NCAC 14C.0303 Replacement Equipment Administrative Rules

Overview

The existing mobile MRI scanner requires temporary replacement for several reasons:

- The existing Signa 407 requires repairs that are estimated to take approximately two weeks
- Service to the existing host sites will be disrupted if a temporary replacement mobile MRI scanner is not provided.
- Patient diagnosis and treatment at the host sites will be disrupted without access to MRI.

• Alliance has no available capacity on other MRI scanners in North Carolina to provide coverage for the unit that needs to be repaired.

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

OrthoCarolina Hickory Orthopaedic Center 214 18th Street SE Hickory, NC 28602

OrthoCarolina-Mooresville 124 Welton Way Mooresville, NC 28117

Compliance Documentation

Compliance with G.S. 131E-176 (22a) Replacement Equipment Definition is evident because the temporary replacement scanner has a fair market value of \$400,000 which is far less than the \$2,000,000 threshold.

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 Healthcare Services 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)This Rule defines 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) "Currently in use" means that the equipment to be replaced has been used by the person requesting the exemption at least 10 times to provide a health service during the 12 months prior to the date the written notice required by G.S. 131E-184(a) is submitted to the CON Section.

Alliance Healthcare Services confirms that SIGNA 407 meets the definition of "currently in use" because the MRI scanner currently serves OrthoCarolina Hickory Orthopaedic Center and OrthoCarolina-Mooresville.

(c) Replacement equipment is not "comparable" if: (1) the replacement equipment to be acquired is capable of providing a health service that the equipment to be replaced cannot provide; or (2) the equipment to be replaced was acquired less than 12 months prior to the date the written notice required by G.S. 131E-184(a) is submitted to the CON Section and it was refurbished or reconditioned when it was acquired by the person requesting the exemption.

The replacement MRI scanner is comparable to the equipment being replaced because the temporary replacement equipment will be used to acquire the same types of MRI images and data. Alliance Healthcare Services certifies that the replacement mobile MRI equipment will be used for the same diagnostic purposes as the existing MRI unit.

The existing equipment to be temporarily replaced was acquired in 2004. The temporary replacement unit will be removed from North Carolina.

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	TEMPORARY REPLACEMENT
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	1S9FA482641182704	1S9FA482451182783
Provider's Method of Identifying Equipment	SIGNA 407	SIGNA 413
Specify if Mobile or Fixed	Mobile	Mobile
Mobile Trailer Serial Number/VIN #	1S9FA482641182704	1S9FA482451182783
Mobile Tractor Serial Number/VIN #	NA – No changes	NA – No changes
Date of Acquisition of Each Component	2004	2006
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	NA	\$400,000 FMV
construction involved)		Already owned by Alliance
Total Cost of Equipment	NA	NA
Fair Market Value of Equipment	NA	NA
Net Purchase Price of Equipment	NA	NA
Locations Where Operated Currently		
Number Days In Use/To be Used in N.C. Per Year	Up to 365	Short Term Replacement
Percent of Change in Patient Charges (by Procedure)	NA	0%
Percent of Change in Per Procedure Operating Expenses (by Procedure)	ΝΑ	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

The temporary use of replacement Signa 413 to serve the OrthoCarolina host sites will be discontinued in approximately two weeks when the repair of Signa 407 has been completed and returned to service.

Thank you for your review and consideration of this information. Please call me at 336 432-8308 if you have any questions.

Sincerely,

Mand J Amph

David J. French

Consultant to Alliance Healthcare Services

P.O. Box 2154 Reidsville, NC 27023 djfrench45@gmail.com

Cc: Rodney Skelding Manager of Operations Alliance Healthcare Services