

ROY COOPER • Governor

MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

May 4, 2021

David J. French Djfrench45@gmail.com

Exempt from Review – Replacement Equipment

Record #: 3551

Date of Request: April 29, 2021

Business Name: Alliance Healthcare Services, Inc.

Business #: 60

Project Description: Temporarily replace mobile MRI scanner Counties: Cabarrus, Guilford, and Mecklenburg

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 GE SIGNA 428 (Serial #1KKVA48225L216959) to temporarily replace the GE SIGNA 451 (Serial #1S9FA482431182635). This determination is based on your representations that, after repairs to the GE SIGNA 451 (Serial #1S9FA482431182635), the temporary replacement unit will be removed from the state, 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,

Julie M. Faenza Project Analyst

for

Lisa Pittman

Acting Chief, Certificate of Need

Gloria C. Hale

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

ALLIANCE HEALTHCARE SERVICES

April 29, 2021

Ms. Lisa Pittman, Acting 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 451

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 451 (Legacy Unit). A copy of the SIGNA 451 2021 Mobile MRI Inventory Form has been submitted to DHSR Health Care Planning. Please accept this notice of exemption to temporarily replace the above unit with SIGNA 428, which is an existing mobile MRI scanner owned by Alliance and utilized in other states or as an approved interim temporary unit.

When SIGNA 428 is no longer needed to serve as a temporary replacement for SIGNA 451 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 451 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.
- Alliance has no available capacity on other MRI scanners in North Carolina to provide coverage for the unit that needs to be repaired.

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

Carolina Neurosurgery and Spine Associates 110 Lake Concord Rd NE Concord, NC 28025 (Cabarrus) Carolina Neurosurgery and Spine Associates 130 N. Church St. Greensboro, NC 27401 (Guilford)

Carolina Neurosurgery and Spine Associates 225 Baldwin Ave Charlotte, NC 28204 (Mecklenburg)

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 451 meets the definition of "currently in use" because the MRI scanner currently serves Carolina Neurosurgery and Spine office in Concord, Greensboro and Charlotte.

(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	1S9FA482431182635	1KKVA48225L216959
Provider's Method of Identifying Equipment	SIGNA 451	SIGNA 428
Specify if Mobile or Fixed	Mobile	Mobile
Mobile Trailer Serial Number/VIN #	1S9FA482431182635	1KKVA48225L216959
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	Carolina Neurosurgery and Spine Concord, Greensboro and Charlotte	Carolina Neurosurgery and Spine Concord, Greensboro and Charlotte
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)	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

The temporary use of replacement Signa 428 will be discontinued in approximately 5 days the repair of Signa 451 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,

David J. French

Consultant to Alliance Healthcare Services

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

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Cc: Rodney Skelding
Manager of Operations
Alliance Healthcare Services