

ROY COOPER • Governor

KODY H. KINSLEY • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

May 10, 2022

David French, Consultant to Alliance Healthcare Services Djfrench45@gmail.com

Exempt from Review - Replacement Equipment

Record #: 3890

Date of Request: May 9, 2022

Business Name: Alliance Healthcare Services, Inc.

Business #: 60

Project Description: Temporarily replace a mobile MRI scanner followed by permanent replacement

of the mobile MRI scanner

County: Wake

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 Siemens mobile MRI scanner (SMP 3606) to temporarily replace the GE Signa mobile MRI scanner (SIGNA 457). 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. Also, you may proceed to acquire without a certificate of need the Siemens mobile MRI scanner (AERA 24) to permanently replace the Siemens mobile MRI scanner (SMP 3606). This determination is based on your representations that the temporary replacement unit will be removed 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,

Michael J. McKillip Project Analyst

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Micheala Mitchell

Chief

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

May 9, 2022

Mr. Mike McKillip, Team Leader 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 and Subsequent Permanent Replacement of Mobile MRI Scanner SIGNA 457 Serial # 1S9FA482181183197 (CON J-7757-06), in Wake County

Dear Mr. McKillip

Raleigh Orthopaedic Clinic (ROC) and Alliance Healthcare Services (Alliance) have an urgent need to temporarily replace mobile MRI scanner SIGNA 457 Serial # 1S9FA482181183197 (CON J-7757-06), in Wake County. Following the temporary replacement of this mobile MRI unit with a Siemen's loaner unit, SMP 3606, the permanent replacement (AERA 24) will follow. In accordance with the CON J-7757-06, this existing MRI scanner (SIGNA 457) is leased to Raleigh Orthopaedic Clinic by Alliance Healthcare Services and has been properly reported to DHSR Healthcare Planning in the 2022 Mobile MRI Inventory Forms.

Please accept this notice of exemption to temporarily replace the above SIGNA 457 unit with the Siemen's unit (SMP 3606) that is on loan to Alliance under a warranty agreement, that will be brought into North Carolina on a short-term basis. Once the permanent replacement unit, AERA 24 becomes available, them the SMP 3630 unit will be removed from North Carolina. Also, the SIGNA 457 mobile MRI unit will be removed from North Carolina as it will be replaced by its temporary unit and then its permanent replacement.

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 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 SIGNA 457 urgently requires repairs to the air conditioning system.
- 2) Service to the existing host site will be disrupted if a temporary replacement mobile MRI scanner, SMP 3606, is not provided.
- 3) The permanent replacement unit, AERA 24, is not yet available for service but is expected in within the month.
- 3) Patient diagnosis and treatment at the host sites will be disrupted without access to MRI.
- 4) Raleigh Orthopaedic Clinic and Alliance have 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 sites that will be served by the temporary and permanent replacement mobile MRI scanners are:

Raleigh Orthopaedic Clinic 3001 Edwards Mill Rd Raleigh, NC 27612

Raleigh Orthopaedic Clinic 115 Kildaire Park Dr Cary, NC 27518

Raleigh Orthopaedic Clinic 10880 Durant Road Raleigh, NC 27614

Raleigh Orthopaedic Clinic 1305 Timber Drive Garner, NC 27529

Compliance Documentation

Compliance with G.S. 131E-176 (22a) Replacement Equipment Definition is demonstrated because the temporary replacement MRI scanner is a no-cost loaner unit that is provided through a warranty agreement with Siemens. The permanent replacement unit, AERA 24, has a purchase cost of \$1,321,450 including sales tax.

The replacement MRI equipment will be used for the same diagnostic purposes as the existing equipment. In addition, Raleigh Orthopaedic Clinic and Alliance are providing prior written notice to the Department in accordance with G.S. 131E-184 (a) (7) Exemption from Review to provide replacement equipment.

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

ROC and Alliance plan to use a Siemen's loaner mobile MRI (SMP 3606) as a temporary replacement. The temporary 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. No increases in costs or patient charges will result from the temporary replacement. The existing equipment SIGNA 457 will be removed from North Carolina.

ROC and Alliance plan to use AERA 24 as the permanent replacement for SIGNA 457. The permanent replacement MRI scanner is comparable to the equipment being replaced because the 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. No increases in costs or patient charges will result from the temporary replacement. The loaner Siemen's unit SMP 3606 will be removed from North Carolina once the AERA 24 is brought into service at the ROC sites.

EQUIPMENT COMPARISON

| | EXISTING | TEMPORARY | PERMANENT |
|--|-----------------------------|---------------------------------|---|
| | EQUIPMENT | REPLACEMENT | REPLACEMENT |
| Type of Equipment (List Each Component) | MRI | MRI | MRI |
| Manufacturer of Equipment | GE | Siemens | Siemens |
| Tesla Rating for MRIs | 1.5T | 1.5T | 1.5T |
| Model Number | SIGNA HDx 8 Ch | AERA | Aera 24-SN# 41944 |
| Serial Number | 1S9FA482181183197 | SMP 3606 | 1S9AC4828NS834853 |
| Provider's Method of Identifying Equipment | SIGNA 457 | SMP 3606 | AERA 24 |
| Specify if Mobile or Fixed | Mobile | Mobile | Mobile |
| Mobile Trailer Serial Number/VIN # | 1S9FA482181183197 | SMP 3606 | 1S9AC4828NS834853 |
| Mobile Tractor Serial Number/VIN # | NA – No changes | No-changes | NA – No changes |
| Date of Acquisition of Each Component | 2008 | 2021 | 9/30/2021 But not yet operational in NC |
| Hold Title or Lease | ROC leases from Alliance | Alliance loaner from Siemens | Alliance Holds Title |
| Specify if Equipment Was/Is New or Used When Acquired | New | Loaner for Replacement Unit | New |
| Total Capital Cost of Project (no construction involved) | NA | NA | \$1,321,450 (includes 7% sales tax) |
| Total Cost of Equipment | NA | NA | |
| Fair Market Value of Equipment | NA | Loaner Unit Temporary | See purchase cost above |
| Net Purchase Price of Equipment | NA | | NA |
| Locations Where Operated Currently | Please see ROC list | Please see ROC list | Please see ROC list |
| Number Days In Use/To be Used in N.C. Per Year | Up to 365 | Temporary | Up to 365 |
| Percent of Change in Patient Charges (by Procedure) | NA | 0% | 0% |
| Percent of Change in Per Procedure Operating Expenses | NA | 0% | 0% |
| (by Procedure) | | | |
| Type of Procedures Currently Performed on Existing | MRI Procedures | MRI Procedures | MRI Procedures |
| Equipment | | | |
| Type of Procedures New Equipment is Capable of | NA | MRI Procedures | MRI procedures |
| Performing | | | |

Thank you for your review and consideration of this information. Please call me 336 432-8308 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: Tina Hinshaw, RVP Mobile Operations Southeast Jennifer Freeman and Rodney Skelding Managers of Operations

Alliance Healthcare Services