

ROY COOPER • Governor

KODY H. KINSLEY • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

January 6, 2022

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

Exempt from Review - Replacement Equipment

Record #: 3771

Date of Request: January 4, 2022

Business Name: Alliance Healthcare Services, Inc.

Business #: 60

Project Description: Temporarily replace a mobile MRI scanner

County: Orange and 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 Espree 1.5T mobile MRI scanner (ESP 52) to temporarily replace the Siemens Symphony 1.5T mobile MRI scanner (SYM 71) that is in need of repair. This determination is based on your representations that, after the existing unit is repaired, 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

Micheala Mitchell

Project Analyst

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

January 4, 2022

Mr. Mike Mckillip, CON Analyst Ms. Micheala Mitchell, 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 SYM 71

Dear Ms. Mitchell and Mr. Mckillip:

I am writing on behalf of my client, Alliance Healthcare Services, regarding the urgent need to temporarily replace mobile MRI scanner SYM 71 (Legacy Unit). As seen in the attached correspondence dated February 4, 2021, the SYM 71 Legacy mobile MRI was brought into North Carolina in February 2021 as a permanent replacement for SYM 65.

Please accept this notice of exemption to temporarily replace the above unit with ESP 52 Serial # 1M9A3A826CH022806, which is an existing mobile MRI scanner owned by Alliance and will be utilized as an interim temporary unit at this location. When ESP 52 is no longer needed to serve as a temporary replacement for SYM 71 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, SYM 71, requires temporary replacement for several reasons:

- Repairs to the MRI lift and floor 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:

Duke Health Heritage 3000 Roger Road Wake Forest, NC 27587

UNC Imaging and Spine Center 1350 Raleigh Rd. Chapel Hill, NC 27517

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 SYM 71 meets the definition of "currently in use" because the MRI scanner provided service at Duke Heritage and UNC Imaging and Spine during the past year. This equipment performed 1,322 MRI procedures during the period from March 1, 2021 through September 30, 2021.

(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.

This exemption notice is for a temporary replacement of a Legacy MRI scanner for repairs. The temporary 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, SYM 71 to be temporarily replaced was originally acquired by Alliance in 2011. The temporary replacement unit, ESP 52 will be removed from North Carolina once repairs to SYM 71 are completed.

Please see the attached Equipment Comparison Form:

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	TEMPORARY REPLACEMENT
Type of Equipment (List Each Component)	MRI	MRI
Manufacturer of Equipment	Siemens	Siemens
Tesla Rating for MRIs	1.5T	1.5T
Model Number	Symphony	ESPREE
Serial Number	# 1M9A3A8244W022381	1M9A3A826CH022806
Provider's Method of Identifying Equipment	Symphony 71	ESP 52
Specify if Mobile or Fixed	Mobile	Mobile
Mobile Trailer Serial Number/VIN #	# 1M9A3A8244W022381	1M9A3A826CH022806
Mobile Tractor Serial Number/VIN #	NA – No changes	NA – No changes
Date of Acquisition of Each Component	2011	2012
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	Duke Health Heritage & UNC Imaging and Spine Wake and Orange Counites	Duke Health Heritage & UNC Imaging and Spine Wake and Orange Counites
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 ESP 52 will be discontinued in approximately two weeks when the repair of SYM 71 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

Dand J Truch

Cc: Rodney Skelding Manager of Operations Alliance Healthcare Services



ROY COOPER • Governor

MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

February 4, 2021

David French, Consultant to Alliance Healthcare Services djfrench45@gmail.com

Exempt from Review - Replacement Equipment

Record #: 3477

Date of Request: February 2, 2021

Business Name: Alliance Healthcare Services, Inc.

Business #: 60

Project Description: Replace mobile MRI scanner

County: Wake and Orange

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 Voyager (VOYA 1) mobile MRI scanner to temporarily replace the Siemens Symphony (SYM 65) mobile MRI scanner. Also, you may proceed to acquire without a certificate of need the Siemens Symphony (SYM 71) mobile MRI scanner to permanently replace the GE Voyager (VOYA 1) mobile MRI scanner. This determination is based on your representations that the existing unit and temporary replacement 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,

Michael J. McKillip Project Analyst

Lisa Pittman

Assistant Chief, Certificate of Need

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

From: Mckillip, Mike
To: Waller, Martha K

Subject: FW: [External] Alliance MRI Equipment Replacement Exemption

Date: Tuesday, January 4, 2022 10:59:48 AM

Attachments: ALLIANCE Temporary Replacement SYM 71 with ESP 52.pdf

FYI

Michael McKillip

Project Analyst

Division of Health Service Regulation, Healthcare Planning and Certificate of Need NC Department of Health and Human Services

Office: 919-855-3877

mike.mckillip@dhhs.nc.gov

809 Ruggles Drive, Edgerton 2704 Mail Service Center Raleigh, NC 27699

Don't wait to vaccinate. Find a COVID-19 vaccine location near you at MySpot.nc.gov.

Twitter | Facebook | YouTube | LinkedIn

Email correspondence to and from this address is subject to the North Carolina Public Records Law and may be disclosed to third parties by an authorized State official. Unauthorized disclosure of juvenile, health, legally privileged, or otherwise confidential information, including confidential information relating to an ongoing State procurement effort, is prohibited by law. If you have received this email in error, please notify the sender immediately and delete all records of this email.

From: David French <djfrench45@gmail.com> **Sent:** Tuesday, January 4, 2022 10:37 AM

To: Mckillip, Mike <mike.mckillip@dhhs.nc.gov>

Cc: Rodney Skelding <rskelding@allianceradiology-us.com>

Subject: [External] Alliance MRI Equipment Replacement Exemption

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to Report Spam.

Hi Mike,

Happy New Year!

Please confirm that you have received the attached Equipment Replacement Exemption request for the Alliance MRI scanner. This is a temporary replacement while SYM 71 is being repaired. Please

call or email me if you have any questions.

Thank you,

David French 336 432-8308