

ROY COOPER • Governor MANDY COHEN, MD, MPH . Secretary MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

March 25, 2019

David French djfrench45@gmail.com

Exempt from Review - Replacement Equipment

Record #:

2906

Facility Name:

Alliance Imaging, Inc.

FID #:

001325

Alliance Healthcare Services, Inc.

Business Name: Business #:

Project Description:

Temporary replacement of mobile MRI scanner SIGNA 407 Serial #

1S9FA82641182704 (Project ID #G-6271-00)

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 March 22, 2019, 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 SIGNA 416, Serial # 159FAU862651182803 mobile MRI scanner to temporarily replace mobile MRI scanner SIGNA 407, Serial # 1S9FA82641182704. This determination is based on your representations that upon repair of the original unit, the replacement 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,

Celia C. Inman Project Analyst

Chief, Healthcare Planning and Certificate of Need Section

Acute and Home Care Licensure and Certification Section, DHSR cc:

elia C. Aluvar

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





March 22, 2019

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 2019 Mobile MRI Inventory Form is attached. Please accept this notice of exemption to temporarily replace the above unit with SIGNA 416 Serial # 159FAU862651182803, which is an existing mobile MRI scanner owned by Alliance and utilized in other states or as an approved interim temporary unit. When this unit 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:

- 1) The existing Signa 407 requires repairs that are estimated to take approximately five days.
- 2) Service to the existing host sites 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 OrthoCarolina host sites that will be served by the replacement mobile MRI scanner are:

OrthoCarolina Hickory	OrthoCarolina-Boone NC
214 18th Street SE	194 Doctors Drive
Hickory, NC 28602	Boone, NC 28607
Catawba County	Watauga County

Compliance Documentation

Compliance with G.S. 131E-176 (22a) Replacement Equipment Definition is demonstrated in Attachment 1 which shows that the temporary replacement scanner has an actual cost of less than \$2,000,000.

No additional shipping or installation costs are expected. The actual purchase for the MRI scanner (2015) is reflected in the attached table

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 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. 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

	EXISTING	TEMPORARY
	EQUIPMENT	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	159FAU862651182803
Provider's Method of Identifying Equipment	SIGNA 407	SIGNA 416
Specify if Mobile or Fixed	Mobile	Mobile
Mobile Trailer Serial Number/VIN #	1S9FA482641182704	159FAU862651182803
Mobile Tractor Serial Number/VIN #	NA – No changes	NA – No changes
Date of Acquisition of Each Component	2004	2015
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	\$1,818,200 (2015)
Total Cost of Equipment	NA	NA
Fair Market Value of Equipment	NA	NA
Net Purchase Price of Equipment	NA	NA
Locations Where Operated Currently	OrthoCarolina Hickory OrthoCarolina Boone	OrthoCarolina Hickory OrthoCarolina Boone
Number Days In Use/To be Used in N.C. Per Year	Up to 365	Up to 365
Percent of Change in Patient Charges (by Procedure)	NA	%0
Percent of Change in Per Procedure Operating Expenses (by Procedure)	NA	%0
Time of Droceding Currently Darformed on Existing Equipment	MDI D.	TANK D
Type of Floreduies Cultering Ferrollised on Existing Equipment	MKI Procedures	MKI Frocedures
Type of Procedures New Equipment is Capable of Performing	NA	MRI procedures

The temporary use of replacement Signa 416 to serve the OrthoCarolina host sites will be discontinued on approximately March 29, 2019 when the repair of Signa 432 has been completed and returned to service.

Thank you for your review and consideration of this information. Please call me at the office at 336 349-6250 or 336 432-8308 (cell phone) if you have any questions.

Sincerely,

David French

Consultant to Alliance Healthcare Services

Sland J Innh

P.O. Box 2154

Reidsville, NC 27023

djfrench45@gmail.com

Cc: Rodney Skelding Manager of Operations Alliance Healthcare Services

ALLIANCE HEALTHCARE SERVICES

March 22, 2019

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 SIGNA 407

Dear Ms. Frisone,

Alliance Imaging intends to temporarily replace its existing mobile MRI Scanner Signa 407, serial number 1S9FA482641182704, with a replacement unit, Signa 416. 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 at 336 580-9061 if you have any questions.

Sincerely,

Rodney Skelding

Manager Operations

Roche, B Stelling

rskelding@allianceradiology-us.com

336 580-9061



Registration and Inventory of Medical Equipment

Mobile Magnetic Resonance Imaging Scanners January 2019 SIGNA 407

Instructions

This is the legally required "Registration and Inventory of Medical Equipment" (G.S. 131E-177) for mobile magnetic resonance imaging (MRI) scanners. Please complete all sections of this form and return to Healthcare Planning by **Friday**, **January 25**, **2019**.

- 1. Complete and sign the form
- 2. Return the form by one of two methods:
 - a. Email a scanned copy to DHSR.SMFP.Registration-Inventory@dhhs.nc.gov.
 - b. Mail the form to Trenesse Michael, Healthcare Planning, 2704 Mail Service Center, Raleigh, NC 27699-2704.

If you have questions, call Trenesse Michael in Healthcare Planning at (919) 855-3867 or email DHSR.SMFP.Registration-Inventory@dhhs.nc.gov.

Section 1: Contact Information

Rodney Skelding

1. Full legal name of corporation, partnership, individual, or other legal entity that acquired the equipment by purchase, donation, lease, transfer, or comparable arrangement:

Alliance HealthCare Services

(Legal Name)

2. Address of the corporation, partnership, individual, or other legal entity that acquired the equipment:

18201 Von Karman #600 (Street and Number)

<u>Irvine CA 92612</u> (800) 544-3215 (City) (State) (Zip) (Phone Number)

3.	Chief Executive Officer or approved designee who is certifying the information in this registration
	form:

	(Name)	(Title)			
	336 580-9061	rskelding@allianceradio	logy-us.com		
	(Phone Numb	er) (Email)			
4.	Information Con	npiled or Prepared by:	David French		
				(Name)	
	(<u>336</u>) <u>349-6250</u>	djfrench45@gmail	.com		-,
	(Phone Number)	(Email)			

Manager Operations



Section	2:	Equipment	and	Procedures	Information
OCCUPANT.		Lquipinicit	uma	1 1 UCCUUI CS	

For DHSR Planning Use	
Only:	
ID #:	

Time Period for Report: $\boxtimes 10/01/2017 - 9/30/2018$ \square Other time period:

(Please make additional copies of pages of this form as needed.) **Mobile Scanner Number** (One scanner per page) Manufacturer/Tesla **GE 1.5 T** Model Number Excite 8 channel Open or Closed Scanner closed Serial or I.D. Number 1S9FA482641182704 Signa 407 Date of acquisition 2004 (This unit replaced 244 in January 2011) Purchase price (if purchased) Previously submitted to DHSR Certificate of Need Project ID G-6271-00 Certificate Holder, as listed on Certificate of Need Alliance Imaging Inc. If Leased or Rented, Name Owner of Equipment NA Service Site Number 1 Service Site Number2 Service Site Information: OrthoCarolina Hickory OrthoCarolina-Boone NC Please include all of the 214 18th Street SE 194 Doctors Drive information requested for Hickory, NC 28602 Boone, NC 28607 each location. Catawba Watauga Inpatient Procedures*: Inpatient: Inpatient: - with Contrast or Sedation with: 0 with: 0 - without Contrast or w/out: 0 w/out: 0 Sedation Total: 0 Total: 0 Outpatient Procedures*: Outpatient: Outpatient: - with Contrast or Sedation with: 229 with: 0 - without Contrast or w/out: 2701 w/out: 0 Sedation Total: 2930 Total: 0 **Total Number of Procedures Total: 2930** Total: 0 Put a check by the days per Days and hours subject to Days and hours subject to change week, and write in the change number of hours per day, the scanner is in operation. Total number of hours in 2600 hrs operation for report period

^{*}An MRI procedure is defined as a single discrete MRI study of one patient (single CPT coded procedure). An MRI study means one or more scans relative to a single diagnosis or symptom. The total number of procedures should be equal to or more than the total number of patients reported on the MRI Patient Origin Table on page 5 of this form.



Section 3: Patient Origin Data by Service Site

Please provide the county of residence for each patient who received MRI services during the time period of this report. Provide patient origin data separately for each service site. Make additional copies of this page as needed. The total number of patients receiving services should be equal to or less than the total number of procedures reported on page two of this form.

Service Site Name: OrthoCarolina Boone, OrthoCarolina Hickory

County in which service was provided: Catawba and Watauga

Patient	Number of	Patient	Number of	Patient	Number of
County	Patients	County	Patients	County	Patients
1. Alamance		37. Gates		73. Person	
2. Alexander		38. Graham		74. Pitt	
3. Alleghany		39. Granville		75. Polk	
4. Anson		40. Greene		76. Randolph	
5. Ashe		41. Guilford		77. Richmond	
6. Avery		42. Halifax		78. Robeson	
7. Beaufort		43. Harnett		79. Rockingham	
8. Bertie		44. Haywood		80. Rowan	
9. Bladen		45. Henderson		81. Rutherford	
10. Brunswick		46. Hertford		82. Sampson	
11. Buncombe		47. Hoke		83. Scotland	
12. Burke		48. Hyde		84. Stanly	
13. Cabarrus		49. Iredell		85. Stokes	
14. Caldwell		50. Jackson		86. Surry	
15. Camden		51. Johnston		87. Swain	
16. Carteret		52. Jones		88. Transylvania	
17. Caswell		53. Lee		89. Tyrrell	
18. Catawba		54. Lenoir		90. Union	
19. Chatham		55. Lincoln		91. Vance	
20. Cherokee		56. Macon		92. Wake	
21. Chowan		57. Madison		93. Warren	
22. Clay		58. Martin		94. Washington	
23. Cleveland		59. McDowell		95. Watauga	
24. Columbus		60. Mecklenburg		96. Wayne	
25. Craven		61. Mitchell		97. Wilkes	
26. Cumberland		62. Montgomery		98. Wilson	
27. Currituck		63. Moore		99. Yadkin	
28. Dare		64. Nash		100. Yancey	
29. Davidson		65. New Hanover			
30. Davie		66. Northampton	***	101. Georgia	
31. Duplin		67. Onslow		102. South Carolina	
32. Durham		68. Orange		103. Tennessee	
33. Edgecombe		69. Pamlico	417	104. Virginia	
34. Forsyth		70. Pasquotank		105. Other (specify)	
35. Franklin		71. Pender		\.l\.\.\.\.\.\.\.\.\.\.\.\.\.\.\.\.\	
36. Gaston		72. Perquimans	363 100 1000 10 10	Total Number of	2930
				Patients	



Section 4: Certification and Signature

The undersigned Chief Executive Officer or approved designee certifies the accuracy of the information contained on all pages of this form.

Signature

Print Name Rodney Skelding

Date signed

January 26, 2019

Rache, B Stell

Note: Healthcare Planning and Certificate of Need may request CPT codes for MRI procedures if further clarification is needed.

Please complete all sections of this form and return to Healthcare Planning by Friday, January 25, 2019.

- 1. Complete and sign the form
- 2. Return the form by one of two methods:
 - a. Email a scanned copy to DHSR.SMFP.Registration-Inventory@dhhs.nc.gov.
 - b. Mail the form to Trenesse Michael in Healthcare Planning, 2704 Mail Service Center, Raleigh, NC 27699-2704.

If you have questions, call Trenesse Michael in Healthcare Planning at (919) 855-3867 or email DHSR.SMFP.Registration-Inventory@dhhs.nc.gov.