



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

December 13, 2019

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

Exempt from Review – Replacement Equipment

Record #: 3152
Business Name: Alliance Healthcare Services, Inc.
Business #: 60
Project Description: Temporarily replace existing mobile MRI scanner
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 December 11, 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 GE 1.5T SIGNA Hdx (SIGNA 492) mobile MRI scanner, Serial #1KKVA482BJL226990 to temporarily replace the grandfathered GE 1.5T SIGNA HDxt mobile MRI scanner, Serial # 1S9FA482431182635 (SIGNA 451), serving Cabarrus, Guilford and Mecklenburg counties. 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,

Celia C. Inman (handwritten signature)

Celia C. Inman
Project Analyst

Martha J. Frisone (handwritten signature)

Martha J. Frisone
Chief

cc: Acute and Home Care Licensure and Certification 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
www.ncdhhs.gov/dhsr • TEL: 919-855-3873

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ALLIANCE HEALTHCARE SERVICES



December 11, 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
Temporary Replacement of Mobile MRI Scanner SIGNA 451 Serial #
1S9FA482431182635 (Grandfathered Unit)

Dear Ms. Frisone:

I am writing on behalf of my clients, Alliance Healthcare Services (Alliance), regarding the urgent need to temporarily replace mobile MRI scanner SIGNA 451 (#1S9FA482431182635). A copy of the Inventory Form for SIGNA 451 is attached. Please accept this notice of exemption to temporarily replace the above unit with SIGNA 492 GE 1.5 T MRI that is 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 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:

- 1) The existing SIGNA 451 requires repairs that are estimated to take approximately 4 to 7 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 host sites that will be served by the replacement mobile MRI scanner are:

Carolina Neuro. & Spine Assoc. 1130 North Church Street Suite 200 Greensboro, NC 27401 Guilford	Carolina Neuro. & Spine Assoc-C 110 Lake Concord Road NE Concord, NC 28025 Cabarrus	Carolina Neurosurgery & Spine Associates 225 Baldwin Ave Charlotte, NC 28204 Mecklenburg
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Compliance Documentation

Compliance with G.S. 131E-176 (22a) Replacement Equipment Definition is demonstrated in Attachment 1 which shows that the temporary replacement scanner is an existing unit owned by Alliance with a current fair market value of \$350,000.

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 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 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 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 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 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 certify 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 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 HDxt	Signa Hdx
Serial Number	1S9FA482431182635	1KKVA482BJL226990
Provider's Method of Identifying Equipment	SIGNA 451	SIGNA 492
Specify if Mobile or Fixed	Mobile	Mobile
Mobile Trailer Serial Number/VIN #	1S9FA482431182635	
Mobile Tractor Serial Number/VIN #	NA – No changes	NA – No changes
Date of Acquisition of Each Component	2006	2004
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 (2006)	\$350,000 (FMV)
Total Cost of Equipment	NA	NA
Fair Market Value of Equipment	NA	NA
Net Purchase Price of Equipment	NA	NA
Locations Where Operated Currently	Please see list	Please see list
Number Days In Use/To be Used in N.C. Per Year	Up to 365	4 to 7 days
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 492 GE 1.5T scanner to serve the host sites will be discontinued on approximately December 20, when the repair of SIGNA 451 has been completed and returned to service. At that time SIGNA 492 will be removed from North Carolina.

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,

A handwritten signature in cursive script, appearing to read "David J. French".

David 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

ALLIANCE HEALTHCARE SERVICES

December 10, 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 451

Dear Ms. Frisone,

Raleigh Orthopaedic Clinic and Alliance Healthcare Services intend to temporarily replace its existing mobile SIGNA 451 with a replacement unit, SIGNA 492

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 if you have any questions.

Sincerely,

Rodney Skelding

Rodney Skelding
Manager of Operations
Alliance Radiology
(Cell) 919-270-5751



**Registration and Inventory of Medical Equipment
Mobile Magnetic Resonance Imaging Scanners
January 2019 SIGNA 451**

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

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)

Irvine CA 92612

(City) (State) (Zip)

(800) 544-3215

(Phone Number)

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

Rodney Skelding **Manager Operations**

(Name)

(Title)

336 580-9061 **rskelding@allianceradiology-us.com**

(Phone Number) (Email)

4. Information Compiled or Prepared by: David French

(Name)

(336) 349-6250

(Phone Number)

djfrench45@gmail.com

(Email)



For DHSR Planning Use
 Only:
 ID #: _____

Section 2: Equipment and Procedures Information

Time Period for Report: 10/01/2017 – 9/30/2018 Other time period: _____

(Please make additional copies of pages of this form as needed.)

	Mobile Scanner Number _____ (One scanner per page)	
Manufacturer/Tesla	GE 1.5T	
Model Number	Signa HDxt	
Open or Closed Scanner	Closed	
Serial or I.D. Number	1S9FA482431182635 Signa 451	
Date of acquisition	Owned by Alliance	
Purchase price (if purchased)		
Certificate of Need Project ID	Grandfathered	
Certificate Holder, as listed on Certificate of Need	Alliance HealthCare Services	
If Leased or Rented, Name Owner of Equipment	NA	
	Service Site Number 1	Service Site Number 2
Service Site Information: Please include all of the information requested for each location.	Carolina Neuro. & Spine Assoc. 1130 North Church Street Suite 200 Greensboro, NC 27401 Guilford	Carolina Neuro. & Spine Assoc-C 110 Lake Concord Road NE Concord, NC 28025 Cabarrus
Inpatient Procedures*: - with Contrast or Sedation - without Contrast or Sedation	Inpatient: with: 0 w/out: 0 Total: 0	Inpatient: with: 0 w/out: 0 Total: 0
Outpatient Procedures*: - with Contrast or Sedation - without Contrast or Sedation	Outpatient: with: 564 w/out: 1138 Total: 1702	Outpatient: with: 147 w/out: 1016 Total: 1163
Total Number of Procedures	Total: 1702	Total: 1163
Put a check by the days per week, and write in the number of hours per day, the scanner is in operation.	Days and hours subject to change	Days and hours subject to change
Total number of hours in operation for report period	1702 hrs	1163 hrs

*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 greater than the total number of patients reported on the MRI Patient Origin Table on page 3 of this form.**

Name of entity that acquired the equipment (from page 1) Alliance HealthCare Services



Time Period for Report: 10/01/2016 – 9/30/2017 Other time period:

(Please make additional copies of pages of this form as needed.)

Mobile Scanner Number _____ (One scanner per page)	
Manufacturer/Tesla	GE 1.5T
Model Number	Signa HDxt
Open or Closed Scanner	Closed
Serial or I.D. Number	1S9FA482431182635 Signa 451
Date of acquisition	Owned by Alliance
Purchase price (if purchased)	
Certificate of Need Project ID	Grandfathered
Certificate Holder, as listed on Certificate of Need	Alliance HealthCare Services
If Leased or Rented, Name Owner of Equipment	NA
	Service Site Number 3
Service Site Information: Please include all of the information requested for each location.	Carolina Neurosurgery & Spine Associates 225 Baldwin Ave Charlotte, NC 28204 Mecklenburg
Inpatient Procedures*: - with Contrast or Sedation - without Contrast or Sedation Outpatient Procedures*: - with Contrast or Sedation - without Contrast or Sedation Total Number of Procedures	Inpatient: with: 0 w/out: 0 Total: 0 Outpatient: with: 88 w/out: 679 Total: 767 Total: 767
Put a check by the days per week, and write in the number of hours per day, the scanner is in operation.	Days and hours subject to change
Total number of hours in operation for report period	767 hrs

*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.**

Name of entity that acquired the equipment (from page 1) Alliance HealthCare Services



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: Carolina Neuro and Spine, (Alliance does not obtain patient origin data.)

County in which service was provided: Cabarrus, Guilford, and Mecklenburg

Patient County	Number of Patients	Patient County	Number of Patients	Patient County	Number of 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		104. Virginia	
34. Forsyth		70. Pasquotank		105. Other (specify)	
35. Franklin		71. Pender			
36. Gaston		72. Perquimans		Total Number of Patients	3632

Name of entity that acquired the equipment (from page 1) Alliance HealthCare Services



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 22, 2019**

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.