



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

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

March 29, 2019

David French
P.O. Box 2154
Reidsville, NC 27323

Exempt from Review – Replacement Equipment

Record #: 2885
Business Name: Alliance Healthcare Services Inc.
Business #: 60
Project Description: Acquire replacement equipment
Counties: Alleghany, Avery, Buncombe, Macon

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 26, 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 67 mobile MRI Scanner, Serial # 1JJV482W4WL512370, to replace the SIGNA 404 mobile MRI Scanner, Serial # 1S9FA482141182724. 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,

Ena Lightbourne
Project Analyst

Martha J. Frisone
Chief, Healthcare Planning and
Certificate of Need Section

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

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER



March 26, 2019

Martha Frisone, Chief
Healthcare Planning and Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Written Notice for Exemption from Review for Replacement Equipment,
Alliance Healthcare Services
MRI Scanner SIGNA 404 Serial Number 1S9FA482141182724

Dear Ms. Frisone:

Alliance Healthcare Services Inc. (Alliance) intends to replace its existing grandfathered MRI scanner, SIGNA 404 Serial Number 1S9FA482141182724 that was acquired in 2004. SIGNA 404 will be removed from North Carolina when its replacement is delivered.

The replacement unit, SIGNA 67 Serial Number 1JJV482W4WL512370 is a mobile MRI scanner that is owned by Alliance; this unit was acquired in 1999 and has a Fair Market Value of \$300,000.

In accordance with NCGS 131 E-184, this letter provides justification and written notice regarding the replacement equipment. Alliance Healthcare Services also provides documentation that the replacement equipment conforms to the Certificate of Need laws and Administrative rules:

G.S. 131E-176 (22a) Replacement equipment definition
G.S. 131E-184 (a) (7) Exemptions from review to provide replacement equipment
10A NCAC 14C.0303 Replacement Equipment Administrative Rules

P.O. Box 2154
Reidsville NC 27323

Overview

The existing mobile MRI scanner number SIGNA 404 Serial Number 1S9FA482141182724 was acquired in 2010 and will be replaced in North Carolina and reassigned to host sites in other states.

- 1) The MRI scanner SIGNA 404 is a grandfathered scanner in North Carolina.
- 2) The replacement SIGNA 67 has the same MRI diagnostic capabilities to serve multiple host sites and will maintain its grandfathered status.
- 3) Healthcare providers in North Carolina have demand for mobile MRI service with specific MRI imaging technology as available with SIGNA 404 and its replacement SIGNA 67.

Alliance Imaging recognizes the need to provide a high quality, cost effective, and reliable mobile MRI scanner service that is consistent with the equipment capabilities of community hospitals.

This specific MRI scanner, number SIGNA 404 Serial Number 1S9FA482141182724 that is being replaced is a grandfathered MRI scanner that has properly been reported on the attached 2019 MRI Equipment Inventory form.

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

Charles A. Cannon Mem. Hosp.
434 Hospital Drive
Linville, NC 28646

Alleghany Memorial Hospital
233 Doctors Street
Sparta, NC 28675

Duke LifePoint Harris Regional
at Franklin Med 55 Holly Springs Park Drive
Franklin, NC 28734

Margaret R Pardee Memorial Hospital
21 Turtle Creek Drive
Asheville, NC 28803

These locations have existing MRI pads and utilities to support the mobile MRI scanner that will be provided through a services agreement by Alliance. As a grandfathered mobile MRI scanner other additional existing host sites with mobile MRI pads may be served.

Compliance Documentation

Compliance with G.S. 131E-176 (22a) Replacement Equipment Definition is demonstrated in Attachment 1 which shows that the replacement MRI scanner and coach with a capital cost less than \$2,000,000.

As seen in Attachment 1, the Alliance Operations Manager documents that the replacement MRI equipment will be used for the same diagnostic purposes as the existing mobile MRI scanner.

The replacement unit SIGNA 67 Serial Number 1JJV482W4WL512370 is a mobile MRI scanner that is owned by Alliance; with a Fair Market Value of \$300,000 as seen in Attachment 2.

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

Alliance Healthcare Services will bring in a mobile MRI scanner as replacement equipment for its existing mobile MRI scanner in accordance with the following *regulatory requirements*:

10A NCAC 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 replacement equipment will also obtain MRI images. The proposed replacement mobile MRI scanner is not an extremity MRI or a dedicated breast MRI unit.

(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 scanner.

(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 sites that will utilize the replacement MRI scanner certify that the acquisition of the replacement equipment will not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months.

Included in Attachment 2 is documentation from Alliance that it will not increase charges by more than 10% to its host sites during the first twelve months of the replacement scanner's operation. Alliance Imaging expects that the projected operating expenses for the replacement MRI scanner will not increase.

(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. As seen in the table on page 5, the equipment being replaced was purchased more than three years ago.

(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. The replacement equipment, SIGNA 67, is existing equipment owned by Alliance that was purchased new more than three years ago..

(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 replacement equipment is a full featured MRI scanner. These features do not change the basic technology or result in the provision of a new health service or type of procedure.

(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 not a dedicated PET scanner, gamma camera or nuclear medicine equipment.

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
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		
Provider's Method of Identifying Equipment	SIGNA 404	SIGNA 67
Specify if Mobile or Fixed	Mobile (Grandfathered)	Mobile (Grandfathered)
Mobile Trailer Serial Number/VIN #	1S9FA482141182724	1JJV482W4WL512370
Mobile Tractor Serial Number/VIN #	NA - No changes	NA - No changes
Date of Acquisition of Each Component	2004	1999
	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	FMV = \$ 300,000
Total Cost of Equipment	NA	NA
Fair Market Value of Equipment	NA	NA
Net Purchase Price of Equipment	NA	NA
Locations Where Operated Currently	Grandfathered Unit See list	Grandfathered Unit See list
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%
Type of Procedures Currently Performed on Existing Equipment	MRI Procedures	MRI Procedures
Type of Procedures New Equipment is Capable of Performing	NA	MRI procedures

Thank you for your review and consideration of this information. Please call me at 336 349-6250 if you have any questions.

Sincerely,

A handwritten signature in cursive script, appearing to read "David French", written over a horizontal line.

David French
Consultant to Alliance Healthcare Services

Cc: Cale Arnold
Rodney Skelding

Attachments:

- 1) CON Capital Cost Form
- 2) Letter from Alliance Regarding Replacement MRI Scanner and Charges to Host Sites
- 3) 2018 MRI Inventory Form for SIGNA 404

Attachment 1. Fair Market Value



March 21, 2019

Cathy Weinhold
Asset Manager
Alliance HealthCare Services

RE: Fair Market Value of Mobile MRI

Dear Ms. Weinhold:

As requested, the following is the estimated "Fair Market Value" for the imaging equipment described below:

1999 GE 1.5 Tesla 8 CH HDxt MRI System Housed in an Ellis & Watts Trailer

Fair Market Value: \$275,000 to \$300,000

Market value is based on the system and trailer as used and to be in good to very good condition.

Please contact me if I can be of further assistance.

Sincerely,

A handwritten signature in black ink that reads 'David J. French'.

David J French
President

P.O. Box 2154
Reidsville NC 27323

Attachment 2. Compliance Letter 10A NCAC 14C.0303

ALLIANCE HEALTHCARE SERVICES

March 21, 2019

Ms. Martha Frisone, Chief
Healthcare Planning and Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Alliance HealthCare Replacement MRI Equipment,
SIGNA 404 Serial Number 1S9FA482141182724

Dear Ms. Frisone,

Alliance Healthcare Services (Alliance) intends to replace its existing grandfathered MRI scanner, SIGNA 404 Serial Number 1S9FA482141182724. The MRI replacement scanner serial number SIGNA 67 Serial Number 1JJV482W4WL512370 is a mobile MRI scanner that is owned by Alliance.

The replacement MRI scanner SIGNA 67 will be used for the same diagnostic purposes as the existing MRI unit.

In accordance with 10A NCAC 14C.0303 Replacement Equipment Administrative Rules, we agree that the replacement MRI equipment will not result in more than a 10 percent increase in charges to the host site within the first twelve months after the equipment is acquired.

Thank you for your consideration. Please call me at if you have any questions.

Sincerely,



Rodney Skelding
Manager Operations
rskelding@allianceraadiology-us.com

Attachment 3. SIGNA 404 2019 Mobile MRI Inventory Form
(Please see attached separate pdf file)



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 Horizon ES LX	
Open or Closed Scanner	Closed	
Serial or I.D. Number	1S9FA482141182724 Signa 404	
Date of acquisition	08/2004	
Purchase price (if purchased)	Previously submitted to DHSR	
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.	Charles A. Cannon Mem. Hosp. 434 Hospital Drive Linville, NC 28646 Avery	Alleghany Memorial Hospital 233 Doctors Street Sparta, NC 28675 Alleghany
Inpatient Procedures*: - with Contrast or Sedation - without Contrast or Sedation	Inpatient: with: 2 w/out: 8 Total: 10	Inpatient: with: 1 w/out: 0 Total: 1
Outpatient Procedures*: - with Contrast or Sedation - without Contrast or Sedation	Outpatient: with: 69 w/out: 287 Total: 356	Outpatient: with: 15 w/out: 85 Total: 100
Total Number of Procedures	Total: 366	Total: 101
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	320 hrs	85 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 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 Horizon ES LX	
Open or Closed Scanner	Closed	
Serial or I.D. Number	1S9FA482141182724 Signa 404	
Date of acquisition	08/2004	
Purchase price (if purchased)	Previously submitted to DHSR	
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 Number 4
Service Site Information: Please include all of the information requested for each location.	Duke LifePoint Harris Regional at Franklin Med 55 Holly Springs Park Drive Franklin, NC 28734 Macon	Margaret R Pardee Memorial Hosp 21 Turtle Creek Drive Asheville, NC 28803 Buncombe
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: 20 w/out: 299 Total: 319	Outpatient: with: 15 w/out: 353 Total: 368
Total Number of Procedures	Total: 319	Total: 368
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	280 hrs	310 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: Cannon Mem., Alleghany Mem., Harris Regional, Pardee Hosp.

County in which service was provided: Avery, Alleghany, Jackson, Henderson (Alliance does not obtain patient origin data)

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	1154

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 24, 2018**

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 DHHS.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 DHHS.SMFP.Registration-Inventory@dhhs.nc.gov.