



NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

September 10, 2019

David French, Consultant to Alliance Healthcare Services
P.O. Box 2154
Reidsville NC 27023

Exempt from Review – Replacement Equipment

Record #: 3038
Business Name: Alliance Healthcare Services, Inc.
Business #: 60
Project Description: Replace an existing mobile MRI scanner
County: Wake and Durham

Dear Mr. French:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of August 16, 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 mobile MRI scanner (AREA SMR) on a temporary basis, and another mobile MRI scanner (FL# 400-598383; AREA 16) to replace the existing mobile MRI scanner (SIGNA 403), on a permanent basis. This determination is based on your representations that the existing unit (SIGNA 403) 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.

Moreover, you need to contact the Agency’s Acute and Home Care Licensure and Certification Section to determine if they have any requirements for development of the proposed project.

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,

[Handwritten signature of Michael J. McKillip]

Michael J. McKillip
Project Analyst

[Handwritten signature of Martha J. Frisone]

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
https://info.ncdhhs.gov/dhstr/ • TEL: 919-855-3873

ALLIANCE HEALTHCARE SERVICES



August 16, 2019

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

RE: Alliance Healthcare Services – Reassignment of Grandfathered MRI Scanners and
Written Notice for Exemption from CON Review for Replacement of Mobile MRI Scanner
(SIGNA 403 to be Replaced)

Dear Ms. Frisone:

Alliance HealthCare Services (Alliance) requests written confirmation from the Agency that the temporary replacement and later permanent replacement of a grandfathered MRI scanner is exempt from CON review. The grandfathered MRI scanner SIGNA 403 is the unit to be removed from North Carolina. All of the Alliance MRI scanners that are involved in the replacement and reassignment of host sites are grandfathered units. The equipment replacement exemption is proposed to occur in addition to the reassignment of host sites to other Alliance grandfathered MRI scanners.

1. AERA Shared Medical Rental (SMR) is the temporary replacement MRI scanner to be brought into North Carolina to serve UNC Hospitals Hillsborough Campus at 430 Waterstone Drive Hillsborough, NC 27278. Alliance will be leasing the AERA SMR from Shared Medical Services for several months until the permanent replacement MRI is available. Then, the AERA SMR unit will be removed from North Carolina.
2. AERA 16 is the permanent replacement MRI scanner to be brought into North Carolina to serve UNC Hospitals Hillsborough Campus at 430 Waterstone Drive, Hillsborough, NC 27278. This unit is owned by Alliance and will become available in several months.
3. The grandfathered MRI scanners to be reassigned to existing host sites are listed as follows:
 - a. ESP 66 is the current temporary replacement grandfathered MRI that is located at UNC Hillsborough. ESP 66 will be reassigned to serve the route currently served by SIGNA 294 at the following host sites:

UNC Burlington Imaging and Breast Center
1225 Huffman Mill Rd # 101, Burlington, NC 27215

Harris Regional Hospital
55 Holly Springs Park Dr. Franklin, NC 28734

Southeastern Sports Medicine
21 Turtle Creek Dr. Asheville NC 28803

Watauga Regional Medical Center
336 Deerfield Rd, Boone, NC 28607

- b. SIGNA 294 is a grandfathered MRI that will be reassigned to serve Duke Regional Hospital located at 3643 N. Roxboro Road, Durham NC 27704.
- c. SIGNA 403 is a grandfathered MRI scanner that is currently providing services to Duke Regional Hospital.

4. The grandfathered MRI scanner SIGNA 403 is the unit to be removed from North Carolina.

Alliance seeks to obtain the replacement exemption for SIGNA 403 to upgrade the MRI equipment capabilities and to make changes to the host sites that are served by grandfathered MRI scanners. The 2019 Equipment Inventory Form for SIGNA 403 is attached.

The overall result is that the leased unit AERA SMR will temporarily be brought into NC. SIGNA 403 will be removed from North Carolina. When the permanent replacement MRI scanner, AERA 16 (owned by Alliance) becomes available, AERA SMR will be removed from North Carolina. When this occurs Alliance will provide timely written notice to the Agency.

The AERA SMR MRI scanner (temporary replacement rental unit), the Vehicle Identification Number (VIN #) 1S9AC4825KS834577 has a fair market value of \$1.5 million for the coach/equipment. Please see the attached equipment comparison form

The AERA 16 MRI scanner (permanent replacement), VIN # 1S9AC4828HS834548 has a fair market value of \$1.5 million for the coach/equipment. Please see the attached equipment comparison form

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 a leased unit with a fair market value of \$1,500,000.

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 Healthcare Services plans to use a leased 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

Both the temporary and permanent replacement MRI scanners are 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.

(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. This notice involves a temporary replacement MRI scanner.

(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

The temporary replacement AERA SMR will be used to serve existing host sites with no increases in charges to the facilities. This unit will be removed from North Carolina when the permanent replacement, AERA 16 (1S9AC4825KS834577), is available to serve North Carolina host sites in approximately 5 months.

The permanent replacement AERA 16, will be used to serve existing host sites with no increases in charges to the facilities.

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
P.O. Box 2154
Reidsville, NC 27023
djfrench45@gmail.com

Cc: Aaron Dunn
Manager of Operations
Alliance Healthcare Services

ALLIANCE HEALTHCARE SERVICES

August 14, 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 Grandfathered MRI
Bring Leased MRI AERA 16 into North Carolina
Remove SIGNA 403 from North Carolina

Dear Ms. Frisone,

Alliance intends to replace its existing mobile MRI SIGNA 403, serial number 1S9FA482X41182706 with a temporary replacement unit, Siemens AERA 16 Siemens FL# 400-555044. The AERA 16 will be leased from Shared Medical Services.

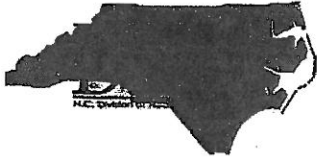
In accordance with 10A NCAC 14C.030 Replacement Equipment Administrative Rules, Alliance agrees that the replacement MRI scanner equipment will not result in more than a 10 percent increase in expense or charges to any MRI host sites. This is a temporary replacement and no changes to the current agreements or charges will result.

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

Sincerely,

Aaron Dunn

Aaron Dunn RT(R)(MR)
Manager of Operations
Alliance Radiology
(Cell) 919-270-5751



**Registration and Inventory of Medical Equipment
Mobile Magnetic Resonance Imaging Scanners
January 2019 SIGNA 403**

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:

Aaron Dunn Manager Operations

(Name)

(Title)

(919) 474-3123

(Phone Number)

adunn@allianceradiology-us.com

(Email)

4. Information Compiled or Prepared by: David French

(Name)

(336) 349-6250

(Phone Number)

difrench45@gmail.com

(Email)

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	TEMPORARY REPLACEMENT	PERMANENT 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	GE Signa	Magnetom	Magnetom
Serial Number	SIGNA 403	AREA SMR	FL# 400-598383
Provider's Method of Identifying Equipment	SIGNA 403	AREA SMR	AREA 16
Specify if Mobile or Fixed	Mobile	Mobile	Mobile
Mobile Trailer Serial Number/VIN #	1S9FA482X41182706	1S9AC4825KS834577	1S9AC4828HS834548
Mobile Tractor Serial Number/VIN #	NA - No changes	NA No changes	NA - No changes
Date of Acquisition of Each Component	2004	Short term lease	2017
Hold Title or Lease	Holds Title	Short term lease	Owned by Alliance
Specify if Equipment Was/Is New or Used When Acquired	New	Used	Used
Total Capital Cost of Project (no construction involved)	NA	Short Term Rental from Shared Medical	Owned by Alliance
Total Cost of Equipment	NA	NA	NA
Fair Market Value of Equipment	NA	\$1,500,000	\$1,500,000
Net Purchase Price of Equipment	NA	NA	NA
Locations Where Operated Currently	Please see list	Please see list	Please see list
Number Days In Use/To be Used in N.C. Per Year	Up to 365	5 months temporary (or less)	Up to 365
Percent of Change in Patient Charges (by Procedure)	NA	0%	0%
Percent of Change in Per Procedure Operating Expenses (by Procedure)	NA	0%	0%
Type of Procedures Currently Performed on Existing Equipment	MRI Procedures	MRI Procedures	MRI Procedures
Type of Procedures New Equipment is Capable of Performing	NA	MRI Procedures	MRI procedures



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	1S9FA482X41182706 Signa 403	
Date of acquisition		
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.	Duke Health Raleigh Hospital 3400 Executive Drive Raleigh NC 27609 Wake	Duke Raleigh Hospital 3643 N Roxboro Rd Durham, NC 27704 Durham
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: 249 w/out: 369 Total: 618	Outpatient: with: 757 w/out: 1212 Total: 1969
Total Number of Procedures	Total: 618	Total: 1969
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	618 hrs	1969 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



	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	1S9FA482X41182706 Signa 403	
Date of acquisition		
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 Information: Please include all of the information requested for each location.	Raleigh Orthopaedic Clinic 3001 Edward Mills Raleigh, NC 27612 Wake	
Inpatient Procedures*: - with Contrast or Sedation - without Contrast or Sedation Outpatient Procedures*: - with Contrast or Sedation - without Contrast or Sedation	Inpatient: with: 0 w/out: 0 Total: 0 Outpatient: with: 0 w/out: 160 Total: 160 Total: 160	
Total Number of Procedures	Total: 160	
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	160 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: Duke Raleigh Hospital (Wake and Durham) and Raleigh Orthopaedic Clinic (Alliance does not obtain patient origin data.)

County in which service was provided: Wake and Durham

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	2727

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 Aaron Dunn

Print Name Aaron Dunn

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.

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