

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

October 8, 2021

David French djfrench45@gmail.com

Exempt from Review – Replacement EquipmentRecord #: 3704October 7, 2021Date of Request:October 7, 2021Business Name:Alliance Healthcare Services, IncBusiness #:60Project Description:Temporarily replace existing mobile MRI scannerCounty:Cabarrus, Guilford and Mecklenburg

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 mobile GE SIGNA 273 mobile MRI scanner to temporarily replace the mobile GE SIGNA 451 mobile MRI scanner. This determination is based on your representations that the mobile MRI scanner GE SIGNA 273 will be brought into North Carolina only for the duration of the repairs to GE SIGNA 451, will be removed from North Carolina once the repairs are complete, 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,

Gregory F. Yakaboski Project Analyst

Micheala Mitchell

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

October 7, 2021

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 SIGNA 451

Dear Ms. Mitchell:

I am writing on behalf of my client, Alliance Healthcare Services, regarding the urgent need to temporarily replace mobile MRI scanner SIGNA 451 (Legacy Unit). A copy of the SIGNA 451 2021 Mobile MRI Inventory Form is attached. Please accept this notice of exemption to temporarily replace the above unit with SIGNA 273, which is an existing mobile MRI scanner owned by Alliance and will be utilized as an interim temporary unit at this location.

When SIGNA 273 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:

- The existing Signa 451 requires repairs that 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:

Carolina Neurosurgery and Spine Associates 110 Lake Concord Rd NE Concord, NC 28025 (Cabarrus) Carolina Neurosurgery and Spine Associates 130 N. Church St. Greensboro, NC 27401 (Guilford)

Carolina Neurosurgery and Spine Associates 225 Baldwin Ave Charlotte, NC 28204 (Mecklenburg)

### **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 SIGNA 451 meets the definition of "currently in use" because the MRI scanner currently serves Carolina Neurosurgery and Spine office in Concord, Greensboro and Charlotte.

(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.

The 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 to be temporarily replaced was acquired in 2004. The temporary replacement unit will be removed from North Carolina.

### 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	SIGNA
Serial Number	1S9FA482431182635	1S9FA482X31182591
Provider's Method of Identifying Equipment	SIGNA 451	SIGNA 273
Specify if Mobile or Fixed	Mobile	Mobile
Mobile Trailer Serial Number/VIN #	1S9FA482431182635	1S9FA482X31182591
Mobile Tractor Serial Number/VIN #	NA – No changes	NA – No changes
Date of Acquisition of Each Component	2004	2006
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	\$400,000 FMV 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	Carolina Neurosurgery and Spine Concord, Greensboro and Charlotte	Carolina Neurosurgery and Spine Concord, Greensboro and Charlotte
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 Signa 273 will be discontinued in approximately 3 weeks when the repair of Signa 451 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,

Mand Jamh

David J. 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



### **Registration and Inventory of Medical Equipment**

Mobile Magnetic Resonance Imaging Scanners January 2021

### 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 29, 2021**.

- 1. Submit one completed Registration and Inventory form per MRI scanner.
- 2. Complete and sign the form
- 3. Return the form by one of two methods:
  - a. Email a scanned copy to <u>DHSR.SMFP.Registration-Inventory@dhhs.nc.gov</u>.
  - 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 Ave.

(Street and Number)

<b>Irvine</b>	, CA	92612
(City)	(State)	(Zip)

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

(800) 544-3215 (Phone Number)

	Manager Operations		
(Name)	(Title)		
Street and Number)	(City	y) (St	tate)
(336) 580-9061	rskelding@allia	nceradiology-us.com	
(Phone Number)		(Email)	
Information compiled	or prepared by: <b>David French</b>		
	(Name)		
( <u>336)</u> 349-6250	<u>djfrench45@gmail</u>	<u>.com</u>	
(Phone Number)	(Em	a:1)	



### Section 2: Equipment and Procedures Information

Reporting Period:  $\square$  10/01/2019 – 9/30/2020  $\square$  Other time period: \_\_\_\_\_

## Do not make extra copies of this page if the entity has multiple MRIs. Submit a complete, separate R&I form for each scanner.

(Please make additional copies of this page as needed for additional Service Sites.)

For DHSR Planning Use Only:		
Manufacturer/Tesla	GE / 1.5 T	
Model number	SIGNA HDxt	
Open or closed (including open bore) scanner	Open  Closed	
Serial or I.D. Number	1S9FA482431182635 SIGNA 451	
Date of acquisition	2004	
Purchase price (if purchased)		
Certificate of Need Project ID (or Legacy)	Egacy Legacy	
Certificate holder, as listed on Certificate of Need	Alliance Healthcare Services Inc.	
If equipment went to only 1 site, is it permanently parked at that site?	Parked 🔀 Not Parked	
	Service Site Number 1	
Service Site Information: Please include <b>all</b> the information requested for each location.	Service Site       Carolina Neurosurgery & Spine Assoc.         Address       110 Lake Concord Road NE         City:       Concord, NC Zip       28025 County         Cabarrus	
Procedures*:	Inpatient: Outpatient:	
- with Contrast or Sedation	with: <u>0</u> with: <u>130</u>	
- without Contrast/ Sedation	w/out: <u>959</u>	
-Total inpatient/outpatient	Total: <u>0</u> Total: <u>1089</u>	
Total Number of Procedures	Total: <u>1089</u>	
For each day of the week, enter the <b><u>number of hours</u></b> the scanner is in operation.	Sunday       Thursday         Monday       Friday         Schedule subject to change         Tuesday       Saturday         Wednesday	
Total number of hours in operation for reporting period	900 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) <u>Alliance Healthcare Services Inc.</u>



### Section 2: Equipment and Procedures Information

Reporting Period:  $\square$  10/01/2019 – 9/30/2020  $\square$  Other time period: \_\_\_\_\_

## Do not make extra copies of this page if the entity has multiple MRIs. Submit a complete, separate R&I form for each scanner.

(Please make additional copies of this page as needed for additional Service Sites.)

For DHSR Planning Use Only:		
Manufacturer/Tesla	GE / 1.5 T	
Model number	SIGNA HDxt	
Open or closed (including open bore) scanner	Open  Closed	
Serial or I.D. Number	1S9FA482431182635 SIGNA 451	
Date of acquisition	2004	
Purchase price (if purchased)		
Certificate of Need Project ID (or Legacy)	Egacy Legacy	
Certificate holder, as listed on Certificate of Need	Alliance Healthcare Services Inc.	
If equipment went to only 1 site, is it permanently parked at that site?	Parked  Not Parked	
	Service Site Number 2	
Service Site Information:	Service Site Carolina Neurosurgery & Spine Assoc.	
Please include <b>all</b> the	Address 130 North Church Street Suite 200	
information requested for each location.	City: Greensboro, NC Zip 27401 County Guilford	
Procedures*:	Inpatient: Outpatient:	
- with Contrast or Sedation	with: <u>0</u> with: <u>486</u>	
- without Contrast/ Sedation	w/out: <u>0</u> w/out: <u>1009</u>	
-Total inpatient/outpatient	Total: <u>0</u> Total: <u>1495</u>	
Total Number of Procedures	Total: <u>1495</u>	
For each day of the week, enter the <b><u>number of hours</u></b> the scanner is in operation.	Sunday       Thursday         Monday       Friday       Schedule subject to change         Tuesday       Saturday         Wednesday       Saturday	
Total number of hours in operation for reporting period	1160 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) <u>Alliance Healthcare Services Inc.</u>



### Section 2: Equipment and Procedures Information

Reporting Period:  $\square$  10/01/2019 – 9/30/2020  $\square$  Other time period: \_\_\_\_\_

## Do not make extra copies of this page if the entity has multiple MRIs. Submit a complete, separate R&I form for each scanner.

(Please make additional copies of this page as needed for additional Service Sites.)

For DHSR Planning Use Only:	
Manufacturer/Tesla	GE / 1.5 T
Model number	SIGNA HDxt
Open or closed (including open bore) scanner	Open  Closed
Serial or I.D. Number	1S9FA482431182635 SIGNA 451
Date of acquisition	2004
Purchase price (if purchased)	
Certificate of Need Project ID (or Legacy)	E Legacy
Certificate holder, as listed on Certificate of Need	Alliance Healthcare Services Inc.
If equipment went to only 1 site, is it permanently parked at that site?	Parked 🗵 Not Parked
	Service Site Number 3
Service Site Information: Please include <b>all</b> the information requested for each location.	Service Site <u>Carolina Neurosurgery &amp; Spine</u> Address <u>225 Baldwin Ave</u> City: <u>Charlotte, NC</u> Zip <u>28204</u> County <u>Mecklenburg</u>
Procedures*:	Inpatient: Outpatient:
- with Contrast or Sedation	with: <u>0</u> with: <u>169</u>
- without Contrast/ Sedation -Total inpatient/outpatient	w/out: <u>0</u> w/out: <u>1089</u> Total: <u>0</u> Total: <u>1254</u>
Total Number of Procedures	Total: <u>1254</u>
For each day of the week, enter the <b><u>number of hours</u></b> the scanner is in operation.	Sunday       Thursday         Monday       Friday       Schedule subject to change         Tuesday       Saturday         Wednesday       Saturday
Total number of hours in operation for reporting period	1040 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) <u>Alliance Healthcare Services Inc.</u>



### 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 Number: \_\_\_\_\_

### Service Site Name: <u>Alliance does not collect patient origin data.</u>

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

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		104. Virginia	
34. Forsyth		70. Pasquotank		105. Other (specify)	
35. Franklin		71. Pender			
36. Gaston		72. Perquimans		Total Number of 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	Richer B. Dello
Print Name	<b>Rodney Skelding</b>
Date signed	<u>January 15, 2022</u>

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



### Section 5: COVID-19 Addendum to Registration and Inventory of Medical Equipment

This special section of the 2021 Registration and Inventory Forms seeks information regarding the facility's experience during the COVID-19 pandemic. This data will assist Healthcare Planning in projecting the need for equipment in the 2022 State Medical Facilities Plan.

### The addendum is not asking for procedures performed on patients diagnosed with or suspected of having COVID-19. Rather, it covers all patients seen at each site entered above between April 1, 2020 through September 30, 2020.

(Please make add	litional copies of this pa	ge as needed for additional Service Si	ites.)
Manufacturer/Tesla	GE / 1.5 T		
Model number	SIGNA HDxt		
Serial or I.D. Number	1S9FA48243118263	35 SIGNA 451	
Certificate of Need Project ID (or Legacy)		X	Legacy
		Service Site Number 1	
Service Site Information: Please include <b>all</b> the information requested for each location.	Address 110 Lake Con	Neurosurgery & Spine Assoc. cord Road NE <u>28025 County Cabarrus</u>	
Procedures*: - with Contrast or Sedation - without Contrast/ Sedation -Total inpatient/outpatient	Inpatient:with:0w/out:0Total:0	<b>Outpatient</b> with: w/out: Total:	<u>53</u> 447
Total Number of Procedures	Total: 500		



### Section 5: COVID-19 Addendum to Registration and Inventory of Medical Equipment

This special section of the 2021 Registration and Inventory Forms seeks information regarding the facility's experience during the COVID-19 pandemic. This data will assist Healthcare Planning in projecting the need for equipment in the 2022 State Medical Facilities Plan.

# The addendum is not asking for procedures performed on patients diagnosed with or suspected of having COVID-19. Rather, it covers <u>all</u> patients seen at each site entered above between <u>April 1</u>, <u>2020 through September 30, 2020</u>.

(Please make add	litional copies of this page	e as needed for additional Service S	ites.)
Manufacturer/Tesla	GE / 1.5 T		
Model number	SIGNA HDxt		
Serial or I.D. Number	1S9FA482431182635	SIGNA 451	
Certificate of Need Project ID (or Legacy)		X	Legacy
		Service Site Number 2	
Service Site Information: Please include <b>all</b> the information requested for each location.	Address 130 North Chu	eurosurgery & Spine Assoc. urch Street Suite 200 Zip 27401County Guilford	
Procedures*: - with Contrast or Sedation - without Contrast/ Sedation -Total inpatient/outpatient	Inpatient: with: <u>0</u> w/out: <u>0</u> Total: <u>0</u>	<b>Outpatient</b> with: w/out: Total:	<u>256</u> <u>544</u>
Total Number of Procedures	Total: <u>800</u>		



### Section 5: COVID-19 Addendum to Registration and Inventory of Medical Equipment

This special section of the 2021 Registration and Inventory Forms seeks information regarding the facility's experience during the COVID-19 pandemic. This data will assist Healthcare Planning in projecting the need for equipment in the 2022 State Medical Facilities Plan.

# The addendum is not asking for procedures performed on patients diagnosed with or suspected of having COVID-19. Rather, it covers <u>all</u> patients seen at each site entered above between <u>April 1</u>, <u>2020 through September 30, 2020</u>.

Manufacturer/Tesla	GE / 1.5 T	s needed for additional Service S	
Model number	SIGNA HDxt		
Serial or I.D. Number	1S9FA482431182635	SIGNA 451	
Certificate of Need Project ID (or Legacy)		X	Legacy
		Service Site Number 3	
Service Site Information: Please include <b>all</b> the information requested for each location.	Service Site <u>Carolina Ne</u> Address <u>225 Baldwin Ave</u> City: <u>Charlotte, NC</u> Zip		
Procedures*: - with Contrast or Sedation - without Contrast/ Sedation -Total inpatient/outpatient	Inpatient:with: <u>0</u> w/out: <u>0</u> Total: <u>0</u>	<b>Outpatient</b> with: w/out: Total:	<u>86</u> <u>484</u>
Fotal Number of Procedures	Total: <u>570</u>		



<u>AUTHENTICATING SIGNATURE</u>: The undersigned submits the COVID-19 Addendum as part of the 2021 Registration and Inventory of Medical Equipment and certifies the accuracy of this information.

Signature	Produe B. Stell
Print Name	<b>Rodney Skelding</b>
Date signed	January 15, 2022

Please complete all sections of this form and return to Healthcare Planning by Friday, January 29, 2021.

- 1. Complete and sign the form
- 2. Return the form by one of two methods:
  - a. Email a scanned copy to <u>DHSR.SMFP.Registration-Inventory@dhhs.nc.gov</u>.
  - 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 <u>DHSR.SMFP.Registration-Inventory@dhhs.nc.gov</u>.