

ROY COOPER • Governor

MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

July 22, 2020

Mr. David French djfrench45@gmail.com

Exempt from Review - Replacement Equipment

Record #: 3320

Business Name: Alliance Healthcare Services

Business #: 60

Project Description: Temporarily replace mobile MRI scanner at Piedmont Healthcare Mooresville

Imaging

County: Iredell

Dear Mr. French:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter dated July 16, 2020, 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 1.5T Excite 269 mobile MRI scanner to replace the SIGNA 1.5T Horizon 413 mobile MRI scanner. This determination is based on your representations that once the existing MRI scanner is repaired, the temporary replacement scanner 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,

Misty L. Piekaar-McWilliams

Martha J. Frisone

Project Analyst

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/dhsr/ • TeL: 919-855-3873

ALLIANCE HEALTHCARE SERVICES

July 16, 2020

Ms. Martha Frisone, Chief Health Care 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 413 Serial # 1S9FA482451182783 (grandfathered unit), located in Iredell County

Dear Ms. Frisone:

Alliance Healthcare Services (Alliance) has an urgent need to temporarily replace mobile MRI scanner Signa 413 Serial # 1S9FA482451182783 (grandfathered unit). This MRI scanner is currently utilized at Piedmont Healthcare located at 128 Medical Park Dr. Suite 102 Mooresville, NC. This MRI scanner has been properly reported in the 2020 MRI Inventory Forms to DHSR Healthcare Planning.

Please accept this notice of exemption to temporarily replace the above unit with SIGNA 269 Serial # 1KKVA48292L208014. This replacement MRI unit is already owned by Alliance. When this unit (SIGNA 269) is no longer needed to serve as a temporary replacement for SIGNA 413 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 and 10A NCAC 14C.0303 Replacement Equipment Administrative Rules.

Overview

The existing mobile MRI scanner requires temporary replacement for several reasons:

- 1) The existing SIGNA 413 urgently requires repairs.
- 2) Service to the existing host site 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 site that will be served by the replacement mobile MRI scanner is:

Piedmont Healthcare 128 Medical Park Dr. Mooresville, NC 28117

Iredell County

Compliance Documentation

Compliance with G.S. 131E-176 (22a) Replacement Equipment Definition is demonstrated because the temporary replacement MRI scanner has a current fair market value of \$450,000.

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 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. Following completion of the repairs 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 Horizon | SIGNA Excite |
| Serial Number | 1S9FA482451182783 | 1KKVA48292L208014 |
| Provider's Method of Identifying Equipment | SIGNA 413 | SIGNA 269 |
| Specify if Mobile or Fixed | Mobile (parked) | Mobile |
| Mobile Trailer Serial Number/VIN # | 1S9FA482451182783 | 1KKVA48292L208014 |
| Mobile Tractor Serial Number/VIN # | NA – No changes | NA – No changes |
| Date of Acquisition of Each Component | 2006 | 2003 |
| 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 | NA |
| Total Cost of Equipment | NA | NA |
| Fair Market Value of Equipment | NA | \$450,000 |
| Net Purchase Price of Equipment | NA | NA |
| Locations Where Operated Currently | Piedmont Healthcare | Piedmont Healthcare |
| Number Days In Use/To be Used in N.C. Per Year | Up to 365 | Temporary |
| Percent of Change in Patient Charges (by Procedure) | NA | 0% |
| Percent of Change in Per Procedure Operating Expenses (by | NA | 0% |
| Procedure) | | |
| 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 unit to serve the host sites will be discontinued when the repair of SIGNA 413 has been completed and the scanner has been returned to service.

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

Sincerely,

David French

Consultant to Alliance Healthcare Services

Sand J Annh

P.O. Box 2154

Reidsville, NC 27023

djfrench45@gmail.com

Cc: Jennifer Freeman and Tina Hinshaw

Alliance Radiology

Alliance Healthcare Services

ALLIANCE HEALTHCARE SERVICES

July 16, 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 SIGNA 413 Serial 1S9FA482451182783 (grandfathered unit)

Dear Ms. Frisone,

Alliance Healthcare Services intends to temporarily replace its existing mobile MRI Serial # 1S9FA482X31182591 (grandfathered unit) with a replacement unit SIGNA 269.

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 if you have any questions.

Sincerely,

Jennifer Freeman

Jennifer Freeman Manager of Operations Alliance Radiology 704-957-9900





Fair Market Valuation

Unit Signa 269

Description: 16 CH Manufacturer: GE

Model: 1.5T Signa HDxt

Date of Manufacture: 2003

Software Version: 23.0

Trailer Manufacturer: Ellis & Watts
Trailer VIN: 1KKVA48292L208014

Fair Market Valuation for system: \$350,000-\$450,000

The Fair Market Value represented is what Block Imaging considers the median range for an "in-place" asset provided the information presented. Other factors must be considered in valuing what the unit is worth to Alliance Healthcare or via orderly liquidation. The replacement value of this unit would include the following items not accounted for in this FMV – site preparation, delivery, installation and service agreements.

Prepared by Block Imaging International 03/04/2020.

From: <u>David French</u>

To: Waller, Martha K; Flores, Disraeliza

Cc: <u>Tina Hinshaw; Rodney Skelding; Jennifer Freeman</u>

Subject: [External] Alliance Temporary Replacement for SIGNA 413 (Iredell County)

Date: Thursday, July 16, 2020 12:11:46 PM

Attachments: Alliance Temporary Replacement SIGA 413 7 16 2020.pdf

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to report.spam@nc.gov

Good afternoon,

Please see the attached temporary replacement exemption for Alliance MRI SIGNA 413.

Thanks

David French 336 432-8308

From: <u>David French</u>
To: <u>Piekaar, Misty L</u>

Subject: [External] Re: Administrative Determination Clarification

Date: Friday, July 17, 2020 10:42:02 AM

Attachments: SIGNA 413 grandfathered mrimobile-2020.pdf

Request for Piedmont HealthCare Relocation 5 31 18 copy.pdf 2627 Iredell Piedmont HealthCare PA 031129 No Review.pdf Piedmont Healthcare Alliance SIGNAS 456 Fixed MRI 2020.pdf

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Good morning,

Good to meet you and I am glad to provide additional information.

The Alliance MRI scanner that is utilized at Piedmont Healthcare in Mooresville is a grandfathered MRI scanner (MRI equipment that was in use in North Carolina prior to CON regulations for MRI). This MRI scanner can be relocated but as s a grandfathered unit it is not required to move to serve two sites per week. According to my records, this grandfathered MRI scanner would be assigned to FID # 001325 (Alliance Imaging Inc. Mobile MRI Diagnostic Program) along with other grandfathered MRIowned by Alliance. Attached is a copy of the 2020 MRI inventory Form for SIGNA 413.

Also attached are documents that relate to the CON-approved fixed MRI (CON F-6957-03, FID # 031129) that is operated by Alliance and Piedmont Healthcare in Statesville. This is a fixed MRI scanner (CON that is located at 619 Sullivan Rd in Statesville, However, this MRI is not located within the urgent care facility. As seen in the attached, the fixed MRI scanner / diagnostic center has obtained a no review letter to allow relocation.

I hope this information helps. Have a great weekend.

David French 336 432-8308

On Fri, Jul 17, 2020 at 9:43 AM Piekaar, Misty L < Misty. Piekaar@dhhs.nc.gov > wrote:

David-

I don't believe we have been introduced but my name is Misty and I was assigned to your administrative determination request (MRI replacement scanner). In looking at our database we had Piedmont Healthcare listed with a Statesville, NC address. With further research, it looks like there are multiple Piedmont Healthcare locations including the Piedmont Healthcare Mooresville Imaging location you referenced in your request. Can you provide me with a FID # for Piedmont Healthcare Mooresville Imaging (the site you referenced in your exemption) so I may ensure our database has correct information and that I am not entering in excessive information if I enter a new record. I did not see the FID number in your request and my apologies in advance, if I missed it, if it was listed.

Lastly, our database showed the Piedmont Healthcare entry (which looks to be called Piedmont Healthcare Statesville Urgent Care) with an address of 619 Sullivan Road, Statesville NC. From a Google maps search, this facility looks to be called Piedmont

Healthcare Statesville Urgent Care. Can you confirm this is the correct name of the facility located at 619 Sullivan road and not just Piedmont Healthcare?

Once I have the following information, I can proceed. Thank you and I look forward working with you!

Misty L. Piekaar-McWilliams, JD

Certificate of Need Project Analyst

Division of Health Service Regulation, Healthcare Planning and Certificate of Need

NC Department of Health and Human Services

Help protect your family and neighbors from COVID-19.

Know the 3 Ws. Wear. Wait. Wash.

#StayStrongNC and get the latest at nc.gov/covid19.

Office: 919-855-3883

Misty.Piekaar@dhhs.nc.gov

809 Ruggles Drive, Edgerton Building

2704 Mail Service Center

Raleigh, NC 27699-2704

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Registration and Inventory of Medical Equipment

Fixed Magnetic Resonance Imaging Scanners
January 2020

Instructions

This is the legally required "Registration and Inventory of Medical Equipment" (G.S. 131E-177) for fixed magnetic resonance imaging (MRI) scanners. Please complete all sections of this form and return to Healthcare Planning by **Friday**, **January 31**, **2020**.

- 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 <u>DHSR.SMFP.Registration-Inventory@dhhs.nc.gov</u>.

Note: Fixed equipment operated in a facility licensed under a hospital should be reported on that hospital's license renewal application, and not duplicated on this form.

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 (Lessor) and Piedmont HealthCare, P.A. (Lessee) (Legal Name)

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

Alliance HealthCare 18201 Von Karman #600 Irvine CA 92612 (800) 544-3215 Piedmont HealthCare 650 Signal Hill Drive Extension Statesville NC 28625 (704) 873-4277

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

| Gregory S. Guin | Chief Financial Officer Pi | <u>edmont Healthcare, P.A.</u> | |
|---|----------------------------|--------------------------------|--|
| (Name) | *** | (Title) | |
| 650 Signal Hill Drive Extension | Statesville | NC 28625 | |
| (Street and Number) | (City) | (State) (Zip) | |
| (704) 873-4277 greg.gu | in@piedmonthealthcare.com | | |
| (Phone Number) | | | |
| 4. Information compiled or prepared by: | - ' | | |
| (Name) | | | |

(Name)

(704) 873-4277

(Phone Number)

(Pame)

(Pame)

(Rame)

(Rame)

(Rame)

(Pame)

(Email)



Section 2: Equipment and Procedures Information

| Time Period for Report: | x 10/01/2018 - 9/30/2019 | ☐ Other time period: | | | | |
|---|--------------------------|----------------------|--|--|--|--|
| (Please make additional copies of this page as needed.) | | | | | | |

Scanner Number 1 Scanner Number DHSR Planning Use Only GE 1.5 T Manufacturer/Tesla Horizon Infinity ES LX Model Number Open or closed (including Closed open bore) scanner Serial or I.D. number 1SF9FA8248183226 SIGNA 456 Date of acquisition 08/2004 Previously Provided to DHSR Purchase price (if purchased) Certificate of Need Project ID F-6957-03 Certificate holder, as listed on Alliance Imaging, Inc. and Piedmont HealthCare, P.A. Certificate of Need If this equipment was originally a mobile scanner, check box if it is now X Parked ☐ Parked permanently parked ("wheels off" or on) or Installed Installed installed in a building Service Site_____ Piedmont HealthCare Service Site Information: Please include all of the 619 Sullivan Road information requested for City: Zip____ each location. Statesville, NC 28677, Iredell County___ Inpatient Procedures*: Inpatient: Inpatient: with: _____ - with Contrast or Sedation with: _____ w/out: _____ w/out: _____ - without Contrast or Sedation Total: Total: _____ Outpatient Procedures*: Outpatient: Outpatient: - with Contrast or Sedation with: 1095 with:_____ - without Contrast or w/out: __2249___ w/out:_____ Sedation Total: __3344___ Total: Total Number of Procedures **Total**: ____3344___ Total: _10 Thursday Sunday Sunday Thursday For each day of the week, _10 Friday 10 Monday Monday ___ Friday enter the number of hours _10 Tuesday Tuesday _10 Saturday Saturday the scanner is in operation. 10 Wednesday Wednesday Total number of hours in 3050 operation for reporting 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 greater than the total number of patients reported on the MRI Patient Origin Table on page 3 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 2 of this form.

Service Site Name: Piedmont HealthCare Statesville MRI Sullivan Road

County in which service was provided: Iredell

| Patient | Number of | Patient | Number of | Patient | Number of |
|----------------|-----------|-----------------|-----------|----------------------|---------------|
| County | Patients | County | Patients | County | Patients |
| 1. Alamance | | 37. Gates | | 73. Person | |
| 2. Alexander | 339 | 38. Graham | | 74. Pitt | |
| 3. Alleghany | 4 | 39. Granville | | 75. Polk | |
| 4. Anson | | 40. Greene | | 76. Randolph | 1 |
| 5. Ashe | 3 | 41. Guilford | 56 | 77. Richmond | |
| 6. Avery | | 42. Halifax | | 78. Robeson | |
| 7. Beaufort | | 43. Harnett | | 79. Rockingham | |
| 8. Bertie | | 44. Haywood | | 80. Rowan | 82 |
| 9. Bladen | | 45. Henderson | | 81. Rutherford | 1 |
| 10. Brunswick | | 46. Hertford | | 82. Sampson | |
| 11. Buncombe | | 47. Hoke | 1 | 83. Scotland | |
| 12. Burke | 4 | 48. Hyde | | 84. Stanly | |
| 13. Cabarrus | | 49. Iredell | 2228 | 85. Stokes | |
| 14. Caldwell | 9 | 50. Jackson | | 86. Surry | 13 |
| 15. Camden | | 51. Johnston | 1 | 87. Swain | |
| 16. Carteret | | 52. Jones | | 88. Transylvania | - |
| 17. Caswell | | 53. Lee | | 89. Tyrrell | |
| 18. Catawba | 95 | 54. Lenoir | | 90. Union | 2 |
| 19. Chatham | | 55. Lincoln | 6 | 91. Vance | |
| 20. Cherokee | | 56. Macon | | 92. Wake | 1 |
| 21. Chowan | | 57. Madison | | 93. Warren | |
| 22. Clay | | 58. Martin | | 94. Washington | |
| 23. Cleveland | | 59. McDowell | 1 | 95. Watauga | 2 |
| 24. Columbus | | 60. Mecklenburg | 18 | 96. Wayne | |
| 25. Craven | | 61. Mitchell | - | 97. Wilkes | 71 |
| 26. Cumberland | | 62. Montgomery | | 98. Wilson | |
| 27. Currituck | | 63. Moore | | 99. Yadkin | 31 |
| 28. Dare | | 64. Nash | | 100. Yancey | |
| 29. Davidson | 1 | 65. New Hanover | | | |
| 30. Davie | 89 | 66. Northampton | | 101. Georgia | 1 |
| 31. Duplin | 1 | 67. Onslow | | 102. South Carolina | 4 |
| 32. Durham | | 68. Orange | - | 103. Tennessee | 3 |
| 33. Edgecombe | | 69. Pamlico | | 104. Virginia | 8 |
| 34. Forsyth | | 70. Pasquotank | | 105. Other (specify) | 3 |
| 35. Franklin | | 71. Pender | | FL 1, MI 1, TX 1 | |
| 36. Gaston | | 72. Perquimans | | Total Number of | 3,047 |
| | | - | | 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 Jegory S. Jun | |
|---------------------------------|--|
| Print Name Gregory S. Guin, CFO | |
| Date signed ///7/2020 | |

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 31, 2020.

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



Post Office Box 2154 Reidsville, NC 27323

May 31, 2018

Ms. Martha Frisone, Chief Mr. Greg Yakaboski, Project Analyst Health Planning and Certificate of Need Section 2704 Mail Service Center Raleigh, NC 27699-2704

RE: Material Compliance for Piedmont HealthCare, P.A., Proposed Relocation of the Diagnostic Center and Medical Office Building and Diagnostic Equipment CON Project ID # 6957-03, FID#031129

Dear Ms. Frisone and Mr. Yakaboski,

I am writing on behalf of Piedmont HealthCare, P.A. ("Piedmont HealthCare") to seek: (1) a determination that the combined operations of existing diagnostic equipment, MRI, and Diagnostic Center to be relocated to 700 Sullivan Road in Statesville for Project I.D. #F-6957-03 is in material compliance with the Certificate of Need issued for the project; and (2) confirmation that the proposed renovations and construction costs to the leased facility at 700 Sullivan Road, Statesville do not require Certificate of Need approval because the total capital cost is projected to be far less than \$2,000,000 and no new institutional health service is proposed. Each component of the request is addressed in the following paragraphs.

Overview

Piedmont HealthCare (MRI scanner lessee) and Alliance HealthCare Services (MRI scanner lessor) obtained Certificate of Need approval for Project I.D. # F-6957-03 to acquire a fixed MRI scanner and establish a diagnostic center at 619 Sullivan Road in Statesville, North Carolina. A copy of the 2018 MRI Inventory Form is provided in Attachment A. The building that houses the Piedmont HealthCare Urgent Care Center and the MRI registration and waiting area is at 619 Sullivan Road. The MRI scanner is a parked full-time fixed MRI scanner that is located in the parking lot at this site. The MRI scanner is provided through an operating lease.

In accordance with the CON approval for the project, Alliance Imaging acquired the MRI scanner that is leased to Piedmont HealthCare. The initial capital costs incurred by Piedmont HealthCare included the MRI pad and other improvements with a total combined capital cost of \$16,797. In 2015, Piedmont HealthCare acquired the DynaCad 3.2 Prostate Diagnostic Imaging System for use with the MRI scanner for a total capital cost of \$46,991. Please see Attachment C for copies of invoices and the fixed asset reports for the MRI scanner and other diagnostic equipment.

Since the time that Alliance Imaging Inc. and Piedmont HealthCare obtained CON approval to acquire a fixed MRI scanner and obtain the designation as a Diagnostic Center, Piedmont HealthCare has acquired additional diagnostic equipment for use in the same building that includes multiple suites. The purchase of additional diagnostic equipment by Piedmont HealthCare to be used in the same building did not require subsequent CON approval because each unit of diagnostic equipment had a total capital cost of less than \$750,000 and did not result in a new institutional health service for major medical equipment as defined by G.S.131E 176 (14o). The building that houses suite 619 Sullivan Road includes physically separate suites that are leased by Piedmont HealthCare as follows:

- Suite 609 Sullivan Road includes a CT scanner that was acquired by Piedmont HealthCare in 2013 that had a total equipment purchase cost of \$262,978. Other capital costs related to the installation of the CT scanner included a laser printer, PACs link, contrast injectors, and software for a total combined capital cost (purchase cost) of \$334,276.
- Suite 617 Sullivan Road includes one mammography unit (purchased in 2014), accessories, and software with a total capital purchase cost of \$324,284.
- Also located in Suite 617 is a bone densitometer that was acquired in 2001 with a total capital purchase cost of \$52,800.
- Suite 611 Sullivan Road includes two ultrasound units (purchased in 2006 and 2016) and accessories including a power table with a total combined purchase cost of \$302,969.

| | | СТ | MAMMOGRAPHY | DEXA | ULTRASOUND (2 machines) | |
|----|-------------------|-------------|------------------------|--------------|-------------------------|-------------|
| | | Ci | (including 3D upgrade) | | US1 Machine | US5 Machine |
| EN | Manufacturer | Neusoft | Hologic | GE Lunar | ACUSON | PHILIPS |
| Z | Model | Neuviz 64E | ASY-06202 | #LU 42733 | SIEMENS#S2000 | #IU22 |
| | Serial # | N64E120022E | 81007143656 | #IRDF+303754 | #212965 | #02RB93 |
| EC | Manufactered Date | 4/1/2013 | 7/1/2014 | 9/1/2016 | 12/1/2015 | 11/1/2016 |

Piedmont HealthCare is the provider that bills patients and payors for the diagnostic services performed throughout the building location. No change in diagnostic equipment ownership is planned as seen in the following table.

| Diagnostic Equipment | Current Ownership | Future Ownership | |
|----------------------------|--------------------------|--------------------------|--|
| Descriptions | Arrangement | Arrangement | |
| MRI Scanner (SIGNA 456) | Operating Lease | Operating Lease | |
| | Alliance Imaging Inc. as | Alliance Imaging Inc. as | |
| | lessor and Piedmont | lessor and Piedmont | |
| | HealthCare as lessee | HealthCare as lessee | |
| CT Scanner and Accessories | Piedmont HealthCare | Piedmont HealthCare | |
| Two Ultrasound Units | Piedmont HealthCare | Piedmont HealthCare | |
| Hologic Mammography | Piedmont HealthCare | Piedmont HealthCare | |
| Bone Densitometer | Piedmont HealthCare | Piedmont HealthCare | |

Combined Operations of Existing Equipment

Piedmont HealthCare previously proposed to and obtained confirmation of material compliance to renovate and consolidate all of the diagnostic equipment at 619 Sullivan Road in Statesville, North Carolina. Please see Attachment B. However, this option is not feasible because:

- Planned roadway improvements are likely to decrease parking and disrupt traffic flow to 619 Sullivan Road and adjoining suites.
- The potential that all or a portion of the property housing the current facility will be sold through negotiation or perhaps eminent domain to provide a new connector road that would run lengthwise through the property making the property potentially unusable.
- The scope of renovations to the building are expected to severely disrupt patient services.

Piedmont HealthCare and Alliance Healthcare Services now intend to relocate the Urgent Care and entire existing Diagnostic Center, including the existing diagnostic equipment and the parked (fixed) MRI to a leased building diagonally across the street at 700 Sullivan Road (approximately $1/8^{th}$ mile from the existing building) in Statesville. Piedmont HealthCare is convinced that this alternative is the most effective option because the renovations to the leased building will have no negative impact to current patient services, the inability to make improvements to the current facility due to the ongoing delay in the City of Statesville's determination of the new connector road placement, and the proposed location has better parking that is not likely to be disrupted by future road improvements.

Piedmont HealthCare respectfully requests confirmation that the combined operations and inventory of the existing diagnostic equipment to be located at the proposed 700 Sullivan Road building would also be permitted in material compliance with the Certificate of Need issued for the Project I.D. # F-6957-03.

Relocation of Diagnostic Center and Building Renovations

Piedmont HealthCare has obtained detailed cost estimates to verify that the planned relocation of the Urgent Care and diagnostic center will have a total capital cost of far less than \$2,000,000. According to N.C. Gen Stat 131E-176(16(b). included among new definitions is:

The obligation by any person of a capital expenditure exceeding two million dollars (\$2,000,000) to develop of expand a health service of a health service facility or which relates to the provision of a health service. The costs of any studies, designs, plans, working drawings, specifications, and other activities including staff effect and consulting and other services, essential to making the acquisition, improvement, expansion or replacement of any plant of equipment with respect to which the expenditure is made shall be included in determining if the expenditure exceeds two million dollars (\$2,000,000).

Please see the chart below that includes all capital costs associated with relocation of the equipment including the renovations of the building:

| RENOVATION COSTS TENANT | \$747,793 | See Architect letter and Cost |
|--------------------------------|-----------|-------------------------------|
| ARCHITECT AND ENGINEERING FEES | \$59,823 | Estimate |
| EQUIPMENT RELOCATION COSTS | \$35,400 | See Equipment Quotes |
| CONSULTING AND CONTINGENCY | \$6,500 | |
| TOTAL CAPITAL COST | \$849,516 | |

The next table provides the detailed breakdown of the capital costs related to the diagnostic equipment, including the costs necessary to make the equipment operational. The equipment related quotes are included in Attachment D.

| EQUIPMENT RELOCA | ATION COST BI | REAKDOWN (SEE | QUOTES) | | |
|---|---------------|------------------------|--------------|-------------------------|-------------|
| | | MAMMOGRAPHY | | ULTRASOUND (2 machines) | |
| | СТ | (including 3D upgrade) | DEXA | US1 Machine | US5 Machine |
| Manufacturer | Neusoft | Hologic | GE Lunar | ACUSON | PHILIPS |
| Model | Neuviz 64E | ASY-06202 | #LU 42733 | SIEMENS#S200 0 | #IU22 |
| Serial # | N64E120022E | 81007143656 | #IRDF+303754 | #212965 | #02RB93 |
| Manufactered Date | 4/1/2013 | 7/1/2014 | 9/1/2016 | 12/1/2015 | 11/1/2016 |
| Moving | \$18,000 | \$6,300 | \$3,500 | \$500 | \$500 |
| Physicist | \$950 | \$625 | \$325 | N/A | N/A |
| Inspection | \$1,300 | \$325 | \$375 | N/A | N/A |
| Contingency (taxes, permits, other moving costs, unforeseen, etc) | \$0 | \$2,700 | \$0 | \$0 | \$0 |
| UNIT TOTALS | \$20,250 | \$9,950 | \$4,200 | \$500 | \$500 |
| TOTAL ESTIMATED E | QUIPMENT RE | LATED COSTS: | | | \$35,400 |

The MRI scanner that is utilized at Piedmont HealthCare is a parked unit in a trailer (listed as fixed) that can be relocated by Alliance Healthcare in accordance with the existing operating lease. The architect cost estimate for the building renovations includes the MRI pad and utilities to make the MRI scanner operational.

Piedmont HealthCare requests confirmation that renovations to the proposed leased building at 700 Sullivan Road in Statesville are not subject to CON review. The proposed changes to the building will improve the configuration of the spaces to enhance patient access and support staff productivity in the physician office building. No additional diagnostic equipment is proposed with the renovations and changes to the building.

Since the CON-approved MRI scanner and Diagnostic Center are considered existing health services, the changes to the leased building do not create any new institutional health service as defined by G.S. 131E 176 (a) through (v). As documented by the project architect in Attachment C the renovation is projected to have a total capital cost of \$849,516 which does not exceed the CON \$2,000,000 threshold

Future Equipment Replacements

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Piedmont HealthCare and Alliance Imaging anticipate that some existing diagnostic equipment may need to be replaced at some future date. Once the information is obtained regarding the type of equipment to be replaced, the appropriate exemption notice and documentation will be provided to the Health Planning and Certificate of Need Section.

Please call me at 336 349-6250 if you have any questions. Contact persons at Piedmont HealthCare are Susan Clohecy, Director of Operations and Greg Guin, Chief Financial Officer. They can be reached at 704 873-4277. Thank you for your time and attention.

Sincerely,

David J. French Consultant

CC: Greg Guin Susan Clohecy

Attachments



Registration and Inventory of Medical Equipment

Mobile Magnetic Resonance Imaging Scanners January 2020 SIGNA 413

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 31, 2020**.

- 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 | (<u>800</u>) <u>544-3215</u> |
|---------------|---------|-------|--------------------------------|
| (City) | (State) | (Zip) | (Phone Number) |

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

| | Roaney Skelaing | <u>Manager Operations</u> | |
|----|--------------------------------|----------------------------|----------|
| | (Name) | (Title) | |
| | 336 580-9061 | rskelding@allianceradiolog | y-us.com |
| | (Phone Number) | (Email) | |
| 4. | Information Compiled of | or Prepared by: David From | ench_ |
| | - | • | (Name) |
| | (<u>336</u>) <u>349-6250</u> | djfrench45@gmail.com_ | |
| | (Phone Number) | (Email) | |



Registration and Inventory of Medical Equipment Mobile Magnetic Resonance Imaging Scanners – January 2020

Page 2 of 4

| For DHSR Planning Use | |
|-----------------------|--|
| Only: | |

ID #:

Section 2: Equipment and Procedures Information

| Time Period for Report: | $\boxtimes 10/01/2018 - 9/30/20$ |)19 | \square Other time period: _ | |
|-------------------------|----------------------------------|--------|--------------------------------|--|
| | (Please make additional | copies | of this page as needed.) | |

| , | Mobile Scanner Number | (One scanner per page) | | | |
|---|--|------------------------|--|--|--|
| Manufacturer/Tesla | GE 1.5T | | | | |
| Model number | Signa Horizon ES LX | | | | |
| Open or closed (including open bore) scanner | Closed | | | | |
| Serial or I.D. Number | 1S9FA482451182783 Signa 413 | | | | |
| Date of acquisition | 02/2006 | | | | |
| Purchase price (if purchased) | Previously submitted | | | | |
| Certificate of Need Project ID | Grandfathered | | | | |
| 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 all of the information requested for each location. | Piedmont Healthcare 128 Medical Park Dr Suite 102 Mooresville, NC 28117 Iredell | | | | |
| Inpatient Procedures*: - with Contrast or Sedation - without Contrast or Sedation Outpatient Procedures*: - with Contrast or Sedation - without Contrast or Sedation Total Number of Procedures For each day of the week, enter the number of hours the scanner is in operation. | Inpatient: with: 0 w/out: 0 Total: 0 Outpatient: with: 755 w/out: 1246 Total: 2001 Total: 2001 Days and hours subject to change. | | | | |
| Total number of hours in operation for reporting period | 1500 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.



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: Piedmont Healthcare Mooresville

County in which service was provided: Iredell (Alliance does not collect patient origin data

| 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 | 2001 |
| | | | | 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 22, 2020

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 31, 2020**

- 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.

Rocky B. Delis

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.