



NC DEPARTMENT OF
**HEALTH AND
 HUMAN SERVICES**
 Division of Health Service Regulation

ROY COOPER • Governor
 MANDY COHEN, MD, MPH • Secretary
 MARK PAYNE • Director

June 26, 2018

David French
 PO Box 2154
 Reidsville, NC 27323

Exempt from Review – Replacement Equipment

Record #: 2625
Facility Name: Alliance Healthcare Services, Inc.
FID #: 020756
Business Name: Alliance Healthcare Services, Inc.
Business #: 60
Project Description: Temporarily replace mobile PET/CT Unit 110
Counties: Statewide

Dear Mr. French:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of June 21, 2018, 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 Siemens Biograph 6 (PET/CT Unit 44, Serial #1M9A6A8256H022243) to temporarily replace the Siemens Biograph 6 (PET/CT Unit 110, Serial #1M9A6A8256H022233). This determination is based on your representations that the PET/CT Unit 44 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 Construction, Radiation Protection, and Acute and Home Care Licensure and Certification Sections 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,

Julie M. Faenza

Julie M. Faenza
 Project Analyst

Martha J. Frisone

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

- cc: Construction Section, DHSR
- Radiation Protection Section, DHSR
- Acute and Home Care Licensure and Certification Section, DHSR
- Amy Craddock, Assistant Chief, Healthcare Planning, 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: 2704 Mail Service Center, Raleigh, NC 27699-2704
 www.ncdhhs.gov/dhsr/ • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

Faenza, Julie M

From: Faenza, Julie M
Sent: Friday, June 22, 2018 8:40 AM
To: 'David French'; Pittman, Lisa
Cc: Rodney Skelding; Andre Kellogg; Melissa VanOostrom
Subject: RE: [External] Temporary Replacement Equipment Notice for Alliance PETCT 110

Received.

Julie M. Faenza, Esq.

Project Analyst

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

NC Department of Health and Human Services

Office: 919-855-3873

[Twitter](#) | [Facebook](#) | [YouTube](#) | [LinkedIn](#)

From: David French [mailto:djfrench45@gmail.com]
Sent: Friday, June 22, 2018 6:34 AM
To: Pittman, Lisa; Faenza, Julie M
Cc: Rodney Skelding; Andre Kellogg; Melissa VanOostrom
Subject: [External] Temporary Replacement Equipment Notice for Alliance PETCT 110

CAUTION: External email. Do not click links or open attachments unless verified. Send all suspicious email as an attachment to [Report Spam](#).

Good morning,

Please confirm that you have received the attached documentation regarding the Temporary Equipment Replacement Exemption for Alliance PETCT 110. Please let me know if you have any questions.

David French
336 432-8308 cell

ALLIANCE HEALTHCARE SERVICES

c/o Rodney Skelding
8390 Hunting Court
Stokesdale, NC 27357



June 21, 2018

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

RE: Emergency Exemption Notice for Temporary Replacement of Mobile PET/CT 110
Date of Replacement June 21, 2018 Until repairs Completed

Dear Ms. Frisone:

I am writing on behalf of my client, Alliance Healthcare Services ("Alliance"), regarding the need to temporarily replace mobile PET/CT Unit 110, Serial Number 1M9A6A8256H022233. This unit has been out of service for two days (beginning June 20, 2018) and repair parts have been ordered. The temporary replacement unit is PET/CT 44, Serial Number 1M9A6A8256H022243, which will be brought to North Carolina to serve host sites that are normally scheduled to be served by PET/CT 110. Once the PET/CT 110 unit is repaired and operational in North Carolina, PET/CT 44 shall be removed from the State.

A previous exemption has been approved to permanently replace the PET/CT 110 with either one new GE PET/CT scanner or one new Siemens PET/CT scanner to be purchased by Alliance, each with a total capital cost of less than \$2,000,000. However, the permanent replacement unit is not yet available for delivery to North Carolina.

This letter provides documentation and written notice regarding the temporary replacement equipment in accordance with NCGS 131 E-184. Alliance also provides verification 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

Overview

The existing PET/CT scanner requires replacement for several reasons:

- 1) The existing PET/CT 110 is ten years old and has required repairs due to the age and condition of the unit and extreme heat.
- 2) Service to the existing host sites will be disrupted if a replacement mobile PET/CT unit cannot be provided.
- 3) Patient diagnosis and treatment at the host sites will be seriously disrupted without access to PET/CT.

Alliance Imaging recognizes the need to provide high quality, cost effective, and reliable mobile PET/CT scanner service.

As seen in Attachment 1, the proposed replacement shall not result in more than a 10% increase in operating expenses to the host sites within the first 12 months after 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. The replacement equipment is functionally similar to the existing equipment and will be used for the same diagnostic procedures as the existing equipment. The temporary replacement PET/CT equipment is used and owned by Alliance. The PET/CT unit to be replaced was acquired by Alliance more than ten 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 existing equipment (PET/CT 110) was new when it was acquired in 2008 and the replacement equipment will be purchased new and owned by Alliance; in the interim, PET/CT 110 will be temporarily replaced by PET/CT 44.

(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.

(4) The replacement equipment is purchased and the existing equipment is leased, unless the lease is a capital lease;

Not applicable. Both the existing and the replacement equipment are owned by Alliance.

(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 gamma camera or nuclear medicine equipment.

Thank you for your review and consideration of this information. Please call me at the office at 336 349-6250 or 336 432-8308 (cell phone) if you have any questions.

Sincerely,

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

David French
Consultant to Alliance Healthcare Services
P.O. Box 2154
Reidsville, NC 27323
djfrench45@gmail.com

Attachments:

Attachment 1 - Letter from Rodney Skelding
Attachment 2 - 2018 PETCT 110 Inventory Form

Cc:

Rodney Skelding
Manager of Operations
Alliance Healthcare Services
8390 Hunting Court
Stokesdale, NC 27357

Melissa VanOostrom
Manager of Operations
Alliance Healthcare Services

Andre' D. Kellogg, Sr., MPA
Director of Operations
Alliance Healthcare Services



Registration and Inventory of Medical Equipment
Mobile Positron Emission Tomography Scanners
January 2018 PET CT 110

Instructions

This is the legally required “Registration and Inventory of Medical Equipment” (G.S. 131E-177) for mobile positron emission tomography scanners. Please complete all sections of this form and return to Healthcare Planning by **Friday, January 26, 2018**.

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 Sharetta Blackwell, Healthcare Planning, 2704 Mail Service Center, Raleigh, NC 27699-2704.

If you have questions, call Sharetta Blackwell in Healthcare Planning at (919) 855-3865 or email DHSR.SMFP.Registration-Inventory@dhhs.nc.gov.

Section 1: Contact Information

1. Full legal name of corporation, partnership, individual, or other legal entity that acquired the equipment by purchase, donation, lease, transfer, or comparable arrangement:

Alliance Healthcare Services

(Legal Name)

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

18201 Von Karman #600

(Street and Number)

Irvine **CA** **92612**

(City) (State) (Zip)

(800) 544-3215

(Phone Number)

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

Rodney Skelding

(Name)

Manager Operations

(Title)

336 580 9061

(Phone Number)

rskelding@allianceradiology-us.com

(Email)

4. Information Compiled or Prepared by: **David French**

(Name)

(336) 349-6250

(Phone Number)

djrench45@gmail.com

(Email)

Section 2: Equipment and Procedures Information

Time Period for Report: 10/01/2016 – 9/30/2017 Other time period 12/21/2016 – 9/30/2017



Section 2: Equipment and Procedures Information

Time Period for Report: 10/01/2016 – 9/30/2017 Other time period 12/21/2016 – 9/30/2017

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

Mobile Scanner Information (one scanner per page)		
Manufacturer	Siemens	
Model Number	PET/CT	
Serial or I.D. Number	PET/CT 110, Serial Number 1M9A6A8256H022233	
Date of purchase	2008 (Replacement Exemption Obtained)	
Purchase price	\$1,902,817	
Certificate of Need Project ID	F-6605-02	
Certificate Holder, as listed on Certificate of Need	Alliance HealthCare	
	Service Site Number <u>3</u>	Service Site Number <u>4</u>
Service Site Information: Please include all of the information requested for each location.	Novant - Huntersville 10030 Gilead Road Huntersville, NC 28078 Mecklenburg	Lake Norman Medical Center 171 Fairview Road Mooresville, NC 28117 Mecklenburg
<u>Procedures* – Inpatient</u>	Inpatient 0	Inpatient 0
<u>Procedures* – Outpatient</u>	Outpatient 3	Outpatient 199
Total # of procedures* for report period	<u>Total 3</u>	<u>Total 199</u>
Put a check by the days per week, and write in the hours per day, the scanner is in operation.	3 hrs 12/21/2016 – 9/30/2016	199 hrs 12/21/2016 – 9/30/2016
Total number of hours in operation by site for report period.	3 hrs	199 hrs

* PET **scan** means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. PET **procedure** means a single discrete study of one patient involving one or more PET scans.

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



Section 2: Equipment and Procedures Information

Time Period for Report: 10/01/2016 – 9/30/2017 Other time period 12/21/2016 – 9/30/2017

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

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Serial or I.D. Number	PET/CT 110, Serial Number 1M9A6A8256H022233	
Date of purchase	2008 (Replacement Exemption Obtained)	
Purchase price	\$1,902,817	
Certificate of Need Project ID	F-6605-02	
Certificate Holder, as listed on Certificate of Need	Alliance HealthCare	
	Service Site Number <u>7</u>	Service Site Number <u>8</u>
Service Site Information: Please include all of the information requested for each location.	Park Ridge Hospital 100 Hospital Drive Fletcher, NC 28732 Henderson	Rowan Regional Medical Center 514 Corporate Circle Salisbury, NC 28147 Rowan
<u>Procedures* – Inpatient</u>	Inpatient 0	Inpatient 0
<u>Procedures* – Outpatient</u>	Outpatient 101	Outpatient 0
Total # of procedures* for report period	<u>Total 101</u>	<u>Total 0</u>
Put a check by the days per week, and write in the hours per day, the scanner is in operation.	101 hrs 12/21/2016 – 9/30/2016	0 hrs 12/21/2016 – 9/30/2016
Total number of hours in operation by site for report period.	101 hrs	0 hrs

* PET **scan** means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. PET **procedure** means a single discrete study of one patient involving one or more PET scans.

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



Section 2: Equipment and Procedures Information

Time Period for Report: 10/01/2016 – 9/30/2017 Other time period 12/21/2016 – 9/30/2017

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

Mobile Scanner Information (one scanner per page)		
Manufacturer	Siemens	
Model Number	PET/CT	
Serial or I.D. Number	PET/CT 110, Serial Number 1M9A6A8256H022233	
Date of purchase	2008 (Replacement Exemption Obtained)	
Purchase price	\$1,902,817	
Certificate of Need Project ID	F-6605-02	
Certificate Holder, as listed on Certificate of Need	Alliance HealthCare	
	Service Site Number <u>11</u>	Service Site Number <u>12</u>
Service Site Information: Please include all of the information requested for each location.	LifePoint WestCare Health System 68 Hospital Drive Sylva, NC 28779 Jackson	Stanly Regional Medical Center 301 Yadkin Street Albemarle, NC 28001 Stanly
<u>Procedures* – Inpatient</u>	Inpatient 0	Inpatient 0
<u>Procedures* – Outpatient</u>	Outpatient 208	Outpatient 171
Total # of procedures* for report period	<u>Total 208</u>	<u>Total 171</u>
Put a check by the days per week, and write in the hours per day, the scanner is in operation.	208 hrs 12/21/2016 – 9/30/2017	171 hrs 12/21/2016 – 9/30/2017
Total number of hours in operation by site for report period.	208 hrs	171 hrs

* PET **scan** means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. PET **procedure** means a single discrete study of one patient involving one or more PET scans.

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



Section 2: Equipment and Procedures Information

Time Period for Report: 10/01/2016 – 9/30/2017 Other time period 12/21/2016 – 9/30/2017

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

Mobile Scanner Information (one scanner per page)		
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Serial or I.D. Number	PET/CT 110, Serial Number 1M9A6A8256H022233	
Date of purchase	2008 (Replacement Exemption Obtained)	
Purchase price	\$1,902,817	
Certificate of Need Project ID	F-6605-02	
Certificate Holder, as listed on Certificate of Need	Alliance HealthCare	
	Service Site Number <u>15</u>	Service Site Number <u>16</u>
Service Site Information: Please include all of the information requested for each location.	Caldwell Memorial Hospital 321 Mulberry Street, SW Lenoir, NC 28645 Caldwell	Novant Thomasville 207 Old Lexington Rd Thomasville, NC 27360 Davidson
<u>Procedures* – Inpatient</u>	Inpatient 0	Inpatient 0
<u>Procedures* – Outpatient</u>	Outpatient 81	Outpatient 0
Total # of procedures* for report period	<u>Total 81</u>	<u>Total 0</u>
Put a check by the days per week, and write in the hours per day, the scanner is in operation.	81 hrs 12/21/2016 – 9/30/2017	0 hrs 12/21/2016 – 9/30/2017
Total number of hours in operation by site for report period.	81 hrs	0 hrs

* PET **scan** means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. PET **procedure** means a single discrete study of one patient involving one or more PET scans.

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



Section 3: PET Procedures by CPT Code

Please write the number of procedures provided by CPT Code during the time period of this report.

CPT Code	CPT Description	Number of Procedures
78608	Brain imaging – metabolic evaluation	1
78609	Brain imaging – perfusion evaluation	
78459	Myocardial imaging - metabolic evaluation	
78491	Myocardial imaging – perfusion; single study at rest or stress	
78492	Myocardial imaging – perfusion; multiple studies at rest and/or stress	
78811	Tumor imaging – limited area (e.g., chest, head/neck)	
78812	Tumor imaging – skull base to mid-thigh	
78813	Tumor imaging – whole body	
78814	Tumor imaging – with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; limited area (e.g., chest, head/neck)	1
78815	Tumor imaging with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; skull base to mid-thigh	2012
78816	Tumor imaging with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization; whole body	125
Please list other CPT codes and number of procedures billed for (make a copy of this page if needed)		
Total Number of Procedures		2139

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



Section 5: 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 26, 2018**

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