



North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt
Division Director

March 11, 2014

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

Exempt from Review - Replacement Equipment

Facility: Alliance Imaging, Inc.
Project Description: Temporarily replace a mobile PET/CT scanner while it is being repaired
County: HSA I, II, III
FID #: 020756

Dear Mr. French:

In response to your letter of February 28, 2014, the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(7). Therefore, you may proceed to utilize, without a certificate of need, the Siemens Biograph Pet CT 110, serial number 1M9A6A82XW022233, as a temporary replacement for the existing Siemens Biograph PET CT 45, serial number 1M9A6A8276H022244 during its repair. Once the Siemens Biograph PET CT 45 is repaired, the Siemens Biograph Pet CT 110 temporary replacement mobile PET/CT scanner will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need.

Moreover, you need to contact the Radiation Protection Section to determine if they have any requirements for development of the proposed project.

It should be noted that this 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 Agency and a separate determination.



Certificate of Need Section

www.ncdhhs.gov

Telephone: 919-855-3873 • Fax: 919-733-8139

Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

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Mr. David French

March 11, 2014

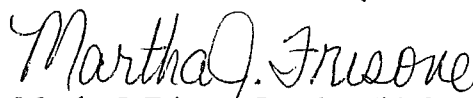
Page 2

If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,



Gloria C. Hale
Project Analyst



Martha J. Frisone, Interim Chief
Certificate of Need Section

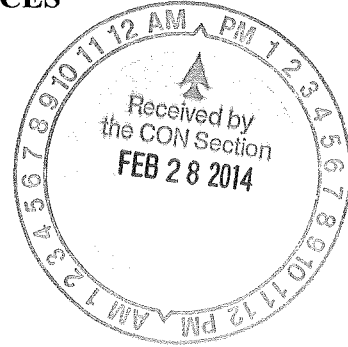
cc: Radiation Protection Section, DHSR
Medical Facilities Planning Branch, DHSR

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ALLIANCE HEALTHCARE SERVICES

February 28, 2014

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



RE: Alliance Imaging Inc. - Written Notice for Exemption from CON Review for **Emergency Temporary Replacement PET/ CT Equipment for the Western Mobile PET/CT Scanner**

Dear Ms Frisone:

I am writing on behalf of my client Alliance Imaging Inc. regarding the urgent need to temporarily replace the mobile PET/ CT scanner that is utilized in western North Carolina, including Health Service Areas I, II and III.

In 2002, Alliance Imaging Inc. obtained approval for project application # F-6605-02 to implement a mobile PET scanner to serve Health Service areas I, II and III. In 2006, Alliance obtained an equipment replacement exemption to replace the PET scanner equipment with a PET/CT. The unit that is currently in use is PET/ CT 45 Serial Number 1M9A6A8276H022244. This unit needs to be removed from service because of the urgent need to complete repairs the trailer.

Please accept this notice of exemption to temporarily replace the above unit with PET/ CT unit 110, serial number 1M9A6A82XWO22233. This unit is owned by Alliance Imaging and is readily available to serve as the temporary replacement for the western PET CT scanner.

This letter provides justification and written notice regarding the replacement equipment in accordance with NCGS 131 E-184. Alliance Imaging Inc. also provides documentation that the replacement equipment conforms to the Certificate of Need laws and Administrative rules:

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

Overview

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

- 1) The repairs to the PET CT will take between 3 to 4 days to complete.
- 2) Service to the existing host sites will be disrupted if a temporary 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.
- 4) Alliance does not have available capacity on other PET/ CT units in North Carolina to provide coverage for the unit that needs to be repaired.

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

Compliance Documentation

Compliance with G.S. 131E-176 (22a) Replacement Equipment Definition is demonstrated in Attachment 1 which shows that the temporary replacement scanner has an actual cost of less than \$2,000,000.

No additional shipping or installation costs are expected. The fair market value for the PET/ CT will be the same as the purchase price of the equipment as reflected in the attached quotes.

The replacement PET/ CT equipment will be used for the same diagnostic purposes as the existing equipment.

In addition, Alliance Imaging 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 Imaging Inc. plans to use an existing mobile PET/ CT 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) *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 Imaging Inc. 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 Imaging Inc. 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 Imaging Inc. 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 PET/ CT scanner is comparable to the equipment being replaced because the temporary replacement equipment will also obtain PET/ CT images and data. The proposed replacement mobile PET/ CT scanner is used to acquire the same type of PET/ CT 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 Imaging Inc. certifies that the replacement mobile PET/ CT equipment will be used for the same diagnostic purposes as the existing 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 sites will utilize the temporary replacement PET/ CT 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. 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 not a gamma camera or nuclear medicine equipment.

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT (To be temporarily removed from NC for repairs.)	TEMPORARY REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	PET CT	PET CT
Manufacturer of Equipment	Siemens	Siemens
Tesla Rating for MRIs	NA	NA
Model Number	Siemens Biograph	Siemens Biograph
Serial Number	1M9A6A8276H022244	1M9A6A82XWO22233
Provider's Method of Identifying Equipment	PET CT 45	PET CT 110
Specify if Mobile or Fixed	Mobile	Mobile
Mobile Trailer Serial Number/VIN #		
Mobile Tractor Serial Number/VIN #	NA - No changes	NA - No changes
Date of Acquisition of Each Component	2006	
Does Provider Hold Title to Equipment or Have a Capital Lease?	Holds Title	Holds Title
Specify if Equipment Was/Is New or Used When Acquired	New when acquired	New when acquired
Total Capital Cost of Project (no construction involved)	NA	Existing equipment
Total Cost of Equipment	NA	Purchased in 2008 at a cost of
Fair Market Value of Equipment	NA	\$1,047,321
Net Purchase Price of Equipment	NA	same
Locations Where Operated	See attached list	Same sites as PET CT 45 list
Number Days In Use/To be Used in N.C. Per Year	365	Specified days for temporary replacement
Percent of Change in Patient Charges (by Procedure)	NA	No increase will result
Percent of Change in Per Procedure Operating Expenses (by Procedure)	NA	No increase will result
Type of Procedures Currently Performed on Existing Equipment	PET CT Procedures	PET CT Procedures
Type of Procedures New Equipment is Capable of Performing	NA	PET CT procedures

The temporary replacement PET/ CT unit 110 will be removed from North Carolina when the repairs to the PET CT 45 has been completed and returned to service.

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 cursive script, appearing to read "David French", written over a horizontal line.

David French
Consultant to Alliance Imaging Inc.
P.O. Box 2154
Reidsville, NC 27323
djfrench45@bellsouth.net

CC: Freda Crawford
Manager of Operations
Alliance Imaging
fcrawford@allianceimaging.com
336 207 5613

List of Host Sites for PET CT 45

Presbyterian Hospital Matthews
1500 Matthews Township Parkway
Matthews, NC 28105

Cleveland Regional Medical Cent
201 East Grover St
Shelby, NC 28150

The Presbyterian Hospital
10030 Gilead Road
Huntersville, NC 28078

Lake Norman Medical Center
171 Fairview Road
 Mooresville, NC 28117

Margaret R. Pardee Memorial Hosp
800 North Justice St
Hendersonville, NC 28791

Northern Hosp of Surry County
830 Rockford Street
Mount Airy, NC 27030

Park Ridge Hospital
100 Hospital Drive
Fletcher, NC 28732

Rowan Regional Medical Center
514 Corporate Circle
Salisbury, NC 28147

Rutherford Hosp., Inc.
288 South Ridgecrest Ave.
Rutherfordton, NC 28193

Watauga Medical Center
336 Deerfield Road
Boone, NC 28607

WestCare Health System
68 Hospital Drive
Sylva, NC 28779

Stanly Regional Medical Center
301 Yadkin Street
Albemarle, NC 28001

Blue Ridge-Valdese Hospital

720 Malcolm Blvd
Rutherford College, NC 28671
Caldwell Memorial Hospital
321 Mulberry Street, SW
Lenoir, NC 28645

Community General Health Partner
207 Old Lexington Rd
Thomasville, NC 27360

Randolph Hospital
364 White Oak Street
Asheboro, NC 27203

Cone Health
2630 Willard Dairy Rd.
High Point, NC 27265