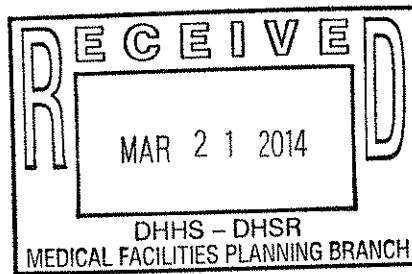


March 21, 2014



2:30 PM
MAR 21 2014

Dassey/Vogel

VIA HAND DELIVERY

Dr. Christopher Ullrich, Chairperson
Technology & Equipment Committee
c/o Division of Health Service Regulation
Medical Facilities Planning Section
Edgerton Building
809 Ruggles Drive
Raleigh, NC 27603

**RE: Novant Health/MedQuest Comments on Mobile PET Scanner
Petition Submitted by Randolph Hospital and Alliance Imaging**

Dear Dr. Ullrich:

Novant Health offers the following comments regarding the petitions filed by Randolph Hospital and Alliance Imaging on March 5, 2014 related to changes in the mobile PET methodology.

Comments on Alliance Imaging Mobile PET Petition

Alliance Imaging has requested an expansion of the types of host sites that can be served despite the fact that it is unable to provide enough mobile PET service for all of its hospital host sites. The proposed expansion to serve additional non-hospital sites will impact the accessibility for local hospitals to obtain adequate mobile PET service and should not be considered. Alliance's requested change regarding the expansion of host sites will actually make the mobile PET capacity problem worse. For example, as noted in the Randolph Hospital mobile PET petition, "*the AI mobile PET] service is available one morning, every other week and the mobile service must end at a set time in order to travel to another site. In order to allow our patients access to this service in their community, we have had to ask patients to arrive for their scan at 4:30 AM in order to accommodate the travel schedule of our mobile services. ...[w]hile we have inquired about expanding our service coverage to include one morning every week, our mobile provider cannot accommodate our request due to capacity constraints.*"

Comments on Randolph Hospital Petition

Randolph Hospital's petition, like Novant's petition, highlights the reasons why the current mobile PET system is not working. Randolph presents very compelling information and data, such as appointments as early as 4:30 am, delays in obtaining service and the analysis regarding linear accelerators and the ratio of PET procedures being lower in areas with access to mobile PET only. Clearly, the status quo (one company owning the only two mobile PET scanners in the State) is not

working and is directly impacting cancer patients. North Carolina is the tenth most populous state in the U.S., with a land mass covering almost 54,000 square miles. Both Randolph Hospital and Novant Health agree that demand exists for additional mobile PET capacity in North Carolina. The question is what is the best method for implementing additional mobile PET capacity?

In its petition, Randolph Hospital has suggested the possibility of a need trigger when the existing mobile PET units exceed 2,080 procedures (with a limit of two need determinations in a given year) and the ability for existing providers to convert existing CON-approved fixed PET scanners to mobile PET units. Novant Health's petition also considered the alternative of establishing a mobile PET need method in the 2015 SMFP; however, one of the disadvantages of this approach is that it will lead to a net increase in the total inventory of mobile and fixed PET/CT scanners in NC. Today, the North Carolina inventory of mobile and fixed PET/CT scanners is 29 units (27 fixed and 2 mobile). If a mobile PET/CT scanner need method were added to the 2015 SMFP it will ultimately result in an increase in the number of fixed and mobile PET/CT scanners from 29 to 31 total scanners. The mobile PET need method may have the unintended consequence of increasing the overall inventory of fixed and mobile PET scanners in NC, at a time when several fixed PET scanners are underutilized. Moreover, with new mobile PET/CT scanners based on an SMFP need determination there may be more than two competing applicants, which makes it likely the applicants who are not approved will appeal, which will impact the timeline to implement while litigation is pursued and settlement explored.

It appears that one of Randolph's concerns is that a conversion of existing fixed PET/CT scanners to mobile PET/CT scanners would primarily serve mobile PET host sites located at entities owned by the health system that converted one of its fixed PET scanners to a mobile PET scanner.

The reasons Novant Health has proposed a conversion policy are numerous:

1. During the most recent PET Scanner Discussion Group, in early February 2014, concern was expressed regarding underutilization of many of the existing 27 fixed PET scanners in North Carolina, based on the current fixed PET scanner capacity definition of 2,600 annual PET scans. Novant Health's plan will create a pathway for an underutilized fixed PET scanner to be converted to a more productive use as a mobile PET unit. This option would not expand the current inventory of 29 fixed and mobile PET scanners, but would use existing PET resources to expand mobile PET capacity to better serve multiple host sites.
2. There is no reason why a converted mobile PET unit would only serve host sites within the health system that converted it. It would be sound business practice to ensure that any mobile PET unit is fully

utilized whether it is serving a large health system internally and/or other independent hospital host sites.

3. The addition of a fixed to mobile PET conversion policy in the 2015 SMFP, as proposed in the Novant Health/MedQuest petition would increase mobile PET capacity: (a) by creating a third mobile PET scanner in North Carolina to service mobile PET host sites within the Novant Health network and elsewhere throughout North Carolina; and (b) by freeing up Alliance Imaging mobile PET at some current Novant Health mobile PET host sites. As an example, if Novant Health has the ability to convert a fixed PET to a mobile PET, then it would provide service to at least four of its own mobile PET host sites that are currently being served by Alliance Imaging. On a monthly basis, the Novant Health mobile PET sites utilize approximately 86 hours of service per month. Using a six hour time slot, Novant Health's ability to serve its host sites would open up roughly 14 half days for other providers utilizing Alliance Imaging's two mobile PET units.
4. Novant Health's approach would foster a measured approach for creating additional mobile PET capacity in order to determine the appropriate balance without flooding the market with too many new mobile PET scanners. Novant Health's mobile PET petition proposes that the initial fixed to mobile PET conversion be permitted to occur only during the 2015 SMFP plan year. By allowing the SMFP fixed to mobile PET scanner conversion policy to move forward before instituting changes to the mobile PET need methodology triggers, it provides the SHCC with the opportunity to monitor the situation by reviewing annual procedure volumes reported on the Mobile PET Equipment Inventory Reports. Once the need triggers are set in place for net new mobile PET/CT scanners, mobile PET capacity could increase too quickly before the market has a chance to adapt. As seen in the case of fixed PET scanners, the overabundance of capacity is not an optimal situation either.

All Three Petitioners Agree: Re-Define Mobile PET Service Area to be Statewide

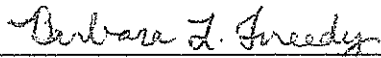
Overall, all of the petitioners, including Novant Health, agree that the East/West service area designation for mobile PET services is no longer useful and should be removed to improve mobile PET service flexibility and efficiencies. Assuming the SHCC Technology & Equipment Committee and State Health Coordinating Council approve the removal of the current mobile PET service area restrictions and allow the creation of a statewide service area, this change would be effective January 1, 2015, allowing the existing mobile PET provider to reorganize its schedule. This immediate change may offer some minimal improvements for mobile PET service coverage for Alliance Imaging's mobile PET clients. However, this action alone is insufficient to fully address the issue of excess demand for mobile PET capacity. As

noted in the Alliance Healthcare Services February 28, 2014 Request to the CON Section for an Emergency Temporary Replacement PET/CT Equipment for Western Mobile PET/CT Scanner: *"Alliance does not have available capacity on the other PET/CT units in North Carolina to provide coverage for the unit that needs to be repaired."* See Attachment A for a copy of the replacement request from Alliance Healthcare Services dated February 28, 2014.

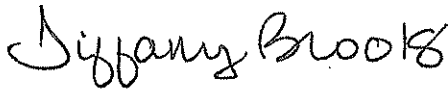
Novant Health has proposed an approach that addresses concerns about underutilized fixed PET scanners, the demand for additional mobile PET capacity and a more efficient service area. Novant Health respectfully requests that the SHCC move forward with its recommended approach for changes to the mobile PET chapter of the 2015 SMFP.

We appreciate the opportunity to comment on this matter. If you have any questions, please do not hesitate to contact us.

Sincerely,



Barbara Freedy, Director, Certificate of Need
Novant Health, Inc.
Phone: (336) 718-4483



Tiffany Brooks, Manager, Certificate of Need
MedQuest Associates, Inc.
Phone: (919) 264-0415

File: NovantHealthMedQuestMobilePETComments 3-21-14 FINAL.docx

ATTACHMENT A



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

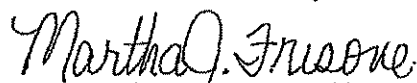
An Equal Opportunity/ Affirmative Action Employer

Mr. David French
March 11, 2014
Page 2

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

Sincerely,

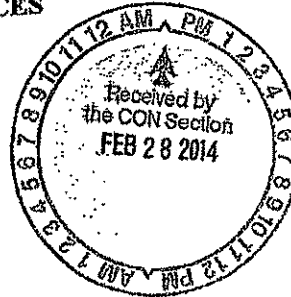

Gloria C. Hale
Project Analyst


Martha J. Frisone, Interim Chief
Certificate of Need Section

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

ALLIANCE HEALTHCARE SERVICES

Howie



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 1M9A6A8276H02244 | Siemens Biograph 1M9A6A82XWO2233 |
| Serial Number | PET CT 45 | PET CT 110 |
| Provider's Method of Identifying Equipment | Mobile | Mobile |
| Specify if Mobile or Fixed | | |
| Mobile Trailer Serial Number/VIN # | NA - No changes | NA - No changes |
| Mobile Tractor Serial Number/VIN # | 2006 | |
| Date of Acquisition of Each Component | Holds Title | Holds Title |
| Does Provider Hold Title to Equipment or Have a Capital Lease? | New when acquired | New when acquired |
| Specify if Equipment Was/Is New or Used When Acquired | NA | Existing equipment |
| Total Capital Cost of Project (no construction involved) | NA | Purchased in 2008 at a cost of |
| Total Cost of Equipment | NA | \$1,047,321 |
| Fair Market Value of Equipment | NA | same |
| Net Purchase Price of Equipment | NA | Same sites as PET CT 45 list |
| Locations Where Operated | See attached 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,



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