

**Technology and Equipment Committee
Agency Report
Petition Related to Mobile PET Services for the
Proposed 2015 State Medical Facilities Plan**

Petitioner 1:

MedQuest Associates, Inc.
3480 Preston Ridge Road, Suite 600
Alpharetta, Georgia 30005

Contact 1:

Tiffany Brooks
Certificate of Need Manager
(919) 263-0415

Novant Health, Inc
2085 Frontis Plaza Blvd.
Winston-Salem, NC 27103

Barbara Freedy
Certificate of Need
(336) 718-4483

Petitioner 2:

Randolph Hospital
P.O. Box 1048
Asheboro, NC 27204

Contact 2:

Barbara Wolfe
V.P., Strategy & Service Development
(336) 629-8882

Petitioner 3:

Alliance Healthcare Services
1233 Front Street, Suite A
Raleigh, NC 27612

Contact 3:

David French
P.O. Box 2154
Reidsville, NC 27323
(336) 349-6250

Request:

MedQuest Associates, Inc. and Novant Health, Inc. request to (1) “establish a 2015 SMFP health-planning based policy that allows existing hospital providers who own and operate more than one CON approved fixed PET/CT scanner, for a one year filing period during the 2015 SMFP plan year (1/1/2015-12/31/2015), to seek approval to convert one of their existing fixed PET/CT scanners to a mobile PET/CT scanner through the replacement provision identified at §N.C. Gen. Stat. 131E-176(22a)”; and (2) “replace the mobile East & West PET/CT service areas defined in current SMFPs with a mobile PET service area that includes the entire state of North Carolina for the 2015 SMFP place year and beyond to permit all mobile PET/CT scanners including the existing mobile PET provider and any subsequent providers to serve all of North Carolina.”

Randolph Hospital requests “that a methodology for mobile Positron Emission Tomography (PET) be established” and that “if the SHCC determines that providers with fixed PET scanners may convert those to mobile PET... either of the following two standards be applied:

- (1) Providers with fixed PET scanners who wish to convert multiple fixed PET scanners to a mobile scanner may do so; however, the approval of a converted mobile PET scanners shall not be considered to meet the need generated by the utilization of existing mobile PET scanners; or
- (2) Providers with fixed PET scanners who wish to convert multiple fixed PET scanners to a mobile scanners must include in the CON application at least one mobile PET host site that does not currently provide fixed PET services.”

Alliance Healthcare requests that the “Positron Emission Tomography basic policies and methodology be changed with the service area definition of a mobile PET scanner to be the entire State of North Carolina and the definition of a mobile PET host site to include existing oncology treatment centers with one or more linear accelerators, existing or proposed Independent Diagnostic Test Facility (IDTF) and existing or proposed licensed acute care hospitals.”

Background Information:

Chapter Two of the 2014 State Medical Facilities Plan (SMFP) states that “Anyone who finds that the North Carolina State Medical Facilities Plan policies or methodologies, or the results of their application, are inappropriate may petition for changes or revisions.... Changes with the potential for a statewide effect are the addition, deletion, and revision of policies or projection methodologies.” The requests made in the above petitions would have statewide effects.

Beginning in the 1980’s with the introduction of Positron Emission Tomography (PET) scanning, the primary use of this technology was more in research than clinical practice, with early clinical applications focused on the heart and the brain. However, this pattern has changed with the clinical use of PET scanning being used more with the diagnosis of cancer. In North Carolina the diagnosis of cancer accounts for well over 80 percent of clinical studies.

§N.C. Gen. Stat. 131E-176(19a) defines a PET scanner as “Equipment that utilizes a computerized radiographic technique that employs radioactive substances to examine the metabolic activity of various body structures.” Dedicated PET scanners are scanners used exclusively for PET imaging and can be fixed or mobile. The differentiation between a fixed and mobile PET scanner is that a mobile PET scanner is defined as a dedicated PET scanner with transporting equipment enabling the scanner to be moved to provide services at two or more host facilities whereas a fixed PET scanner is stationary. As PET scanners increased in utilization in North Carolina and the technology improved, the option to include mobile as well as fixed PET scanners was discussed.

During the State Health Coordinating Council (SHCC) public hearing held on February 21, 2001, a petition was introduced by Alliance Imaging, Inc. to request the development of two mobile PET scanner demonstration projects to be allocated to three western Health Service Areas (HSAs) - HSA I, II, and III - and three eastern HSAs – HSA IV, V and VI portions of North Carolina. The Alliance Imaging petition stated the following:

“Five factors provide justification for mobile PET scanners: Cost Effectiveness, Accessibility, Quality of Service, Success of other Mobile Medical Technology Service and Collaboration between Hospitals to enhance services.”

In the May 23, 2001 SHCC meeting, the council decided to approve the part of the petition, referenced above, that would clarify that requests for any future need determinations for PET scanners in the SMFP would be for mobile or fixed dedicated scanners due to the fact that the standard PET methodology did not distinguish between fixed and mobile PET scanners. However, during this meeting, the request for the demonstration projects was denied.

In August of 2001, petitions were filed with the agency and approved by the SHCC to allocate one mobile PET scanner to the western region comprised of HSA I, II and III and one to the eastern region comprised of HSA IV, V and VI. Alliance Imaging, Inc. was awarded the Certificate of Need for one mobile PET scanner in the western and one in the eastern region of North Carolina. Since that time, the number of sites in each region have varied as need dictated and as additional fixed PET scanners were developed. Currently, Alliance Healthcare Services has 18 mobile PET sites in the western region and 11 sites in the eastern region.

As outlined in the 2014 State Medical Facilities Plan (SMFP), service areas for PET scanners are defined as follows:

- 1) *A fixed PET scanner's service area is the Health Service Area (HSA) in which the scanner is located. There are six multi-county groupings.*
- 2) *A mobile PET scanner's service area is the planning region in which the scanner is located. The two mobile PET scanner planning regions have been defined as the west region (HSAs I, II, and III) and the east region (HSAs IV, V, and VI).*

There have been three petitions for adjusted need determinations for mobile PET in the last four years (neo pet in 2010, Carolinas Medical Center in 2011 and MedQuest/Novant in 2013). All three were denied and mobile PET capacity has remained the same in North Carolina since the 2003 SMFP. The 2013 petition presented by MedQuest/Novant led the SHCC's Technology and Equipment Committee to begin discussions with stakeholders across the state to explore whether changes need to be made to the mobile PET methodology and policies. On February 5, 2014, the Division of Health Service Regulation (DHSR) hosted a meeting that included SHCC members, stakeholders and other interested parties to discuss possible future directions for mobile PET in North Carolina. The requests in these petitions represent some of the alternative presented at that meeting.

For each facility that operates a PET scanner, the total number of procedures performed on the PET scanners located at the facility must be reported to the Division of Health Service Regulation on either a Hospital License Renewal Application for hospital-based facilities or on a Registration and Inventory of Equipment form for non-hospital-based facilities. The reporting period for both of these forms is a 12-month period from October to September. For example, the data utilized to develop tables and determine needs found in the 2014 SMFP was reported on

the 2013 Hospital License Renewal Application or 2013 Registration and Inventory forms covering the reporting period of October 1, 2011 through September 30, 2012.

The PET scanner need methodology consists of several steps delineated into two parts to determine the number of PET scanners needed in the PET service areas. Methodology Part 1 is the standard methodology for determining need for additional fixed PET scanners. The need exists for one additional fixed dedicated PET scanner in a service area when a provider's utilization of the existing fixed PET scanner is at or above 80 percent (2,400 procedures) of the defined capacity of 3,000 procedures during the 12-month reporting period described above. Methodology Part 2 provides a condition to determine a need for a hospital based major cancer treatment facility, program or provider that does not own or operate a fixed dedicated PET scanner. A maximum need determination has been established as no more than two additional fixed PET scanners for any single service area in any given year regardless of the numbers generated individually by each part of the methodology. As already noted, no distinct methodology has been developed specifically for mobile PET scanners. Mobile capacity has been defined as in the SMFP as 2,600 procedures.

Analysis/Implications:

The two existing mobile PET scanners are over-capacity and patient access is impacted as a result. Beginning in 2009, one unit (West) has been over capacity, which is defined as 2,600 PET scans, every subsequent year. The second unit was over capacity in 2010, but has been consistently over capacity beginning in the 2013 SMFP as shown in Table 1 below.

TABLE 1: ANNUAL PROCEDURES ON MOBILE UNITS 2007-2012 SMFP

SMFP Year	Mobile Unit West	Mobile Unit East
2009	2,826	2,036
2010	3,196	2,619
2011	2,821	2,437
2012	2,861	2,550
2013	3,066	2,650
2014	2,760	2,811

The three petitions submitted make overlapping requests and each request is discussed below, taking all three petitions' requests into consideration.

Conversion from Fixed to Mobile.

The petitions submitted by MedQuest/Novant and Randolph Hospital request a policy to allow existing or approved fixed PET scanners to be converted to mobile scanners.

Despite the presence of under-utilized fixed scanners, between 2004 and 2012 mobile service sites have risen on the whole, 72% (from 8 to 11) and the number of procedures performed has increased by 40% (from 1,094 to 2,809). Fixed scanners have also shown an increase in utilization in number of overall procedures performed across the state, from 8 in 2004 to 15 in

2012 (53% increase) and from 7,464 procedure to 17,667 (42% increase) despite the increase of mobile PET host sites. Mobile and fixed PET scanners seem to be operating different growth trajectories with potentially different factors impacting their utilization. Reported factors contributing to under-utilization of fixed scanners are acuity of patients using PET scan services, lack of accessibility within patients own community and increased travel time/expense for patients who do not live in urban areas. Creating a policy to allow the conversion of fixed PET scanners to mobile scanners would alleviate some of the issues associated with accessing PET services while not impacting overall PET capacity in the state, a concern previously raised by the SHCC.

Randolph Hospital addresses this issue with its request to include language in the proposed policy as follows: “Providers with fixed PET scanners who wish to convert multiple fixed PET scanners to a mobile scanner must include in their CON application at least one mobile PET host site that does not currently provide fixed PET services.” In its April 24, 2013 meeting the SHCC’s Technology and Equipment Committee (TEC) expressed concern that fixed scanners converted to mobile would continue to primarily serve urban patients instead of expanding service to rural areas where there is the most unmet need. Data presented by Randolph Hospital shows that the TEC’s concerns were well-placed. Rural residents have less access and received fewer PET scans than urban residents in the state. While this language would address the concerns raised by the TEC by increasing the likelihood that rural counties will be served by providers who convert, the Agency believes this policy could be strengthened by adding the requirement that converted mobile PETs establish at least one host site in a county with a population under 50,000 (the criteria for a rural designation by the U.S. Census Bureau). In 2012, there were forty-seven counties in North Carolina that met this definition according to population data from the North Carolina Office of State Budget and Management.

Randolph Hospital also requests that “providers with fixed PET scanners who wish to convert multiple fixed PET scanners to a mobile scanner may do so; however, the approval of a converted mobile PET scanner shall not be considered to meet the need generated by the utilization of existing mobile PET scanners.” This condition of the proposed conversion policy would only apply if the SHCC adopted a mobile PET scanner methodology and would effectively exclude all converted scanners from the planning inventory. At this point in time, there are no data available to predict the number of providers who will choose to convert. Enacting this policy with an exemption of all converted PET scanners from the planning inventory included could result in a considerable surplus of mobile services should a mobile PET methodology be established in the future.

MedQuest/Novant proposes restricting conversion from fixed to mobile to providers who have more than one fixed PET scanner because “it ensures that the conversion of a fixed PET unit to a mobile PET unit would not result in the elimination of fixed PET service from a county or service area.” This would apply to four providers: Forsyth Medical Center, Carolinas Medical Center, Duke University Hospital and University of North Carolina Hospital. All of these scanners are located in urban centers. Restricting the conversion of scanners to only hospitals located in major urban centers would likely not increase access to PET services for rural residents. Additionally, only eight of the twenty-seven fixed PET scanners in North Carolina were utilized above 50% capacity 2012, as reported in the 2014 SMFP. It should be noted that

two (Duke University Hospital and Carolinas Medical Center) of the four providers who have more than one fixed PET scanner were among the hospitals that reflected utilization above 50% capacity in the 2014 SMFP. Providers with low utilization would be more likely to undergo the expense of converting, making it less likely that restricting the conversion in the way MedQuest/Novant suggests may not increase mobile PET scanner capacity in any substantial way. An alternative to MedQuest/Novant's request would be to require providers who choose to convert to continue servicing the facility in which the original fixed scanner was located or was approved to be located as a host site.

MedQuest/Novant also requests restricting the allowable time to apply to DHSR's Certificate of Need Section for approval to convert a fixed scanner to one year. The Agency finds no reason to restrict the application period for conversion to a single year. Given that smaller to mid-sized hospitals might require a longer period of time before conversion becomes financially feasible, restricting the time period for applications to a single year presents an unfair advantage to larger facilities. Additionally, all policies contained in the SMFP are reviewed annually by the SHCC in the Spring when the first drafts of SMFP tables are presented to each Committee. If the SHCC determines that the proposed conversion policy should be eliminated from a future SMFP, it will have the opportunity to enact such a change after reviewing the most recent data on how converted mobile PET scanners are impacting PET service utilization. At this point, it is unclear whether allowing conversion for a single year would be a sufficient time period to increase the needed mobile PET capacity in North Carolina.

Statewide Service Area

All three petitions request the removal of the East/West service areas in favor of a single statewide service area. In some cases, like with Randolph Hospital, the service area delineation prevents a host site that would like to access available time on a less utilized mobile unit from doing so because that unit would need to cross into a different designated service area. The current mobile PET scanner service areas were selected by the SHCC in 2001 in response to a petition from Alliance Healthcare for two mobile scanners, one for each half of the state. In tandem with the proposed conversion policy, creating a single statewide service area would more effectively utilize resources by allowing providers in the middle of the state to serve nearby host sites regardless of the East/West designation. This change could also reduce travel time for mobile units between sites, allowing for more onsite availability, something both MedQuest/Novant and Randolph Hospital raise as an existing issue in their petitions. It should be noted that there was wide approval from stakeholders attending the February 2014 PET scanner meeting for moving to a statewide service area to allow more flexibility in scheduling host sites and would allow maximum utilization of mobile PET scanners.

Creating a Mobile PET Methodology

Randolph Hospital requests the development of a mobile PET methodology for inclusion in the SMFP. The Agency supports the development of such a methodology. However, if the above changes are implemented they could alleviate the current restrictions to access to such a degree that a new methodology, developed concurrently to these changes, might over-project need. The general opinion in the February 2014 stakeholder meeting was that the other changes should be implemented first and their impact measured before creating a separate methodology for mobile PET scanners. Given the current over-utilization of the two existing units and the absence of

data about what is the best threshold for generating a need determination based on utilization with additional units added to the inventory, setting a definitive threshold for generating a need determination for additional mobile PET scanners while concurrently implementing other substantial changes to mobile PET policies would not be advisable and may lead to an over-capacity of the service.

Changing Definition of a Host Site

Alliance Healthcare requests changes to the definition of “host site” in §N.C. Gen. Stat. 10 NCAC 14C .3700. “Host site” is not defined in this statute and nothing in the statute precludes Independent Diagnostic Testing Facilities from becoming host sites as long as they meet the criteria for the information required of an applicant, performance standards, support services, and staff and staff training. It should be specifically noted that applicants do not have to directly provide the services listed under §N.C. Gen. Stat. 10 NCAC 14C .3702(b)(2). The statute states only that applicants are required to show documentation that “arrangements made between the applicant and other providers to assure the patient the facility will *have access to...*” these services. Addressing the issue of defining a host site more specifically would require a rule change, which is outside the purview of the SHCC.

Agency Recommendation:

Given available information and comments submitted by the March 5, 2014 deadline date for comments on petitions and comments, and in consideration of factors discussed above, the agency recommends denial of all petitions. In regard to the petition from MedQuest/Novant, the Agency finds no reason to limit conversion applications to providers with multiple PET scanners. In regard to the petition from Randolph Hospital, the Agency does not believe establishing a methodology concurrently with proceeding with a fixed-to-mobile PET conversion would be the appropriate course of action due to the difficulty it would create with projecting need for PET services. In regard to the petition from Alliance Healthcare, there is no statutory restriction on IDTFs serving as PET host sites, and modifying such a statute would be beyond the purview of the SHCC.

Furthermore, the Agency proposes that the State Health Coordinating Council adopt the following recommendations:

1. Revise the current East and West service areas to a statewide service area to allow flexibility in servicing mobile PET sites.
2. Approve a policy to allow the conversion of fixed PET scanners to mobile PET scanners that requires converted PET scanners to: (1) continue to serve the facility in which the fixed PET scanner was located; (2) move the converted mobile PET scanner at least weekly to serve at least one facility other than the original site of the converted fixed PET scanner; (3) serve at least one facility in a county that meets the U.S. Census Bureau’s criteria (Population less than 50,000) as a rural county using data starting with the certified 2012 population estimates from the North Carolina Office of State Budget and Management, that subsequently will be updated annually; and (4) not serve any mobile host facility located in the county where any existing or approved fixed PET scanner is

The Agency recommends the following language for the creation of a policy to allow fixed-to-mobile conversion of PET equipment:

POLICY PET-1: CONVERSION OF FIXED PET SCANNERS TO MOBILE PET SCANNERS

Facilities with an existing or approved fixed PET scanner may apply for a Certificate of Need (CON) to convert the existing or approved fixed PET scanner to a mobile PET scanner if the converted mobile PET scanner:

- a. Shall continue to operate as a mobile PET scanner at the facility, including satellite campuses, where the fixed PET scanner is located or was approved to be located.
- b. Shall be moved at least weekly to provide services at two or more host facilities.
- c. Shall serve at least one mobile host facility in one of the rural counties listed below:
 - 1. Alexander
 - 2. Alleghany
 - 3. Anson
 - 4. Ashe
 - 5. Avery
 - 6. Beaufort
 - 7. Bertie
 - 8. Bladen
 - 9. Camden
 - 10. Caswell
 - 11. Cherokee
 - 12. Chowan
 - 13. Clay
 - 14. Currituck
 - 15. Dare
 - 16. Davie
 - 17. Gates
 - 18. Graham
 - 19. Greene
 - 20. Hertford
 - 21. Hoke
 - 22. Hyde
 - 23. Jackson
 - 24. Jones
 - 25. Macon
 - 26. Madison
 - 27. Martin
 - 28. McDowell
 - 29. Mitchell
 - 30. Montgomery
 - 31. Northampton
 - 32. Pamlico
 - 33. Pasquotank
 - 34. Perquimans
 - 35. Person
 - 36. Polk
 - 37. Richmond
 - 38. Scotland
 - 39. Stokes
 - 40. Swain
 - 41. Transylvania
 - 42. Tyrell
 - 43. Vance
 - 44. Warren
 - 45. Washington
 - 46. Yadkin
 - 47. Yancey
- d. Shall not serve any mobile host facility located in the county where any existing or approved fixed PET scanner is located, except as required by subpart (a) above.