Technology and Equipment Committee
Agency Report
Petition Related to Mobile PET Services for the 2014 State Medical Facilities Plan

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Petitioner:

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Contact:

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Request:

MedQuest Associates, Inc. and Novant Health, Inc. request the establishment of a "methodology for mobile PET scanners that generates a need determination for a new mobile PET scanner when an existing mobile PET/CT scanner in the defined service area exceeds the 2,600 annual procedure capacity".

Background Information:

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.

General Statute 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.

Chapter Two of the 2013 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 petition is requesting the establishment of a mobile PET methodology in the SMFP. This change would have a statewide effect.

As outlined in the 2013 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).*

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 2013 SMFP was reported on the 2012 Hospital License Renewal Application or 2012 Registration and Inventory forms covering the reporting period of October 1, 2010 through September 30, 2011.

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:

MedQuest Associates, Inc. and Novant Health Inc. have submitted a petition to establish a mobile PET need methodology consistent with the fixed PET need methodology in order to generate one new mobile PET scanner for each mobile PET scanner planning region.

Data utilized in the petition was obtained from historical SMFP data. The primary comparisons are made from the data in the 2013 SMFP in comparison to the recently submitted 2013 Hospital License Renewal Applications and the 2013 Registration and Inventory forms (data filed). Since submission of the petition, revisions to utilization data on the data filed (updated data) have been submitted to the Medical Facilities Planning Branch and incorporated into this analysis.

The petition's chart on page four reports 3,136 total mobile PET procedures according to data filed in the western region. However, in Table A, updated data from two western mobile PET sites results in a total of 2,760 mobile PET procedures for that region. The updated data reveals a 10 percent decrease in utilization from the total mobile PET procedures reported for use in the 2013 SMFP (3,066 to 2,760 procedures). Table A also shows that updated data of combined fixed and mobile PET utilization of 20,427 procedures declined by approximately eight percent in the western region compared to 22,188 combined fixed and mobile PET procedures for the 2013 SMFP.

Table A - Western Mobile PET Region

H S A I, II, III Reporting Period	SMFP	# Fixed PET Scanners	Fixed PET Volume	Total Fixed Utilization Rate	# Mobile PET Sites	Mobile PET Volume	Total Mobile Utilization Rate	Total PET Volume - Fixed and Mobile	Rate of Change Mobile PET	Rate of Change Fixed PET	Rate of Change Combined
2011-2012	*	15	17667	39%	18	2,760	106%	20,427	-10%	-8%	-8%
2010-2011	2013**	15	19122	42%	18	3,066	118%	22,188	18%	-7%	-4%
2009-2010	2012	15	20537	46%	17	2,588	100%	23,125	-8%	-3%	-4%
2008-2009	2011	14	21226	51%	13	2,821	109%	24,047	-12%	8%	5%
2007-2008	2010	14	19742	47%	13	3,196	123%	22,938	13%	4%	5%
2006-2007	2009	12	18972	53%	14	2,826	109%	21,798	68%	19%	24%
2005-2006	2008	12	15947	44%	15	1,685	65%	17,632	44%	32%	33%
2004-2005	2007	11	12050	37%	9	1,172	45%	13,222	27%	61%	58%
2003-2004	2006	8	7464	28%	7	924	36%	8,388		76%	98%
2002-2003	2005	5	4231	20%	0	-	0%	4,231			

* Updated data to be used for Proposed 2014 SMFP

* *Mobile site at CMC Union ceased operations 05/2011

As shown on Table B as well as in the chart on page two of the petition, the eastern PET planning region realized a six percent increase in utilization of mobile PET procedures, from 2,650 total mobile PET procedures in the 2013 SMFP to 2,811 total mobile PET procedures from data filed. In reviewing the combined utilization of mobile and fixed PET scanners in the eastern PET planning region, Table B demonstrates there has been an overall decrease of three percent utilization – from 18,428 procedures shown in the 2013 SMFP to 17,873 procedures from updated data.

Table B - Eastern Mobile PET Region

H S A IV, V, VI Reporting Period	SMFP	# Fixed PET Scanners	Fixed PET Volume	Total Fixed Utilization Rate	# Mobile PET Sites	Mobile PET Volume	Total Mobile Utilization Rate	Total PET Volume - Fixed and Mobile	Rate of Change Mobile PET	Rate of Change Fixed PET	Rate of Change Combined
2011-2012	*	12	15062	31%	11	2,811	108%	17,873	6%	-5%	-3%
2010-2011	2013	12	15778	33%	11	2,650	102%	18,428	4%	-2%	-1%
2009-2010	2012	12	16085	36%	10	2,550	98%	18,635	5%	3%	3%
2008-2009	2011	12	15653	37%	9	2,437	94%	18,090	-7%	17%	13%
2007-2008	2010	11	13426	34%	8	2,619	101%	16,045	29%	-5%	-1%
2006-2007	2009	11	14157	39%	7	2,036	78%	16,193	17%	15%	16%
2005-2006	2008	11	12268	34%	8	1,743	67%	14,011	-20%	33%	23%
2004-2005	2007	10	9220	26%	8	2,175	84%	11,395	82%	31%	38%
2003-2004	2006	8	7038	21%	8	1,197	46%	8,235		44%	68%
2002-2003	2005	5	4896	33%	0	-	0%	4,896			

*Updated data to be used for Proposed 2014 SMFP

The petition points out that both mobile PET scanners have exceeded the 2,600 annual mobile PET scan capacity threshold described in the 2013 SMFP. The petition states the following:

1) *The failure to define capacity and initiate triggers for need determinations for new mobile PET service is missing from the SMFP, is not part of the North Carolina health planning process, and is adversely affecting patients and healthcare providers.*

2) *The omission of a need methodology in the State Medical Facilities Plan that would generate need determinations for additional mobile PET scanners in North Carolina is effectively restricting access to this important diagnostic service for underserved groups across North Carolina….*

Although mobile PET scanners performed above the 2,600 capacity as defined in the 2013 SMFP, the petition omits the fact that fixed scanners across the state operated below their capacity. The petition focuses on mobile PET availability, within each of the service areas. However, there are existing fixed PET scanners that are currently operating below capacity and available to provide services to the public within each of the service areas.

To illustrate utilization, there are 27 fixed PET scanners across the state as reported in updated data, none of which are operating at capacity (as defined in the 2013 SMFP as 3,000 procedures). One of the 27 facilities are operating below 10 percent utilization. At the facility level, updated data report current utilization rates for fixed PET scanners as low as eight percent of capacity with 14 out of 27 facilities operating under 50 percent of capacity. Further, five of the six HSAs have realized a decrease in fixed PET scanner utilization according to the updated data ranging from a one percent decline in HSA III to 12 percent decline in utilization in HSA II in comparison to the 2013 SMFP data. The only exception was HSA V which updated data reported a one percent increase in utilization to date.

Statewide, mobile PET scanner utilization decreased by three percent from procedures reported in the 2013 SMFP (5,716 to 5,571 procedures) as shown in Table C. The combined mobile PET scanner utilization has decreased by three percent according to the updated data in comparison to the 2013 SMFP. The combined mobile PET scanner utilization statewide has seen a decrease in three out of the past four filed and updated data reporting periods since 2011SMFP. Table C shows that total fixed PET utilization at a statewide level decreased six percent from the 2013 SMFP to the updated data (34,900 to 32,729 procedures). Combined fixed and mobile PET utilization statewide declined by six percent from 40,616 procedures for the 2013 SMFP down to 38,300 procedures from updated data. Since the 2011 SMFP, a decline has been realized in the combined utilization of fixed and mobile PET scanners statewide for each SMFP as described in Table C.

Table C – Statewide PET Procedures

Statewide Reporting Period	SMFP	# Fixed PET Scanners	Fixed PET Volume	Total Fixed Utilization Rate	Mobile PET Volume	Total Mobile Utilization Rate	Total PET Volume - Fixed and Mobile	Rate of Change Mobile PET	Rate of Change Fixed PET	Rate of Change Combined
2011-2012	*	27	32,729	40%	5,571	107%	38,300	-3%	-6%	-6%
2010-2011	2013	27	34,900	43%	5,716	110%	40,616	11%	-5%	-3%
2009-2010	2012	27	36,622	45%	5,138	99%	41,760	-2%	-1%	-1%
2008-2009	2011	27	36,879	47%	5,258	101%	42,137	-10%	12%	9%
2007-2008	2010	27	32,831	46%	5,815	112%	38,646	20%	-1%	2%
2006-2007	2009	27	33,129	48%	4,862	94%	37,991	42%	17%	20%
2005-2006	2008	25	28,215	41%	3,428	66%	31,643	-5%	33%	27%
2004-2005	2007	22	21,270	34%	3,621	70%	24,891	61%	61%	61%
2003-2004	2006	22	13,198	27%	2,248	43%	15,446		45%	69%
2002-2003 da	2005	19	9,127	61%	-	0%	9,127			

*Updated data to be used for the Proposed 2014 SMFP

The low rates of fixed PET scanner utilization across the state as well as overall decreasing utilization of PET scanning services demonstrate access and availability for PET scanning services for the citizens of the state. It is also noted that three of the four hospitals named in the petition have reported a decrease in the number of mobile procedures in the updated data in comparison to the number of mobile procedures reported for the 2013 SMFP.

The petition's requested revision for mobile PET scanner methodology resulting in the need determination for two additional mobile PET scanners would be duplicative of both the existing fixed and mobile scanners. The addition of mobile scanners, as proposed, may result in little benefit and probable harm to the utilization of the existing fixed PET sites. The fixed PET scanners represent a large investment in facilities and equipment. The intent of the planning and CON process is avoidance of excess capacity that results in costly duplication and underuse of facilities that leads to an economic burden on the public.

The three basic principles that govern the development of the SMFP are safety and quality, access and value. The 2013 SMFP defines value for health care as "the maximum health care benefit per dollar expended." This key principle guides the effort to formulate and implement recommendations for the SMFP in order to maximize the health benefit for the entire population of North Carolina. Collaborative efforts and coordinated services are needed to reduce duplication of care and maintain the balance of value, quality and access.

The petition states that patients must travel out of county to access PET services. While it is true that every county does not have access to PET scanning services within the county, the intent of the methodology does not have the goal of services in every county. Planning for PET scanning services is handled on a regional basis. As stated above, six service areas have been established for need determination for fixed PET scanners and two planning service areas are used for mobile PET scanners designation. All six Health Service Areas are served by both fixed and mobile PET scanners, providing adequate access to services. As more fixed PET scanners have

been developed, the distribution of sites for mobile PET scanners have changed in order to provide access throughout each region.

Agency Recommendation:

Given available information and comments submitted by the March 22, 2013 deadline date for comments on petitions and comments, and in consideration of factors discussed above, the agency recommends denial of the petition. The Agency supports the standard methodology for dedicated fixed PET scanners. The Agency also supports no changes be made to develop a distinct mobile PET scanner methodology. The combined utilization rates for mobile and fixed PET scanners indicate sufficient availability of PET scanning services to meet demand. While the overall snapshot of PET service capacity and utilization indicates availability of services, the Agency recognizes a continued interest in mobile PET scanning services. More in-depth analysis or discussion may be needed to understand the distribution of mobile PET scanning services. Options and alternatives may need to be explored by the Technology and Equipment Committee to meet this request.