

**PETITION**

**TO:** Christopher Ullrich, M.D., Chairman  
North Carolina State Health Coordinating Council and Technology and  
Equipment Committee  
c/o Medical Facilities Planning Branch  
2704 Mail Service Center  
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**RE:** Petition for an Adjusted Need Determination for No Conversions of Fixed PET  
Scanners to Mobile PET Scanners in the 2016 State Medical Facilities Plan

Alliance Healthcare Services ("Alliance") petitions for an adjusted need determination to establish that no additional fixed PET scanners can be converted to mobile PET in the context of the 2016 State Medical Facilities Plan. This requested adjustment is justified because there will be excess capacity of both mobile PET scanners and fixed PET scanners throughout North Carolina if CON approval is granted for the 2015 CON application that proposes the conversion of one fixed PET to a mobile PET.

**Background Information**

The Proposed 2016 State Medical Facilities Plan shows that the 28 existing fixed PET scanners are underutilized and the two mobile PET scanners are operating at high utilization. The need methodology for fixed PET shows no unmet needs in any of the Health Service Areas. Mobile PET scanners now have a statewide service area but no need methodology. Policy TE-1 provides opportunity for providers to submit certificate of need applications to convert fixed PET scanners to mobile PET scanners based on certain conditions. The PET administrative rules are outdated and in conflict with the requirements of Policy TE-1. (This concern was previously communicated to the Division of Health Service Regulation in October 2014 but to date there has been no action.)

Novant Health Forsyth Memorial submitted a CON application to convert a fixed PET to mobile PET on June 15, 2015. The outcome of this CON review and future changes in PET utilization at multiple locations will take a couple of years' time to be assessed.

The unique characteristics of the PET utilization, service areas and planning methodologies related are outlined as follows:

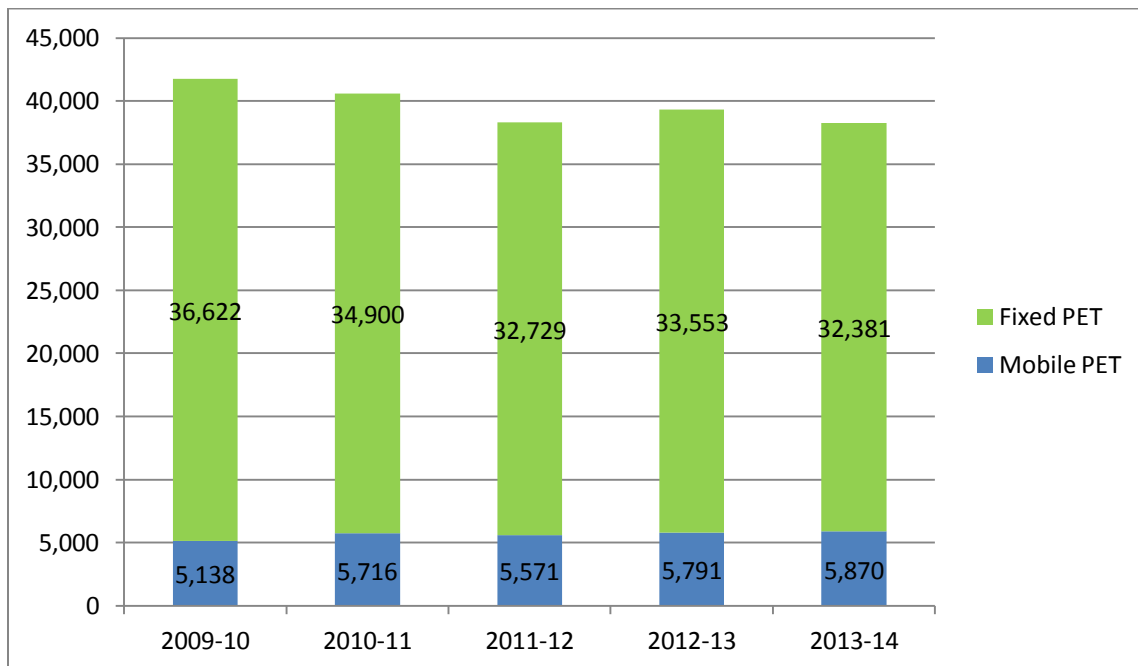
- Fixed PET scanners are assigned to the six Health Service Areas; mobile PET scanners now have a statewide service area.
- A need methodology exists for fixed PET but no methodology is promulgated for mobile PET.
- Statewide total PET scanner utilization shows a declining trend.
- Excess capacity of fixed PET scanners exists in each of the six Health Service Areas.
- Policy TE-1 restricts the group of potential applicants and potential host sites.
- Changes to the PET inventories would result if fixed PET scanners are changed to mobile PET scanners.
- The Proposed 2016 SMFP includes no “placeholder” mechanism for pending CON applications that relate to the conversion of fixed PET scanners to mobile PET scanners.

Given these unique circumstances, the requested adjustment would be in the best interest of the citizens of North Carolina to avoid the proliferation of unnecessary health services.

### Data and Analysis

The compound annual growth rate for total combined fixed and mobile PET scans in North Carolina is **-2.17 percent** based on 41,760 total scans in 2009-10 which dropped to 38,215 total scans in 2013-14.

	2009-10	2010-11	2011-12	2012-13	2013-14
Mobile PET	5,138	5,716	5,571	5,791	5,870
Fixed PET	36,622	34,900	32,729	33,553	32,381
Totals	41,760	40,616	38,300	39,344	38,251



For the most recent year, fixed PET scanners throughout the state are underutilized at a combined 38.55 percent of capacity and reported a 3.49 percent decrease in utilization during the previous year. While mobile PET utilization increased slightly last year, the total combined utilization for fixed and mobile PET decreased by 2.78 percent as seen in the following table.

	2012-13	2013-14	% Change
Fixed PET	33,553	32,381	-3.49%
Mobile PET	5,791	5,870	1.36%
Totals	39,344	38,251	-2.78%

Sources: Tables 9L and 9M(1) of the 2015 SMFP and Proposed 2016 SMFP

The low rate of fixed PET scanner utilization across the state, as well as decreasing utilization of PET scanning services, demonstrates access and availability for PET scanning services for the citizens of the state. With declining total PET utilization, there is no unmet need that the population has for a mobile PET scanner as a more effective alternate to a fixed PET scanner. No need exists for additional fixed PET scanners anywhere in state. The proposed 2016 SMFP includes no methodology to quantify an unmet need for additional mobile PET capacity. The purpose of Alliance’s requested adjustment is to prevent “unnecessary duplication” of existing or approved health service capabilities or facilities.”

According to Radiology Today, PET/CT manufacturers are implementing changes to the technology to reduce both the radiation dose and the image acquisition time.<sup>1</sup> These improvements are aimed at enhancing patient safety and image quality. Alliance is concerned that the overall surplus of PET capacity in North Carolina will cause providers to delay upgrading their scanners. Additional mobile PET scanners will draw patients away from existing fixed PET scanners, thereby causing these facilities to be less able to justify replacing outdated fixed PET technology.

Alliance asserts that it is unreasonable to expect that any current or future proposals to convert underutilized fixed PET scanners to become mobile units are going to reverse the overall trend of decreasing PET utilization. Therefore the petitioner requests that an adjusted need determination that no additional conversions of existing fixed PET to become mobile PET scanners should be included in the 2016 SMFP. The requested adjustment is consistent with the following statements included in § 131E-175 Findings of Fact:

**“That the proliferation of unnecessary health service facilities results in costly duplication and underuse of facilities, with the availability of excess capacity leading to unnecessary use of expensive resources and overutilization of health care services.”**

**“That excess capacity of health service facilities places an enormous economic burden on the public who pay for the construction and operation of these facilities as patients, health insurance subscribers, health plan contributors, and taxpayers.”**

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<sup>1</sup> Orenstein. Beth W., Reducing PET Dose, *Radiology Today* Vol. 17 No. 1 P. 22

### Requested Adjusted Need Determination

The petitioner requests that Chapter 9 of the 2016 State Medical Facilities Plan include the following language and Table:

Table 9P: No Need Determinations for Conversions of Fixed PET to Mobile Dedicated PET Scanner (Scheduled for Certificate of Need Review Commencing in 2016)

Service Area	PET Need Determination	Certificate of Need Application Due Date	Certificate of Need Beginning Review Date
It is determined that there is no need for additional conversions of fixed PET to mobile dedicated PET scanners anywhere in the state and no other CON reviews are scheduled.			

### Adverse Effects Will ensue if the Adjustment is Not Made

Excess capacity of fixed and mobile PET scanners cannot be mitigated by substituting more mobile PET scanners for underutilized fixed PET scanners. The declining statewide PET utilization means that the overall expense per PET scanner is already increasing because of the smaller number of annual scans. The purchase cost for a new mobile PET scanner is unnecessary because there is sufficient capacity with the existing mobile and fixed PET scanners to serve the needs of North Carolina citizens. If yet another mobile PET scanner conversion from a fixed unit to mobile is approved and implemented, this unit can only increase its utilization by usurping the utilization that could have been performed at less cost with the existing PET capacity.

### Statement of Alternatives to the Proposed Adjustment

The petitioner considered two alternatives to the proposed adjustment including maintaining the status quo and petitioning for an adjusted need determination to allow only proposals for one additional mobile PET for the replacement of two or more underutilized fixed PET scanners.

The alternative of maintaining the status quo was not selected because the proposed 2016 SMFP does not attempt to determine what would be the optimal number of fixed and mobile PET scanners to serve the needs of the population. There is no data to demonstrate that additional mobile PET scanners that may be converted from underutilize fixed scanners are needed anywhere in North Carolina.

An adjusted need determination that facilitates replacing two or more underutilized fixed PET with a single mobile PET has limited potential because Alliance could not identify two or more fixed PET providers that would consider this option. Most underutilized PET scanners are at regional hospitals where the full time access to this imaging technology is considered important to the overall continuity and timeliness of cancer care.

The requested adjustment for no additional conversions of existing fixed PET scanner to become mobile PET scanners is the only alternative that responds to the excess capacity of fixed PET scanners and the decline in statewide PET utilization. Approval of the adjustment provides time to assess the future mobile PET inventory and capacity based on the outcome of the 2015 Novant CON application. Given the fact that only one CON application was submitted in the 2015 review, it is apparent that Policy TE-1 has limited appeal to fixed PET facilities.

### **Requested Adjustment Would Not Result in Unnecessary Duplication of Health Resources**

Alliance's requested adjustment allows for no additional conversions of existing fixed PET scanners to become mobile PET scanners in the 2016 SMFP. Approval of the proposed adjustment would not increase the inventory of either mobile PET scanners or fixed PET scanners. Also, the requested adjustment puts a hold on new CON proposals for the conversion of PET scanners to provide time for the PET administrative rules to be amended to be consistent with Policy TE-1: Conversion of Fixed PET Scanners to Mobile PET Scanners.

### **Requested Adjustment is Consistent with the Basic Principles: Safety and Quality, Access and Value**

The petitioner's requested adjustment is consistent with the Basic Principles in several ways:

Safety and quality programs and policies that are in place at existing fixed and mobile PET sites will continue to be provided in accordance with their institutional policies and accreditation standards. If the requested change is approved, then there is an opportunity to update the PET administrative rules to include safety and quality standards that relate to Policy TE-1.

Patient access to PET services would not be diminished by the requested adjustment because there is abundant capacity at existing PET scanners and total PET utilization declined during the previous year. Existing site locations served by the Alliance mobile PET CT scanners include a balance of rural and urban facilities.

The petitioner's requested adjustment promotes cost effective services and value by preventing unnecessary capital expenditures that would result in duplication of PET services. Mobile PET scanners have transportation costs that make it highly unlikely that additional conversions of fixed PET scanners to mobile units are a cost effective strategy.

In conclusion, Alliance respectfully requests that the State Health Coordinating Council approve the requested adjustment based on the facts and analysis provided in this petition.