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PETITION

North Carolina State Health Coordinating Council

Submitted to:
Dr. Christopher G. Ullrich, Chair
Technology and Equipment Committee
c/o Medical Facilities Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

Submitted by:
F. Del Murphy, Jr.
Vice President
Carolinas HealthCare System
1000 Blythe Boulevard
Charlotte, North Carolina 28203
(704) 355-6060
Del.Murphy@carolinashealthcare.org

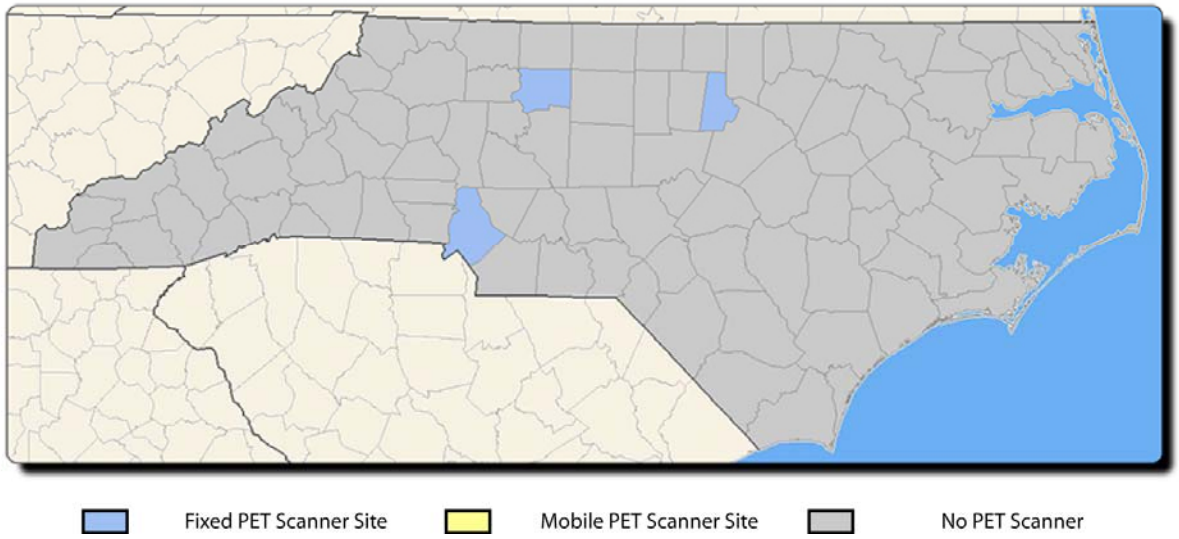
Requested Change

Carolinas HealthCare System (CHS) requests that a new methodology be developed to determine the need for additional mobile PET scanners.

Evolution of PET Methodology

As defined in General Statute § 131E-176(19a), a Positron Emission Tomography (PET) Scanner is a unit of equipment that "utilizes a computerized radiographic technique that employs radioactive substances to examine the metabolic activity of various body structures." PET technology became available in the mid-1980s, and the first PET scanner in North Carolina was developed in 1985 at Duke University Hospital. The use of PET technology was initially limited to research purposes, and no methodology to determine the need for additional fixed PET scanners was included in the *State Medical Facilities Plan (SMFP)* until 1995. At that time, North Carolina Baptist Hospitals, Carolinas Medical Center and Duke University Hospitals were the only providers of PET services. In the *1995 SMFP*, it was stated that a need for an additional PET scanner would be generated if an existing provider performed more than 524 procedures in a given year. As the technology became more widely applicable, the annual capacity of a fixed PET scanner was increased to 1,524 in 1998. However, no need determinations for additional dedicated fixed PET scanners were generated until 2001 when the State Health Coordinating Council (SHCC) made substantial changes to the methodology. As shown in the following map Mecklenburg, Durham and Forsyth counties remained the only counties with PET scanners as inventoried in the 1995 to 2000 *SMFPs*.

PET Scanner Capacity in North Carolina, 1995-2000 State Medical Facilities Plans



In 2001, the *SMFP* provided a one-year methodology, including three conditions which would trigger the need for an additional PET scanner. First, a need would be generated in each Health Service Area (HSA) without an existing PET scanner. Second, a need existed in an HSA when an existing provider's utilization of a fixed PET scanner was at or above 80.0 percent of the defined capacity of 1,524 procedures, or 1,220 procedures during the previous federal fiscal year. Lastly, the *SMFP* stated that there was no demonstrated need for mobile PET scanners, coincidence cameras, or hybrid machines anywhere in the state. Qualified applicants were hospitals that served a multi-county area, served as a teaching site for post graduate medical education, and provided open heart surgery and comprehensive cancer services.

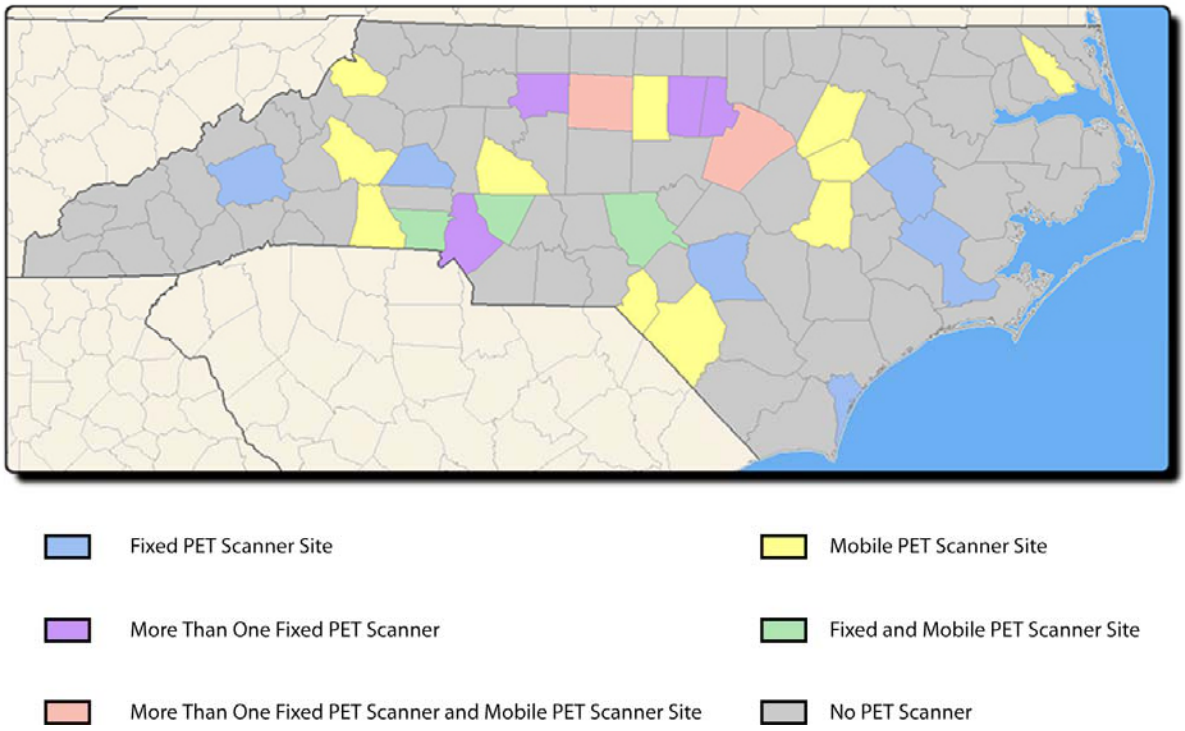
By 2002, the need to locate a PET scanner in each HSA had been met. As such, the only stated methodology for generating a need for an additional PET scanner was when an existing fixed PET scanner began performing at 80.0 percent of capacity. It should be noted, however, that an adjusted need determination for two mobile PET scanners was placed in the *2002 SMFP* in response to two special need petitions. One mobile PET scanner was expected to provide services to host sites located within PET Scanners Planning Region I consisting of HSAs I, II and III, and the other mobile scanner was expected to provide services to host sites located within PET Scanners Planning Region II consisting of HSAs IV, V and VI. These scanners were ultimately awarded to Alliance Imaging, and currently remain the only mobile PET scanners in the state.

In 2003, the PET methodology was updated again to include a second condition under which the need for an additional PET scanner could be generated. The new condition stated that one dedicated fixed PET scanner is needed for each hospital-based major cancer treatment facility that did not own or operate a dedicated fixed PET scanner. For the purposes of the PET methodology, a major cancer treatment facility was defined as a provider that performed over "12,500 Procedures/ESTVs" in the previous federal fiscal year.

As a result of the updates to the methodology described above, dedicated fixed and mobile PET services became more accessible to the residents of North Carolina. The following map shows

the supply of operational PET scanners as of the *2006 SMFP*. Please note that this was the first year that volume for mobile PET sites was included in the *SMFP*.

Operational PET Scanners as of the 2006 State Medical Facilities Plan

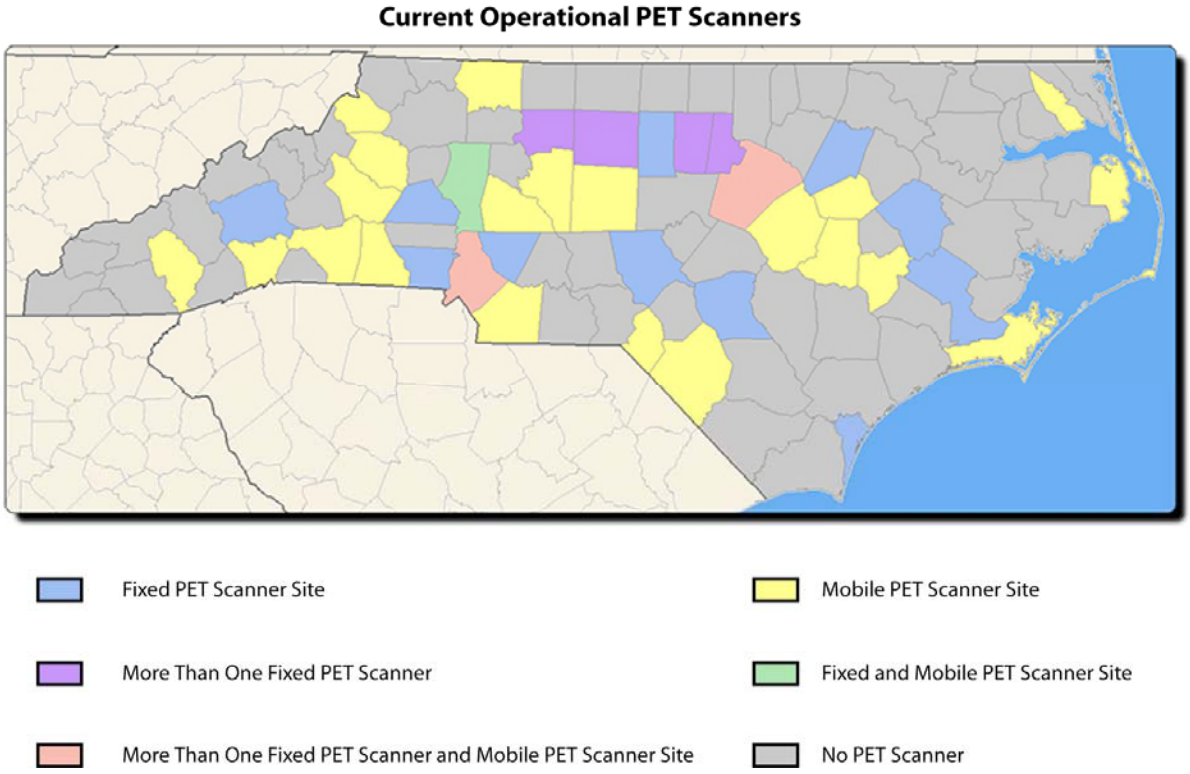


Note: There are multiple mobile PET sites in Burke County.

In 2006, the major cancer treatment facility definition was updated to providers that "performed over 12,500 Procedures/ESTVs in the previous year *OR* has two operational linear accelerators." This resulted in need determinations in HSAs II, III and VI. The definition was updated in 2007 to state that a major cancer treatment facility "performed over 12,500 Procedures/ESTVs in the previous year *AND* has two operational linear accelerators." No providers have generated a need for a dedicated fixed PET scanner under the current definition, and it is likely that no providers will generate a need for a dedicated fixed PET scanner in the near future based on the current linear accelerator volumes and capacities across the state.

Over the years, the SHCC has continued to refine the defined annual capacity of a dedicated fixed PET scanner. The *2005 SMFP* stated that the annual capacity of a dedicated fixed PET scanner was 4,000 procedures. Thus, an existing provider must have performed 3,200 procedures in the previous year to generate a need for an additional dedicated fixed PET scanner. In 2006, the capacity factor was updated to 2,600 procedures a year, generating a need at 2,080 procedures, or 80.0 percent of capacity. The most recent change to the PET methodology occurred in 2009 and changed the capacity of a dedicated fixed PET scanner from 2,600 to 3,000 procedures. The most recent need determinations for PET scanners occurred in 2008. The capacity methodology produced a need for one additional dedicated fixed PET scanner in HSA II, and a special need petition was approved, resulting in need for a dedicated fixed PET scanner in HSA III.

The map on the following page shows the existing supply of operational PET scanners as shown in the *2011 SMFP*.



Note: There are multiple mobile PET sites in Burke, Henderson and Surry counties. Please note that Nash General Hospital discontinued its mobile service and began its fixed PET service in April 2009.

As shown in the map above, while PET service has become available in many counties throughout the state, there are still many counties without a dedicated fixed PET scanner or a mobile PET site. Some of these counties may not have a need for PET technology, as they do not have a hospital and/or do not have a hospital with the service lines that support the demand for PET services (cardiology, neurology and oncology). However, CHS believes that there are still several counties that are home to hospitals that may require access to PET services now or in the future. Mobile PET technology is ideal for these counties that cannot support a fixed PET scanner at this time, but need access to PET services. It should be noted there are currently three counties with at least one dedicated fixed PET scanner *AND* mobile PET sites. This indicates that some of the existing mobile PET capacity is being used to create competition in some larger health care markets across the state. As a result, this capacity is not available to expand access in more rural areas of the state.

The following table summarizes the development of fixed and mobile PET technology in North Carolina since 1994.

SMFP	*Number of Approved Fixed PET Scanners*	*Fixed PET Scanner Volume*	*Number of Approved Mobile PET Scanners*	*Mobile PET Scanner Volume*	*Total Volume*
1994	3	514	-	-	514
1995	3	551	-	-	551
1996	3	669	-	-	669
1997	3	799	-	-	799
1998	3	1,171	-	-	1,171
1999	3	1,798	-	-	1,798
2000	3	2,415	-	-	2,415
2001	4	3,683	-	-	3,683
2002	6	4,717	-	-	4,717
2003	8	5,840	-	-	5,840
2004	17	7,658	2	0	7,658
2005	19	8,430	2	0	8,430
2006	22	13,198	2	2,248	15,446
2007	22	21,270	2	3,621	24,891
2008	25	28,215	2	3,248	31,463
2009	27	33,089	2	4,862	37,951
2010	27	32,303	2	5,815	38,118
2011	27	36,869	2	5,258	42,127

As demonstrated by the narrative and table above, the utilization of PET technology in North Carolina has increased substantially since 1994, resulting in one of the most dynamic services regulated in the *SMFP*. Dedicated fixed PET volume has grown as the number of providers has increased, but has also increased on a per site basis. The average number of scans per dedicated fixed PET scanner has increased substantially since the service was first reported in the *1995 SMFP*. Further, mobile PET volume per scanner has increased 134 percent since it was originally reported in the *2006 SMFP*. Although there has been some variation in the procedures by scanner in the past several years for both fixed and mobile units, it should be noted that much of the variation is the result of the discontinuation of mobile services as new fixed scanners are developed. For example, the decline in mobile PET volume in the *2011 SMFP* is likely the result of newly-approved fixed sites developing scanners (Alamance Regional Medical Center and Nash General Hospital). The following sections will outline the current status of the PET methodology, as well as CHS's proposed changes.

Current Status

There are currently 27 approved and 26 operational[1] dedicated fixed PET scanners in North Carolina, serving each of the six Health Service Areas (HSAs) in the state. The need for an additional dedicated fixed PET scanner is generated by a two-part methodology. The first part of the methodology states that there is a need for an additional PET scanner in an HSA for each existing fixed dedicated PET scanner that was utilized at or above 80.0 percent capacity, or 2,400 procedures, in the most recent federal fiscal year. The second part of the methodology states that each hospital-based facility without an existing dedicated fixed PET scanner that operates two linear accelerators and performed over 12,500 ESTV procedures in the most recent federal fiscal year will generate the need for an additional dedicated fixed PET scanner in its HSA. The *2011 SMFP* determined that there was not a need for an additional fixed PET scanner at this time. It is important to note that at this time, the need for dedicated fixed PET scanners is based on the utilization of fixed PET scanners alone and does not account for the utilization of mobile PET scanners.

In order to serve smaller hospitals that are currently unable to fully utilize a dedicated fixed PET scanner, one mobile PET scanner serves western North Carolina (HSAs I, II and III) and one mobile PET scanner serves eastern North Carolina (HSAs IV, V and VI). In federal fiscal year 2010, the mobile PET scanners serving western and eastern North Carolina performed 2,589 and 2,568 PET scans[2], respectively, and as such, both scanners operated over 80.0 percent of the fixed PET scanner capacity. However, there is no methodology to determine the need for an additional mobile scanner. ***Without such a methodology, these scanners could continue operating at increasing levels of utilization indefinitely, and no need for additional mobile scanners would be generated***.

In addition, many community hospitals report that they are unable to secure sufficient, accessible hours with the existing mobile vendor due to the capacity constraints on the mobile scanners. Although the vendor may state that there is sufficient capacity to serve all existing and future mobile PET sites, the capacity available does not offer a practical solution for many providers. As shown in the table below, each of the existing mobile scanners serves greater than seven sites, with the scanner in the west serving 18 sites—an average of more than two sites per day on a seven day per week schedule.

1 Please note the approved PET scanner at CMC-Union is not yet operational.

2 Source: 2011 Registration and Inventory of Medical Equipment forms.

SMFP	Western North Carolina		Eastern North Carolina	
	Volume	*Sites*	*Volume*	*Sites*
2006	1,051	9	1,197	8
2007	1,446	10	2,175	8
2008	1,685	15	1,743	8
2009	2,826	14	2,036	7
2010	3,196	15	2,619	8
2011	2,821	14	2,437	9
2012*	2,589	18	2,568	10

*Source: 2011 Registration and Inventory Medical Equipment Forms.

As a result, some sites are unable to secure mobile PET services each week, and are forced to provide services only every other week. In addition, some mobile sites can only provide PET services on weekends, which can pose access concerns for patients. For example, CMC-Union, the most recent facility to be approved to develop a dedicated fixed PET scanner, stated in its 2008 CON application that Alliance's mobile service was on-site every other Friday and one Saturday per month. Other recently approved hospitals, including Alamance Regional Medical Center and Nash General Hospital were able to secure service every Friday and Saturday, respectively.[3] The majority of PET patients are cancer patients who often have multiple physician appointments and treatments each week. In addition, as a result of their illness and the side effects of cancer treatment, these patients often tire easily. It is less than optimal for patient care to ask these patients to return on a weekend for a PET scan, when their other medical appointments, such as doctor visits and tests, are likely scheduled on weekdays. As such, the limited practical availability of the mobile scanners results in limited access to mobile PET services, particularly in Western North Carolina. Further, Alliance HealthCare Services, Inc. was recently granted a declaratory ruling to fill the time slot and host site to be vacated by CMC-Union with Stanly Regional Medical Center prior to the discontinuation of service at CMC-Union.[4] This is an indication that there is no shortage of facilities ready to become host sites as the time becomes available.

For comparison purposes, CHS reviewed the average number of host sites for mobile MRIs in North Carolina. Based on the data provided on the 2010 Registration and Inventory Medical Equipment forms[5], the 59 existing mobile MRI scanners serve an average of 4.72 host sites each, compared to an average of 14 sites for each of the mobile PET scanners. CHS recognizes the differences in the two services, including the greater use rate of MRI services compared to PET

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[3] It should be noted that Alamance Regional Medical Center and Nash General Hospital are both served by the mobile scanner in Eastern North Carolina which has fewer total sites than the scanner in Western North Carolina allowing more days of care per site.

[4] In April 2009, CMC-Union was issued a CON to obtain a dedicated fixed PET scanner. CMC-Union was approved to lease a scanner temporarily until the fixed scanner is operational, and CMC-Union no longer requires the services of a mobile scanner. (see http://www.ncdhhs.gov/dhsr/declrule/2011/20110216Alliance.pdf for a copy of the declaratory ruling received by Alliance HealthCare Services, Inc.)

[5] Please note that the full set of 2011 forms was not available at the time this petition was developed. As such, CHS used the most recent year of complete data.

services and the need for significantly more scanners across the state. However, it is worth noting that because the mobile MRIs serve significantly fewer sites, the majority of mobile MRI scanners spend less time traveling between sites and are able to provide more reasonable days of service. This includes providing more hours/days at each site as needed, as well as fewer weekends. The development of additional mobile PET scanners as capacity and access begin to decrease would likely result in the same benefits for patients and providers.

As a result, there is a clear and present need to establish a methodology to determine the need for additional mobile PET scanners.

Proposed Mobile PET Methodology

CHS believes that the most effective mobile PET methodology would be simple and consistent with the existing methodology for fixed PET scanners. As stated in the *2011 SMFP*, the capacity of a dedicated fixed PET scanner is 3,000 procedures and the need for an additional dedicated fixed PET scanner is generated when a scanner performs at 80.0 percent of that capacity, or 2,400 scans. CHS proposes that the need for an additional PET scanner in a mobile PET service area (defined as eastern and western North Carolina above) should be generated when an existing mobile PET scanner performs 2,400 procedures in the previous federal fiscal year. As shown in the table below, the Western North Carolina PET scanner has performed greater than 2,400 procedures each year since the 2009 SMFP. The scanner in Eastern North Carolina has performed greater than 2,400 procedures for the past three years.

SMFP	*Western NC*	*Eastern NC*
2006	1,051	1,197
2007	1,446	2,175
2008	1,685	1,743
2009	**2,826**	2,036
2010	**3,196**	**2,619**
2011	**2,821**	**2,437**
2012*	**2,589**	**2,568**

*Source: 2011 Registration and Inventory Medical Equipment Forms.

Please note that CHS is aware that the western North Carolina mobile PET volume has declined in recent years. This is likely partially attributable to the discontinuation of high volume host sites as facilities developed dedicated fixed PET scanners, and the replacement of those sites with lower volume sites. Although the new sites are contracted to have the mobile scanner on site during a set schedule, these sites are likely not using the scanner to full capacity yet. However, it is likely that the volume of these scanners will increase in the near future, as the majority of host sites experience a ramp up in utilization following the development of mobile PET services. Further, the western North Carolina scanner was operating well above capacity as shown in the *2010 SMFP*. As stated previously, this resulted in many facilities being offered time slots that were less than optimal for cancer patients, and may have contributed to the decline in utilization.

In addition, CHS recognizes that many of the dedicated fixed PET scanners in North Carolina are currently underutilized, which could lead to concern over unnecessary duplication. However, there is currently capacity needed in areas of the state with no access to PET services at all. As shown in the map on page 4, there are some counties in North Carolina which are located a significant distance from both mobile and fixed PET services. As PET technology becomes part of the standard of care for cancer and other diseases, it is reasonable that all cancer programs in North Carolina, particularly those located in more remote and rural regions of the state, be able to access PET services. The State has already indicated that it is important to provide cancer patients with care close to home, by approving the development of linear accelerators in these locations despite low volumes in other parts of the state. Further, there is a need to increase the capacity of existing mobile PET sites that do not have a need for a fixed scanner at this time, but have reached their available capacity based on days available on the existing mobile PET scanners.

Regardless, based on the most recent data available on the 2011 Registration and Inventory of Medical Equipment forms, the proposed methodology would generate a need for one additional scanner in each mobile PET service area in the *2012 SMFP*.

Impact of Request/Implications if Petition is Not Approved

As outlined above, approval of this petition as proposed will result in the allocation of two additional mobile PET scanners – one in each mobile PET service area, based on the FY 2010 utilization of the existing mobile PET scanners.

If this petition is not approved, the development of future mobile PET scanners will be reliant on the submission and approval of special need petitions. Although special need petitions can be effective methods in unique circumstances, a need methodology in the *SMFP* will provide a more uniform, statewide process for determining the need for mobile PET technology. As this technology continues to develop, it is important that a process is in place to appropriately monitor its growth statewide, providing equitable distribution of services as well as keeping costs low. In addition, the failure to approve this petition will likely limit the development of mobile PET services. As such, mobile PET sites will continue to face limited availability of mobile PET services, perpetuating access concerns for those communities.

Adverse Effects on Population

Given the analysis provided in this petition, including the high utilization of existing mobile PET scanners and the fact that there will likely be no new need determinations for additional dedicated fixed PET scanners for the foreseeable future, CHS believes that approval of the proposed petition will prevent providers and consumers, particularly in rural areas, from suffering the adverse effects of limited access to PET technology.

Alternatives Considered

The only realistic alternative to the proposed request is to maintain the status quo. As stated previously, the lack of a mobile PET methodology will result in the use of special need petitions

to secure additional capacity. The only way to ensure the equitable and cost effective distribution of mobile PET scanners is to develop a need methodology for the *SMFP.*

Impact of Proposed Changes on Unnecessary Duplication

The proposed changes will ensure that additional mobile PET scanners are allocated as warranted by the growth in the utilization of existing mobile scanners. As such, the methodology itself would ensure no unnecessary duplication of existing mobile PET scanners. Moreover, the need for mobile PET scanners is primarily in areas without access to fixed PET scanners and would thus not be duplicative of fixed capacity.

In order to further ensure that existing and newly allocated mobile PET scanners do not provide service at sites that might be unnecessarily duplicative, CHS suggests that language be added to the *SMFP* regarding the need for mobile PET to serve otherwise underserved or unserved areas, before adding service to areas that already have sufficient access to fixed or mobile PET services. Further, it should be stated that mobile PET providers should ensure that areas with limited or no access to PET services be granted priority in the host site selection process.

Proposal's Consistency with the Basic Principles of the SMFP

The proposed mobile PET methodology will ensure greater safety, quality, access and value. By ensuring sufficient capacity of mobile PET scanners, safety and quality will be enhanced through more appropriate utilization of the two existing scanners. Access will also be enhanced, particularly for sites that have no or limited service. Finally, healthcare value will be maximized through the careful but planned allocation of mobile PET scanners based on a standard methodology.

Summary

Based on the evidence presented above, CHS believes that the proposed mobile PET methodology merits approval in order to provide an equitable, consistent process for determining statewide need for additional mobile PET scanners.