PETITION

To the State Health Coordinating Council Related to Mobile PET Services for The 2014 State Medical Facilities Plan

Tiffany Brooks, Certificate of Need Manager MedQuest Associates, Inc. 3480 Preston Ridge Road, Suite 600 Alpharetta, Georgia 30005 (919) 264-0415 tbrooks@medquestmail.com

Barbara Freedy, Director, Certificate of Need Novant Health, Inc. 2085 Frontis Plaza Blvd. Winston-Salem, NC 27103 (336) 718-4483 blfreedy@novanthealth.org

Statement of the Requested Change:

Establish the 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

There are currently only two (2) mobile PET/CT scanners in North Carolina and those two (2) mobile PET scanners provide service to 29 mobile PET host sites¹. The original need determinations for mobile PET/CT scanners were generated, over 11 years ago, in the 2002 State Medical Facilities Plan, which divided North Carolina into two mobile PET service regions. The West Region service area consists of Health Service Areas I, II and III with over 5.1 million residents in 2013. The East Region service area consists of Health Service Areas IV, V and VI with over 4.7 million residents. The last CON for a mobile PET scanner in the West Region was awarded in 2003 (Project I.D. No. F-6605-02). The last CON for a mobile PET scanner in the Eastern Region was awarded in 2003 (Project I.D. No. H-6706-02). Both mobile PET scanners are owned and operated by one sole provider - Alliance Imaging.

¹ The number of active mobile PET host sites identified in Alliance Imaging's 2013 Registration and Inventory of Medical Equipment Mobile Positron Emission Tomography Scanners. See Attachment 1 for copies of the reports.

Since the 2002 SMFP need determination for the mobile PET scanners, there have been no subsequent need determinations for new mobile PET scanners despite significant growth in volumes and the number of mobile host sites served as detailed in the following chart. The two (2) mobile PET units serve a combined 29 host sites across the entire state of North Carolina.

<u>Eastern Region – Mobile PET</u>

During FY 2010-11 and FY 2011-12, the Eastern Region mobile PET scanner exceeded 2,600 procedures, which is defined in the 2013 SMFP, Chapter 9, Tables M(1) & (2) at page 160 as the annual capacity of a mobile PET unit, regardless of the number of host sites served. The number of host sites has increased from eight sites during FY 2003-04 to eleven in FY 2010-2011.

Eastern North Carolina - Historical Mobile PET Utilization

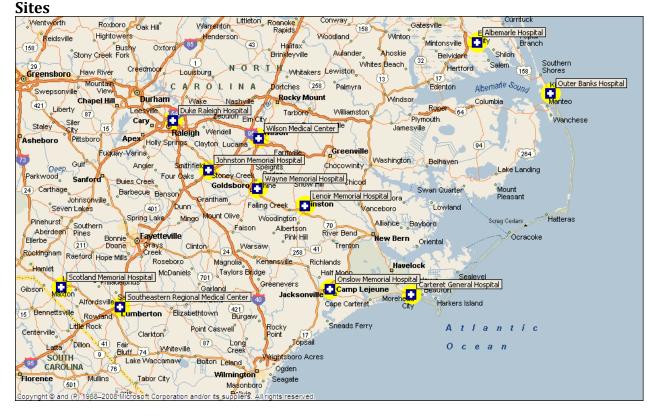
SMFP*	No. of Host Sites*	PET volume	% Change
2006	8	1,094	
2007	8	2,175	98.8%
2008	7	1,543	-29.0%
2009	7	2,036	32.0%
2010	8	2,619	28.6%
2011	9	2,437	-6.9%
2012	10	2,550	4.6%
2013	11	2,650	3.9%
2014	11	2,809	6.0%

^{*}No. of host sites is based on sites reported in each SMFP that performed 1 or more scans. Data for 2014 obtained from the Registration and Inventory of Medical Equipment Mobile Positron Emission Tomography Scanners January 2013 filed by Alliance Imaging.

NOTE: SMFP Year 2012, for example, is based on FFY 2010 data.

Only **one** piece of mobile PET equipment serves all of the 11 host sites in the Eastern Region, as shown on the map below. The distance from Scotland Memorial to the Outer Banks Hospital is nearly 300 miles. The Eastern Region mobile PET unit covers an area encompassing approximately 18,000 square miles of eastern North Carolina, which is home to 4.7 million residents.

Eastern Region - Mobile PET Host



<u> Western Region – Mobile PET</u>

In every reporting year since FY 2006-07 (2009 SMFP), the Western Region mobile PET scanner has exceeded 2,600 procedures. The number of host sites has dramatically increased from 7 sites during FY 2003-04 to 18 sites in FY 2012-2013. It should be noted that a comparison of FY 2011-12 mobile PET data provided by the hospitals in the 2013 Acute Care Facility License Renewal Applications and the data reported by Alliance Imaging in the 2013 Medical Equipment Inventory Report is not consistent². Based on the hospitals' reports, the western mobile PET scanner performed a total of 3,136 procedures during FY 2011-12.

²We believe the DHSR Medical Facilities Planning Branch will seek to reconcile this information as part of its process of preparing the draft 2014 SMFP. For purposes of this petition we chose to rely on the PET scan volumes reported by the hospital mobile PET scanner host sites. Since the hospitals bill payors for the PET procedures performed, this includes reporting functions to track the PET scans performed as accurately as possible.

Western Region Mobile PET Host Sites

Mobile PET Procedures FY 2011-12

Facility	Hospital Data	Alliance Data
Presbyterian Hospital Matthews	106	104
Cleveland Regional Medical Center	856	471 *
Presbyterian Hospital Huntersville	211	208
Lake Norman Regional Medical	191	190
Margaret Pardee Hospital	167	167
Northern Hospital of Surry	104	105
Park Ridge Hospital	151	151
Rowan Regional Medical Center	267	264
Rutherford Hospital	126	127
Watauga Medical Center	106	106
WestCare Health System	288	61 *
Stanly Regional Medical Center	74	115 *
Blue Ridge - Grace Hospital	93	94
Blue Ridge - Valdese Hospital	55	104 *
Caldwell Memorial Hospital	132	124
Thomasville Medical Center	91	86
Randolph Hospital	107	107
Cone Health	11	11
Totals	3136	2595

Sources:

Hospital Data - 2013 Acute Care Facility License Renewal Applications submitted by the hospitals Alliance Data - 2013 Registration and Inventory of Medical Equipment Mobile Positron Emission Tomography Scanners January 2013 submitted by Alliance Imaging.

Although this reporting discrepancy is an issue that the Medical Facilities Planning Section will likely research further, the mobile PET volumes for the western region unit remain high and continue to exceed the suggested capacity definition in this Petition.

^{*}Excerpts from these hospitals' 2013 License Renewal Applications are included in Attachment 2.

Western North Carolina - Historical Mobile PET Utilization

SMFP	No. of Host Sites*	PET volume	% Change
2006	7	1,154	
2007	8	1,446	25.3%
2008	13	1,885	30.3%
2009	14	2,826	49.9%
2010	15	3,196	13.1%
2011	14	2,821	-11.7%
2012	18	2,861	1.4%
2013	18	3,066	7.2%
2014	18	3,136#	2.3%

^{*}No. of host sites is based on sites reported in each SMFP that performed 1 or more scans.

#The totals provided by Alliance Imaging in its 2013 Report do not reconcile with the numbers reported by the hospitals in the individual 2013 Hospital License Renewal Applications. See Attachment 2 for the relevant pages from the western mobile host sites. For purposes of this discussion, the Petitioners have relied on the hospital data as each hospital is responsible for billing the procedures.

Only **one** piece of mobile PET equipment serves all of the 18 host sites in the Western Region. From the furthest points east (Randolph Hospital) and west (MedWest Harris), the Western Region mobile PET scanner covers a distance of over 200 miles. The Western Region mobile PET unit covers an area encompassing approximately 21,000 square miles of western North Carolina, which is home to 5.1 million residents. The following map identifies the Western Region mobile PET host sites.

Western Mobile PET Host Sites



Mobile PET Services at Novant Facilities

Of all the vast number of host sites served by the sole mobile PET scanner in the Western Region, Novant Health operates four of these sites: Thomasville Medical Center, Rowan Regional Medical Center, Presbyterian Hospital Huntersville and Presbyterian Hospital Matthews. The following chart details the current schedule for mobile PET services for each of these Novant Health facilities as well as documents which facilities currently have a need for additional mobile PET services.

Novant Health - Western Region Mobile PET Host Sites

Mobile PET Host Site	Current Monthly Mobile PET Service Days	Requested Additional Time
Thomasville Medical Center	Every Other Tuesday (Half Day-2;30-8:00 pm)	Yes – request denied
Rowan Regional Medical Center	Every Other Thurs (Full Days-7 am-10pm) Every Other Thurs (Half Days-2-6pm)	Yes – request denied
Presbyterian Hospital – Huntersville	One Monday per month (Full Day-7am-10pm) Every Other Thursday (Half Day-2:30-8:00pm)	Yes – request denied
Presbyterian Hospital- Matthews	One Monday Per Month (Half Day-2:30-8:00pm) One Friday Per Month (Half Day-2;30 -8:00pm)*	Yes – request denied

Source: Current Alliance HealthCare Services-Novant Health mobile PET service contract.

Novant currently contracts with Alliance Imaging for mobile PET service at these host sites and Alliance representatives have specifically told Novant that additional days of service are not available due to the number of sites being serviced. Based on input from hospital representatives, the following are some of the facility-specific issues:

<u>Thomasville Medical Center</u> – Patients are having difficulty getting PET procedures scheduled and must travel to other facilities; additional mobile PET time has been requested and is not available; there have been some instances of downtime or delays that have resulted in the mobile PET service not being available during its scheduled time.

Rowan Regional Medical Center – Patients are having difficulty getting PET procedures scheduled and must travel to other facilities in Charlotte or Winston-Salem; physicians in Rowan County are unhappy with the lack of more accessible mobile PET service and the need to send patients to other health systems for imaging; additional mobile PET time has been requested and is not available.

^{*}NOTE: Recently adjusted mobile PET schedule at PHMatthews to every other Friday for half days.

<u>Presbyterian Hospital Huntersville</u> – Patients are having difficulty getting PET procedures scheduled and must travel to other facilities; additional mobile PET time has been requested and is not available; patients have had to be rescheduled due to equipment failure; one instance of the mobile PET unit being taken to the wrong facility which required PHH's patients to be rescheduled.

Presbyterian Hospital Matthews – Patients are having difficulty getting PET procedures scheduled and must travel to other facilities; additional mobile PET time has been requested and is not available.

See **Attachment 3** for letters of support from local physicians.

Rowan Regional Medical Center has a busy and well-established cancer treatment program in radiation therapy. Professional coverage for the care of RRMC cancer patients is provided by the board-certified medical oncologists at Carolina Oncology Associates, with an office based in Salisbury near Rowan Regional Medical Center. See the Rowan physician support letters found in Attachment 3. RRMC currently offers radiation therapy treatments on its linear accelerator and radiation therapy treatment planning services on its CT simulator. During FFY 2012, as reported in the RRMC 2013 annual Hospital Licensure Renewal Application, RRMC performed 8,138 radiation therapy treatments for 550 cancer patients. In FFY 2011, RRMC performed 6,100 radiation therapy treatments for 509 patients. And in FFY 2010, RRMC performed 6,267 radiation therapy treatments for 532 patients. During the past three years, RRMC performed 267 to 320 annual PET/CT scans on the contracted mobile unit.

During FFY 2012 as reported in the **Thomasville Medical Center's** 2013 Hospital Licensure Renewal Application, TMC was only able to perform 91 PET scans for the two-three Tuesdays per month (every other Tuesday), when the AI mobile PET scanner is contracted to be at the TMC host site for 5.5 hours every other Tuesday. The medical oncology group, Piedmont Hematology Oncology Associates (POHA) has a busy satellite office in Davidson County, between Lexington and Thomasville (near the edge of Thomasville), where they offer medical and gyn oncology services, as well as chemotherapy on site. As noted in the PHOA physician letters attached to this petition, they believe that 11 to 16.5 hours per month of available mobile PET scan time is insufficient and results in too many PHOA patients being unable to have their PET/CT scan performed locally, in Davidson County. The alternatives are to travel to Winston-Salem, Greensboro, High Point, or Charlotte.

During that same time period, **Presbyterian Hospital Huntersville** was able to perform 211 PET scans on the AI mobile PET scanner hosted at PHH for every other Thursday (Half days of 5.5 hours) and one Monday per month (Full day for 15 hours) Presbyterian Hospital Huntersville offers a dedicated Breast Imaging Center for its patients. In addition, there are five medical oncologists are on the active medical staff at

Presbyterian Hospital Huntersville. The two medical oncology groups that provide medical oncology care for PHH's patients are: Southern Oncology Specialists with offices in Huntersville and the Mallard Creek area of Charlotte and Lake Norman Hematology Oncology with offices in Huntersville and Mooresville. See **Attachment 3** for letters of support from physicians practicing with both these medical oncology groups.

Also, during FFY 2012 **Presbyterian Hospital Matthews** performed 106 PET scans on the AI mobile PET scanner during the one Monday per month (Half day-5.5 hours) and one Friday per month (Half day-5.5 hours). Southeastern Radiation Oncology (SERO), a group of radiation oncologists, operates a linear accelerator in a medical office building located on the Presbyterian Hospital Matthews campus. In addition, professional coverage for cancer patients at PHMatthews is provided by the four medical oncologists and hematologists at Matthews Hematology Oncology Associates. See **Attachment 3** for letters of support from these physicians. MHOA also offers chemotherapy services at their office. The availability of the mobile PET at Presbyterian Hospital Matthews for only 11-16.5 hours per month is insufficient to permit routine local access to PET/CT scans that are an essential part of the care of cancer patients. Especially in light of the fact that the linear accelerator in the medical office building on the PHMatthews campus is one of the single busiest linear accelerators in North Carolina on a year-in, year-out basis.

Action by the SHCC IS Necessary to Address the Need for Additional Mobile PET Scanner Choices and Capacity

The State Medical Facilities Plan (SMFP) fails to address need for additional mobile PET scanner capacity when an existing mobile PET scanner unit(s) exceeds the capacity threshold set forth in Table 9M(1) of the 2013 SMFP, in the column heading called "Utilization Rate: year 2011-2012 Procedures/2600 as Capacity." This is the annual capacity of one mobile PET/CT scanner regardless of the number of host sites served. It is not clear that the 2,600 PET scans per year was intended to be applied to the annual volumes at each mobile PET host site in a region³, when each host site was only getting access to a fraction of the capacity of a single mobile PET unit, due to the vendor's schedule which allows most mobile PET sites an average of about 2 days per month of mobile PET service. In recent planning cycles, there have been two petitions submitted related to mobile PET scanners both of which have been denied by the Technology & Equipment Committee and the State Health Coordinating Council⁴. The lack of formal need determinations for mobile PET scanners is creating unnecessary hardships for healthcare providers and patients and requires the action of the State Health Coordinating Council.

While the 2013 SMFP clearly and specifically defines the methodology for *fixed* PET scanners, there is no such provision or methodology for additional *mobile* PET scanners. Essentially, since the 2002 SMFP, there has been a moratorium on new mobile PET

³ As is done in Table 9M(2) of the 2013 SMFP, Chapter 9, page 160.

⁴ In August 2010, Neo Pet, LLC submitted a petition requesting a special need determination for a mobile PET to serve the western region. Carolinas Medical Center filed a petition in March 2011 requesting a need determination for mobile PET scanners.

scanners in North Carolina and only a single mobile PET provider has been CON-approved to contract with providers for mobile PET services. On page 160 of the 2013 SMFP, Table 9M(1) identifies the procedure volume for both mobile PET scanners as indicated in the chart below:

2013 State Medical Facilities Plan - Chapter 9, page 160:

Table 9M(1): PET Scanner Provider of Mobile Dedicated Scanners

			1
		S	Utilization Rate
PET		dur	
Scanners		900.	Year 2011-2012 Procedures /
Planning Region		- E	2600 as Capacity
1 (HSAs I, II, III)	Alliance Imaging	3,066	
2 (HSAs IV, V, VI)	Alliance Imaging	2,650	
TOTAL	•	5.716	

Procedures by mobile unit divided by 2600 would show over 100% capacity

Table $9M(2)$:	PET Scanner	Sites Utilization	of Existing	Mobile I	Dedicated Scanners

						83	Utilization Rate	Need Determination
Center	2007-	2008-	2009-	2010-	HSA	Sites	Year 2011 Procedures/	by Criteria - 80%
	2008	2009	2010	2011		L	2600 as Capacity	1
Caldwell Memorial Hospital	143	159	129	113	I	1	4%	0
Cleveland Regional Medical Center	278	358	419	449	I	1	17%	0
Grace Hospital	93	68	74	91	I	1	4%	0
Margaret R Pardee Memorial Hospital	141	162	140	175	I	1	7%	0
Park Ridge Health	205	210	143	155	I	1	6%	0
Rutherford Regional Medical Center	6	128	135	143	I	1	6%	0
Valdese General Hospital	108	109	102	108	I	1	4%	0
Watauga Medical Center	138	118	96	134	I	1	5%	0
MedWest Harris	251	243	243	295	I	1	11%	0
Alamance Regional Medical Center	440	0	0	0	II	0	0%	0
Hugh Chatham Memorial Hospital	138	108	5	0	II	0	0%	0
Randolph Hospital			9	86	II	1	3%	0
Thomasville Medical Center			105	109	II	1	4%	0
Northern Hospital of Surry County	189	250	230	166	II	1	6%	0
CMC - Union	350	298	287	189	Ш	1	7%	0
Lake Norman Regional Medical Center	199	217	203	195	Ш	1	8%	0
Rowan Regional Medical Center	517	393	49	306	Ш	1	12%	0
Stanly Regional Medical Center				44	Ш	1	2%	0
Presbyterian Hospital - Huntersville			130	221	Ш	1	9%	0
Presbyterian Hospital - Matthews			89	87	Ш	1	3%	0
Duke Raleigh Hospital	554	548	537	590	IV	1	23%	0
Johnston Memorial Hospital		10	142	150	IV	1	6%	0
Scotland Memorial Hospital	117	123	148	161	V	1	6%	0
Southeastern Regional	290	315	296	282	V	1	11%	0
Albemarle Health: A Vidant Partner in Health	250	217	243	258	VI	1	10%	0
The Outer Banks Hospital	230	21/	120	136	VI	1	5%	0
-	 					_		0
Carteret General Hospital Lenoir Memorial Hospital	235	197	102 150	139 130	VI VI	1	5% 5%	0
•	253	197	130			_		0
Onslow Memorial Hospital				75	VI	1	3%	
Nash General Hospital	434	274	0	0	VI	0	0%	0
Wayne Memorial Hospital	418	406	394	338	VI	1	13%	0
Wilson Medical Center	321	347	418	391	VI	1	15%	0
TOTAL	5,815	5,258	5,138	5,716		29		0

Individual host site procedures divided by 2600 is unreasonable due to lack of availability

As previously stated herein, the only two (2) mobile PET scanners in North Carolina exceeded the 2,600 annual PET scan capacity threshold for a single mobile PET scanner in the 2013 SMFP. The Western Region Mobile PET was at 117.9% capacity and the Eastern Region was at 101.9% capacity and realistically cannot increase much further due to limitations on the number of sites a single unit can physically serve. In Table

9(M)(2), the capacity of 2,600 procedures per mobile host site is completely unreasonable and has no basis in actual daily operations. The majority of these mobile PET host sites have between 1 and 2 days of service per MONTH. Practically speaking, the ability of a mobile PET host site to reach 2,600 procedures with 12 to 24 days of service annually would require 108 to 217⁵ PET procedures per day of service, which is logistically impossible. The more appropriate and reasonable measure of capacity for mobile PET service should equate to the total number of procedures performed on each mobile PET unit compared to a predetermined capacity number (in this case procedures). 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.

Current Mobile PET Data Shows Need

The 2013 Medical Equipment Inventory Reports, which is the basis for the data utilized in the 2014 SMFP shows the following:

- a. The Eastern Region PET scanner performed a total of **2,809** procedures and provided service to over 11 host sites.
- b. The Western Region PET scanner performed a total of **3,136** procedures and provided service to over 18 host sites.

The utilization information provided by Alliance Imaging, the sole CON-approved North Carolina mobile PET provider, further supports the importance of implementing a need methodology for mobile PET scanners. Again, the only two (2) mobile PET scanners in North Carolina have exceeded the 2,600 procedure capacity. If corrective action is not taken now for the 2014 SMFP, this problem will continue to adversely affect North Carolina residents' access to mobile PET services.

As it stands, the State Medical Facilities Plan provides no need methodology for new mobile PET scanners. The threshold of 2,600 procedures annually has been surpassed by the two (2) existing mobile PET units in the last two data reporting periods. By maintaining the status quo as it relates to mobile PET scanners, the citizens of North Carolina and their healthcare providers will continue to be limited to accessing only one mobile PET scanner for all of Eastern North Carolina and only one PET scanner for all of Western North Carolina. With a combined host sites total of 29 for only two (2) mobile PET scanners, this effectively means that on average, each host site can only access one day of service, one time per MONTH. In addition, considering the significant amount of travel time for these two mobile PET scanners, it is very likely that the equipment will require more downtime and maintenance, which could further adversely impact both patients and healthcare providers.

⁵ 2,600 procedures ÷ 12 days = 217 procedures/day of service; 2600 procedures ÷ 24 days = 108 procedures/day of service

Suggested Revision for the Mobile PET Scanner Methodology

Novant and MedQuest would suggest the following change to the mobile PET need methodology for future State Medical Facilities Plan (using the 2013 SMFP as an example);

PROPOSED REVISION for 2014 SMFP: Table 9M(1): PET Scanner Provider of Mobile Dedicated Scanners

PET Scanners Planning Region	Provider Name	Procedures	Utilization Rate Year 2010-2011 Procedures/2600 as Capacity	Determination by Criteria - 80% of Present Capacity
1 (HSAs I, II, III)	Alliance Imaging	3,066	3,066/2,600 = 1.18	1
2 (HSAs IV, V, VI)	Alliance Imaging	2,650	2,650/2,600 = 1.02	1
		5,716		

The suggested change for mobile PET scanners is consistent with the treatment of fixed PET scanners. If capacity is defined as 2,600 procedures annually, then a need determination would be generated when a single existing mobile PET scanner reaches 2,080 procedures (2,600 x .80 = 2,080 procedures). If the SHCC is inclined to increase capacity for mobile PET scanners to 3,000 procedures (the current level for fixed PET scanners), then a need determination would be triggered at 2,400 procedures (= 80% X 3,000 mobile PET procedures annually). We would recommend that no more than one new mobile PET scanner for each Mobile PET Region, be determined for each annual SMFP.

Statement of Adverse Effects on the providers or consumers of health services that are likely to ensue if the change is not made.

According to a study⁶ published in *Radiology* and conducted by researchers at Duke University and the University of North Carolina, Medicare beneficiaries with non-small cell lung cancer didn't receive equal access to PET scans, as fewer scans are done on patients who are older, African-American, or who live in less educated or economically advantaged areas of the country. As shown in the mobile PET host site data for Thomasville Medical Center, Rowan Regional Medical Center, Presbyterian Hospital Huntersville, and Presbyterian Hospital Matthews, a large proportion of mobile PET services are accessed by Medicare recipients at these four mobile PET sites:

⁶ Variations in Use of PET among Medicare Beneficiaries with Non-Small Cell Lung Cancer, 1998-2007. Michaela Dinan, PhD, Lesley H. Curtis, PhD, William R. Carpenter, PhD, et al. See Attachment 4.

- At Presbyterian Hospital Huntersville, 50% Medicare in 2013 Year to Date⁷ and in CY 2012, 52.6% Medicare for mobile PET scans provided
- At Presbyterian Hospital Matthews, 50% Medicare in 2013 Year to Date and in CY 2012, 57.1% Medicare for mobile PET scans provided
- At Rowan Regional Medical Center (Salisbury, NC), 30.8% Medicare in 2013 Year to Date and in CY 2012, 57.9% Medicare for mobile PET scans provided
- At Thomasville Medical Center, 66.7% Medicare in 2013 Year to Date and in CY 2012, 71.4% Medicare for mobile PET scans provided

The availability of mobile healthcare services, like PET imaging, at smaller community-based hospitals has a direct, positive impact on <u>patients</u>. One of the basic tenets of the certificate of need process is to provide accessibility to services for rural communities and underserved populations. N.C. Gen. Stat. §131E-175, states the following:

(3a) That access to health care services and health care facilities is critical to the welfare of rural North Carolinians, and to the continued viability of rural communities, and that the needs of rural North Carolinians should be considered in the certificate of need review process.

In addition to the consideration of the needs of rural communities, another vital component of the health planning process is the availability of services for the "underserved" populations⁸. 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 services for underserved groups across North Carolina, including the Medicare populations depending on TMC, RRMC, PHH, and PHM for local access to PET imaging, as discussed above.

The availability of PET technology largely benefits cancer patients, although there are applications for patients with cardiac issues and lung cancer. According to data from the State Center for Health Statistics, the number of projected **new** cancer cases in North Carolina continues to increase. See the following chart:

⁷Through Jan. 31, 2013.

⁸ Underserved populations are defined as low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups. See N.C. Gen. Stat. §131E-183(3), commonly referred to as Review Criterion 3.

North Carolina Cancer Rates - Projected New Cancer Cases

Year	Projected New Cancer Cases	% Change
2009	46,417	
2010	49,586	6.82%
2011	51,690	4.24%
2012	55,444	7.26%
2013	56,164	1.30%

Source: North Carolina State Center for Health Statistics. www.schs.state.nc.us/schs/CCR/projections.html

While residents in most large metropolitan areas have access to fixed PET sites⁹, providers and hospitals in medium sized cities, smaller counties and rural areas rely almost exclusively on mobile PET service to offer enhanced accessibility to this important diagnostic tool for their residents. If mobile PET services are not available in a patient's home county, the patient would have to travel out of county or beyond in order to have access to these essential services. Below are examples of distances (one-way) patients who reside in mobile PET counties would have to travel to find fixed PET sites:

- A patient from Salisbury in Rowan County would have to travel 43 miles to Charlotte or 39 miles to Winston-Salem.
- An Onslow County patient in Jacksonville would have to travel 37 miles to New Bern, 58 miles to Wilmington or 72 miles to Greenville to reach a fixed PET scanner.
- A patient from Laurinburg in Scotland County would travel 33 miles to Lumberton or 43 miles to Fayetteville.
- A patient from Elkin in Surry County would travel 44 miles to Winston-Salem or 37 miles to Statesville.
- A patient from Boone in Watauga County would likely drive 45 miles to Hickory.

To a healthy person, this may sound like a minor inconvenience but to a cancer patient, this amount of travel could be debilitating. The following chart highlights the projected number of new cancer cases by county for the mobile PET host sites. Although each case may not require a PET scan, this information does provide a quantitative measure of the number of residents with the potential need for PET services.

⁹ According to the 2013 SMFP at page 159, Table 9L there are 27 fixed PET scanners in NC.

Mobile PET Host Sites - New Cancer Cases by County 2013

Host Site	County	No. of New Cancer Cases
	-	by County- 2013
Albemarle Hospital	Pasquotank & Camden	291
	Counties	
Caldwell Memorial	Caldwell	544
Grace Hospital	Burke	597
Valdese General Hospital	Burke	397
Carteret General Hospital	Carteret	534
Cleveland Regional Medical	Clarata d	(10
Center	Cleveland	618
Johnston Memorial Hospital	Johnston	900
Lenoir Memorial Hospital	Lenoir	384
MedWest Harris	Jackson	259
Northern Hospital of Surry		404
County	Surry	484
Onslow Memorial Hospital	Onslow	703
Park Ridge Health	Henderson	893
Randolph Hospital	Randolph	880
Rutherford Regional Medical	D .1 .6 .1	400
Center	Rutherford	482
Scotland Memorial Hospital	Scotland	213
Outer Banks Hospital	Dare	245
Watauga Medical Center	Watauga	281
Wayne Memorial Hospital	Wayne	706
Wilson Medical Center	Wilson	499
TOTAL NEW CANCER CASES	9,513	
MOBILE PET SERVICES (WITH	7,010	

Source: North Carolina State Center for Health Statistics, NC Cancer Projections 2000-2013. www.schs.state.nc.us/schs/data/cancer.cfm. See Attachment 5. Mobile PET host sites located in counties with fixed PET scanners were not included in this chart (ex. Duke Raleigh Hospital in Wake County and Lake Norman Regional in Iredell County were excluded due to availability of fixed PET services in county.)

Statement of alternatives to the proposed change that were considered and found not feasible.

The viable options to address the lack of mobile PET capacity are extremely limited. Healthcare providers can continue to reluctantly ask patients to travel out of county to obtain this important diagnostic service at fixed PET sites. This alternative is not feasible for many reasons, including, but not limited to, the following:

- 1. Excessive travel time for patients suffering serious illnesses.
- 2. The loss of work/wages for spouses and/or caregivers to assist the patient.
- 3. The length of time required to travel and obtain a PET procedure at a fixed site.

4. The additional costs to the patient associated with out of county travel, which may include gas, food, lodging, etc.

The option of requesting additional mobile PET time from the existing two mobile PET units may not be feasible since both existing PET units exceed a reasonable capacity threshold of 2600 scans annually and because each mobile already has a significant number of host sites that to which they have already, by contact, committed time. Based on the current service load for these mobile PET units, it would be difficult for existing PET sites or hospitals looking to add mobile PET services to obtain the mobile PET time necessary to develop a consistent program or grow its existing service.

The alternative of applying for a fixed PET scanner is limited by the annual need determinations in the SMFP, which are based on six multi-county Health Service Areas (HSAs). Providers may not be allowed to apply for fixed PET scanners until a need determination is generated in the SMFP for a specific Health Service Area ("HSA"). During the past five years of SMFPs (2009-2013 SMFPs), the annual state health plans have only shown a need for one new fixed PET scanner, which is for Health Service Area II (the Triad) in the 2013 SMFP. A mobile PET scanner also differs from fixed PET scanners in that a single mobile PET scanner is capable of serving a larger portion of the State, covering three health service areas, which extends PET service to multiple providers.

The only acceptable alternative is the implementation of need determinations for mobile PET scanners based on existing units exceeding a defined capacity threshold. This is a standard health planning practice that is applied in some form or another to fixed PET services, MRI scanners (including fixed *and mobile*), lithotripters, cardiac catheterization equipment, acute care beds, operating rooms, and nursing facility beds.

Evidence that the proposed change would not result in unnecessary duplication of health resources in the area.

The establishment of an SMFP need methodology for mobile PET scanners will not result in unnecessary duplication of health services in North Carolina. Clearly, there is a need for additional mobile PET capacity as indicated by the data presented in this Petition and the physician letters of support in **Attachment 3**. Furthermore, the inherent nature of a need methodology will only produce need determinations for new equipment when the established thresholds have been exceeded by existing equipment. The number of mobile PET sites, even without considering the unfulfilled requests for mobile PET time by TMC, PHH, PHM, and RRMC, has surpassed the ability and capacity of the two existing mobile PET units. The existing mobile PET units are reaching the seven year mark¹⁰ and undoubtedly will begin requiring more maintenance and downtime which could further impact the current availability of mobile PET services.

¹⁰ According to Alliance, replacement exemptions were obtained in 2006. See **Attachment 1**.

Evidence that the requested change is consistent with the three Basic Principles governing the development of the North Carolina State Medical Facilities Plan: Safety and Quality, Access, and Value.

The request to implement a mobile PET methodology is consistent with the three Basic Principles governing the development of the State Medical Facilities Plan. The ability of healthcare providers to offer the best technology for patients improves the quality and effectiveness of care that patient receives. Accessibility to services has always been an integral issue for health planning in North Carolina and a top priority for the SHCC. The accessibility to mobile PET services for healthcare providers, particularly in smaller counties and rural areas, has reached a point that action must be taken by the SHCC in order to improve the availability of these services that providers and patients are demanding. Healthcare value will be achieved by reducing costs to patients for unnecessary out of county travel, improving the quality of care, increasing accessibility to PET services for all North Carolina residents and local healthcare providers, and eliminating the need for other studies or procedures that PET can replace thereby increasing efficiency and reducing healthcare costs.

Conclusion

The petitioners, Novant Health, Inc. and MedQuest Associates, Inc., are requesting that the State Health Coordinating Council recognize the disparity in the treatment of mobile PET services in the State Medical Facilities Plan and request that the SHCC take action to rectify the lack of an SMFP-based need methodology and need determinations for new mobile PET services. Current data from the only two (2) existing mobile PET scanners in North Carolina continues to indicate that these two (2) mobile units are stretched beyond reasonable capacity. Without the intervention of the SHCC, this problem will only continue to place a strain on patients and healthcare providers by depriving patients and their physicians of access to essential mobile PET services.