

## ATTACHMENTS

**Attachment A: Historical Fixed PET and Mobile PET Scanner Annual Volumes**

**Attachment B: Article in [AuntMinnie.com](http://AuntMinnie.com) entitled “CMS bends on oncology PET coverage, will pay for 3 scans,” (6/12/2013)**

**Attachment C: Location Maps for Fixed PET/CT Scanners & Mobile PET CT/Scanners In North Carolina (July 2014)**

**Attachment D: Hospital Letters of Support for Conversion of Fixed PET to Mobile PET**

**Attachment E: CON Criteria and Standards for Positron Emission Tomography Scanners**

**Attachment F: NC State Center for Health Statistics data (cancer incidence rates)**

**Attachment G: Oncology Roundtable article, “*What’s driving PET/CT Growth?*,” May 31, 2012**

# **Attachment A**

## **North Carolina Fixed & Mobile PET Scanners Annual Volumes**

NORTH CAROLINA ANNUAL FIXED PET/CT SCAN VOLUMES

SMFP Year	Data Year	# of Fixed PET Scanners	Total Annual		Annual Year to Year Fixed PET Scan Growth	Annual Capacity of Fixed PET Scanner	
			Fixed PET Scans	Scans		Fixed PET Scanner	Scanner
1994	FFY 91-92		514			524	3 fixed PET scanners at Duke, NCBH, & CMC
1995	FFY 92-93	3	551	26.9%		524	3 fixed PET scanners at Duke, NCBH, & CMC
1996	FFY 93-94	3	699	14.3%		524	3 fixed PET scanners at Duke, NCBH, & CMC
1997	FFY 94-95	3	799	46.6%		524	3 fixed PET scanners at Duke, NCBH, & CMC
1998	FFY 95-96	3	1,171	53.5%		1,524	New Fixed PET Need triggered at 80% of 1,524
1999	FFY 96-97	4	1,798	34.3%		1,524	annual PET scans or 1, 200 scans
2000	FFY 97-98	4	2,415	52.5%		1,524	
2001	FFY 98-99	4	3,683	28.1%		1,524	6 PET scanners at 4 Academic Med Centers + CMC
2002	FFY 99-00	6	4,717	23.8%		1,524	
2003	FFY 00-01	8	5,840	27.4%		1,524	
2004	FFY 01-02	17	7,441	22.7%		4,000	
2005	FFY 02-03	19	9,127	44.6%		2,600	
2006	FFY 03-04	22	13,198	61.2%		2,600	
2007	FFY 04-05	22	21,270	32.7%		2,600	
2008	FFY 05-06	25	28,215	17.3%		3,000	
2009	FFY 06-07	27	33,089	-0.8%		3,000	
2010	FFY 07-08	27	32,831	12.4%		3,000	Amended by AI to 36,879
2011	FFY 08-09	27	36,897	-0.7%		3,000	
2012	FFY 09-10	27	36,622	-4.7%		3,000	
2013	FFY 10-11	27	34,900	-6.2%		3,000	
2014	FFY 11-12	27	32,729	2.5%		3,000	
2015*	FFY 12-13	28	33,553				

\*Note: DHSR keying error for NH FMC PET Scans corrected to reflect 2,650 PET scans in FFY 2013 rather than 1,650 PET scans  
 And this increased the total FFY 2013 fixed PET scans from 32,553 to 33,553.

File: FixedPETScannerAnnual\Volumes\FINAL.07.29.14.xls

SMFP Year	Data Year	# Mobile PET Host Sites	Annual Total Mobile PET Scans	Annual Year to		Annual Mobile PET Scanner Capacity	% of Annual Mobile PET Capacity	# of Mobile PETs In Operation
				Year Mobile PET Scan Growth	Annual Mobile PET Scanner Capacity			
2005	FFY 02-03	0	0			2,600	86%	1
2006	FFY 03-04	22	2,248			2,600	70%	2
2007	FFY 04-05	18	3,621	61%		2,600	70%	2
2008	FFY 05-06	23	3,428	-5%		2,600	66%	2
2009	FFY 06-07	25	4,862	42%		2,600	94%	2
2010	FFY 07-08	27	5,815	20%		2,600	112%	2
2011	FFY 08-09	23	5,258	-10%		2,600	101%	2
2012	FFY 09-10	28	5,138	-2%		2,600	99%	2
2013	FFY 10-11	29	5,716	11%		2,600	110%	2
2014	FFY 11-12	29	5,571	-3%		2,600	107%	2
2015	FFY 12-13	29	5,791	4%		2,600	111%	2

NORTH CAROLINA ANNUAL MOBILE PET SCAN VOLUMES

File: FixedPETScannerAnnualVolumesfinal.07.29.14.xls

SMF#	Plan Year	Data Year	Annual Fixed			Annual Mobile			Annual Year to Year PET Scan Growth Rate
			MRI Scans	PET Scans	& Fixed PET Scans	PET Scans	& Fixed PET Scans		
<b>NORTH CAROLINA ANNUAL MOBILE &amp; FIXED PET/CT SCAN VOLUMES</b>									
1999	FFY 96-97		1,798		1,798				
2000	FFY 97-98		2,415		2,415		34%		
2001	FFY 98-99		3,683		3,683		53%		
2002	FFY 99-00		4,717		4,717		28%		
2003	FFY 00-01		5,840		5,840		24%		
2004	FFY 01-02		7,441		7,441		27%		
2005	FFY 02-03		9,127		9,127		23%		
2006	FFY 03-04		13,198	2,248	15,446		69%		
2007	FFY 04-05		21,270	3,621	24,891		61%		
2008	FFY 05-06		28,215	3,428	31,643		27%		
2009	FFY 06-07		33,089	4,862	37,951		20%		
2010	FFY 07-08		32,831	5,815	38,646		2%		
2011	FFY 08-09		36,897	5,258	42,155		9%		
2012	FFY 09-10		36,622	5,138	41,760		-1%		
2013	FFY 10-11		34,900	5,716	40,616		-3%		
2014	FFY 11-12		32,729	5,571	38,300		-6%		
2015*	FFY 12-13		33,553	5,791	39,344		3%		

File: FixedPETScannerAnnualVolumes.FINAL.07.29.14.xls



**ATTACHMENTS**  
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Interimaps Platform



**AuntMinnie.com**

## CMS bends on oncology PET coverage, will pay for 3 scans

By [Brian Casey, AuntMinnie.com staff writer](#), [Wayne Forrest, AuntMinnie.com staff writer](#)

June 12, 2013 -- In a victory for PET proponents, the U.S. Centers for Medicare and Medicaid Services (CMS) on Tuesday issued a final decision on coverage of oncology FDG-PET scans, agreeing to pay for three follow-up studies rather than just one, as it had proposed three months ago.

In a final decision memo announcing the change, CMS said it was responding to comments received since it issued its proposed policy change in March to the national coverage determination (NCD) governing how Medicare pays for oncology FDG-PET scans. CMS had proposed paying for just one initial PET scan for oncology applications and one subsequent scan, with payment for any additional scans to be determined by local Medicare Administrative Contractors (MACs).

That proposal had [drawn the ire](#) of PET advocates, who believed that the lack of a national policy for oncology FDG-PET reimbursement could mean that many patients wouldn't get the scans even though they were clinically necessary for follow-up after therapy.

CMS said it received 175 comments opposing the one-scan limitation. Many of the respondents indicated that patients undergoing second- or third-line anticancer treatment typically receive three scans in the course of their therapy.

"CMS appreciates these comments and will nationally cover at least three additional scans," the agency wrote in its final decision memo. "Coverage of additional scans (that is, more than three) shall be determined by the local MACs."

The decision demonstrates the success of the National Oncologic PET Registry (NOPR), the body created in 2006 to serve as a vehicle for data collection on PET's effectiveness in changing the management of patients with solid tumors. Under the agency's coverage with evidence development program, PET sites were able to receive Medicare coverage for their studies only if they reported their data to NOPR. With this week's decision, PET sites will no longer have to participate in NOPR to receive FDG-PET reimbursement.

In the June 11 decision, CMS acknowledged that NOPR served its purpose well, gathering data on far more patients than were found in the more traditional clinical studies that the agency also reviewed in crafting its new policy. According to NOPR data, physicians reported that FDG-PET changed their management of patients by 35% to 40%.

At the same time, however, the agency found flaws in the NOPR process. For one, NOPR only recorded intended changes in patient management as reported by physicians, not actual changes. This limitation makes it impossible to determine whether the intended changes in management actually conferred a benefit in long-term patient outcomes, the agency wrote.

"Nevertheless, NOPR-derived results have informed our consideration of the evidence base for covering FDG-PET imaging for this oncologic indication," CMS wrote. "In the setting of anticancer treatment we believe that the choices made by treating physicians in many instances change the patient's experience of illness. Therefore we have largely accepted the persuasiveness of the NOPR report, except where we believe there is other evidence available to better support an alternative conclusion."

PET proponents also scored a victory by convincing CMS to back away from its initial decision not to include PET for prostate cancer in the list of covered clinical indications. In March, CMS said that clinical evidence did not support the use of FDG-PET for prostate cancer follow-up once therapy had been completed; instead, another radiopharmaceutical, choline-11, might be better suited.

In its final decision memo, however, the agency noted that it received public comments indicating that several more recent articles had demonstrated the value of FDG-PET scans for prostate cancer. CMS decided the modality was useful for determining the effects of treatment, particularly for progressive prostate disease.

### Utilization growth?

Tuesday's decision memo also addressed the agency's concerns over an increase in PET utilization, particularly if asymptomatic patients were scanned for routine surveillance with no evidence of recurrence after their initial therapy. This fear was what had driven the agency to propose the one-scan limitation, CMS wrote.

might not be successful could be candidates for second-line or even further treatment, and for this reason, CMS decided to permit local Medicare contractors to determine coverage for additional FDG-PET scans beyond the initial three.

Upon hearing of the CMS edict late Tuesday at its annual meeting in Vancouver, the Society of Nuclear Medicine and Molecular Imaging (SNMMI) applauded the agency's actions. SNMMI expressed hope that local Medicare contractors would agree to pay for more follow-up PET scans than just the three mandated by the new policy.

"I appreciate the fact that CMS has changed the limit from one scan to three," said SNMMI Vice President-Elect Dr. Hossein Jadvar, PhD, in a statement. "However, it will be important for the local contractors to allow more than three when clinically necessary."

SNMMI also supports the use of FDG-PET/CT to guide treatment for patients with prostate cancer as reasonable and necessary. "Monitoring metastatic prostate cancer therapy can be difficult," said SNMMI President Dr. Gary Dillehay. "However, in some indications PET can provide useful information for physicians in creating an effective treatment plan."

The society noted that PET sites must continue to work through the NOPR process to get reimbursement for sodium fluoride (NaF) scans. SNMMI "will continue working to develop evidence for NaF-PET through the NOPR program," Dillehay said.

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Last Updated bc 6/12/2013 2:58:58 PM

## Forum Comments

3 comments so far ...

6/13/2013 12:03:32 PM Is it CMS's intention that the 3 exams is a "lifetime" total?  
Atomtom

6/13/2013 3:09:02 PM 1. CMS criteria is still evolving, so lets not freeze or fret here. 2. There's a lot of clinical/ research/ [:@]administrative/ insurance Politics [:]and Gate-Management here at this point in time. 3. There has been some abuse on "repeat f/u PET/CT study", they probably picked such up on q3 or 4-month follow up repeat PET/CT imaging tendencies/ data-tracking stats, so they moved to close the loophole. 4. Its a freakin' money saving tactic (hello, read 'Bottomline Management'[8]) for ObamaCare by number crunchers or other jokers [:](), forced upon our Referring doc community that also affects Rad reads (repeat volume). 5. IMHO, these 'decision makers' dont really care about clinical outcome or patient well being as driving factor. They look at #s & \$s. 6. We need to step up to the game, and have more of us Rads/ reasoning scientific Docs (those who want to do Admin/ get MHA/ MBA etc) among those who have a firm hold in directing medicine, its delivery, and its projected path. This is where we lack. Rare are the instances where a clinical MD is CEO/COO other than as a chosen pawn & rubber stamp they shamelessly deploy against ourselves/ us Rads/docs. 7. None of these 'gurus' actually practice medicine or presumably have had a family member's life taken by the politics of care delivery. 8. Gather up, my fellow Attendings, we need more of "us" amongst "them" :op .....reminds me of "Us and Them" / Pink Floyd, LOL  
Sharp Rad

6/15/2013 7:46:59 AM  
BigDesk

*Quote from Sharp Rad*

1. CMS criteria is still evolving, so lets not freeze or fret here. 2. There's a lot of clinical/ research/ [:@]administrative/ insurance Politics [:]and Gate-Management here at this point in time. 3. There has been some abuse on "repeat f/u PET/CT study", they probably picked such up on q3 or 4-month follow up repeat PET/CT imaging tendencies/ data-tracking stats, so they moved to close the loophole. 4. Its a freakin' money saving tactic (hello, read 'Bottomline Management'[8]) for ObamaCare by number crunchers or other jokers [:](), forced upon our Referring doc community that also affects Rad reads (repeat volume). 5. IMHO, these 'decision makers' dont really care about clinical outcome or patient well being as driving factor. They look at #s & \$s. 6. We need to step up to the game, and have more of us Rads/ reasoning scientific Docs (those who want to do Admin/ get MHA/ MBA etc) among those who have a firm hold in directing medicine, its delivery, and its projected path. This is where we lack. Rare are the instances where a clinical MD is CEO/COO other than as a chosen pawn & rubber stamp they shamelessly deploy against ourselves/ us Rads/docs. 7. None of these 'gurus' actually practice medicine or presumably have had a family member's life taken by the politics of care delivery. 8. Gather up, my fellow Attendings, we need more of "us" amongst "them" :op

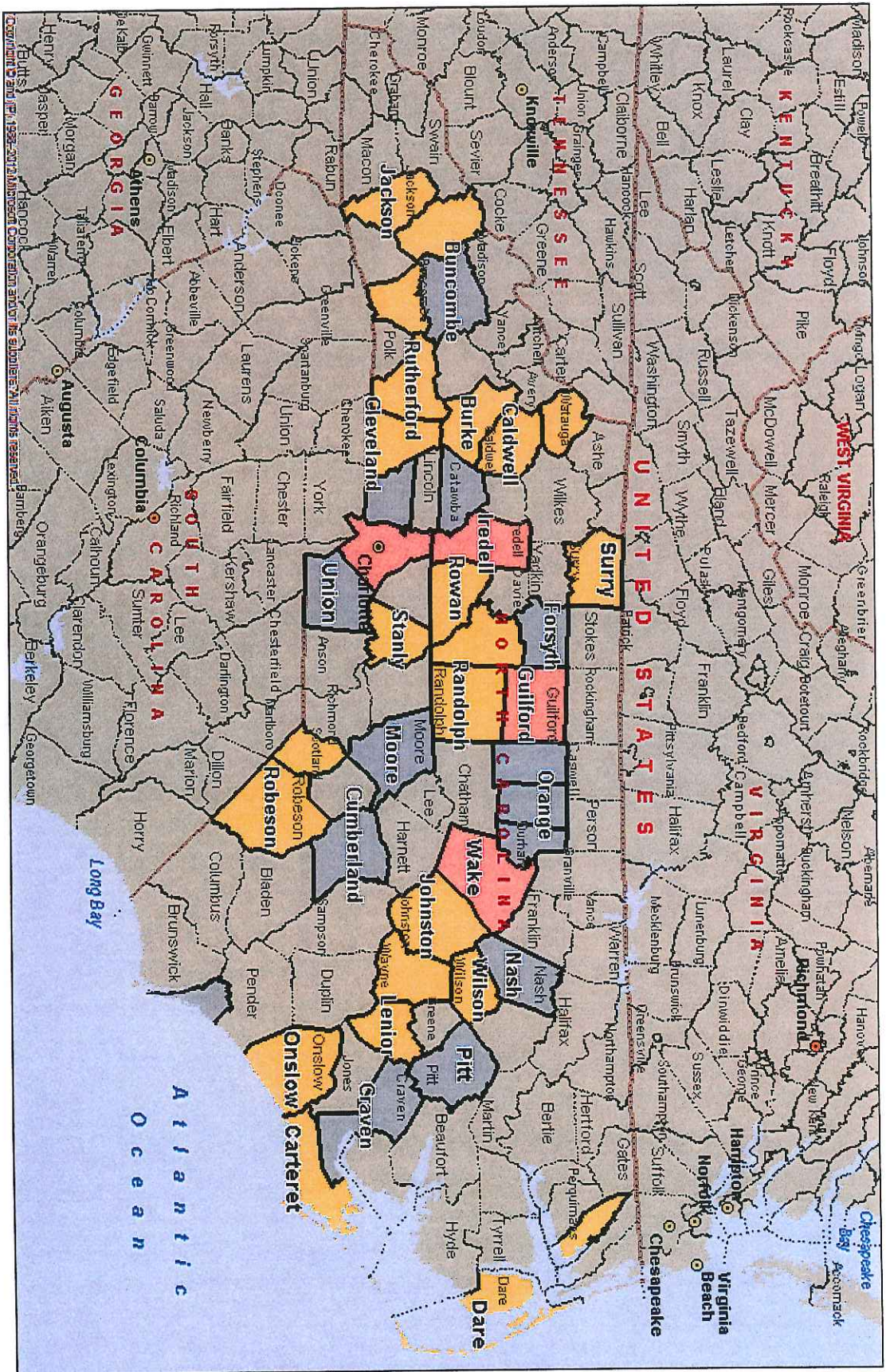
# **Attachment C**

## **Maps of North Carolina Fixed & Mobile PET/CT Scanner Locations-July 2014**



**Fixed and Mobile PET Host Sites by County – July 2014**

# Fixed and Mobile PET Host Sites by County – July 2014



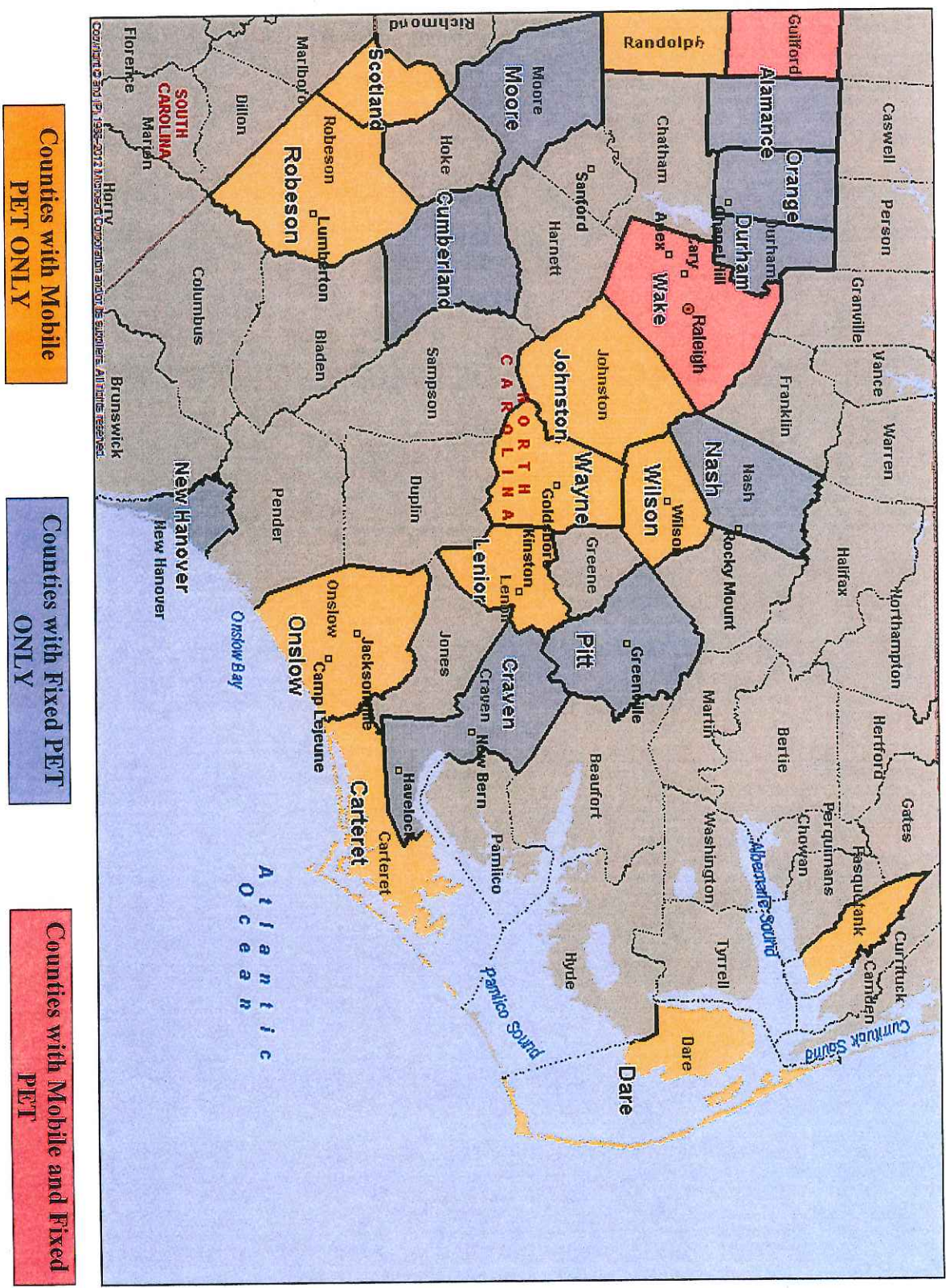
Counties with Mobile PET ONLY

Counties with Fixed PET ONLY

Counties with Mobile and Fixed PET

# Fixed and Mobile PET Host Sites by County – July 2014

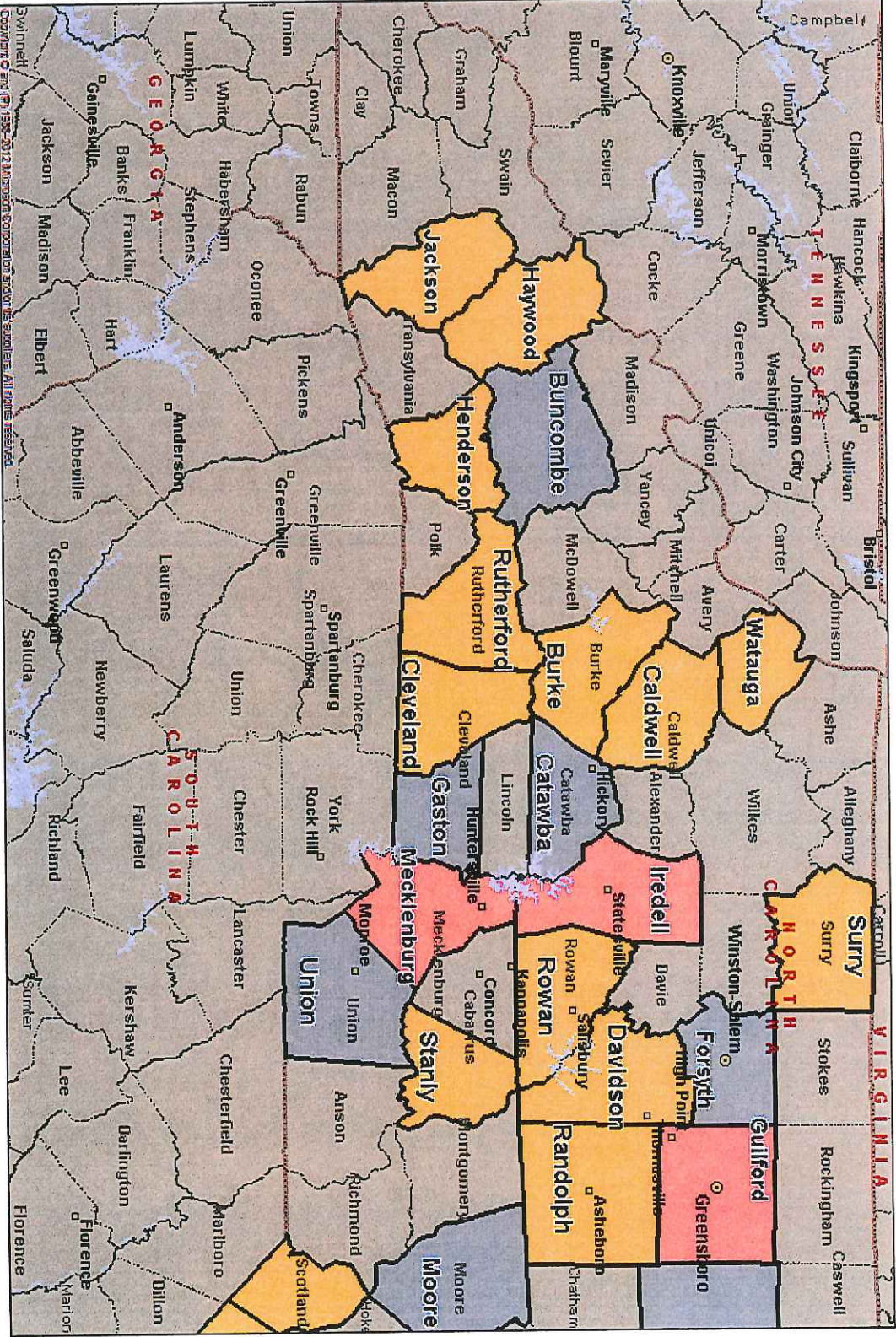
## Eastern North Carolina



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# Fixed and Mobile PET Host Sites by County – July 2014

## Western North Carolina



Counties with Mobile PET ONLY

Counties with Fixed PET ONLY

Counties with Mobile and Fixed PET

**Fixed and Mobile PET Host Sites by County – July 2014**

**Counties Excluded from New Provider Mobile PET Service:**

- Buncombe
- Catawba
- Forsyth
- Guilford
- Alamance
- Mecklenburg
- Union
- Gaston
- Iredell
- Durham
- Orange
- Wake
- New Hanover
- Cumberland
- Moore
- Pitt
- Craven
- Nash

**Counties with Fixed and Mobile PET sites**

# **Attachment D**

## **Letters of Support**



# Ashe Memorial Hospital

200 Hospital Avenue, Jefferson, North Carolina 28640 (336) 846-7101

July 28, 2014

Dr. Christopher Ullrich, Chair  
State Health Coordinating Council  
C/O Division of Health Service Regulation, Medical Facilities Planning Branch  
809 Ruggles Dr.  
Raleigh, NC 27603

Dear Dr. Ullrich:

I am the President and CEO of Ashe Memorial Hospital, Jefferson, NC in Ashe County. We are located in a rural county in the western North Carolina Mountains. Our hospital offers inpatient, outpatient and emergency medicine services. We also offer pharmacy, laboratory, rehabilitation services for inpatients, outpatients, and diabetes management, cardiopulmonary services and testing, surgeries, GI endoscopies, pain management and imaging. We have a full-service radiology department which included the following imaging modalities: fixed MRI, CT, ultrasound, mammography, X-Ray, Fluoroscopy, SPECT, Bone Density studies, and Gamma Camera. We also operate an urgent care center, a Birthing Center in our hospital, and the Ashe Women's Center offering gynecologic care for women of all ages and also providing mammograms. We have a medical staff which includes anesthesiologist, cardiologist, ENT, family practitioners, emergency medicine physicians, general surgeons, hospitalists, internal medicine physician, orthopedic surgeons, obstetrics & gynecology, and radiology.

Unfortunately, one key component is missing from our continuum of imaging services is local access to PET/CT diagnostic imaging performed on a PET/CT scanner. We do not have a fixed PET/CT scanner on our campus at this time, nor are we able to contract with the state's sole CON-approved mobile PET/CT scanner vendor, Alliance Imaging, as they have no capacity to add a host site in Jefferson at this time. PET or Positron Emission Tomography, detects disease more quickly and accurately by identifying biochemical changes in the body. The PET/CT scanner has a variety of oncology applications from early detection, determining the stage of cancer, checking for recurrence and assessing the effectiveness of chemotherapy. In addition, there are neurological and cardiac applications.

The current CON and health planning framework in North Carolina does not provide a pathway by which a fixed PET/CT scanner can be converted to a mobile unit. We support a process to expand access to mobile PET/CT scanners in North Carolina. Currently the only CON-approved mobile PET vendor is operating above capacity on its two existing mobile PET/CT scanners and cannot accommodate more mobile PET time for new mobile PET host sites. We believe a change in the state health planning and CON processes that would allow the expansion of the number of mobile PET vendors in North Carolina would be beneficial for community hospitals such as Ashe Memorial Hospital, as well as other hospitals that lack local access to mobile PET services today.

We are not aware of any other CON-regulated service in North Carolina where a sole vendor has been the only option for over a decade. Alliance Imaging has had the opportunity since 2002 to be the only CON-approved mobile PET scanner provider in North Carolina. While they have sought to do a reasonable job to serve all 29 mobile PET host sites where they have contracts in North Carolina, the result is sometimes that many of their clients get less frequent and less predictable mobile PET service than they desire due to AI's capacity constraints and the sheer size of North Carolina. One mobile PET vendor operating only two mobile PET scanners, covering the 39,000 square miles of North Carolina, which is home to almost 10 million residents, is not sustainable from a provider, physician, and patient perspective.

We encourage the state to permit the conversion of existing fixed PET scanners to mobile PET scanners, by updating the annual State Medical Facilities Plan PET Scanner chapter to allow the development of additional mobile PET scanner options in North Carolina. We believe this is a reasonable request whose time has come.

Sincerely,

Laura Lambeth, RN, BSN  
CEO, Ashe Memorial Hospital

File: MobilePETSupportLtrAsheMemHosp.07.27.14.docx

July 24, 2014



Brunswick Medical Center

240 Hospital Drive, Northeast  
Bolivia, NC 28422

novanthealth.org

Dr. Christopher Ullrich, Chair  
State Health Coordinating Council  
C/O Division of Health Service Regulation, Medical Facilities Planning Branch  
809 Ruggles Dr.  
Raleigh, NC 27603

Dear Dr. Ullrich:

I am the President of Novant Health Brunswick Medical Center, Bolivia, NC in Brunswick, NC in coastal North Carolina. NH Brunswick Medical Center is a 74-bed community hospital offering inpatient, outpatient and emergency medical care including imaging, pharmacy, pathology, respiratory therapy, rehabilitation, infusion services, diabetes care, pain management, surgery pulmonary and sleep medicine, gastroenterology services, women's services including obstetrics, cardiology, orthopedics, podiatry, ENT, ophthalmology, urology, plastic surgery, pediatrics. In addition, the Novant Health Medical Group practices in Brunswick County include 23 physicians and surgeons and 9 physician extenders practicing as inpatient care specialists, internal medicine physicians, family practitioners (with a convenient care clinic), pulmonary and sleep medicine, general surgeons, and urologists.

We have a full-service radiology department at the hospital including x-ray, mammography, bone density, fluoroscopy, CT, and MRI. However, we do not have local access in Brunswick County to either fixed or mobile PET/CT diagnostic imaging services.

We believe a change in the state health planning and CON processes that would allow the expansion of the number of mobile PET vendors in North Carolina would be beneficial for community hospitals such as Brunswick Medical Center, as well as other hospitals that lack local access to mobile PET services today. We are not aware of any other CON-regulated service in North Carolina where a sole vendor has been the only option for over a decade. Alliance Imaging has had the opportunity since 2003 to be the only CON-approved mobile PET scanner provider in North Carolina. While they have sought to do a reasonable job to serve all 29 mobile PET host sites where they have contracts in North Carolina, the result is sometimes that many of their clients get less frequent and less predictable mobile PET service than they desire due to AI's capacity constraints and the sheer size of North Carolina. One mobile PET vendor operating only two mobile PET scanners, covering the 39,000 square miles of North Carolina, which is home to almost 10 million residents, is not sustainable from a provider, physician, and patient perspective.

We encourage the state to permit the conversion of existing fixed PET scanners to mobile PET scanners, by updating the annual State Medical Facilities Plan PET Scanner chapter to allow the development of additional mobile PET scanner options in North Carolina. We believe this is a reasonable request whose time has come.

Sincerely,

A handwritten signature in cursive script that reads 'Shelbourn Stevens'.

Shelbourn Stevens, President  
Novant Health Brunswick Medical Center

*File: MobilePETSupportLtrBrunswickMedCenter.07.23.14.docx*





July 29, 2014

Dr. Christopher Ullrich, Chair  
State Health Coordinating Council  
C/O Division of Health Service Regulation, Medical Facilities Planning Branch  
809 Ruggles Dr.  
Raleigh, NC 27603

Dear Dr. Ullrich:

I am the President and CEO of Halifax Regional Medical Center, Roanoke Rapids, NC in Halifax County. We are located in a rural area in eastern North Carolina. Our hospital offers inpatient, outpatient and emergency medicine services. We also offer pharmacy, laboratory, rehabilitation services for inpatients, outpatients, cardiopulmonary services and testing, surgeries (including minimally invasive surgeries), GI endoscopies, pain management, dialysis services, laboratory & pathology services, and imaging. We have a full-service radiology department which includes the following imaging modalities: fixed MRI, CT, ultrasound, mammography, X-Ray, Fluoroscopy, and nuclear medicine. We also operate a Wound Care Center, a Sleep Lab, an Occupational Medicine program, and a Birthing Center in our hospital. We have a medical staff which includes anesthesiologists, cardiologists, ENT, family practitioners, emergency medicine physicians, gastroenterologists, general surgeons, hospitalists, internists, infectious disease specialists, nephrologists, oncologists, obstetrics & gynecology, ophthalmologists, orthopedists, pathologists, pediatricians, psychiatrists, radiologists, and urologists.

Unfortunately, one key component is missing from our continuum of imaging services is local access to PET/CT diagnostic imaging performed on a PET/CT scanner. We do not have a fixed PET/CT scanner on our campus at this time, nor are we able to contract with the state's sole CON-approved mobile PET/CT scanner vendor, Alliance Imaging, as they have no capacity to add a host site in Roanoke Rapids at this time. PET or Positron Emission Tomography, detects disease more quickly and accurately by identifying biochemical changes in the body. The PET/CT scanner has a variety of oncology applications from early detection, determining the stage of cancer, checking for recurrence and assessing the effectiveness of chemotherapy. In addition, there are neurological and cardiac applications.

The current CON and health planning framework in North Carolina does not provide a pathway by which a fixed PET/CT scanner can be converted to a mobile unit. We support a process to expand access to mobile PET/CT scanners in North Carolina. Currently the only CON-approved mobile PET vendor is operating above capacity on its two existing mobile PET/CT scanners and cannot accommodate more mobile PET time for new mobile PET host sites. We believe a change in the state health planning and CON processes that would allow the expansion of the number of mobile PET vendors in North Carolina would be beneficial for community hospitals such as Halifax Regional Medical Center, as well as other hospitals that lack local access to mobile PET services today.

We are not aware of any other CON-regulated service in North Carolina where a sole vendor has been the only option for over a decade. Alliance Imaging has had the opportunity since 2002 to be the only CON-approved mobile PET scanner provider in North Carolina. While they have sought to do a reasonable job to serve all 29 mobile PET host sites where they have contracts in North Carolina, the result is sometimes that many of their clients get less frequent and less predictable mobile PET service than they desire due to AI's capacity constraints and the sheer size of North Carolina. One mobile PET vendor operating only two mobile PET scanners, covering the 39,000 square miles of North Carolina, which is home to almost 10 million residents, is not sustainable from a provider, physician, and patient perspective.

We encourage the state to permit the conversion of existing fixed PET scanners to mobile PET scanners, by updating the annual State Medical Facilities Plan PET Scanner chapter to allow the development of additional mobile PET scanner options in North Carolina. We believe this is a reasonable request whose time has come.

Sincerely,

William Mahone V, President  
Halifax Regional Medical Center



*Our Region's CHOICE  
for TECHNOLOGY & CARE*

July 29, 2014

Dr. Christopher Ullrich, Chair  
State Health Coordinating Council  
C/O Division of Health Service Regulation, Medical Facilities Planning Branch  
809 Ruggles Dr.  
Raleigh, NC 27603

Dear Dr. Ullrich:

I am the CEO of Hugh Chatham Memorial Hospital in Elkin, NC (Surry County). Our hospital offers inpatient, outpatient and emergency medicine services. In addition, a wide array of cancer services is offered on the HCMH campus and nearby in the Comprehensive Cancer Center of Wake Forest Medical Center at Elkin. The Radiation Therapy Department at Hugh Chatham Memorial Hospital recently was awarded a three-year term of accreditation from the American College of Radiology and HCMH operates one linear accelerator which performed over 4,700 radiation therapy treatments during FFY 2013 for 178 unique patients. The Comprehensive Cancer Center of Wake Forest Medical Center at Elkin offers medical oncology services including chemotherapy and biotherapy, treatment for chemotherapy side effects, bone marrow biopsies, on-site lab testing, phlebotomies, access to clinical trials, genetic testing, peripheral blood smear interpretation, consults for HCMH inpatients, consultation and follow-up care, and home health and hospice referrals. The medical staff at HCMH includes medical and radiation oncologists, radiologists, pathologists, gastroenterologists, pulmonology, general surgery, urology, neurology, ENT, ophthalmology, etc. In addition, in support of these cancer services our hospital also provides pathology, pharmacy, respiratory therapy, and lab services.

Unfortunately, one key component is missing from our cancer programs and that is local access to PET/CT diagnostic imaging performed on a local PET/CT scanner. We do not have a fixed PET/CT scanner on our campus at this time, nor are we able to contract with the state's sole CON-approved mobile PET vendor, Alliance Imaging, as they have no capacity to add a host site in Elkin at this time. PET or Positron Emission Tomography, detects disease more quickly and accurately by identifying biochemical changes in the body. The PET/CT scanner has a variety of oncology applications from early detection, determining the stage of cancer, checking for recurrence and assessing the effectiveness of chemotherapy. In addition, there are neurological and cardiac applications.

The current CON and health planning framework does not provide a pathway by which a fixed PET/CT scanner can be converted to a mobile unit. We support having the opportunity to expand access to mobile PET/CT scanners in North Carolina. Currently the sole, CON-approved mobile PET vendor is operating above capacity on its two existing mobile PET/CT scanners and cannot accommodate more mobile PET time for any additional host sites.

We believe a change in the state health planning and CON processes that would allow the expansion of the number of mobile PET vendors in North Carolina would be beneficial for community hospitals such as Hugh Chatham Memorial Hospital, as well as other hospitals that lack local access to mobile PET services today. We are not aware of any other CON-regulated service in North Carolina where a sole vendor has been the only option

for over a decade. Alliance Imaging has had the opportunity since 2003 to be the only CON-approved mobile PET scanner provider in North Carolina. While they have sought to do a reasonable job to serve all 29 mobile PET host sites where they have contracts in North Carolina, the result is sometimes that many of their clients get less frequent and less predictable mobile PET service than they desire due to AI's capacity constraints and the sheer size of North Carolina. One mobile PET vendor operating only two mobile PET scanners, covering the 39,000 square miles of North Carolina, which is home to almost 10 million residents, is not sustainable from a provider, physician, and patient perspective.

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Sincerely,



Paul H. Hammes, CEO  
Hugh Chatham Memorial Hospital



July 8, 2014

Dr. Christopher Ullrich, Chair  
State Health Coordinating Council  
C/O Division of Health Service Regulation, Medical Facilities Planning Branch  
809 Ruggles Dr.  
Raleigh, NC 27603

**Huntersville Medical Center**

10030 Gilead Road  
Huntersville, NC 28078

novanthealth.org

Dear Dr. Ullrich:

I am the President of Novant Health Huntersville Medical Center (NHHMC) Huntersville, NC (Mecklenburg County). Our hospital currently has a service contract with the mobile PET vendor Alliance Imaging such that the mobile PET scanner is on the NHHMC campus one Monday per month for a full day, from 7:00am – 10:00pm and every other Thursday for a half day, defined as 2:30 – 8:00 pm. Thus, we have local access to mobile PET diagnostic imaging for only about 26 hours each month. During FFY 2013, we were able to offer about 197 mobile PET scans and for FFY 2014 we are on track to perform 204 PET scans by year's end. We are certain that demand for PET diagnostic imaging will increase on our campus in 2015 as we are currently installing a linear accelerator on the NHHMC campus which will become operational during March 2015.

The Novant Health Huntersville Medical Center Medical Staff includes hematologist/oncologists, radiation oncologists, surgeons (specializing in cancer surgeries), as well as radiologists and pathologists. In order to support cancer services offered on the NHHMC campus (which includes chemotherapy, radiation therapy, related inpatient and outpatient services), we would like very much to increase the amount of time that the mobile PET/CT scanner is on our campus. This would be very beneficial for our cancer patients, their families and the cancer physicians. The literature and data tell us that PET scans related to a cancer diagnosis are still today the most prevalent use of PET diagnostic imaging technology. However, since there is only one existing mobile PET/CT scanner vendor serving 18 mobile PET host sites in Western North Carolina, we are not able to expand the time when the mobile PET unit is on our NHHMC campus. I am told that during FFY 2013, the Alliance Imaging mobile PET scanner was operating at 113% of capacity and that the Western NC Alliance Imaging (AI) mobile PET scanner has operated at more than 100% of its capacity since FFY 2007. That may make for good business at AI, but not for very desirable and plentiful access for mobile PET imaging at NHHMC. The closest fixed PET scanners to NHHMC are in downtown Charlotte at Novant Health Presbyterian Medical Center or Carolinas Medical Center. Neither of these are ideal options from a continuity of care perspective, or from the travel burden that is imposed on fragile cancer patients and their families.

Thus, we are very supportive of a change state health planning and CON processes that would allow the expansion of the number of mobile PET vendors in North Carolina. I am not aware of any other CON-regulated service in North Carolina where a sole vendor has been the only option for over a decade. Alliance Imaging has had the opportunity since 2003 to be the only CON-approved mobile PET scanner provider in North Carolina. While they have sought to do a reasonable job to serve all 29 mobile PET host sites where they have contracts in North Carolina, the result is sometimes that many of their clients get less frequent and less predictable mobile PET service than they desire due to AI's capacity constraints and the sheer size of the state of North Carolina from the mountains to the coast. One mobile PET vendor operating only two mobile PET scanners, covering the 39,000 square miles of North Carolina, which is home to almost 10 million residents is not sustainable from a provider, physician, and patient perspective.

We encourage the state to permit the conversion of existing fixed PET scanners to mobile PET scanners, by updating the annual State Medical Facilities Plan PET Scanner chapter to allow the development of additional mobile PET scanner options in North Carolina. We believe this is a reasonable request whose time has come.

Sincerely,

Tanya S. Blackmon, President  
Novant Health Huntersville Medical Center  
Huntersville, North Carolina

File: MobilePETSuppLtrNHHMCJuly2014FINAL.docx



July 9, 2014

Dr. Christopher Ullrich, Chair  
State Health Coordinating Council  
C/O Division of Health Service Regulation, Medical Facilities Planning Branch  
809 Ruggles Dr.  
Raleigh, NC 27603

**Kernersville Medical Center**

1750 Kernersville Medical Parkway  
Kernersville, NC 27284

NovantHealth.org

A department of Novant Health  
Forsyth Medical Center

Dear Dr. Ullrich:

I am the President of Novant Health Kernersville Medical Center (NHKMC), Kernersville, NC (western Forsyth County). Our hospital does not currently have a service contract with the mobile PET vendor Alliance Imaging, as they lack the capacity and flexibility to accommodate our desire for local access to mobile PET diagnostic imaging services. The closest fixed PET Scanners to Kernersville are either located out of County in Guilford County at Moses Cone Health System or High Point Regional Medical Center or in Winston-Salem at NH Forsyth Medical Center or North Carolina Baptist Medical Center. Asking fragile cancer patients and their families to travel these distances for diagnostic PET imaging is less than optimal and is disruptive to continuity of care. The data and literature show that the greatest use of PET imaging has been and continues to be for patients with a cancer diagnosis.

During the summer of 2013, NHKMC opened a satellite cancer program on its campus affiliated with the excellent and well-established Cancer Center at Novant Health Forsyth Medical Center. The NHKMC satellite cancer center includes a linear accelerator, chemotherapy, and other related inpatient and outpatient services. The Kernersville Medical Center Medical Staff includes hematologists/oncologists, radiation oncologists, and surgeons specializing in cancer surgeries, as well as radiologists and pathologists, all of whom also practice with the cancer program at NH Forsyth Medical Center. In order to support the continued growth of cancer services offered on the NHKMC campus, we would like very much to offer convenient local access to mobile PET/CT scanner services on our campus. This would be very beneficial for our cancer patients, their families and the cancer physicians. However, since there is only one existing mobile PET/CT scanner vendor serving 18 mobile PET host sites in Western North Carolina, we are not able to get any time from the mobile PET vendor. I am told that during FFY 2013, the Alliance Imaging mobile PET scanner for western NC is operating at 113% of capacity and that the AI western NC mobile PET scanner has operated at more than 100% of its capacity since FFY 2007. That may make for good business at AI, but not for very desirable and plentiful access for mobile PET imaging at NHKMC.

Thus, we are very supportive of a change in state health planning and CON processes that would allow the expansion of the number of mobile PET vendors in North Carolina. I am not aware of any other CON-regulated service in North Carolina where a sole vendor has been the only option for over a decade. Alliance Imaging has had the opportunity since 2003 to be the only CON-approved mobile PET scanner provider in North Carolina. While they have sought to do a reasonable job to serve all 29 mobile PET host sites where they have contracts in North Carolina, the result is sometimes that many of their clients get less frequent and less predictable mobile PET service than they desire due to AI's capacity constraints and the sheer size of North Carolina. One mobile PET vendor operating only two mobile PET scanners, covering the 39,000 square miles of North Carolina, which is home to almost 10 million residents, is not sustainable from a provider, physician, and patient perspective.

We encourage the state to permit the conversion of existing fixed PET scanners to mobile PET scanners, by updating the annual State Medical Facilities Plan PET Scanner chapter to allow the development of additional mobile PET scanner options in North Carolina. We believe this is a reasonable request whose time has come.

Sincerely,

A handwritten signature in blue ink that reads 'Joanne Allen'.

Joanne Allen, President  
Novant Health Kernersville Medical Center

*File: MobilePETSuppLtrNHKMCJuly2014.docx*



July 8, 2014

Dr. Christopher Ullrich, Chair  
State Health Coordinating Council  
C/O Division of Health Service Regulation, Medical Facilities Planning Branch  
809 Ruggles Dr.  
Raleigh, NC 27603

**Matthews Medical Center**

1500 Matthews Township Parkway  
Matthews, NC 28106

novanthealth.org

Dear Dr. Ullrich:

I am the President of Novant Health Matthews Medical Center, Matthews NC (Mecklenburg County). Our hospital currently has a service contract with the mobile PET vendor Alliance Imaging such that the mobile PET scanner is on the NHMMC campus every other Friday for Half-Days, defined as 2:30 to 8:00pm. Thus, we have local access to mobile PET diagnostic imaging for only about 11 hours each month. During FFY 2013, we provided about 134 mobile PET scans to our patients and in FFY 2014 we are on track to provide about 131 mobile PET scans to our patients by year's end. So in the limited mobile PET time we are allocated, we make the most of it.

A very busy linear accelerator (owned by the radiation oncologists) is located on our hospital campus, as well. The Matthews Medical Center Medical Staff includes hematologist/oncologists, radiation oncologists, surgeons specializing in cancer surgeries, as well as radiologists and pathologists. In order to support cancer services offered on the NHMMC campus (which include chemotherapy, radiation therapy, related inpatient and outpatient services, including a hospice inpatient bed unit), we would like very much to increase the amount of time that the mobile PET/CT scanner is on our campus. This would be very beneficial for our cancer patients, their families and the cancer physicians. However, since there is only one existing mobile PET/CT scanner vendor serving 18 mobile PET host sites in Western North Carolina, we are not able to expand the time when the mobile PET unit is on our NHMMC campus. I am told that during FFY 2013, the Alliance Imaging mobile PET scanner was operating at 113% of capacity and that the AI mobile PET scanner has operated at more than 100% of its capacity since FFY 2007. That may make for good business at AI, but not for very desirable and plentiful access for mobile PET imaging at NHMMC.

Thus, we are very supportive of a change to the state health planning and CON processes that would allow the expansion of the number of mobile PET vendors in North Carolina. I am not aware of any other CON-regulated service in North Carolina where a sole vendor has been the only option for over a decade. Alliance Imaging has had the opportunity since 2003 to be the only CON-approved mobile PET scanner provider in North Carolina. While they have sought to do a reasonable job to serve all 29 mobile PET host sites where they have contracts in North Carolina, the result is sometimes that many of their clients get less frequent and less predictable mobile PET service than they desire due to AI's capacity constraints and the sheer size of North Carolina. One mobile PET vendor operating only two mobile PET scanners, covering the 39,000 square miles of North Carolina, which is home to almost 10 million residents, is not sustainable from a provider, physician, and patient perspective.

We encourage the state to permit the conversion of existing fixed PET scanners to mobile PET scanners, by updating the annual State Medical Facilities Plan PET Scanner chapter to allow the development of additional mobile PET scanner options in North Carolina. We believe this is a reasonable request whose time has come.

Sincerely,

Roland Bibeau, President  
Novant Health Matthews Medical Center  
Matthews, NC

# **MOREHEAD**

MEMORIAL HOSPITAL

July 28, 2014

Dr. Christopher Ullrich, Chair  
State Health Coordinating Council  
C/O Division of Health Service Regulation, Medical Facilities Planning Branch  
809 Ruggles Dr.  
Raleigh, NC 27603

Dear Dr. Ullrich:

I am the Interim President and CEO of Morehead Memorial Hospital, Eden, NC in Rockingham County. Our hospital offers inpatient, outpatient and emergency medicine services. In addition, we have a well-established and busy cancer program. The John Smith Jr./Dalton McMichael Cancer Center on the campus of Morehead Memorial Hospital provides advanced, high-quality, easily-accessible cancer care to residents of Rockingham County and surrounding areas and eliminates the need for residents to leave the area to obtain cancer treatment services. The center employs some of the best medical and radiation oncologists in the region. The oncologists, along with our highly-trained nurses and cancer center staff, work with patients' regular physicians so that they remain active in their patients' medical care. By combining both medical and radiation oncology services in one facility, patients benefit from a greatly enhanced coordination of cancer care. The center's medical oncology unit provides medical diagnosis and treatment services such as cancer diagnosis and staging, chemotherapy, blood product replacement, hydration therapy, pain management, anti-emetic therapy and use of biological response modifiers. A comfortable six-bed chemotherapy station is included in the medical oncology area. The center's radiation oncology unit houses a linear accelerator capable of delivering intensity modulated radiation therapy (IMRT). During FFY 2013 our linear accelerator performed over 5,100 radiation therapy treatments. Our medical staff includes medical oncologists, cancer surgeons, and radiation oncologists.

Unfortunately, one key component is missing from our cancer programs and that is local access to PET/CT diagnostic imaging performed on a PET/CT scanner. We do not have a fixed PET/CT scanner on our campus at this time, nor are we able to contract with the state's sole CON-approved mobile PET/CT scanner vendor, Alliance Imaging, as they have no capacity to add a host site in Eden at this time. PET or Positron Emission Tomography, detects disease more quickly and accurately by identifying biochemical changes in the body. The PET/CT scanner has a variety of oncology applications from early detection, determining the stage of cancer, checking for recurrence and assessing the effectiveness of chemotherapy. In addition, there are neurological and cardiac applications.

The current CON and health planning framework in North Carolina does not provide a pathway by which a fixed PET/CT scanner can be converted to a mobile unit. We support a process to expand access to mobile PET/CT scanners in North Carolina. Currently the sole, CON-approved mobile PET vendor is operating above capacity on its two existing mobile PET/CT scanners and cannot accommodate more mobile PET time for new mobile PET host sites.

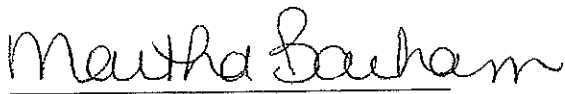
We believe a change in the state health planning and CON processes that would allow the expansion of the number of mobile PET vendors in North Carolina would be beneficial for community hospitals such as Morehead Memorial Hospital, as well as other hospitals that lack local access to mobile PET services today. We are not aware of any other

117 East Kings Highway  
Eden, North Carolina 27288-5201  
TEL 336.623.9711  
[www.morehead.org](http://www.morehead.org)

CON-regulated service in North Carolina where a sole vendor has been the only option for over a decade. Alliance Imaging has had the opportunity since 2002 to be the only CON-approved mobile PET scanner provider in North Carolina. While they have sought to do a reasonable job to serve all 29 mobile PET host sites where they have contracts in North Carolina, the result is sometimes that many of their clients get less frequent and less predictable mobile PET service than they desire due to AI's capacity constraints and the sheer size of North Carolina. One mobile PET vendor operating only two mobile PET scanners, covering the 39,000 square miles of North Carolina, which is home to almost 10 million residents, is not sustainable from a provider, physician, and patient perspective.

We encourage the state to permit the conversion of existing fixed PET scanners to mobile PET scanners, by updating the annual State Medical Facilities Plan PET Scanner chapter to allow the development of additional mobile PET scanner options in North Carolina. We believe this is a reasonable request whose time has come.

Sincerely,

A handwritten signature in cursive script that reads "Maura Bacham". The signature is written in dark ink and is positioned above a horizontal line.

Interim President & CEO, Morehead Memorial Hospital

*File: MobilePETSupportLtrMoreheadMemHosp.07.24.2014.docx*





July 8, 2014

Rowan Medical Center

612 Mocksville Avenue  
Salisbury, NC 28144

Dr. Christopher Ullrich, Chair  
State Health Coordinating Council  
c/o Division of Health Service Regulation, Medical Facilities Planning Branch  
809 Ruggles Dr.  
Raleigh, NC 27603

novanthealth.org

Dear Dr. Ullrich:

I am the President of Novant Health Rowan Medical Center, Salisbury, NC (Rowan County). Our hospital currently has a service contract with the mobile PET vendor Alliance Imaging such that the mobile PET scanner is on the NHRMC campus every other Thursday for Full -Days defined as 7:00 am – 10:00 pm and every other Thursday for Half-Days defined as 2:30 pm – 6:00 pm. Thus, we have local access to mobile PET diagnostic imaging for only about 41 hours each month. During FFY 2013, we provided about 223 mobile PET scans to our patients and in FFY 2014 we are on track to provide about 222 mobile PET scans to our patients by year's end. So in the limited mobile PET time we are allocated, we make the most of it.

We have busy and established radiation therapy program that includes a recently replaced linear accelerator and CT simulator unit. The Rowan Medical Center Medical Staff includes hematologist/oncologists, radiation oncologists, surgeons specializing in cancer surgeries, as well as radiologists and pathologists. During FFY 2013, NHRMC provided 7,615 unweighted radiation therapy treatments to 246 unique patients. In order to support cancer services offered on the NHRMC campus (which include chemotherapy, radiation therapy, related inpatient and outpatient services), we would like very much to increase the amount of time that the mobile PET/CT scanner is on our campus. This would be very beneficial for our cancer patients, their families, and the cancer physicians. However, since there is only one existing mobile PET/CT scanner vendor serving 18 mobile PET host sites in Western North Carolina, we are not able to expand the time when the mobile PET unit is on our NHRMC campus. I am told that during FFY 2013, the Alliance Imaging mobile PET scanner was operating at 113% of capacity and that the AI mobile PET scanner has operated at more than 100% of its capacity since FFY 2007. That may make for good business at AI, but not for very desirable and plentiful access for mobile PET imaging at NHRMC.

Thus, we are very supportive of a change state health planning and CON processes that would allow the expansion of the number of mobile PET vendors in North Carolina. I am not aware of any other CON-regulated service in North Carolina where a sole vendor has been the only option for over a decade. Alliance Imaging has had the opportunity since 2003 to be the only CON-approved mobile PET scanner provider in North Carolina. While they have sought to do a reasonable job to serve all 29 mobile PET host sites where they have contracts in North Carolina, the result is sometimes that many of their clients get less frequent and less predictable mobile PET service than they desire due to AI's capacity constraints and the sheer size of North Carolina. One mobile PET vendor operating only two mobile PET scanners, covering the 39,000 square miles of North Carolina, which is home to almost 10 million residents, is not sustainable from a provider, physician, and patient perspective.

We encourage the state to permit the conversion of existing fixed PET scanners to mobile PET scanners, by updating the annual State Medical Facilities Plan PET Scanner chapter to allow the development of additional mobile PET scanner options in North Carolina. We believe this is a reasonable request whose time has come.

Sincerely,

A handwritten signature in blue ink that reads "Darise D Caldwell".

Darise Caldwell, RN, PhD, FACHE  
President  
Novant Health Rowan Medical Center  
Salisbury, North Carolina



Thomasville Medical Center  
207 Old Lexington Road  
Thomasville, NC 27360

July 9, 2014

Dr. Christopher Ullrich, Chair  
State Health Coordinating Council  
C/O Division of Health Service Regulation, Medical Facilities Planning Branch  
809 Ruggles Dr.  
Raleigh, NC 27603

Dear Dr. Ullrich:

I am the President of Novant Health Thomasville Medical Center (NHTMC), Thomasville, NC (Davidson County). Our hospital does currently have a service contract with the mobile PET vendor Alliance Imaging, such that the AI mobile PET is on the NHTMC campus every other Tuesday for a Half-Day, defined as 2:30- 8:00 pm. Thus, we have local access to mobile PET diagnostic imaging for only 11 hours per month. The closest fixed PET Scanners to Thomasville are either located out of county in Guilford County at Moses Cone Health System or High Point Regional Medical Center or in Winston-Salem at NH Forsyth Medical Center or North Carolina Baptist Medical Center. Asking fragile cancer patients and their families to travel these distances for diagnostic PET imaging is less than optimal and is disruptive to continuity of care. The data and literature show that the greatest use of PET imaging has been and continues to be for patients with a cancer diagnosis. During FFY 2013, NHTMC provided local access to patients for 98 mobile PET scans and for FFY 2014 NHTMC is on track to perform 89 mobile PET scans.

A group of medical and specialty hematologists/oncologists, Piedmont Hematology Oncology Associates, affiliated with Novant Health, has a satellite office in Davidson County located between Thomasville and Lexington. At the PHOA satellite office in Davidson County they offer medical and gyn oncology services, as well as chemotherapy. It is a busy satellite office. In order to support the PHOA practice and their patients to continue to provide local access to mobile PET services, NHTMC would like to be able to expand beyond 11 hours per month. Expansion of mobile PET services on the NHTMC campus could be very beneficial for our cancer patients, their families and the cancer physicians. There is also a linear accelerator at Lexington Memorial Hospital in Davidson County and their patients would also benefit from expanded local access to mobile PET services. LMH does not currently offer mobile PET services on their campus. However, since there is only one existing mobile PET/CT scanner vendor serving 18 mobile PET host sites in Western North Carolina, we are not able to get any time from the mobile PET vendor. I am told that during FFY 2013, the Alliance Imaging mobile PET scanner for western NC was operating at 113% of capacity and that the AI western NC mobile PET scanner has operated at more than 100% of its capacity since FFY 2007. That may make for good business at AI, but not for very desirable and plentiful access for mobile PET imaging at NHTMC.

Thus, we are very supportive of a change state health planning and CON processes that would allow the expansion of the number of mobile PET vendors in North Carolina. I am not aware of any other CON-regulated service in North Carolina where a sole vendor has been the only option for over a decade. Alliance Imaging has had the opportunity since 2003 to be the only CON-approved mobile PET scanner provider in North Carolina.

While they have sought to do a reasonable job to serve all 29 mobile PET host sites where they have contracts in North Carolina, the result is sometimes that many of their clients get less frequent and less predictable mobile PET service than they desire due to AI's capacity constraints and the sheer size of North Carolina. One mobile PET vendor operating only two mobile PET scanners, covering the 39,000 square miles of North Carolina, which is home to almost 10 million residents, is not sustainable from a provider, physician, and patient perspective.

We encourage the state to permit the conversion of existing fixed PET scanners to mobile PET scanners, by updating the annual State Medical Facilities Plan PET Scanner chapter to allow the development of additional mobile PET scanner options in North Carolina. We believe this is a reasonable request whose time has come.

Sincerely,



Kathie Johnson, President

Novant Health Thomasville Medical Center

*File: MobilePETSuppLtrNHTMCJuly2014FINAL.docx*

# **Attachment E**

## **North Carolina CON Criteria & Standards for Positron Emission Standards**

## SECTION .3700 - CRITERIA AND STANDARDS FOR POSITRON EMISSION TOMOGRAPHY SCANNER

### 10A NCAC 14C .3701 DEFINITIONS

The following definitions shall apply to all rules in this Section:

- (1) "Approved positron emission tomography (PET) scanner" means a PET scanner which was not operational prior to the beginning of the review period but which had been issued a certificate of need.
- (2) "Cyclotron" means an apparatus for accelerating protons or neutrons to high energies by means of a constant magnet and an oscillating electric field.
- (3) "Dedicated PET Scanner" means PET Scanners as defined in the applicable State Medical Facilities Plan.
- (4) "Existing PET scanner" means a PET scanner in operation prior to the beginning of the review period.
- (5) "Mobile PET Scanner" means a PET scanner and transporting equipment that is moved, at least weekly, to provide services at two or more host facilities.
- (6) "PET procedure" means a single discrete study of one patient involving one or more PET scans.
- (7) "PET scan" means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure.
- (8) "PET scanner service area" means the PET Scanner Service Area as defined in the applicable State Medical Facilities Plan.
- (9) "Positron emission tomographic scanner" (PET) is defined in G.S. 131E-176(19a).
- (10) "Radioisotope" means a radiochemical which directly traces biological processes when introduced into the body.

*History Note: Authority G.S. 131E-177(1); 131E-183(b);  
Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;  
Eff. January 4, 1994;  
Temporary Amendment Eff. January 1, 2001;  
Temporary Amendment Eff. January 1, 2002;  
Amended Eff. August 1, 2002;  
Temporary Amendment effective January 1, 2002 amends and replaces the permanent rule effective August 1, 2002;  
Temporary Amendment Eff. January 1, 2003;  
Amended Eff. August 1, 2004; April 1, 2003.*

**10A NCAC 14C .3702 INFORMATION REQUIRED OF APPLICANT**

(a) An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall use the Acute Care Facility/Medical Equipment application form.

(b) An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall provide the following information for each facility where the PET scanner will be operated:

- (1) The projected number of procedures to be performed and the projected number of patients to be served for each of the first three years following completion of the proposed project. Projections shall be listed by clinical area (e.g., oncology, cardiology), and all methodologies and assumptions used in making the projections shall be provided.
- (2) Documentation of arrangements made between the applicant and other providers to assure patients of the facility will have access to all of the following services:
  - (A) nuclear medicine imaging services;
  - (B) single photon emission computed tomography (including brain, bone, liver, gallium and thallium stress);
  - (C) magnetic resonance imaging scans;
  - (D) computerized tomography scans;
  - (E) cardiac angiography;
  - (F) cardiac ultrasound;
  - (G) neuroangiography;
  - (H) radiation oncology;
  - (I) medical oncology; and
  - (J) surgical oncology.
- (3) Documentation that the facility will:
  - (A) establish the clinical PET unit, and any accompanying equipment used in the manufacture of positron-emitting radioisotopes, as a regional resource that will have no administrative, clinical or charge requirements that would impede physician referrals of patients for whom PET testing would be appropriate; and
  - (B) provide scheduled hours of operation for the PET scanner of a minimum of 60 hours per week, except for mobile scanners.

(c) An applicant proposing to acquire a mobile PET scanner shall provide copies of letters of intent from and proposed contracts with all of the proposed host facilities at which the mobile PET scanner will be operated.

(d) An applicant proposing to acquire a mobile PET scanner shall demonstrate that each host facility offers or contracts with a hospital that offers comprehensive cancer services including radiation oncology, medical oncology, and surgical oncology.

(e) An applicant shall document that all equipment, supplies and pharmaceuticals proposed for the service have been certified for use by the U.S. Food and Drug Administration or will be used under an institutional review board whose membership is consistent with U.S. Department of Health and Human Services' regulations.

(f) An applicant shall document that each PET scanner and cyclotron shall be operated in a physical environment that conforms to federal standards, manufacturer's specifications, and licensing requirements. The following shall be addressed:

- (1) quality control measures and assurance of radioisotope production of generator or cyclotron-produced agents;
- (2) quality control measures and assurance of PET tomography and associated instrumentation;
- (3) radiation protection and shielding;
- (4) radioactive emission to the environment; and
- (5) radioactive waste disposal.

*History Note: Authority G.S. 131E-177(1); 131E-183(b);  
Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;  
Eff. January 4, 1994;  
Temporary Amendment Eff. January 1, 2002;  
Temporary Amendment effective January 1, 2002 amends and replaces a permanent rulemaking originally proposed to be effective August 1, 2002;*

*Amended Eff. April 1, 2003;*  
*Temporary Amendment Eff. February 1, 2006;*  
*Amended Eff. November 1, 2006;*  
*Temporary Amendment Eff. February 1, 2008;*  
*Amended Eff. November 1, 2008.*

**10A NCAC 14C .3703 PERFORMANCE STANDARDS**

(a) An applicant proposing to acquire a dedicated PET scanner, including a mobile dedicated PET scanner, shall demonstrate that:

- (1) the proposed dedicated PET scanner, including a proposed mobile dedicated PET scanner, shall be utilized at an annual rate of at least 2,080 PET procedures by the end of the third year following completion of the project;
- (2) if an applicant operates an existing dedicated PET scanner, its existing dedicated PET scanners, excluding those used exclusively for research, performed an average of at least 2,080 PET procedures per PET scanner in the last year; and
- (3) its existing and approved dedicated PET scanners shall perform an average of at least 2,080 PET procedures per PET scanner during the third year following completion of the project.

(b) The applicant shall describe the assumptions and provide data to support and document the assumptions and methodology used for each projection required in this Rule.

*History Note: Authority G.S. 131E-177(1); 131E-183(b);  
Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;  
Eff. January 4, 1994;  
Temporary Amendment Eff. January 1, 2002; January 1, 2001;  
Amended Eff. August 1, 2002;  
Temporary Amendment effective January 1, 2002 amends and replaces the permanent rule effective August 1, 2002;  
Temporary Amendment Eff. January 1, 2003;  
Amended Eff. August 1, 2004; April 1, 2003;  
Temporary Amendment Eff. January 1, 2005;  
Amended Eff. November 1, 2005;  
Temporary Amendment Eff. February 1, 2006;  
Amended Eff. November 1, 2006.*



**10A NCAC 14C .3704 SUPPORT SERVICES**

(a) An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall document that radioisotopes shall be acquired from one or more of the following sources and shall identify the sources which will be utilized by the applicant:

- (1) an off-site medical cyclotron and radioisotope production facility that is located within two hours transport time to each facility where the PET scanner will be operated;
- (2) an on-site rubidium-82 generator; or
- (3) an on-site medical cyclotron for radio nuclide production and a chemistry unit for labeling radioisotopes.

(b) An applicant proposing to acquire an on-site cyclotron for radioisotope production shall document that these agents are not available or cannot be obtained in an economically cost effective manner from an off-site cyclotron located within 2 hours total transport time from the applicant's facility.

(c) An applicant proposing to develop new PET scanner services, including mobile PET scanner services, shall establish a clinical oversight committee at each facility where the PET scanner will be operated before the proposed PET scanner is placed in service that shall:

- (1) develop screening criteria for appropriate PET scanner utilization;
- (2) review clinical protocols;
- (3) review appropriateness and quality of clinical procedures;
- (4) develop educational programs; and
- (5) oversee the data collection and evaluation activities of the PET scanning service.

*History Note: Authority G.S. 131E-177(1); 131E-183(b);  
Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;  
Eff. January 4, 1994;  
Temporary Amendment Eff. January 1, 2002;  
Amended Eff. April 1, 2003;  
Temporary Amendment Eff. February 1, 2006;  
Amended Eff. November 1, 2006.*

**10A NCAC 14C .3705 STAFFING AND STAFF TRAINING**

(a) An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall document that the scanner will be staffed by the following personnel:

- (1) One or more full-time nuclear medicine imaging physicians who:
  - (A) are licensed by the State to handle medical radioisotopes;
  - (B) have specialized in the acquisition and interpretation of nuclear images, including tomographic studies, for at least one year;
  - (C) have acquired knowledge about PET through experience or postdoctoral education; and
  - (D) have had practical training with an operational PET scanner;
- (2) Engineering and physics personnel with training and experience in the operation and maintenance of PET scanning equipment;
- (3) Radiation safety personnel with training and experience in the handling of short-lived positron emitting nuclides; and
- (4) Nuclear medicine technologists certified in this field by the Nuclear Medicine Technology Certification Board or the American Registry of Radiologic Technologists with training and experience in positron emission computed tomographic nuclear medicine imaging procedures.

(b) An applicant proposing to acquire a cyclotron shall document that the cyclotron shall be staffed by radiochemists or radiopharmacists who:

- (1) have at least one year of training and experience in the synthesis of short-lived positron emitting radioisotopes; and
- (2) have at least one year of training and experience in the testing of chemical, radiochemical, and radionuclidic purity of PET radiopharmaceutical synthesis.

(c) An applicant proposing to acquire a PET scanner, a mobile PET scanner, or a cyclotron, shall document that the personnel described in Paragraphs (a) and (b) of this Rule shall be available at all times that the scanner or cyclotron are operating.

(d) An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall document that a program of continuing staff education will be provided that will insure training of new personnel and the maintenance of staff competence as clinical PET applications, techniques and technology continue to develop and evolve.

*History Note: Authority G.S. 131E-177(1); 131E-183(b);  
Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;  
Eff. January 4, 1994;  
Temporary Amendment Eff. January 1, 2002;  
Amended Eff. April 1, 2003.*

# **Attachment F**

## **North Carolina State Center for Health Statistics Cancer Rates**

### Projected New Cancer Cases

COUNTY	2010	2011	2012	2013	2014
Guilford	2,521	2,587	2,713	2,758	2,836
Iredell	850	879	939	950	974
Forsyth	1,886	1,968	2,003	2,030	2,073
Cumberland	1,288	1,382	1,522	1,515	1,560
Mecklenburg	4,156	4,108	4,280	4,425	4,646
Wake	4,177	3,987	4,297	4,430	4,624
Buncombe	1,391	1,485	1,590	1,640	1,663
Durham	1,215	1,231	1,297	1,315	1,395
Davidson	924	953	1,026	1,028	1,035
Brunswick	699	937	954	970	1,010
New Hanover	1,081	1,170	1,217	1,251	1,289
Union	960	930	1,023	1,045	1,073
Cabarrus	903	892	954	967	995
<b>North Carolina</b>	<b>49,586</b>	<b>51,690</b>	<b>55,444</b>	<b>56,164</b>	<b>57,298</b>
<b>% Change</b>		<b>4.24%</b>	<b>7.26%</b>	<b>1.30%</b>	<b>2.02%</b>

Source: North Carolina State Center for Health Statistics

COUNTY	2010	2011	2012	2013	2014
Mecklenburg	4,156	4,108	4,280	4,425	4,646
% Change		-1.15%	4.19%	3.39%	4.99%

Source: North Carolina State Center for Health Statistics

## What's driving PET/CT growth?

May 31, 2012

**Brian Clement, Oncology Roundtable**

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Our Technology Insights program has projected that PET/CT utilization will grow 22% over the next five years and 55% over the next ten years. Technological advances, demographic trends, decreasing price points, and reimbursement changes are driving this projected growth.

### **PET/CT technological capabilities still increasing**

While PET/CT scanners are already the standard for oncology imaging, several developments in scanning technology have the potential to make PET/CT an even more powerful tool for treatment planning in the future.

- More precise measurement: increased granularity in tumor imaging will allow for better differentiation and measurement of tumors.
- Increased data storage: greater data storage capacity will allow providers to archive more information from patients' previous scans and help oncologists track tumor developments over time.
- Less patient movement: changes in the physical design of the newest PET/CT scanners provide better patient movement restriction to ensure consistent, precise imaging.

### **Aging baby boomers will increase cancer incidence**

While this isn't news to most of the oncology community, it bears repeating: increasing cancer incidence as baby boomers age will drive up demand for oncology imaging services such as PET/CT scans.

For a better understanding of how these changes will impact oncology volumes at your hospital, access the [Oncology Outpatient Market Estimator](#).

### **PET/CT machines becoming more affordable**

The falling costs of investing in a PET/CT machine could substantially change ROI projections. While the price range of these scanners used to span from \$1.8 million-\$3 million, they're now sold for \$1.2 million-\$2.3 million.

### **Increased efficiency as scanning time decreases**

As equipment costs have dropped, patient scan time has also decreased precipitously. A full body scan will take 5-15 minutes, compared to older equipment that required 45-60 minutes per scan.

Increased efficiency means that more patients can be scanned per day, which enhances the financial attractiveness of PET/CT scanners for oncology imaging.

### **Expanded payer coverage**

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Recent payment changes by CMS—which were also widely followed by private payers—are also likely to drive PET/CT growth. These changes have expanded coverage for FDG-PET, which accounts for 90–95% of all PET studies.

Scans are now covered for the following purposes:

- **Staging:** one FDG-PET scan is covered by Medicare for initial treatment strategy—local Medicare contractors have the ability to authorize additional FDG-PET scans on a case-by-case basis.
- **Treatment monitoring:** one FDG-PET scan for assessing subsequent treatment strategy will also be covered by Medicare.

### **Learn more**

For more information about PET/CT growth prospects, view Technology Insights' article, "[PET/CT: Strong growth ahead.](#)"

Members may also access "[Oncology Technology Update 2011](#)" to view a webconference that provides a general overview of oncology technology.

The advisory Board Company,