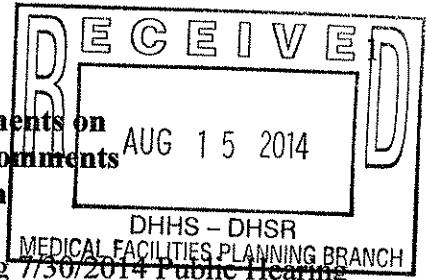


**Novant Health and MedQuest Associates 8/15/2014 Comments on
The Alliance Imaging, Inc. July 30, 2014 Public Hearing Comments
On the Proposed 2015 State Medical Facilities Plan**



Novant Health and MedQuest will address the issues raised in the Alliance Imaging 7/30/2014 Public Hearing comments in the order in which they appear in AI's remarks.

Alliance Imaging Is Opposed to SMFP Policy TE-1 "CONVERSION OF FIXED PET SCANNERS TO MOBILE PET SCANNERS"

In its public hearing remarks¹, Alliance Imaging states: "Alliance Imaging is opposed to the draft PET policy to allow CON Applications to convert underutilized fixed PET scanners to become mobile PET scanners because this policy is contrary to the intent of the CON law in several ways."

As put forward in the Proposed 2015 SMFP, Policy TE-1 is composed of four conditions and reads as follows:

Facilities with an existing or approved fixed PET scanner may apply for a Certificate of Need (CON) to convert the existing or approved PET scanner to a mobile PET scanner if the converted mobile PET scanner:

1. *Shall continue to operate as a mobile PET scanner at the facility, including satellite campuses, where the fixed PET scanner is located or was approved to be located.*
2. *Shall be moved at least weekly to provide services at two or more host facilities.*
3. *Shall serve at least one mobile host facility in one of the [47] rural counties listed below:*

Alexander	Clay	Macon	Richmond
Alleghany	Currituck	Madison	Scotland
Anson	Dare	Martin	Stokes
Ashe	Davie	McDowell	Swain
Avery	Gates	Mitchell	Transylvania
Beaufort	Graham	Montgomery	Tyrell
Bertie	Greene	Northampton	Vance
Bladen	Hertford	Pamlico	Warren
Camden	Hoke	Pasquotank	Washington
Caswell	Hyde	Perquimans	Yadkin
Cherokee	Jackson	Person	Yancy
Chowan	Jones	Polk	

4. *Shall not serve any mobile host facility located in the county where any existing or approved fixed PET scanner is located, except as required by subpart (1) above.*

FOOTNOTE 1: The council recommended the revision of the current East and West service areas to a statewide service area to allow flexibility in servicing mobile PET sites.

FOOTNOTE 2: rural County as defined by the U.S. Census Bureau's Criteria of population less than 50,000. This data is to be updated annually starting with the certified 2012 population estimates from the North Carolina Office of State Budget and Management.

Policy TE-1 is not "contrary to the intent of the CON law" as asserted by AI in its comments. Rather, the CON law includes the following findings of fact that are relevant to the mobile PET expansion scenario.

"The General Assembly of North Carolina makes the following findings at NC General Statutes Section 131E-175:

(2) ...the increasing cost of health care services...threatens the health and welfare of the citizens of this State in that citizens need assurance of economical and readily available health care....

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

These two findings of fact are addressed by the language of Policy TE-4. First, Alliance Imaging and its two mobile PET/CT scanners have been the sole vendor of mobile PET services in North Carolina since 2003, and as such there is no choice or beneficial competition for host sites seeking a mobile PET service agreement. It is well documented that competition drives down prices, such as the AI prices charges in its mobile PET service agreements with its 29 existing mobile PET sites. Second, Policy TE-1, Condition #3 requires that each new mobile PET provider provide mobile PET service in at least one of the 47 rural counties listed above. Alliance Imaging does not have to operate under this condition, as it is an existing mobile PET provider.

Alliance's Assertion of Available Mobile PET Capacity To Be Redistributed

In its 7/30/14 comments, AI asserts that it "*continually adjusted its mobile PET routes to redistribute days of service in as equitable fashion as possible...however, some host sites are not well utilizing the available time at their facilities which leaves the PET scanner idle for those scheduled time slots.*" AI fails to note that some of the time slots may not be well utilized because there is not routine weekly local mobile PET service. When there is not routine and regular mobile PET access, patients and referring physicians choose not to wait for the next date the mobile PET scanner is in town and send the patient to a fixed PET scanner that is not located close to where the patient lives or gets their cancer care. For example, NH Matthews Medical Center's service agreement with AI for mobile PET service provides mobile PET services on the NHMMC campus one Monday per month and every other Thursday for one-half day. NHMMC offers cancer care services including chemotherapy, inpatient hospice care, a linear accelerator operated by the radiation oncology group on its campus, and other cancer physicians on its medical staff. Essentially, NHMMC patients have access to the mobile PET/CT scanner on the MMC campus for 11 hours per month. Novant Health Huntersville Medical Center patients are in a similar situation, as the Alliance Imaging mobile PET is at NHHMC is one Monday per month and one half-day every other Thursday or 26 hours per month.

In addition, the historical annual mobile PET scan data for Alliance Imaging for suggests that from FFY 2004 through FFY 2013, there were positive mobile PET scan annual growth rates and collectively the two AI mobile PET scanners operated at 94% to 111% of capacity in seven of the years from FFY 2004 to FFY 2013. See the data table below.

Annual Mobile PET Scan Volumes in NC: FFY 2004-FFY 2013

SMFP Year	Data Year	# of Mobile PET Host Sites	Annual Total Mobile PET Scans	Annual Yr to Yr Mobile PET Scan Growth	Annual Mobile PET Scanner Capacity	% of Annual Mobile PET Capacity	# of Mobile PET Scanners in Operation
2005	FFY 02-03	0	0				
2006	FFY 03-04	22	2,248		2,600	87%	1
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

Thus, it seems like it would be difficult for AI to create any meaningful additional capacity just based on shifting around mobile PET days of service relinquished by existing customers, at the discretion of that customer. The two existing mobile PET scanners operated by AI have collectively operated at more than 99-100% of capacity each year from FFY 2008 through FFY 2013. Alliance's characterization in its comments that it has "available capacity that can be used"² seems a bit optimistic given the above mobile PET annual utilization shows that AI is running at the practical limits of capacity on its two mobile PET scanners, which serve mobile PET host sites 7 days per week and up to 2 shifts per day.

Considered separately, the two AI mobile PET units have exceeded the annual capacity defined by the State for numerous years. The AI eastern region mobile PET scanner has exceeded the 2,600 procedure threshold for the last three reporting cycles (FFY 2011 –FFY 2013) operating at 102 to 110% of capacity. The AI western region mobile PET has exceeded the threshold for the last seven reporting cycles (FFY 2007 – FFY 2013) operating at 108% to 123% of capacity. For obvious reasons, Alliance would prefer to maintain the status quo and argue that new entrants to the mobile PET market would lead to unnecessary duplication.

Alliance Opines that SMFP Policy TE-1 Conflicts with NCGS Section 131E-175(4) of the CON Law³

This provision of the CON Law (unnecessary duplication of services) is part of the Findings of Fact must be taken in the context of the other eleven findings of fact. As mentioned above, in NCGS Section 131E-175 (2) and (3a), the NC General Assembly also finds:

(2)...the increasing cost of health care services...threatens the health and welfare of the citizens of this State in that citizens need assurance of economical and readily available health care....

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

²See AI 7/30/2014 Public Hearing Comments at page 1, paragraph #2

³See AI 7/30/2014 Public Hearing Comments at page 1, paragraph #4

Condition #3 of Policy TE-1 specifically addresses expanding mobile PET access for 47 rural counties, by requiring future mobile PET vendors to serve these counties. This is consistent with the findings of fact in NCGS 131E-175(2). And as discussed above Alliance Imaging and its two mobile PET/CT scanners have been the only vendor of mobile PET services in North Carolina since 2003, and as such there is no choice or beneficial competition for host sites seeking a mobile PET service agreement. It is well documented that competition drives down prices, such as the AI prices charged in its mobile PET service agreements with its 29 existing mobile PET sites. This is consistent with the findings of fact in NCGS 131E-175(3a).

Moreover, given that the two AI mobile PET scanners have been operating at 99-100% of capacity for the past five years and mobile PET volumes have increased during the time period FFY 2009 (5,258 annual mobile PET scans) to FFY 2013 (5,791 mobile PET scans). Thus, there is no basis to support AI's assertion that "*PET utilization in North Carolina continues to decline.*"⁴ See the table below, which includes annual mobile and fixed PET scan volumes.

North Carolina Annual Mobile & Fixed PET/CT Scans

SMFP Plan Year	Data Year	Annual Fixed PET Scans	Annual Mobile PET Scans	Total Annual Fixed & Mobile PET Scans	Annual Yr to Yr PET Scan Growth Rate (All Scans)
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	2.5%

Alliance Imaging has expressed concerns that both mobile and fixed PET scans are not increasing and will not continue to grow in the future. These concerns are misplaced, in light of the historical actual annual mobile and fixed PET scan volumes for the period FFY 1997 through FFY 2013 and current literature.

The data indicates that PET volumes are growing. Fixed PET scan volumes have increased dramatically in the last 17 years, from FFY 1997 through FFY 2013. Annual fixed PET scans in North Carolina experienced positive growth rates for 13 of those 17 years and in only three of those years were there negative growth rates, two of which were less than 1%. See Attachment A.

⁴ See AI 7/30/2014 Public Hearing Comments at page 1, paragraph #4

In the last year (FFY 2012 to FFY 2013), annual fixed PET volumes in North Carolina increased by 2.5% from 32,729 to 33,553 PET Scans. Fixed PET scan volumes appear to be turning around due to the CMS coverage change and the improving economy. The fixed PET volume for Novant Health Forsyth Medical Center was incorrectly entered in Proposed 2015 SMFP Table 9L as 1,560 procedures instead of 2,560 procedures as reported on its 2014 Acute Care Hospital Licensure Renewal Application⁵, which is consistent with previous years' utilization data. Thus, this data correction yielded a positive growth rate for annual fixed PET scans in NC.

In the last year (FFY 2012 to FFY 2013), mobile PET volumes increased by 3.9% despite the severe limitations of only two mobile PET units to serve all of North Carolina. Moreover, from FFY 2003 to FFY 2013 annual mobile PET scan volumes increased for 5 of those years and had negative growth rates for 4 of those years. Further, both mobile PET scanners are operating at capacity levels in excess of the SMFP defined target for mobile PET scanners of 2,600 PET scans annually as reflected in the Proposed 2015 SMFP PET Chapter.

Finally, there are several qualitative factors that also support the future growth of PET/CT scan diagnostic imaging. These factors include:

- The Advisory Board's Oncology Roundtable is projecting that PET/CT scan utilization will grow 55% over the next ten years. The article is in Attachment G.
- While PET/CT scanners are already the acknowledged standard for oncology imaging, developments in scanning technology have the potential to make PET/CT an even more powerful diagnostic tool for treatment planning in the future
 - More precise measurement with increased granularity in tumor imaging will promote better differentiation and measurement of tumors
 - Increased data storage capacity will allow providers to archive more information from patients' prior scans and will assist oncologists track tumor development over time
 - Less patient movement will occur due to changes in the design of the newest PET/CT scanners to provide better patient movement restriction to further consistent, precise imaging
- Aging baby boomers will increase cancer incidence, which in turn will drive up oncology imaging such as PET/CT scans
- According to the World Health Organization in a report issued in February 2014, cancer cases are expected to surge 57% worldwide in the next 20 years and calls cancer an imminent "human disaster".
- PET/CT scanners are continuing to become more affordable, which could substantially improve the financial feasibility of these projects
- As PET/CT scanning times have decreased dramatically, compared to older PET scanners which required 45-60 minutes per scan; this increased efficiency permits more patients to be scanned each day
- Recent payment changes by CMS, which are typically followed by private payers, may also drive PET/CT scan growth, including CMS's recent advisory that up to three PET/CT scans per patient would be covered⁶

⁵DHSR Planning Section staff has been notified about this data entry error in Table 9L of the 2015 Draft SMFP.

⁶See AuntMinnie.com for article entitled "CMS bends on oncology PET coverage, will pay for 3 scans," (6/12/2013) See also Attachment B.

Alliance Incorrectly Concludes That Fixed PET/CT Scanners in NC Are Underutilized

Alliance Imaging seems to base its characterization fixed PET scanners as underutilized on the data in Table 9L in the annual SMFPs. First, it should be noted that the annual capacity definition for fixed PET scanners is 3,000 scans annually, which is higher than the annual capacity defined for a mobile PET scanner at 2,600 annual scans. Second, based on the FFY 2013 annual fixed PET scan volumes in Proposed 2015 SMFP Table 9L, there are ten of the existing 28 fixed PET scanner sites operating at 50% or more of capacity.⁷ These 10 fixed PET scanner sites are operating at utilization rates well above the average fixed PET scanner utilization of about 40%⁸ for all North Carolina fixed PET Scanners based on FFY 2013 data. Third, Policy TE-1 establishes a framework that permits underutilized fixed PET scanners to be converted to mobile PET scanners. This process does not increase the overall number of fixed and mobile PET scanners in use in the state. Instead, it permits the re-purposing of a fixed PET scanner to a mobile PET scanner that can serve multiple host sites to enhance local access to PET imaging services.

Alliance Mistakenly Asserts that North Carolina Fixed PET Utilization is Declining Without Specifying the Timeframes On Which This Conclusion is Based⁹

This is addressed in the data table above in this document with annual mobile and fixed PET scan volumes in North Carolina.

This data shows the following:

In the most recent past two years for which data is publicly available (FFY 2012 to FFY 2013), annual fixed PET volumes in North Carolina increased by 2.5% from 32,729 to 33,553 PET Scans. Fixed PET scan volumes appear to be turning around due to the CMS coverage change and the improving economy. The fixed PET volume for Novant Health Forsyth Medical Center was incorrectly entered in Proposed 2015 SMFP Table 9L as 1,560 procedures instead of 2,560 procedures as reported on its 2014 Acute Care Hospital Licensure Renewal Application¹⁰, which is consistent with previous years' utilization data. Thus, this data correction yielded a positive growth rate for annual fixed PET scans in NC.

In the most recent past two years for which data is publicly available (FFY 2012 to FFY 2013), mobile PET volumes increased by 3.9% despite the severe limitations of only two mobile PET units, operating above 100% of capacity, to serve all of North Carolina. Moreover, from FFY 2003 to FFY 2013 annual mobile PET scan volumes increased for 5 of those years and had negative growth rates for 4 of those years. Further, both mobile PET scanners are and have been operating at capacity levels in excess of the SMFP defined target for mobile PET scanners of 2,600 PET scans annually as reflected in the Proposed 2015 SMFP PET Chapter.

⁷These 8 sites include: CMC, Cone Health, NH Presbyterian Medical Center, Duke University Hospital, UNC Hospitals, Rex Hospital, New Hanover Regional Medical Center, Vidant Medical Center, Mission Hospital, and NH Forsyth Medical Center (85% utilization as only 1 of the 2 NHFMC PET scanners was in operation during FFY 2013).

⁸Calculation: 33,553 annual fixed PET scans/28 PET scanners (existing & approved) = 39.94% or ~40%

⁹See AP's 7/30/14 comments at page 2, first paragraph

¹⁰DHSR Planning Section staff has been notified about this data entry error in Table 9L of the 2015 Draft SMFP.

Alliance Erroneously Asserts That Policy TE-1 “Sets No Minimum Standards for the Utilization of Converted Mobile PET Units”¹¹

Without foundation, Alliance states that Policy TE-1 in the draft 2015 SMFP “sets no minimum standards for the utilization of the converted PET units.” However, the language of Policy TE-1 contradicts this hypothesis by AI. The opening paragraph of Policy TE-1 states:

“Facilities with an existing or approved fixed PET scanner may apply for a Certificate of Need (CON) to convert the existing or approved PET scanner to a mobile PET scanner if the converted mobile PET scanner:” ...[emphasis added]

This important introductory paragraph of Policy TE-1 specifies that a CON Application is to be filed to seek the CON Agency’s review and approval to convert an existing or approved PET scanner to a mobile PET scanner. The CON application and review process is a thorough one and any CON approval of the conversion of a fixed PET scanner to a mobile PET scanner will include review of the CON Application for conformity with CON statutory review criteria, one of which includes demonstration of quantitative and qualitative need for the proposed mobile PET scanner and “conditions of approval” formulated by the CON Agency which are included on the face to the Certificate of Need issued to the successful, approved applicant. These routine steps are undertaken in all CON Application reviews, including those to convert a fixed PET scanner to a mobile unit. The current CON PET/CT Scanner Regulations¹², which would be addressed by the applicant in a CON Application for the conversion of a fixed PET scanner to a mobile PET scanner. Thus, AI’s concerns that no minimum standards will be addressed for the utilization of converted mobile PET units are unfounded.

Alliance Imaging Proposes A Limit on the Number of Mobile PET Scanners to Be Converted¹³

Since the initial paragraph of Policy TE-1 requires that a provider seeking to convert a fixed PET scanner to a mobile must first file a CON Application and be approved, this CON Regulatory, which requires the applicant to demonstrate the need for a mobile PET scanner serves as a “limit” on the number of new mobile PET scanners. Only the applicants who have successfully demonstrated, in their CON Applications, the “need” for a mobile PET scanner will be approved and receive a Certificate of Need to operate a mobile PET unit.

In addition, Alliance fails to articulate whether such a limit would specify number of fixed PET scanners that can be converted to mobile PET scanners via CON Application during a single year or whether such a limit would specify a maximum number of mobile PET scanners that could operate in North Carolina for the foreseeable future¹⁴.

Alliance Expresses Concern Regarding the Future Financial Feasibility of New Mobile PET Providers¹⁵

Since Policy TE-1 requires each provider seeking to convert a fixed PET scanner to a mobile, requires that a CON Application be filed the matter of financial feasibility will be addressed in the CON application. And

¹¹ AI 7/30/14 comments at page 1, paragraph #4

¹² See 10A NCAC 14C.3700

¹³ AI’s 7/30/14 Comments at page 2, paragraph #2

¹⁴ Similar to the annual SMFP “virtual moratorium” on new mobile PET scanners which has existed from the 2003 SMFP to the 2014 SMFP.

¹⁵ AI’s 7/30/14 Comments at page 2, paragraph #3

the CON statutory review criteria in North Carolina require that the CON Agency make a determination that the project is financially feasible.

Furthermore, as noted in Novant Health/MedQuest's July 30th public hearing remarks:

SMFP Policy TE-1 is not a radical proposal for North Carolina in terms of using mobile methods to make important healthcare technologies more accessible to local communities. Mobile healthcare services regulated and managed today under the SMFP framework include MRI scanners, cardiac catheterization units, lithotripters, and mobile PET/CT scanners. Both mobile PET and mobile MRI have many clinical and operational similarities including an imaging unit in a trailer with a cab, the purchase of contrast to be used with the imaging, a driver to move the unit from host site to host site, on-board technologists to perform the scans, and service agreements between the mobile technology vendor and each host site. The same mobile pad that supports mobile MRI technology at host sites can be used to support mobile PET technology.

Today, MedQuest, a division of Novant Health, operates the second-largest mobile MRI program in North Carolina and is experienced at delivering cost-effective, efficient, and quality mobile imaging services. We are confident that as a result of Policy TE-1, the ability to reduce costs associated with the availability of new mobile PET services is possible. Based on our preliminary financial assessment, MedQuest/Novant Health could provide mobile PET service, including all necessary operational expenses, at a cost per PET scan that is **more than 50% lower** than our current contracted rates. This would result in a savings for both payors and patients.

*Alliance Advocates That Changes to the SMFP Require Changes to the State's CON Administrative Rules for Fixed and Mobile PET Scanners*¹⁶

First, the following provisions of the existing CON Regulations for Fixed and Mobile PET scanners impose requirements that providers seeking to convert fixed PET scanners to mobile PET scanners will probably be required by the state to address in their CON Application:

- 10A NCAC 14C. 3702 (a), (b), (c) & (d)-Information Required of the Applicant
- 10A NCAC 14C.3703 (a) & (b)-Performance Standards
- 10A NCAC 14C.3704 (a) & (c)-Support Services
- 10A NCAC 14C.3705 (a), (c), & (d)-Staffing and Staff Training

These are the same or very similar to the PET Scanner CON Regulations that Alliance Imaging was required to address in its two CON Application for 2 mobile PET scanners.

Novant Health/MedQuest believes that sufficient CON regulatory framework exists today to permit a full and complete review of future CON applications to convert an existing fixed PET scanner to a mobile PET scanner. In addition, the process of amending the CON Regulations for PET/CT scanners is a resource intense and time consuming process for executive branch staff. Thus, the practical impact of the rulemaking process may be to allow AI to continue to operate its two mobile PET scanners, while potential new applicants cannot file CON Applications to seek to convert a fixed PET scanner to a mobile PET scanner until at least temporary rule changes are in place. This would, in effect, perpetuate the status quo in mobile PET access for North Carolina for another year or more.

¹⁶ AI's 7/30/14 Comments at page 2, paragraph #4

In spite of AI's assertion to the contrary, the State Health Coordinating Council is not "trying to side-step the administrative rulemaking process that has been established by the NC General Assembly."¹⁷ There are sufficient CON Mobile and Fixed PET scanner regulatory provisions in place today to fully and fairly permit the conversion of fixed PET scanners to mobile PET scanners that can offer beneficial competition and choice to the AI alternatives.

Alliance Opines That It Will Not Have Access to the Proposed Statewide Mobile PET Service Area¹⁸

AI seems to be concerned that the language of the 2002 SMFP and/or the Conditions of Approval on the Certificates of Need for their two existing PET scanners will not permit them to use their eastern mobile PET scanner to serve western NC host sites and will not permit their western NC mobile PET scanner to serve eastern NC host sites. However, we believe it would be feasible for AI to file with the CON Agency two Material Compliance Requests to seek to have those conditions of approval adjusted, so that AI can participate fully in the new statewide mobile PET service area.

Alliance Imaging Recommends the Removal of Policy TE-1 From the Draft 2015 SMFP

The effect of AI's recommendation would be to nullify the work of SHCC and the DHSR Planning staff on the PET discussion group, and numerous mobile PET petitions that have been submitted to the SHCC in the past few years. As a practical matter, AI's recommendation preserves the status quo and maintains AI as the sole provider of mobile PET services in North Carolina.

In addition, ten hospitals in and health systems in North Carolina have signed letters of support for the conversion of fixed PET scanners to mobile PET scanners and for the option of having the choice of more than a single mobile PET vendor. These hospitals and health systems include providers located in urban, suburban, and rural areas as well as eastern and western North Carolina and some are current AI clients:

- Ashe Memorial Hospital, Jefferson, NC (Ashe County)-has no cancer treatment program and no local access to PET imaging
- Novant Health Brunswick Medical Center, Bolivia, NC (Brunswick County)
- Cape Fear Valley Medical Center, Fayetteville, NC (Cumberland County)- has a cancer treatment program and an existing fixed PET scanner
- Halifax Regional Medical Center, Roanoke Rapids, NC (Halifax County)-has no cancer treatment program and no local access to mobile
- Hugh Chatham Memorial Hospital, Elkin, NC (Surry County)-has a cancer program but no mobile PET services currently
- Novant Health Huntersville Medical Center, Huntersville, NC (Mecklenburg County)-has a cancer treatment program, soon to include a linear accelerator and is current AI customer
- Novant Health Matthews Medical Center, Matthews, NC (Mecklenburg County- has a cancer treatment program and is current AI customer
- Morehead Memorial Hospital, Eden, NC (Rockingham County)-has a cancer treatment program and lacks local access to PET diagnostic imaging services
- Novant Health Rowan Medical Center, Salisbury, NC (Iredell County)-has a cancer program and is a current AI mobile PET customer
- Novant Health Thomasville Medical Center, Thomasville, NC (Davidson County)-does not have a full-service cancer treatment program and is a current AI mobile PET customer

¹⁷See AI's 7/30/14 Comments at page 3, paragraph #2

¹⁸AI's 7/30/14 Comments at page 3, paragraph #1

Summary

Novant Health and MedQuest Associates respectfully request that the SHCC continue the hard work of updating the mobile PET health planning framework in North Carolina and adopt Draft 2015 SMFP Policy TE-1, with the changes to Condition #4 of the Policy as laid out in the Novant Health/MedQuest Petition/Comment submitted on July 30, 2014.

Attachment A

North Carolina Fixed & Mobile PET Scanners Annual Volumes

NORTH CAROLINA ANNUAL FIXED PET/CT SCAN VOLUMES

SMF#P Year	Data Year	# of Fixed PET Scanners	Total Annual		Annual Capacity of Fixed PET Scanner
			Fixed PET Scans	Fixed PET Scans	
1994	FFY 91-92		514		524 3 fixed PET scanners at Duke, NCBH, & CMC
1995	FFY 92-93	3	551	7.2%	524 3 fixed PET scanners at Duke, NCBH, & CMC
1996	FFY 93-94	3	699	26.9%	524 3 fixed PET scanners at Duke, NCBH, & CMC
1997	FFY 94-95	3	799	14.3%	524 3 fixed PET scanners at Duke, NCBH, & CMC
1998	FFY 95-96	3	1,171	46.6%	1,524 New Fixed PET Need triggered at 80% of 1,524
1999	FFY 96-97	4	1,798	53.5%	1,524 annual PET scans or 1, 200 scans
2000	FFY 97-98	4	2,415	34.3%	1,524
2001	FFY 98-99	4	3,683	52.5%	1,524 6 PET scanners at 4 Academic Med Centers + CMC
2002	FFY 99-00	6	4,717	28.1%	1,524
2003	FFY 00-01	8	5,840	23.8%	1,524
2004	FFY 01-02	17	7,441	27.4%	4,000
2005	FFY 02-03	19	9,127	22.7%	2,600
2006	FFY 03-04	22	13,198	44.6%	2,600
2007	FFY 04-05	22	21,270	61.2%	2,600
2008	FFY 05-06	25	28,215	32.7%	3,000
2009	FFY 06-07	27	33,089	17.3%	3,000
2010	FFY 07-08	27	32,831	-0.8%	3,000 Amended by AI to 36,879
2011	FFY 08-09	27	36,897	12.4%	3,000
2012	FFY 09-10	27	36,622	-0.7%	3,000
2013	FFY 10-11	27	34,900	-4.7%	3,000
2014	FFY 11-12	27	32,729	-6.2%	3,000
2015*	FFY 12-13	28	33,553	2.5%	

*Note: DHSR keying error for NH FM/C 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.

Annual Year to

NORTH CAROLINA ANNUAL MOBILE PET SCAN VOLUMES

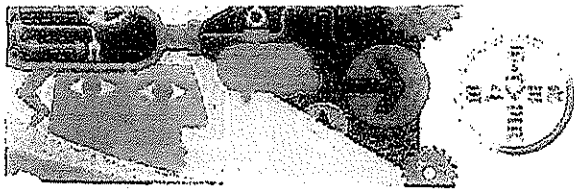
SMFP Year	Data Year	# Mobile PET Host Sites	Annual Total Mobile PET Scans	Year Mobile PET Scan Growth	Annual Mobile PET Scanner Capacity	% of Annual Mobile PET Capacity	# of Mobile PETS In Operation
2005	FFY 02-03	0	0				
2006	FFY 03-04	22	2,248		2,600	86%	1
2007	FFY 04-05	18	3,621	61%	2,600	70%	2
2008	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
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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

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SMFP	Annual Fixed	Annual Mobile	& Fixed PET	Scans	Scans	Annual Year to
Plan Year	MRI Scans	PET Scans	& Fixed PET	Scans	Scans	Year PET Scan
Data Year						Growth Rate
NORTH CAROLINA ANNUAL MOBILE & FIXED PET/CT SCAN VOLUMES						
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

ATTACHMENT B



ATTACHMENT B
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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. "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 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 Jafarzadeh, 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
Atomtom Is it CMS's intention that the 3 exams is a "lifetime" total?

6/13/2013 3:09:02 PM
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" :opreminds me of "Us and Them" / Pink Floyd, LOL

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

Quote from Sharp Rad

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ATTACHMENT G

What's driving PET/CT growth?

May 31, 2012

Brian Clement, Oncology Roundtable

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

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,