TO: Medical Facilities Planning Section

Division of Health Service Regulation

2714 Mail Service Center

Raleigh, North Carolina 27699-2714

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RE: Comments Regarding Carolinas Healthcare System Petition for Change in

Methodology for Mobile PET Scanners

Thank you for the opportunity to submit comments regarding the petition submitted by Carolinas Healthcare System (CHS) requesting that a new methodology be developed to determine the need for additional mobile PET scanners. As stated in the petition, the proposed methodology would result in the allocation of two additional mobile PET scanners – one in each mobile PET service area.

Alliance HealthCare Services, LLC currently provides mobile PET services in North Carolina and offers the following comments regarding the petition:

- Last year, fixed PET utilization declined from 36,869 scans in the previous year to 36,334 scans for the most recent annual period ending September 30, 2010. Mobile PET utilization increased slightly but remains less than the annual utilization for the reporting period two years previous. Combined fixed and mobile PET utilization declined by approximately 1 percent from 42,127 scans in 2008-09 down to 41,747 scans in the 2009-10 reporting period. Based on this drop in PET demand in North Carolina, there is no justification to hurriedly change the PET methodology and fabricate a need for two additional mobile PET scanners.
- Rather than performing a comprehensive analysis of the total PET utilization in the
 Health Service Areas, the petitioner mistakenly focuses on hospitals in counties that
 might want additional mobile PET service. Also, the CHS methodology examines only
 the capacity and utilization of the existing mobile PET scanners and ignores the severe
 underutilization of most of the existing fixed PET equipment. A more rational analysis
 would consider the capacity and utilization of both fixed and mobile PET scanners.
- The CHS proposal to allocate need determinations for two additional mobile PET scanners would clearly be duplicative of both the existing fixed and mobile scanners.
 Adding mobile PET scanners, as proposed by CHS, has little benefit and will hurt the utilization of the existing fixed and mobile sites.

Combined Fixed and Mobile PET Utilization Declined Last Year

The following table provides a summary of the North Carolina PET utilization showing the decline in fixed PET utilization and total PET utilization.

		Approved Mobile		Mobile PET Scanner Volume	Fixed PET Scanner Volume	Total PET Volume	
2008-09 Reporting Period	2010 SMFP	2	27	5,815	32,831	38,6	346
2009-10 Reporting Period	2011 SMFP	2	27	5,258	36,869	42,1	127
2010-11 Reporting Period	Draft 2012 SMFP	2	27	5,411	36,334	41,7	745

The most recent utilization data for the fixed PET scanners shows that statewide utilization declined 1.4 percent last year. Mobile PET utilization increased slightly but the total combined fixed and mobile PET declined from 42,127 in the previous year to 41,745 for the annual reporting period ending September 30, 2010. According to the most recent 2009-10 data, overall demand for PET scans in North Carolina has declined.

This most recent trend is contrary to the assumptions and methodologies for the CON-approved fixed PET scanners that were approved and have been implemented in the past three years. Consequently, there is an abundance of fixed PET scanners in North Carolinas that remain underutilized. Attachment 2 includes tables showing the utilization of fixed PET facilities and all mobile PET host sites.

<u>Health Service Areas Are the Geographic Planning Area for PET Inventory, Utilization</u> Analysis and Planning Purposes

The CHS petition mistakenly focuses on hospitals in counties that might want additional mobile PET service. This targeted approach ignores the Health Service Area and Planning Region definitions for PET. Fixed PET scanner service areas are defined as the six Health Service Areas (HSAs) with each comprised of multiple counties. The mobile PET scanner service areas are defined as PET Scanner Region 1 that includes HSAs I, II and III; PET Scanner Region 2 includes HSAs IV, V and VI. These service area definitions should continue to be the framework for evaluating the utilization data for existing PET scanners. Attachment 1 provides maps of the Health Service Areas and the location of exiting fixed PET facilities and mobile PET host sites.

The CHS petition neglects to discuss the interrelated utilization of mobile PET and fixed PET. As fixed PET scanners have been implemented, Alliance Healthcare has extended mobile PET service to enhance access. During the period from October 1, 2009 through September 30, 2010, the two mobile PET scanners improved geographic access by adding a total of six new hospital host sites, including four rural hospitals. This was accomplished following the

increased availability of mobile PET capacity that resulted from fixed scanners being implemented at CON-approved hospitals.

During 2010, utilization of the mobile PET unit that serves in the western planning region was elevated due to the high utilization at CMC-Union; this site continues to rely on mobile PET even though it obtained CON approval for a fixed PET in April 2009. Once CMC-Union no longer requires the use of the mobile PET scanner, the days of service will be reassigned to at least one existing PET site and one new PET site. During this same time, mobile PET utilization in the eastern planning region grew with the addition of two new hospital host sites, both in rural counties. This expansion of service occurred following the implementation of a fixed PET scanner at Nash General Hospital, freeing the mobile PET to serve new sites.

Examine Utilization and Capacity of Both Fixed and Mobile PET Scanners

Any future changes to the PET methodology need to be based on a unified methodology that examines the utilization and capacity of both fixed and mobile PET scanners in the context of the Health Service Areas. This is the most reasonable approach because fixed PET scanners comprise 93 percent of the total inventory and represent a large investment in facilities and equipment. The two following tables show the combined 2009-10 utilization and capacity of fixed and mobile PET scanners in PET Planning Region 1 and PET Planning Region 2.

				PET Planning
Health Service Areas I, II and III	HSA I	HSA II	HSA III	Region 1
# Counties	27	11	8	46
Total Combined Populations	1,445,815	1,618,366	1,937,689	5,001,870
# Mobile PET Sites	9	4	5	18
# CON Approved Fixed PET scanners	2	6	7	15
# of PET scanners below 60% annual capacity	2	4	7	13
Total Volume for mobile PET sites	1483	349	1029	2861
Total Volume for fixed PET scanners	3,056	9,314	7,882	20,252
Combined mobile and fixed PET volumes	4,539	9,663	8,911	23,113
Total Capacity for mobile PET scanner				3,000
Total Capacity for fixed PET scanners	6,000	18,000	21,000	45,000
Combined capacity for fixed and mobile PET				48,000
Total Utilization as Percentage of Capacity for fixed and mob	oile PET combined	in 2009-2010		48.15%

^{*}Mobile sites include Hugh Chatham which discontinued mobile PET service in late 2009.

Health Service Areas IV, V and VI	HSA IV	HSA V	HSA VI	PET Planning Region 2	
# Counties	9	16	29	54	
Total Combined Populations	1,721,925	1,420,027	1,375,206	4,517,158	
# Mobile PET Sites	2	2	6	10	
# Fixed PET scanners	6	2	3	12	
# of PET scanners below 60% annual capacity	2	2	5	9	
Total Volume for mobile PET sites	679	444	1,427	2,550	
Total Volume for fixed PET scanners	9,478	3,782	2,822	16,082	
Combined mobile and fixed PET volumes	10,157	4,226	4,249	18,632	
Total Capacity for mobile PET scanner				3,000	
Total Capacity for fixed PET scanners	18,000	6,000	9,000	33,000	
Combined capacity for fixed and mobile PET				36,000	
Total Utilization as Percentage of Capacity for fixed and mob	oile PET combined	in 2009-2010		51.76%	

Sources: Utilization data for the above tables was obtained from the 2011 Hospital License Renewal Applications and the 2011 PET Scanner Inventory Reports. For the purposes of these comments, annual capacity of 3,000 scans is assigned to each fixed and mobile PET scanner.

The above tables demonstrate that fixed and mobile PET service is widely available in all six of the Health Service Areas. Health Service Areas I and VI, which have the largest number of counties, have the highest number of mobile PET sites to enhance geographic access. The total combined utilization of 23,113 scans for the fifteen fixed and one mobile PET scanner in PET Planning Region 1 represents 48.15% of available capacity. The total combined utilization of 18,632 scans for the thirteen fixed PET and one mobile PET scanner in PET Planning Region 2 represents 51.76% of available capacity. Based on these statistics, the vast majority of fixed PET scanners are underutilized.

The low utilization of fixed PET scanners is an important issue because the issue of excess capacity is at the heart of the North Carolina CON Law. Section 131E-175, Findings of Fact, states as follows:

- (4) That the proliferation of unnecessary health service facilities results in costly duplication and underuse of facilities, with the availability of excess capacity leading to unnecessary use of expensive resources and overutilization of health care services.
- (6) That excess capacity of health service facilities places an enormous economic burden on the public who pay for the construction and operation of these facilities as patients, health insurance subscribers, health plan contributors, and taxpayers.

Additional Mobile PET Scanners Would Result in Duplication of Services

The CHS petition does not attempt to predict future years' PET utilization for the fixed and mobile sites. If the utilization in 2011 through 2012 shows no growth or minimal growth then the demand for PET can certainly be met by the existing inventory of fixed and mobile scanners. Given this circumstance, allocation of two additional mobile PET scanners will certainly reduce the utilization of existing providers. Consequently, the CHS petition incorrectly requests to add mobile PET that is duplicative of the existing fixed and mobile PET capacity.

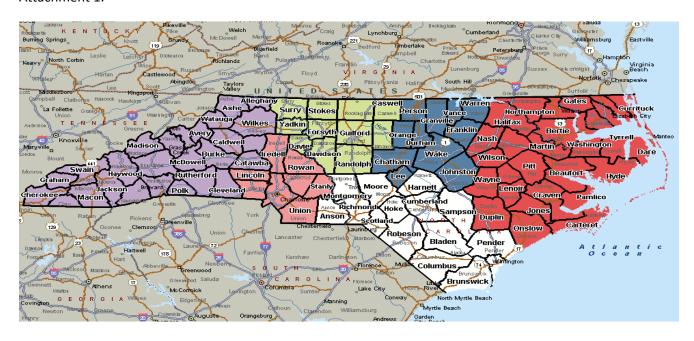
The CHS petition acknowledges that of the counties without a fixed PET scanner, many simply do not need a PET scanner because they do not have a hospital or programs which would give rise to PET utilization. Yet, CHS suggests that there is "capacity needed" (or, in other words, a demand for PET services) now or in the future in "several" counties without a fixed PET scanner. CHS provides no data on these counties; CHS does not identify these counties nor does CHS provide the number of patients from these counties traveling to receive service on existing PET equipment. If demand was causing a high number of patients to travel for PET services, one would expect to see reasonably high levels of utilization on existing PET scanners. Yet, existing fixed PET scanners are not utilized at or even near their capacity on average across the State. Moreover, CHS acknowledges that these counties might well be served by a mobile PET scanner; again, CHS does not document that the hospitals in these unidentified counties lack the ability to contract for mobile PET service on the Alliance mobile equipment. Without any data on demand or any suggestion that demand cannot be met on existing fixed and mobile equipment, this supposed need cannot be used as support for the CHS petition.

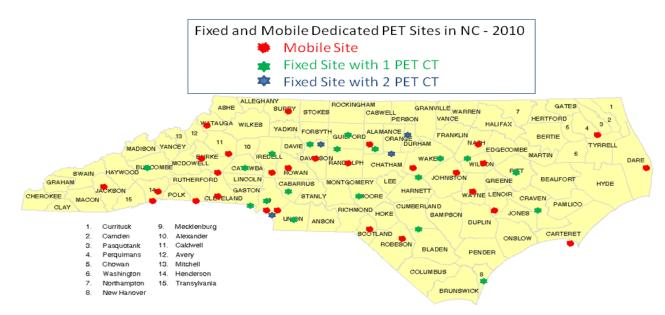
The CHS petition for a new mobile PET methodology also fails to include a performance standard regarding a minimal volume of potential PET scans for a new host site and a demonstration that the proposed project will not significantly diminish the utilization at existing fixed PET facilities and mobile PET host sites. Performance standards are an important part of the development of methodologies and existing fixed and mobile providers should be included in the discussion of potential changes related to PET.

Summary

Alliance Healthcare Services provides excellent quality mobile PET service to hospitals throughout North Carolina and continually evaluates fixed and mobile PET utilization and host site satisfaction. Over the past five years, almost every CON-approved fixed PET scanner in North Carolinas has fallen short of its utilization projections. Similarly, some mobile PET host sites overestimate their demand and request additional days of service even when their current utilization is weak. For these reasons, and the factors described in previous sections, the CHS petition should be denied.

Attachment 1.





Attachment 2

Fixed PET Summary

			Procedure	s		H.S.A. Utilization Rate							
	2005 - 2006	2006 - 2007	2007- 2008	2008 - 2009	2009 - 2010	H.S.A.	Inventory	2010 Procedures/ 3000 as Capacity		H.S.A.	Fixed PET	Capacity	% Capacity
Mission Hospital	1,003	1,607	1,674	1,710	1,618	- 1	1	53.93%]				
Catawba Valley/ Frye Regional	1,258	1,574	1,597	1,539	1,438		1	47.93%	1	3,056	2	6000	50.9%
N.C. Baptist Hospitals	1,477	1,919	2,011	2,151	2,337	- II	1	77.90%	ĺ				
Moses Cone Health System	1,760	1,955	2,161	2,105	2,014	II	1	67.13%	1				
Forsyth Medical Center	2,417	2,983	3,208	3,762	3,346	II	2	55.76%	1 [9,314	. 6	18000	51.7%
High Point Regional	574	785	1,101	1,278	1,049	II	1	34.96%					
Alamance Regional Medical Center	374	480	37	618	568	II	1	18.93%	11				
Carolinas Medical Center	3,635	3,654	3,510	3,392	3,190	III	2	53.16%	Ιí				
*CMC-Union (not yet installed)				0	0	III	1	0.00%					
Gaston Memorial Hospitals/CIS Summit	846	984	870	929	1,521	=	1	50.70%		7,882	. 7	21000	37.5%
CMC-NorthEast Medical Center	615	818	868	1,046	1,106	III	1	33.53%			(includes (CMC-Union	n in inventory)
Presbyterian Hospital	1,988	2,173	2,062	2,126	1,629	III	1	54.30%					
Iredell Memorial Hospital		NA	306	560	436	III	1	14.53%	J				
Duke University Hospital	3,596	3,858	3,924	4,272	4,403	IV	2	73.38%] [
UNC Hospital	1,386	1,878	2,081	2,682	2,822	IV	2	47.03%		9,478	6	18000	52.7%
Rex Hospital	1,913	2,139	1,704	1,887	1,675	IV	1	55.83%]				
Wake PET Services, Wake Radiology Oncology, Wake Radiology	NA	NA	NA	324	578	IV	1	19.27%					
New Hanover Regional Medical Center	755	895	1,020	1,023	1,100	٧	1	36.66%	l				
Cape Fear Medical Center	2,069	2,268	1,672	1,740	1,558	٧	1	51.93%	I	3,782	. 3	9000	42.0%
First Imaging of the Carolinas	550	865	1,036	1,147	1,124	٧	1	37.47%]]				
Pitt County Memorial	832	981	1,120	1,293	1,304	VI	1	43.46%	1	2,822	. 3	9000	31.4%
CarolinaEast Medical Center	831	852	869	1,048	1,003	VI	1	33.43%	1 ŀ				
Nash General Hopital	336	421	0	237	515	VI	1	17.16%	IJ				
Total	28,215	33,089	32,831	36,869	36,334		27		1				

^{*}CMC Union volume was performed on mobile PET because fixed PET is not yet installed

27 Fixed PET includes 26 existing plus 1 PET that is CON-approved and yet to be installed.

			44.9%	of Total Capacity
Total	27	36,334	1,346	per Fixed PET
Fixed PET between 66% to 80%	4		Average	
Fixed PET between 51% to 65%	9			
(includes CMC-Union)				
Fixed PET at less than 50% Capacity	14			

PET Mobile Sites

Caldwell Memorial	Combined HSA Volume	2010 Host Sites	-	H.S.A	2009- 2010	2008- 2009	2007- 2008	2006- 2007	2005- 2006	Mobile PET Sites
Grace Hospital 101 78 93 68 74 1			1	1	131	159	143	78	0	Caldwell Memorial
Margaret Pardee				- 1	419	358	278	190	67	Cleveland Regional
Park Ridge				- 1	74	68	93	78	101	Grace Hospital
Rutherford Hospital				- 1	140	162	141	178	113	Margaret Pardee
Valdese Hospital 101 105 108 109 102 1	1,483	9 sites	-9	- 1	143	210	205	216	91	Park Ridge
Watauga Medical Center				- 1	135	128	6			Rutherford Hospital
West Care Harris Regional				- 1	102	109	108	105	101	Valdese Hospital
Alamance Regional 374 471 440 0 0 0				I	96	118	138	123	101	Watauga Medical Center
**Hugh Chatham			J	I	243	243	251	241	197	West Care Harris Regional
Northern Hospital Surry 90 129 189 250 230 II			Г	Ш	0	0	440	471	374	Alamance Regional
Community General Health Partnership 105 II Randolph Hospital 9 II				II	5	108	138	103	84	**Hugh Chatham
Randolph Hospital 9 1	349	4 sites	4	II	230	250	189	129	90	Northern Hospital Surry
*CMC - Union 60 350 350 298 285 III Lake Norman Medical Center 121 199 217 203 III The Presbyterian Hospital 130 III Presbyterian Hospital 130 III Souther The Presbyterian Hospital 130 III Presbyterian Hospital, Matthews 88 III Duke Raleigh Hospital 303 375 554 548 537 IV Johnston Memorial 10 142 IV 2 sites Scotland Memorial 93 155 117 123 148 V Southeastern Regional 268 274 290 315 296 V Southeastern Regional 268 274 290 315 296 V Albemarle Hospital 261 268 250 217 243 VI Lenoir Memorial Hospital 261 268 250 217 243 VI Nash General Hospital 336 423 434 274 0 VI Wayne Memorial 190 274 418 406 394 VI Wayne Memorial 190 274 418 406 394 VI Wilson Medical Center 292 267 321 347 418 VI Outer Banks Hospital 120 VI Carteret General Hospital 102 VI				П	105					Community General Health Partnership
The Presbyterian Hospital 130 110 130 111 150 130 111 150 130 111 150 130 111 150 130 111 150 130 111 150 130 111 150 130 111 150 130			١٦	II	9					Randolph Hospital
The Presbyterian Hospital 130 III 5 sites Presbyterian Hospital, Matthews 290 443 517 393 323 III Duke Raleigh Hospital 303 375 554 548 537 IV Johnston Memorial 10 142 IV 2 sites Scotland Memorial 93 155 117 123 148 V Southeastern Regional 268 274 290 315 296 V Albemarle Hospital 261 268 250 217 243 VI Lenoir Memorial Hospital 336 423 434 274 0 VI Wayne Memorial 190 274 418 406 394 VI Wilson Medical Center 292 267 321 347 418 VI Outer Banks Hospital 102 VI			\neg	III	285	298	350	350	60	*CMC - Union
Presbyterian Hospital, Matthews 290 443 517 393 323 III				III	203	217	199	121		Lake Norman Medical Center
Rowan Regional 290 443 517 393 323 III Duke Raleigh Hospital 303 375 554 548 537 IV Johnston Memorial 10 142 IV 2 sites Scotland Memorial 93 155 117 123 148 V Southeastern Regional 268 274 290 315 296 V Albemarle Hospital 261 268 250 217 243 VI Lenoir Memorial Hospital 235 197 150 VI Nash General Hospital 336 423 434 274 0 VI Wayne Memorial 190 274 418 406 394 VI Wilson Medical Center 292 267 321 347 418 VI Outer Banks Hospital 120 VI Carteret General Hospital 102 VI	1,029	-5 sites		III	130					The Presbyterian Hospital
Duke Raleigh Hospital 303 375 554 548 537 IV Johnston Memorial 10 142 IV 2 sites Scotland Memorial 93 155 117 123 148 V Southeastern Regional 268 274 290 315 296 V Albemarle Hospital 261 268 250 217 243 VI Lenoir Memorial Hospital 235 197 150 VI Nash General Hospital 336 423 434 274 0 VI Wayne Memorial 190 274 418 406 394 VI Wilson Medical Center 292 267 321 347 418 VI Outer Banks Hospital 120 VI Carteret General Hospital 102 VI				III	88					Presbyterian Hospital, Matthews
Johnston Memorial 10 142 IV 2 sites			IJ	III	323	393	517	443	290	Rowan Regional
Scotland Memorial 93 155 117 123 148 V Southeastern Regional 268 274 290 315 296 V Albemarle Hospital 261 268 250 217 243 VI Lenoir Memorial Hospital 235 197 150 VI Nash General Hospital 336 423 434 274 0 VI Wayne Memorial 190 274 418 406 394 VI Wilson Medical Center 292 267 321 347 418 VI Outer Banks Hospital 120 VI Carteret General Hospital 102 VI			L	IV	537	548	554	375	303	Duke Raleigh Hospital
Southeastern Regional 268 274 290 315 296 V Albemarle Hospital 261 268 250 217 243 VI Lenoir Memorial Hospital 235 197 150 VI Nash General Hospital 336 423 434 274 0 VI Wayne Memorial 190 274 418 406 394 VI Wilson Medical Center 292 267 321 347 418 VI Outer Banks Hospital 120 VI Carteret General Hospital 102 VI Carteret General Hospital 102 VI Carteret General Hospital 102 VI Carteret General Hospital 268 274 290 315 296 V VI VI VI VI VI VI VI	679	2 sites	2	IV	142	10				Johnston Memorial
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Wayne Memorial 190 274 418 406 394 VI Wilson Medical Center 292 267 321 347 418 VI Outer Banks Hospital 120 VI Carteret General Hospital 102 VI				VI	150	197	235			Lenoir Memorial Hospital
Wilson Medical Center 292 267 321 347 418 VI Outer Banks Hospital 120 VI Carteret General Hospital 102 VI				VI	0	274	434	423	336	Nash General Hospital
Outer Banks Hospital 120 VI Carteret General Hospital 102 VI	1,427	6 sites	6	VI	394	406	418	274	190	Wayne Memorial
Carteret General Hospital 102 VI				VI	418	347	321	267	292	Wilson Medical Center
				VI	120					Outer Banks Hospital
TOTAL 2 412 4 963 5 915 5 259 5 411			\vdash	VI	102					Carteret General Hospital
101AL 3,412 4,602 3,013 3,236 3,411					5,411	5,258	5,815	4,862	3,412	TOTAL

^{*}Approved for fixed PET - volume was performed on mobile unit

^{**}Discontinued Service Per Request of Hospital