AUG 1 5 2014

DHHS – DHSR MEDICAL FACILITIES PLANNING BRANCH

#### Novant Health and MedQuest Associates 8/15/2014 Comments on Carolinas HealthCare System July 30, 2014 Public Hearing Comments On the Draft 2015 State Medical Facilities Plan Policy TE-1: Conversion of Fixed PET Scanners to Mobile PET Scanners

Carolinas HealthCare System ("CHS") states its overall support for Draft 2015 SMFP Policy TE-1 and the four conditions included in that policy. In addition, CHS suggests three more requirements or conditions. Novant Health and MedQuest offer their comments on these three additional conditions and the potential impact these requirements may have on the implementation of new mobile PET scanners.

CHS Expresses Support for Policy TE-1 Condition #4 Prohibiting New Mobile PET Vendors From Serving Host Sites in the Nineteen North Carolina Counties With Existing Fixed PET/CT Scanners

SMFP Policy TE-1 Condition #4 as proposed in the 2015 SMFP has the unintended consequence of hampering the efforts of existing and developing health networks, often comprised of large, medium, and small hospitals located in urban and rural areas of North Carolina, to achieve cost savings by using their own mobile PET scanners to serve their own hospitals and facilities. We believe that the goal of increasing mobile PET access in rural areas and allowing health networks like Novant to serve their own hospitals and facilities are complementary goals that can successfully co-exist – they do not need to be mutually exclusive. One of the principles of the CON program is cost control. Providers are encouraged to look for ways to reduce cost whenever possible, and to make the most of their existing resources. That is exactly what Novant could do if allowed to convert an existing PET scanner to a mobile PET scanner.

Policy TE-1, Condition #4 creates an uneven playing field for new mobile PET market entrants, as the two existing Alliance Imaging mobile PET scanners would not be barred in the future from the serving the 19 counties where there are existing fixed PET scanners. In fact, today AI provides mobile PET services in counties where there are existing fixed PET scanners including Mecklenburg, Guilford, and Iredell counties.

Thus, Condition #4 of the proposed draft 2015 SMFP Policy TE-1 has the <u>unintended consequence</u> of giving the sole existing mobile PET vendor greater operational flexibility in the geographies that can be served than would be afforded to new mobile PET market entrants. This may unintentionally weaken the impact of competition and beneficial choice for providers seeking to contract for the first time for mobile PET services or add more mobile PET days of service. This handicaps new mobile PET providers and provides the existing mobile PET provider with advantages not available to other future mobile PET providers

The nineteen counties that have fixed PET/CT scanners in operation today are listed in the table below along with the county population.

Counties With Fixed PET Scanners Excluded For Access to New Mobile PET Units

County	Projected 2015 County Population	Health Service Area
Buncombe	255,061	I
Catawba	155,630	1
Forsyth	365,734	II
Guilford	518,603	II
Alamance	154,869	II
Mecklenburg	1,032,096	III
Union	219,403	III
Gaston	212,423	III
Cabarrus	192,552	III
Iredell	169,133	III
Durham	296,679	IV
Orange	143,105	IV
Wake	1,055,322	IV
New Hanover	221,812	V
Cumberland	336,340	V
Moore	94,306	V
Pitt	176,885	V
Craven	104,566	V
Nash	94,134	V
TOTAL-19	5,748,662	
Counties		
North Carolina	10,055,337	

Source: 2015 Draft SMFP and Office of State Management & Budget County Population Estimates for 2010-2019<sup>1</sup> OSMB County Population Table is attached to this comment.

The above table shows that almost 5.8 Million North Carolina residents of the above 19 counties would not have the option to have access to mobile PET services from any of the new mobile PET providers and would be left with Alliance Imaging as the only option. This represents 58% of North Carolina's population that is carved out of the geographies that can be served by new mobile PET providers that converted a fixed PET scanner to a mobile. The unintended consequence of the implementation of Policy TE-1as drafted is that it creates a two-tier system where AI is able to serve all 100 North Carolina Counties and new mobile PET market entrants can only serve 81 North Carolina counties and the two most populous counties in North Carolina (Wake and Mecklenburg) are off limits to new mobile PET providers. Surely, this approach does not promote long overdue and beneficial competition and choice in mobile PET services.

<sup>&</sup>lt;sup>1</sup>NC Office of State Management and Budget County Population estimates for 2010-2019 were used in the above table. Specifically, the county population estimates for July 2015 were used, as CY 2015 would be the first year under the 2015 SMFP that providers could file a CON Application to seek the state's approval to convert their previously CON-approved fixed PET scanner to a new mobile PET scanner.

To ensure the beneficial impact of competition and related cost reduction opportunities, the language of Condition #4 should be adjusted to permit Novant Health and other new entrants to the mobile PET market to have the ability to serve their own hospitals and facilities<sup>2</sup>. A provider seeking to convert a fixed unit of equipment to a mobile unit will only undertake this conversion if the regulatory structure and criteria encourages operational efficiency and financial feasibility and the ability to lower the cost of healthcare at its own facilities. This conversion policy offers a critical step in introducing competition in a closed market where one provider has controlled all mobile PET service availability for more than a decade.

In the 7/30/14 Novant Health and MedQuest comment/petition asked the SHCC to consider one recommended change to the language of condition #4 of SMFP Policy TE-1. It was an amendment of the language of Condition #4 which prohibits a new mobile PET provider from offering mobile PET services in counties with an existing fixed PET scanner. Novant Health and MedQuest would ask that committee members consider and support an addendum to Policy TE-1 Condition #4 that would allow a provider proposing to convert a fixed PET to a mobile PET the ability to serve its own related and affiliated entities in any county regardless of whether there is an existing fixed PET scanner in that county.

The language of Policy TE-1, Condition #4 could be supplemented as follows:

"...the converted mobile PET scanner...shall not serve any mobile host facility in a county where any existing or approved fixed PET scanner is located, except as required by subpart (1) above...or except if the mobile PET host site is an owned, related, or affiliated entity of the mobile PET vendor or its parent organization."

## CHS Recommends Including A Requirement That The Fixed PET Scanner Proposed for Conversion be Underutilized

As an initial matter, CHS does not define what is meant by "underutilized." More specifically, the framework of the Policy TE-1 acknowledges that underutilized fixed PET capacity exists hence the conversion to a mobile unit in order to increase utilization. It is unnecessary to add an "underutilized" requirement to the policy. The language of Policy TE-1 as proposed in the draft 2015 SMFP seems to contemplate the inclusion of existing and approved fixed PET scanners as eligible for conversion to mobile PET. The first sentence of Policy TE-1 says: "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..." Novant Health and MedQuest support the language of the first sentence of Policy TE-1 as presented in the draft 2015 SMFP so that both existing and previously CON-approved fixed PET scanners would be eligible for conversion to a mobile PET scanner.

<sup>&</sup>lt;sup>2</sup> For the SHCC's consideration, Novant Health/MedQuest's proposed language to supplement the existing language of Condition #4 of SMFP Policy TE-1 is discussed extensively in its July 30, 2014 comment/petition submitted to the DHSR Planning Section.

### CHS Suggests A Limit of Two Fixed PET to Mobile PET Conversions in a Calendar Year

Novant Health and MedQuest concur with CHS's statement that "there is a need for additional mobile PET capacity...." In considering CHS's recommendation for "some limitation" placed on the annual number of fixed to mobile PET conversions, the SHCC and DHSR Planning staff may want to consider how a defined quantitative limit on annual new mobile PET scanners, somewhat analogous to an annual SMFP need determination, would interact with the provision of Policy TE-1 specifying that "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." As a practical matter such a limitation would specify the maximum new mobile PET scanners that could be approved annually. So hypothetically, if there were three CON applicants in one year for fixed to mobile PET conversions and the limit was two new mobile PET scanners per year, then only two of the three CON applications could be approved. It is important to remember that these applicants were previously approved to offer fixed PET services. It is unlikely that a multitude of providers will undertake a mobile PET conversion and those providers that are able to successfully do so should not be limited by a maximum number of approvals. This limitation increases the potential that the unsuccessful applicant would consider filing an appeal, which would delay the development of additional mobile PET scanners until such litigation is resolved and Certificates of Need for new mobile PET scanners could be issued by the state. CON litigation is both costly and time-consuming. Therefore, Novant and MedQuest do not support a maximum limit on the number of conversions that can be approved.

# CHS Proposes the Establishment of a Single CON Application Filing Deadline Each Year to Promote the Competitive Review of Fixed to Mobile PET Conversion CON Applications

Novant and MedQuest do not support the encouragement of a competitive review for the conversion of fixed to mobile PET scanners. The applicants for a mobile PET conversion will be providers that have been previously approved by the Certificate of Need Section to offer fixed PET services. Considering this policy allows for conversion of existing resources and will not increase overall PET equipment inventory, there is no valid basis for the requirement of a competitive review when considering previously CON-approved equipment. There is no clear rationale to compare applications competitively when the potential applicants' service areas could vary dramatically. The moratorium on mobile PET capacity, which has lasted for well over a decade, has impacted patients in service areas across the State. The intent of Policy TE-1 is to improve accessibility and increase capacity for mobile PET services for residents of North Carolina as soon as possible.

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#### **ATTACHMENT A - POPULATION TABLES**

		Estim	ites				Project	ions		
County	Jul-10	Jul-11	Jul-12	Jul-13	Jul-14	Jul-15	Jul-16	Jul-17	Jul-18	UI-19
Alamance	151,468	152,091	152,957	153,642	154.256	154.869	155.483	156.095	156.708	157.321
Alexander	37,245	37,534	37,391	37,448	37,429	37,410	37,393	37.378	37,364	37,352
Alleghany	11.148	11.077	11,000	11,029	11.033	11,040	11.048	11.053	11.060	11,066
Anson	26,875	25,820	26,626	26,322	26,429	26,429	26,427	26,430	26.427	26.428
AST e	27,256	27,433	27,385	27,442	27,425	27,461	27,458	27,483	27,486	27,506
Avery	17,751	17,978	17,788	17,866	17,868	17,869	17,868	17,868	17,869	17,870
Beautort	47,764	47,801	47,869	47,791	47,791	47,791	47,791	47,792	47,790	47,792
Berlie	21,200	20,996	20,676	20,586	20,581	20,599	20,618	20,518	20,393	20,247
Bladen	35,171	35,197	35,206	35,219	35,250	35,283	35,315	35,347	35,378	35,412
Brunswick	108,064	110,312	112,615	115,666	118,634	121,736	124,840	127,941	131,044	134,146
Buncombe	238,884	243,673	245,381	248,929	251,995	255,061	258,129	261,195	264,263	267,329
Burke	90,775	90,674	89,982	89,552	89,184	88,854	88,563	88,303	88,072	87,868
Cabarrus	178,517	180,846	183,465	186,502	189,528	192,552	195,578	198,602	201,629	204,654
Caldwell	82,947	82,913	82,582	82,536	82,405	82,313	82,231	82,155	82,089	82,029
Camden	9,983	10,065	10,014	10,040	10,092	10,135	10,179	10,221	10,264	10,307
Carteret	66,711	67,614	68,395	69,258	70,101	70,944	71,786	72,628	73,471	74,312
Caswell	23,665	23,910	23,591	23,736	23,708	23,720	23,715	23,717	23,718	23,718
Catawba	154,260	154,728	155,484	155,463	155,545	155,630	155,711	155,795	155,879	155,961
Chatham	63,751	65,630	66,478	67,638	68,770	69,901	71,035	72,167	73,298	74,432
Cherokee	27,438	27,541	27,406	27,156	27,060	27,061	27,059	27,061	27,060	27,061
Chowan	14,757	14,774	14,715	14,806	14,839	14,873	14,908	14,944	14,978	15,012
Clay	10,568	10,687	10,723	10,628	10,621	10,613	10,607	10,600	10,596	10,589
Cleveland	98,030	98,228	97,689	97,442	97,245	97,071	96,918	96,783	96,665	96,562
Columbus	57,918	58,009	58,037	57,536	57,376	57,378	57,377	57,377	57,379	57,377
Craven	104,138	104,685	105,203	104,435	104,288	104,566	105,552	107,074	108,914	110,755
Cumberland	327,445	330,548	330,215	332,595	334,466	336,340	338,213	340,086	341,957	343,830
Currituck	23,647	23,996	24,155	24,055	24,055	24,055	24,053	24,053	24,055	24,055.
Dare	34,006	34,267	34,872	35,182	35,471	35,736	35,983	36,212	36,423	36,619
Davidson	162,874	163,559	163,273	163,826	164,110	164,485	164,828	165,181	165,532	165,884
Davie	41,312	41,385	41,378	41,524	41,647	41,771	41,895	42,018	42,140	42,264
Duplin	58,664	59,486	60,017	60,122	60,453	60,780	61,109	61,436	61,764	62,090
Durham	271,297	274,844	281,224	286,142	291,413	296,679	301,940	307,195	312,447	317,691
Edgecombe	56,604	26,090	56,062	55,723	55,735	55,509	55,456	55,277	55,192	55,035
Forsyth	351,380	353,949	357,593	360,589	363,211	365,734	368,157	370,489	372,731	374,887
Franklin	60,813	61,598	61,825	62,720	63,496	64,211	64,894	65,629	66,356	9/0/29
Gaston	206,139	207,262	208,484	209,606	210,980	212,423	213,867	215,314	216,758	218,204
Gates	12,168	12,170	12,114	11,654	11,263	11,021	10,874	10,782	10,728	10,695
Graham	8,870	8,917	8,850	8,845	8,979	9,038	9,103	9,168	9,232	9,297
Granville	57,578	58,231	58,004	57,925	58,042	58,128	58,216	58,302	58,389	58,473
Greene	21,225	21,569	21,358	21,081	21,059	21,058	21,058	21,059	21,059	21,058
Guilford	489,677	494,596	501,845	507,578	513,089	518,603	524,113	529,626	535,137	540,648
Halifax	54,559	54,444	54,223	53,718	53,432	53,115	52,793	52,475	52,155	51,835
Harnaff	115 757	118 441	124 239	103 257	105.646	197 887	130 128	130 370	134 612	138 853

Haywood Provided the Control of the	58.968	59.476	59.261	59 890	קס מגק	60 227	A0 545	AOT 08	£4 072	0000
Henderson	106 951	108.041	108 069	109305	110.284	111.197	440,440	112,003	442,070	7.7.7.7
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	3 i i	24,550 And Ca	700,42	000,44	110,47	24,400	24,417	Z4,5/U	74,324	24,278
	8/C',74	48, 154	50,U31	50,678	51,434	52,289	53,290	54,428	55,684	57,016
	5,788	5,826	5,745	5,801	5,837	5,874	5,910	5,947	5,984	6,021
	159,766	161,211	162,967	165,025	167,078	169,133	171,189	173,245	175,303	177,359
Jackson	40,345	40,554	40,666	40,812	40,951	41,091	41,231	41,371	41,509	41.649
<b>John Stone</b>	169,633	172,606	174,686	177,372	180,064	182,756	185,448	188,140	190,831	193,525
Self-self-self-self-self-self-self-self-s	10,081	10,550	10,615	10,554	10,579	10,601	10,627	10,652	10,677	10,701
	57,859	58,127	59,039	59,356	60,314	60,982	62,030	62,866	63,831	64,590
<b>lioue1</b>	59,408	59,361	59,383	59,063	59,016	58,966	58,918	58,870	58,821	58,773
	78,406	78,874	79,204	79,768	80,329	80,889	81,452	82,013	82,573	83,136
Macon Control of the	33,928	34,213	33,974	34,149	34,133	34,160	34,184	34,207	34,231	34,249
Madison	20,773	21,151	21,206	21,370	21,440	21,514	21,588	21,659	21,730	21,802
Martin	24,463	24,163	23,982	23,755	23,608	23,458	23,306	23,157	23,009	22,859
WicDowell	45,060	45,263	45,264	45,245	45,298	45,345	45,387	45,423	45,460	45,492
Wecklenburg	923,390	939,802	962,460	991,970	1,010,211	1,032,096	1,053,980	1,075,864	1,097,749	1,119,633
Wildhell	15,542	15,446	15,416	15,388	15,357	15,328	15,306	15,285	15,266	15,250
Worlgomery	27,942	28,063	27,910	27,775	27,742	27,765	27,778	27,728	27,670	27,663
Woole	88,526	89,339	90,725	91,954	93,144	94,306	95,437	96,537	97,610	099'86
Nash S	95,917	95,813	95,434	94,776	94,459	94,143	93,825	93,511	93,192	92,876
New Hanover	203,299	206,333	209,915	213,876	217,844	221,812	225,780	229,749	233,718	237,685
Northampton	22,022	21,931	21,539	21,218	20,958	20,691	20,432	20,166	19,904	19,640
Onslow	186,869	186,601	191,508	193,911	197,742	200,913	204,292	207,672	211,052	214,431
Orange	134,303	135,080	138,366	139,738	141,422	143,105	144,787	146,469	148,152	149,834
Pamilco	13,095	13,312	13,188	13,071	13,071	13,072	13,07.1	13,072	13,071	13,072
Pasquotank	40,644	40,322	40,131	39,298	38,919	38,667	38,498	38,386	38,313	38,263
Pender	52,384	53,473	54,368	55,587	56,589	57,728	58,789	59,890	60,975	62,060
Perquimans	13,482	13,540	13,679	13,735	13,823	13,946	14,104	14,294	14,496	14,701
Person	39,442	39,609	39,161	39,189	39,231	39,273	39,313	39,350	39,388	39,419
Ħ.	168,787	169,840	172,529	173,938	175,446	176,885	178,322	179,759	181,197	182,634
Pok	20,442	20,533	20,312	20,528	20,603	20,679	20,753	20,822	20,888	20,951
Kandolph	141,874	142,578	142,546	142,614	142,678	142,742	142,802	142,863	142,925	142,987
Kichmond	46,635	46,465	46,183	46,053	46,030	46,001	45,976	45,947	45,922	45,893
Kobeson	134,422	134,240	134,341	133,984	133,599	133,216	132,832	132,447	132,062	131,681
Kockingnam	93,596	93,391	92,822	92,259	91,775	91,354	91,004	90,714	90,472	90,269
Kowan	138,379	138,294	138,141	138,708	139,161	139,617	140,072	140,528	140,981	141,438
Kumenora	67,763	68,238	67,956	67,764	67,535	67,315	67,121	66,948	66,798	66,664
Campson	63,441	63,663	64,121	64,335	64,553	64,770	64,987	65,204	65,421	65,638
Scotland	36,097	36,291	36,358	36,231	36,120	35,970	35,836	35,696	35,559	35,420
Stanly	60,533	60,751	60,430	60,631	60,562	60,860	61,105	61,353	61,599	61,846
Stokes	47,352	47,480	47,035	46,747	46,409	46,097	45,809	45,547	45,307	45,086
Surry	73,682	73,450	73,676	73,367	73,368	73,368	73,369	73,368	73,367	73,369
Swain	13,997	14,220	14,466	14,596	14,750	14,904	15,058	15,211	15,367	15,522
Iransylvania	33,061	33,247	33,000	33,222	33,231	33,337	33,530	33,768	34,035	34,313
lyrrell	4,397	4,342	4,148	4,142	4,114	4,087	4,059	4,032	4,006	3,978
Varion	202,164	205,337	207,835	211,558	215,416	219,403	223,439	227,564	231,746	235,994
Valice	45,358	45,434	45,455	45,070	44,977	44,888	44,811	44,751	44,701	44,659

Wake	606'906	1000	945,254	964,928	985,146		1,025,498	1,045,673	1,065,847	1,086,022
	20,940		20,665	20,457	20,368	20,278	20,198	20,125	20,057	19,994
Washington	13,173	13,022	12,807	12,830	12,754	12,690	12,624	12,559	12,492	12,429
Watauga	51,009	, Nie	52,480	52,692	52,959	53,224	53,490	53,757	54,021	54,287
	122,845	123,604	124,954	125,143	125,656	125,982	126,332	126,766	127,357	128,101
	69,234		69,710	69,774	69,817	69,860	69,905	69,948	066'69	70,034
	81,302	81,370	81,706	81,419	82,175	83,085	84,550	85,865	86,990	87.604
	38,401	38,400	38,235	38,146		37,913	37,815	37,724	37,640	37,566
	17,787	18,053	17,869	17,919	17,940		17,977	17,997	18,016	18,036
STATE	9,574,477 9,666,	9,666,342	9,762,822	9,861,952	တ		10,156,537	725		10,462,726
TOTAL-19 FIXED PET COUNTIES	Section 1					5,748,662				
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