Novant HEALTH

Remarkable People. Remarkable Medicine.

August 16, 2012

TJ Pulliam, MD Interim Chairman
State Health Coordinating Council
Division of Health Service Regulation
2714 Mail Service Center

Re: Response to Comments submitted by North Carolina Baptist Hospital and Alliance Imaging pertaining to PET scanners in the 2013 Draft SMFP

Dear Chairman Pulliam:

Novant Health, Inc. and its affiliate MedQuest Associates, Inc. (collectively referred to as "Novant") are submitting this letter in response to correspondence from North Carolina Baptist Hospital ("NCBH") and Alliance Imaging, Inc. ("Alliance") to the State Health Coordinating Council ("SHCC") regarding PET scanners dated August 1, 2012 and July 16, 2012 respectively. NCBH and Alliance's comments should be rejected as there is clearly a legitimate need for a PET scanner in the 2013 Draft SMFP.

North Carolina Baptist Hospital

NCBH is asking that the SHCC remove the need determination for one additional fixed PET scanner in the 2013 SMFP, which need was established based on the actual FFY 2011 PET scan volumes performed in HSA II. NCBH does not dispute the accuracy of current PET scan volumes or that the need for a new PET scanner was properly calculated according to the SMFP. Rather, NCBH contends that it has the responsibility to seek to eliminate the need for an additional PET scanner in the multi-county PET service area of Health Service Area II based on NCBH's assumption in its petition that NCBH's PET scan volumes generated the current need determination for a new PET scanner in HSA II in the draft 2013 SMFP. NCBH's approach has the impact of depriving other entities that wish to seek to accommodate the undisputed patient, physician and hospital need for additional PET services in HSA II. Thus, NCBH's petition should be rejected since the need for additional PET services may be met by any applicant - not just the entity that has achieved the target utilization.

NCBH's proposal, if approved by the SHCC, would establish precedent that could allow one provider in a service area to manipulate need determinations intended for a large service area. In this case, the service area is HSA II, which encompasses 11 counties and accounts for over 1,475,000 North Carolina residents. There are currently five providers of fixed PET services in HSA II (NCBH, Forsyth Medical Center, Moses Cone Hospital, High Point Regional Medical Center, and Alamance Regional Medical Center). If NCBH believes that no need exists for additional PET capacity, then it has the option of not filing a Certificate of Need application for the additional PET scanner. Any applicant for the 2013 need determination for a PET scanner in HSA II must show

the Certificate of Need Section that a need actually exists for its proposed project and the applicant must comply with applicable CON PET scanner regulations[1]. Indeed, under NCBH's logic, if only one PET provider existed in a service area, that provider alone could dictate if and when a PET scanner would be available, regardless of whether or not the public actually needed the additional services.

A petition filed by a single provider should not be allowed to determine the fate of the 2013 PET scanner, regardless of whether or not it actually generated the need for an additional scanner. Accordingly, Novant respectfully requests that the SHCC reject NCBH's proposal to unilaterally determine whether or not there is a need for an additional PET scanner and instead allow the current need determination specified in the 2013 State Medical Facilities Plan to stand.

Alliance Imaging

In an apparent effort to maintain the status quo and protect its own interests, Alliance has commented that there is no current (and potentially no future) need for more than two (2) mobile PET scanners in North Carolina. In support of its comments, Alliance first contends that the current annual capacity number of 2,600 procedures for a mobile PET scanner is unreasonable and that the threshold should be raised to the fixed PET scanner threshold of 3,000. This argument lacks any basis in fact and is simply unreasonable. The mobile PET threshold is justifiably lower than the fixed PET scanner threshold for at least two basic reasons. First, a fixed PET scanner has the potential of operating 24 hours a day / 7 days a week while a mobile PET scanner serves several host sites and has to be transported to each site several days a week. Second, mobile PET procedures typically last longer than those on a fixed scanner since it generally takes additional time for the patient to be escorted to and from the mobile unit. These two reasons alone justify the roughly 13% difference in mobile and fixed PET scanner capacity.

Alliance also contends that raising the threshold would make the "presentation of mobile PET utilization data consistent with other CON regulated health services..." Raising the threshold for mobile PET scanners, however, would actually create an inconsistency with other established thresholds for similarly utilized equipment such as mobile MRI scanners. It is well established that mobile MRI scanners have a lower annual capacity than fixed MRI for the same reasons mobile PET scanners have a lower annual capacity than fixed PET scanners. Alliance's attempt to change or modify these well-established differences in mobile versus fixed capacity should be rejected.

It is not surprising that Alliance has raised these points since the facts show that it owns and operates the sole mobile PET scanner in HSAs I, II and III; that said scanner has exceeded 2,600 scans in 2010; and that said single mobile PET scanner has an unprecedented number of host sites. According to the last declaratory ruling filed by Alliance, the Alliance mobile PET scanner currently serves at least **seventeen (17) active host sites**. Alliance's claim that this single mobile PET scanner has additional capacity available is dubious in light of the significant number of existing host sites and because

[1] This is consistent with 2013 Draft SMFP which states in Chapter 9, under the PET discussion, "the need generated by this part of the methodology may be met by any applicant, and not just the owner or operator of the scanner that HSA achieved the target utilization".

Alliance has stated to Novant that it has no flexibility to make any changes to the mobile PET scanner's current schedule. Moreover, if the Alliance PET scanner goes down or is in need of repair for any reason, there is simply no second mobile PET scanner that would be permitted to serve the western portion of North Carolina. Consequently, should a significant service event arise for Alliance's mobile PET unit, the population in the HSA would clearly and unavoidably be negatively impacted. Despite Alliance's argument to the contrary, the current utilization of the only mobile PET scanner in western North Carolina shows that there is a clear need for a second mobile PET scanner and that that need should be addressed.

Proposed Solution. Although Novant submits that the comments filed by Alliance and NCBH concerning PET capacity and need should be rejected by the SHCC, the SHCC should consider allowing an applicant to apply for the fixed PET scanner available in the 2013 SMFP through either a fixed or a mobile alternative. PET is a unique modality because, although patient and physician need for PET services clearly exists, that need tends to exist in smaller volumes spread across numerous providers. Access to PET services is similarly unique. The total aggregate PET volume in HSAs I, II and III clearly supports additional PET scanner capacity, although individual facility volumes, along with NCBH's comments, indicate that there may be questionable need at any given single facility. PET services therefore, under certain circumstances, may be more appropriately offered in fractional capacity at several host sites through a mobile PET scanner. In addition, mobile PET scanners can provide a cost effective approach in introducing PET services to more rural providers in the service area. Accordingly, Novant submits that the SHCC should allow any applicant the option of applying for a mobile PET scanner as an alternative to applying for the fixed PET that is available in 2013 in order to help alleviate overutilization of the sole PET mobile scanner in the region and to address the need for additional PET services in HSA II.

Sincerely,

Barbara L. Freedy
Director, Certificate of Need
Novant Health, Inc.
blfreedy@novanthealth.org
PH: 336-718-4483

Tiffany Brooks
Manager, Certificate of Need
MedQuest Associates, Inc.
tbrooks@medquestmail.com
PH: 919-264-0415

File: Novant Response to Comments NCBH AllianceFINAL 8-15-12.docx