Novant Health and MedQuest Comments
on the July 29, 2015 Petition filed by
Alliance Healthcare Services
Regarding An Adjusted Need Determination for No New Mobile PET Scanners
Through the Conversion of Existing Fixed PET Scanners for the
Proposed 2016 North Carolina State Medical Plan
Pursuant to SMFP Policy TE-1 "Conversion of Fixed PET Scanners to Mobile PET Scanners"

Introduction

Alliance Healthcare Services ("AHS"), based in Newport Beach, California, has been the sole provider of mobile PET imaging in North Carolina since its first mobile PET CON application was approved in 2002. Policy TE-1 creates potential competition for AHS. To prevent potential competition for mobile PET in North Carolina, AHS's Petition essentially requests that Policy TE-1 be eliminated or, at the very least, suspended in the 2016 SMFP. Policy TE-1 was first adopted by the SHCC in the 2015 North Carolina annual State Medical Facilities Plan. SMFP Policy TE-1 is also included in the proposed 2016. 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 fixed PET scanner to a mobile PET scanner if the applicant(s) demonstrates in the CON Application that 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 not serve any host site that is not owned by the PET certificate holder or an entity related to the PET certificate holder such as a parent or subsidiary that is located in the county where any existing or approved fixed PET scanner is located, except as required by subpart (1).

**NOTE: the Council (SHCC) recommended the revision of the current East and West service areas to a statewide service area to allow flexibility in servicing mobile PET sites.*

As discussed in these comments, AHS's Petition is without merit, and Policy TE-1 should be included in the 2016 SMFP. Likewise, AHS' proposed adjusted need determination for the 2016 SMFP to allow no additional conversions of an existing fixed PET scanner to become a mobile PET scanner is without merit and should also be denied.

The Issue Is Not a Matter of An SMFP Adjusted Need Determination

The Petition begins with a flawed premise: that there should be an adjusted need determination to establish that no additional fixed PET scanners can be converted to mobile PET in the 2016 SMFP. See Petition, p. 1.However, Policy TE-1 is not a need determination at all. Rather, Policy TE-1 describes a process that facilities may follow if they wish to convert a fixed PET scanner to a mobile scanner. Specifically, a CON application must be filed that meets the three requirements of Policy TE-1. Only if the CON application is approved can the fixed PET scanner be converted to a mobile PET scanner. Moreover, there are other policies in the SMFP that facilitate similar activities such as Policy AC-4 for the Reconversion of Rehabilitation, Psychiatric, and SNF beds to Acute beds; Policy TE-2[1] for Intraoperative MRI Scanners for

[1] The spring 2015 petition to create a special allocation for one intraoperative MRI scanner (iMRI) for HSAs I-II-III was denied by the SHCC. However, the DHSR staff and SHCC recommended instead that Policy TE-2 "Intraoperative Magnetic Resonance Scanners: be added to the 2016 SMFP to identify qualified applicants. There were no summer 2015 comments or petitions which opposed Policy TE-2.

hospitals performing at least 500 inpatient neurosurgical cases annually; and Policy NH-2 to allow Continuing Care Retirement Communities to add SNF beds without regard to SMFP need determinations for SNF beds.

Policy TE-1 was thoroughly reviewed in connection with the process of drafting, preparing, and approving 2015 SMFP. The SHCC, its committees, and the DHSR Healthcare Planning staff devoted many hours to this issue and received input from all stakeholders, including AHS in a PET discussion group organized by the SHCC Chairman and DHSR Planning staff. There is no need to redo or undo this analysis. During the petition processes for the 2014 SMFP and 2015 SMFP, AHS fought vigorously to prevent competition in the mobile PET arena in North Carolina, where it currently has a monopoly. Ultimately, the SHCC determined that it is the best interests of the citizens of North Carolina to have competition, choice, and enhanced local access for the provision of mobile PET, and Policy TE-1 was included in the 2015 SMFP. Nothing in the language of Policy TE-1 states or implies that it was intended to be a one year trial or a demonstration project. And even before the draft 2015 SMFP, the issue of mobile PET was examined and debated in connection with the draft 2014 SMFP.

SMFP Policy TE-1 Will Not Increase the Inventory of Fixed & Mobile PET Scanners in North Carolina

Policy TE-1 does not envision adding PET scanners as is the case with a typical SMFP need determination which states, for example, that there is a need for an additional MRI scanner in a county or a need for additional beds in a county. Rather, Policy TE-1 allows conversion, *i.e.,* taking an existing fixed PET scanner and making it mobile.

The Petition then states that "[t]his requested adjustment is justified because there will be excess capacity of both mobile and fixed PET scanners throughout North Carolina if CON approval is granted for the 2015 CON application that proposes the conversion of one fixed PET to a mobile PET." Petition, page 1, paragraph 1, last sentence.

There are several problems with this statement. First, the CON application that AHS mentions is currently under review by the CON Section and was filed on June 15, 2015, the CON Application filing deadline specified by the state in the 2015 SMFP. A CON decision is not expected until late November 2015. The last SHCC meeting to finalize the draft 2016 SMFP is October 7, 2015, and the draft 2016 SMFP will be submitted to the Governor soon thereafter for review and signature. A decision on Policy TE-1 cannot be made based on a CON decision that has not happened. Second, AHS is implicitly inviting the SHCC to get involved in a CON determination, by arguing that a positive decision on the CON application will create excess capacity. AHS seems to be hoping that SHCC action on Policy TE-1 will cause the CON Section to deny the pending application. The SHCC does not, as a matter of practice, get involved in CON decisions, and it should not do so here. The SHCC is a gubernatorially appointed body with the responsibility to undertake health planning activities for the state and to develop the annual North Carolina State Medical Facilities Plan to reflect the decisions made on health planning for the state. The SHCC's responsibility (developing an SMFP) is distinct from the CON Section's role (reviewing and making decisions to approve or deny CON applications). The two functions should not be merged, as AHS implicitly urges. Third, there is a defined comment process to be followed under the CON Law for expressing concerns about a CON application to the CON Section. See NCGS Section 131E-185(a1)(1)-(2). AHS has taken full advantage of this process and has submitted written comments critiquing the Novant Health Forsyth Medical Center mobile PET CON Application. AHS has also requested that the CON Section hold a CON public hearing on this project, which is scheduled for August 18, 2015. Fourth, the Policy TE-1 conversion process does not, by definition, create excess capacity, because it is not additive to the overall inventory of PET scanners in North Carolina. Rather, an existing fixed PET scanner is taken out of service and replaced with a mobile scanner or a previously CON-approved but undeveloped fixed PET scanner is converted to a mobile PET scanner. If anything, Policy TE -1 reduces excess capacity by allowing underutilized resources to be put to productive use. Fifth, AHS offers no substantiation for its conclusory statement that "there will be excess

capacity of both mobile PET scanners and fixed PET scanners throughout North Carolina if CON approval is granted for the 2015 CON application that proposes the conversion of one fixed PET to a mobile PET." Indeed, the very next sentence of AHS's Petition states that the two mobile PET scanners now in operation [and owned by AHS] are operating at "high utilization." Policy TE-1 did not cause, nor will it cause in the future, underutilization of fixed PET scanners in North Carolina. As AHS acknowledges elsewhere in the Petition[2], there has not been, nor is there likely to be, a sudden surge of providers filing CON applications to convert fixed PET scanners to mobile scanners.

The State's PET Scanner CON Regulations are Not Outdated or In Conflict with SMFP Policy TE-1

The Petition states that the "PET administrative rules are outdated and in conflict with the requirements of Policy TE-1." Petition, p. 1. The PET administrative rules are applicable to CON applications, not to SMFP policies. The SHCC does not handle these administrative rules. There is a specific rulemaking process (defined in statute) AHS can follow if it believes the rules are outdated.

AHS's Seven Unique Characteristics of PET Utilization Will Not Cause the Proliferation of Unnecessary Health Services

AHS then lists seven "unique characteristics" of PET utilization. Petition, p.2. None of these so-called "unique characteristics" supports AHS's statement that "it would be in the best of the citizens of North Carolina to avoid the proliferation of unnecessary health services."

For example, AHS states that Policy TE-1 "restricts the group of potential applicants and potential host sites." That is correct, and is one way to control "the proliferation of unnecessary health services." AHS asserts that changes to PET inventories would result if fixed PET scanners are changed to mobile PET scanners. However, the change in the North Carolina PET scanner inventory is not an increase in the total number of fixed and mobile PET scanners, rather it is merely a change the mix of fixed and mobile PET scanners. Moreover, this kind of change in inventory does not harm the citizens of North Carolina, who are interested in having ready, local access to PET scanner services at affordable prices. Inventories frequently change without doing harm to the health planning process; this is not the unusual event that AHS portrays. AHS states that excess capacity of fixed PET scanners exists in each of the six Health Service Areas. To the extent there is excess capacity with regard to fixed PET scanners, this underscores the wisdom and relevance of Policy TE-1 which allows providers to take underutilized capacity and convert it to productive use, for the benefit of North Carolina citizens. AHS states there is no "placeholder" mechanism for pending CON applications filed under Policy TE-1. A placeholder mechanism is not required, but it is easy to add if the SHCC finds it useful.

AHS states there is no need methodology for mobile PET. There has never been a need method for mobile PET scanners since the time that fixed PET scanners became regulated by SMFP need determinations. As a practical matter, AHS has benefited for the past 13 years from the absence of a mobile PET need method in the SMFP, as it has been the sole provider of mobile PET scanner services from 2002 to the present time (2015). Finally, a need methodology is not required because Policy TE-1 is not additive to the overall inventory of PET scanners in North Carolina.

AHS's Data Assessment is Skewed and Unreliable

AHS states that "statewide total PET scanner utilization shows a declining trend." This is true only with respect to fixed PET scan volumes. Mobile PET scan volumes are growing. See Petition, p. 2. Moreover, in AHS' 7/24/2015 Comments critiquing the NHFMC mobile PET Scanner CON Application, AHS stated at page 12: *"Over the past three years the two Alliance [mobile] PET scanners provided a combined average of 5,744 annual scans or 2,872 procedures per unit….With the change to a statewide mobile PET service area, the two Alliance mobile PET scanners can increase annual capacity to exceed 3,000*

[2] AHS petition page 2, Bullet point #4: "Policy TE-1 restricts the group of potential applicants and potential host sites."

procedures per scanner per year." This reflects AHS' opinion that mobile PET volumes will grow in the future.

AHS states that fixed PET scanners are assigned to the six Health Service Areas of the state while mobile PET scanners have a statewide service area. This is correct at this time, but has nothing to do with the validity of Policy TE-1.

In the "Data and Analysis" portion of its Petition, AHS states that the compound annual growth rate for total combined fixed and mobile PET scans in North Carolina is -2.17 percent. There are factors not related to Policy TE-1 that impact the growth of PET scans performed on fixed PET scanners including rigorous prior authorization requirements by many health insurance companies; Yet AHS's chart shows that the volume of mobile PET scans is *growing.* In fact, it has grown by approximately 14.2% since 2009.

Thus, page 3 of AHS's Petition, which talks about "the decreasing utilization of PET scanning services," paints a false picture and leads to a false conclusion: "there is no unmet need that the population has for a mobile PET scanner as a more effective alternate to a fixed PET scanner. No need exists for additional fixed PET scanners anywhere in state. The proposed 2016 SMFP includes no methodology to quantify an unmet need for additional mobile PET capacity." Petition, p. 3. As the Petition itself shows, demand for mobile PET is growing. It will be the CON applicant's burden to demonstrate an unmet need and that it has chosen the least costly or most effective alternative. These are CON issues that cannot, and should not be decided in the context of Policy TE-1.

AHS's Concern About Negative Future Fixed PET Scanner Upgrades is Misplaced

AHS then discusses changes to technology that allow for lower radiation doses and reduced image acquisition time. AHS claims that it is concerned that that the overall surplus of PET capacity in North Carolina will cause providers to delay upgrading their scanners. Petition page 3, paragraph 3. AHS asserts that "[a]dditional mobile PET scanners will draw patients away from existing PET scanners, thereby causing these facilities to be less able to justify replacing outdated fixed PET technology." AHS offers no substantiation whatsoever for these statements. AHS's speculation provides no basis for overturning Policy TE-1.

AHS's Request for An Adjusted Need Determination Targeted to Mobile PET Scanners is Misdirected

On page 4 of the Petition, under the heading "Requested Adjusted Need Determination," AHS offers proposed Table 9P, which states that "[i]t is determined that there no need for additional conversions of fixed PET to mobile dedicated PET scanners anywhere in the state and no other CON reviews are scheduled." This table is wholly unnecessary since Policy TE-1 is not a need determination. Notably, there is no Table 9P equivalent in the PET scanner chapter of the 2015 SMFP. The total number of fixed and mobile PET scanners in the inventory in North Carolina will not increase, if NHFMC is permitted to convert one of its two fixed PET scanners to a mobile PET scanner. The same would be true for future CON applications filed pursuant to Policy TE-1. The "mix" of PET scanners (fixed v. mobile) would change, but the overall inventory does not change, as Policy TE-1 deals only with existing or approved PET scanners. Again, it is the CON process, not the SMFP that determines whether an applicant has demonstrated the need to convert a fixed PET scanner to a mobile PET scanner. Policy TE-1 merely provides the mechanism to file such an application.

AHS's Assessment of Adverse Effects Without Its Proposed Adjustment is Unsubstantiated

Under the heading, "Adverse Effects Will Ensue if the Adjustment is Not Made," AHS provides more unsubstantiated assertions. It states that "[e]xcess capacity of fixed and mobile PET scanners cannot be mitigated by substituting more mobile PET scanners for underutilized fixed PET scanners." Petition, p. 4. There is no evidence that the existing mobile PET scanners owned by AHS have excess capacity, nor would it be reasonable to make such an assumption given the double-digit growth AHS shows on page 2 of the petition. Moreover, in AHS's 7/24/2015 Comments critiquing the NHFMC mobile PET Scanner CON Application, AHS stated at page 12: *"Over the past three years the two Alliance [mobile] PET scanners provided a combined average of 5,744 annual scans or 2,872 procedures per unit….With the change to a statewide mobile PET service area, the two Alliance mobile PET scanners can increase annual capacity to exceed 3,000 procedures per scanner per year."* This reflects AHS' opinion that mobile PET volumes will grow in the future.

AHS then states that "[t]he declining statewide PET utilization means that the overall expense per PET scanner is already increasing because of the smaller number of annual scans." AHS provides no evidence that this is the case. Nor does this assertion seem reasonable. The expense of the existing PET scanners has already occurred; how can an expense that has already been incurred be "increasing?" Again, it will be up to the CON Section (not the SHCC) to decide whether an applicant has demonstrated the need to spend whatever the capital cost is to acquire a mobile PET scanner. AHS states that "[i]f yet another mobile PET scanner conversion from a fixed unit to mobile is approved and implemented, this unit can only increase its utilization by usurping the utilization that could have been performed at less cost with the existing PET capacity. AHS is once again putting the cart before the horse – it is impossible to know whether another CON application will be filed, and it will be the applicant's duty to satisfy the CON Law. AHS continues to ignore that mobile PET scans are growing. AHS is not entitled to perform all mobile PET scans in North Carolina, nor is it entitled to capture all of the growth in mobile PET scanning in North Carolina. Policy TE-1 does not "usurp" anything from AHS. . Further, AHS offers no substantiation that PET scans could have been performed at less cost with the existing PET capacity.

The Two Alternatives Considered by AHS Preserve the Status Quo Where AHS Maintains its Monopoly on Mobile PET Services in NC

In its evaluation of the alternatives, AHS states that it rejected the status quo because "… the proposed 2016 SMFP does not attempt to determine what would be the optimal number of fixed and mobile PET scanners to serve the needs of the population." Petition, p. 4. The SMFP does not need to make such a determination. AHS hypothesizes a second alternative which is the Adjusted Need Determination for Zero New Mobile PET scanners in the 2016 SMFP. Petition page 5, 1st paragraph. This alternative is somewhat self-serving as it preserves and extends the AHS dozen year monopoly on mobile PET services in this state.

On the last page of its petition (page 5, 1st paragraph) AHS states that "[t]he requested adjustment for no additional conversions. . . is the only alternative that responds to the excess capacity of fixed PET scanners and the decline in statewide utilization." AHS does not explain how this is possible. Eliminating Policy TE-1 would restrict competition and access for mobile PET services in North Carolina. The SHCC has already determined that access to additional mobile PET services in needed by citizens of North Carolina. The AHS petition is not in the best interest of North Carolina residents and should simply be denied.

Contrary to AHS's assertion, elimination of Policy TE-1 would result in unnecessary duplication. As AHS repeatedly states, overall utilization of fixed PET scanners is declining. These underutilized fixed PET scanners can either continue to be underutilized, or they can be put to more productive use. Policy TE-1 is designed to allow underutilized resources to be put to more productive use, thereby eliminating unnecessary duplication.

AHS's Proposed Adjusted Need Determination is Self-Serving and Does Not Further SMFP Basic Principles of Quality, Access and Value

The proposed adjustment (which makes it impossible for anyone else to file a CON application to convert a fixed PET scanner to a mobile scanner) does not further the basic principles of safety and quality, access and value. AHS states that "[i]f the requested change is approved, then there is an opportunity to update the PET administrative rules to include safety and quality standards that relate to Policy TE-1." Again, the rulemaking process is entirely separate from the SMFP process and is not relevant to Policy TE-1. If Policy TE-1 is jettisoned, as AHS wishes, then there would not be a reason to update the PET administrative rules.

AHS ends the petition with more supposition (Petition page 5, paragraph 6): that transportation costs make it highly unlikely that additional conversions of fixed PET scanners to mobile units are a cost effective strategy. Absolutely no data is provided showing why this would be the case. Further, it will be up to the CON applicant to demonstrate, under Criterion (4) of the CON review criteria, that it has chosen the least costly or most effective alternative. A petition to the SHCC is not the place to debate a CON application, especially one that has not even been filed.

Summary

In sum, Novant Health and MedQuest respectfully request that the SHCC deny the AHS Petition. SMFP Policy TE-1 is a carefully crafted and well thought out policy that addresses the interests of North Carolina citizens in having choice, local access, and competition. This is consistent with themes heard throughout this year in the legislature, as well. Over the last several years, various providers and petitioners have demonstrated the need for additional mobile PET capacity in North Carolina. The Technology & Equipment Committee as well as the SHCC has spent countless hours developing a reasonable solution that would provide a vehicle for creating mobile PET capacity without increasing the overall PET scanner inventory. AHS has offered no valid reason why the SHCC should undo all of its hard work after only one year of Policy TE-1's existence. Simply put, AHS's request should be denied because it fails to promote the basic tenets of competition, access and quality that represent the foundation for sound health planning in North Carolina.

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