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July 30, 2009

### VIA HAND DELIVERY

North Carolina State Health Coordinating Council  
c/o Medical Facilities Planning Section - DHR  
NC Department of Health and Human Services  
701 Barbour Drive  
Raleigh, NC 27603

DFS Health Planning  
RECEIVED

JUL 30 2009

Medical Facilities  
PLANNING SECTION

### **Re: Written Comment Regarding Proposed 2010 State Medical Facilities Plan**

Dear Council Members:

I am writing on behalf of our client Alliance HealthCare Services, Inc. ("Alliance") with regard to the Proposed 2010 State Medical Facilities Plan ("SMFP"). As provided on page 15 of the 2009 SMFP, the "[d]eadline for receipt by MFPS of . . . written comments regarding the Proposed 2010 SMFP" is July 31, 2009. As a result, this written comment is timely and should be considered by the State Health Coordinating Council ("SHCC") in its development of the 2010 SMFP.

The Proposed 2010 SMFP contains the following new language regarding mobile PET scanner service areas:

A mobile PET scanner's service area is the planning region in which the scanner is located. There are two mobile PET scanner planning regions, the west region (HSAs I, II, and III as described in Appendix A) and the east region (HSAs IV, V, and VI as described in Appendix A).

This change to the SMFP was proposed by the SHCC's Technology and Equipment Committee at its meeting on April 29.<sup>1</sup>

<sup>1</sup> Alliance attempted to voice its concerns about this proposed language to the Committee members when they were considering this addition to the SMFP. Alliance provided copies of its written comment to the Planning Section the day before the Committee meeting. However, the Committee Chair deemed the written comment to be an untimely "petition" for a statewide change and, therefore, declined to provide copies of Alliance's comment to the other members of the Committee. It was only after the Committee's discussion of this issue had concluded that the Chair mentioned receipt of this comment to the other Committee members and, upon request of several Committee members, provided them with copies of the comment. As a result, when the Committee voted in favor of this change to the SMFP, it did so without the benefit of Alliance's comment on this proposed change.

If this language were adopted as part of the final 2010 SMFP, it would be the first time that the SMFP defined a “service area” for mobile PET scanners. No prior SMFP has contained a definition of the “service area” for mobile PET scanners.

This proposed definition of the service area for mobile PET would simply equate the “planning regions” for mobile PET scanners to their “service areas.” This would essentially divide the State in half, such that HSAs I, II and III would comprise a western mobile PET service area and HSAs IV, V, and VI would comprise an eastern mobile PET service area. It would draw a line across the state and prevent a mobile PET scanner located in the eastern half of the State from providing any services on the western side of this line and visa versa. While this line may make sense as a “planning region” for purposes of health planning, it is contrary to one of the fundamental purposes of the CON Law and the SMFP—increasing access to healthcare services.

Accordingly, Alliance strongly opposes the addition to the SMFP of a service area for mobile PET that is defined in this manner. If the SHCC deems it appropriate to add language to the SMFP defining the service area for mobile PET scanners, then Alliance respectfully suggests that the service area should be the entire state.

In fact, this is exactly how the Proposed 2010 SMFP defines the service area for another type of mobile medical equipment – lithotripters. According to the Proposed 2010 SMFP, of the 14 lithotripsy units in North Carolina only one is a fixed unit and the other 13 are mobile units. The Proposed 2010 SMFP provides the following new language regarding the service area of lithotripters:

A lithotripter’s service area is the lithotripter planning area in which the lithotripter is located. The lithotripter planning area is the entire state.

#### **1. Background of Mobile PET Scanners in North Carolina**

The SMFP has only once included a need determination for mobile PET scanners in North Carolina. That was in the 2002 SMFP, in response to a petition submitted by Alliance. This need determination provided that one mobile PET scanner was needed to serve sites in Planning Region 1 (the three western HSAs) and one mobile PET scanner was needed to serve sites in Planning Region 2 (the three eastern HSAs). Alliance applied for and obtained the two CONs for these two mobile PET scanners, which are the only two mobile PET scanners operating in North Carolina. Since 2003, Alliance has used one of the scanners to only serve sites in the eastern half of the State and the other scanner to only serve sites in the western half of the State.

Since 2003, there have been significant changes in the need for mobile PET services across the State. Alliance’s mobile services have allowed six of its (now former) host sites to

develop the patient volumes necessary to obtain CONs for fixed PET scanners. In addition to losing some host sites, Alliance has also added several new host sites over the years. As a result of these changes, Alliance's eastern scanner now serves eight host sites, while its western scanner currently serves 14 sites—nearly twice as many.

It is, of course, no surprise that there have been changes in where mobile PET scanner services are needed across North Carolina. That is the whole point of mobile equipment—to adjust to changing needs and provide local access to important healthcare services where there is a need. Recognizing this, the Department of Health and Human Services routinely grants declaratory rulings, allowing CON-approved mobile healthcare equipment (such as MRI, cardiac catheterization, and lithotripsy) to change host sites as the need for these services changes over time.

2. **There Are Two Main Problems with Defining the “Service Area” for Mobile PET Scanners as the “Planning Region”.**

The proposal to define the “service area” for mobile PET scanners as the “planning region” for this equipment is problematic for two main reasons.

First, the planning regions that divide the State in half simply do not correspond to the current demand for mobile PET services, which is constantly evolving. This is shown quite starkly by the fact that, while the planning regions may have been reasonably balanced when they were developed in 2001, Alliance's western scanner is currently providing services at 14 host sites, while its eastern scanner is currently providing services at eight sites. At one point within the past year, Rowan Regional Medical Center requested additional days of mobile PET services from Alliance, but Alliance was unable to provide the requested services at that time because its western PET scanner's route was then full. Alliance could, however, have provided the requested services on its eastern PET scanner at that time.

This is just a snapshot of the demand as it exists today, which is constantly evolving over time.<sup>2</sup> Perhaps five years from now, the western PET scanner will have available capacity and the eastern PET scanner will not. Either way, it does not serve the purposes of the CON Law to define a service area for this mobile equipment in a way that will result in it sitting idle on one side of an artificial boundary while healthcare providers on the other side of the line would like access to it for the benefit of their patients.

Second, defining the service area in terms of the planning region boundary would prevent Alliance from providing occasional cross coverage when one scanner is temporarily unavailable. Equipment requires maintenance and repair, staff becomes ill and unable to work, and weather

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<sup>2</sup> In fact, Alliance was just approved on July 21 to add two host sites to its eastern scanner's route, and on July 20 Alliance requested the addition of three host sites to its western scanner's route, which is now possible because of reduced demand at three existing western host sites, and Alliance's ability to therefore “split days” of service between host sites. Once Alliance begins serving these new sites, the eastern scanner will serve ten host sites, while its western scanner will serve 17 sites.

conditions ranging from snowstorms to hurricanes can periodically make it impossible for a mobile PET scanner to meet its scheduled route. The results to the patients, their physicians and other providers include wasted time, frustrated appointments, required rescheduling, increased travel times and expenses, increased time away from work and lost income, and delays in diagnoses.

**3. A Statewide Service Area for Mobile PET is a Better Alternative.**

As a result, it is Alliance's position that the 2010 SMFP should not be revised to add new language that defines the service area for mobile PET scanners as the planning regions for this equipment. A far wiser approach would be for the SHCC to adopt language that recognizes a statewide service area for these limited, important, and expensive health care resources. This would allow Alliance the flexibility to provide these services when and where they are needed across the State. This would also allow Alliance to more readily respond to temporary situations by using one of its mobile PET scanners to cover for the other one, whenever possible.

Further, it must be noted how the Proposed 2010 SMFP addresses the service area for other types of mobile medical equipment, which is set forth below.

<u>Type of Mobile Medical Equipment</u>	<u>Service Area Definition in Proposed 2010 SMFP</u>
MRI	No service area defined
Cardiac Catheterization	No service area defined
Lithotripters	"entire state"
PET	State divided in half

As noted above, of the four types of mobile medical equipment addressed in the Proposed 2010 SMFP, there is no service area definition provided for mobile MRI or mobile cardiac catheterization equipment. Instead, the Proposed 2010 SMFP only addresses the service area for fixed MRI and cardiac catheterization. With regard to mobile lithotripters, the service area is defined as the "entire state."

Mobile PET is the only type of mobile medical equipment that the Proposed 2010 SMFP has singled out for this type of limitation on its service area. There is no good policy reason why North Carolina's 13 mobile lithotripters should have a service area that spans the entire State, while the only two mobile PET scanners in the State are each limited to mutually-exclusive halves of the State.

4. **Changes in Host Sites for Mobile PET Will Still Require Approval By the Department.**

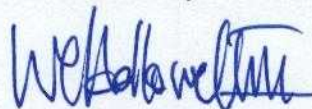
Even if the SHCC decides to define the service area for mobile PET scanners as statewide, Alliance will continue to be required to seek a declaratory ruling from the Department prior to adding any new host sites for its mobile PET scanners. The Department has well-settled standards for evaluating such requests that it has applied to innumerable requests from providers of mobile medical equipment over the years.

Having a statewide service area for mobile PET services would just mean that the Department would not be compelled to rigidly divide the State in half because of a "service area" definition in the SMFP.

5. **Conclusion.**

In conclusion, the definition of "service area" for mobile PET scanners in the Proposed 2010 SMFP should not be adopted. If the SHCC deems it appropriate to define a service area for mobile PET scanners in the SMFP, then the service area should be defined as the entire state.

Sincerely,  
Nelson Mullins Riley & Scarborough LLP



Wallace C. Hollowell, III

cc: Ms. Angie Caporiccio  
Mr. David French