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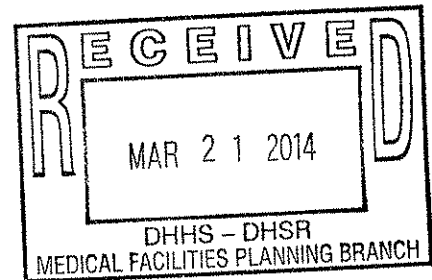
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Lynn S. Pitman  
Associate Vice President

March 21, 2014

Mr. Jerry Parks  
Chairman, North Carolina State Health Coordinating Council  
c/o North Carolina Division of Health Service Regulation  
Medical Facilities Planning Branch  
2714 Mail Service Center  
Raleigh, NC 27699-2714



Dear Chairman Parks:

Thank you for the opportunity to comment on the Petition submitted by Novant Health, Inc. and MedQuest Associates, Inc. ("Petitioners") to the State Health Coordinating Council ("SHCC"). The Petition requests:

1. The establishment of a Policy to allow existing hospital providers who own and operate more than one CON-approved fixed PET/CT scanner, for a one year filing period during the 2015 SMFP plan year (1/1/2015-12/31/2015), to seek approval to convert one of their existing fixed PET/CT scanners to a mobile PET/CT scanner through the replacement equipment provision identified at N.C. Gen. Stat. §131E-176(22a); and
2. Replacement of the mobile East and West mobile PET/CT service areas defined in current SMFPs, with a mobile PET/CT service area that includes the entire state of North Carolina for the 2015 SMFP plan year and beyond.

Wake Forest Baptist Health opposes the Petitioners' first request,<sup>1</sup> because it conflicts with the spirit and intent of the CON Law by eliminating any requirement that providers actually demonstrate a need for mobile PET/CT services. Further, the proposed Policy will do nothing to ensure that the potential need for additional PET/CT services in rural counties is met. Instead, it would simply allow the unnecessary proliferation of PET/CT services in urban areas where no additional PET/CT scanners are needed.

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<sup>1</sup> Wake Forest Baptist Health does not oppose expansion of the service area for existing mobile PET/CT scanners to include the entire State. Further, for the reasons discussed below, if the SHCC determines that additional mobile PET/CT scanners are needed, Wake Forest Baptist Health does not oppose a proposed statewide service area for such services, so long as any need determination or policy related to additional mobile PET/CT services requires the applicant to show that they will serve underutilized rural populations.

**NEED DETERMINATIONS FOR ADDITIONAL PET/CT SCANNERS**

N.C. Gen. Stat. §131E-175 sets forth the General Assembly's Findings of Fact outlining the bases for North Carolina's CON law. Those findings of Fact include the following:

(7) That the general welfare and protection of lives, health, and property of the people of this State require that new institutional health services to be offered within this State be subject to review and evaluation as to need, cost of service, accessibility to services, quality of care, feasibility, and other criteria as determined by provisions of this Article or by the North Carolina Department of Health and Human Services pursuant to provisions of this Article prior to such services being offered or developed in order that only appropriate and needed institutional health services are made available in the area to be served (emphasis added).

New institutional health services such as PET/CT scanners are subject to the annual need determinations in the SMFP. N.C. Gen. Stat. §131E-176(16) f1 and (25), §131E-183(a)(1). The service area for fixed PET/CT scanners has been the Health Service Area ("HSA") where the need is generated. The current service area for the two approved mobile PET scanners in the State are the Eastern three and Western three HSAs. The 2014 SMFP does not identify a need for any additional fixed or mobile PET/CT scanners in the State.

**RECENT SHCC INVESTIGATION INTO ADDITIONAL MOBILE PET/CT NEED**

As reported at the March 5, 2014 SHCC Meeting, by Christopher Ullrich, M.D., Chair of the Technology and Equipment Committee, a meeting of interested parties was convened on February 5, 2014 to discuss the need for additional PET/CT service (hereinafter, the "PET Working Group"). Much of that discussion related to the potential need for additional mobile PET/CT services. In this regard, Dr. Ullrich reported that the PET Working Group found that the two mobile PET/CT scanners owned by Alliance are fully utilized, and there was agreement that there is need to make mobile PET/CT more accessible. Options discussed included expanding Alliance's mobile PET/CT service areas statewide, identifying a need for new mobile PET/CT scanners, and allowing existing providers to file CON applications to convert existing fixed PET/CT scanners to mobile PET/CT scanners. However, there was a general consensus among the PET Working Group that to the extent that there is a need for more mobile PET/CT access, it is in the rural, not urban counties. Patients in North Carolina's urban counties currently have adequate access to PET/CT services.

### NOVANT'S PETITION

Petitioners' Petition seeks to circumvent the requirement to demonstrate a need for a mobile PET/CT scanner, and simply allow their related hospitals (or any other hospital with two or more fixed PET/CT scanners) to replace an existing PET/CT scanner through the replacement equipment exemption in N.C. Gen. Stat. §131E-176(22a) and 131E-184(a)(7). The Petition is flawed and inconsistent with sound health planning practices for multiple reasons.

#### **1. The Petition Would Allow the Provider to Change the Area Served**

First, the Petition would allow a provider to significantly change the area its PET/CT scanner was approved to serve. This was one of the reasons that the Director of the Division of Health Service Regulation (the "Director") in 2011 denied a Declaratory Ruling Request by Novant and Forsyth Medical Center, Inc. to convert an approved CON for a fixed PET/CT scanner to a mobile PET/CT scanner.

*Petitioners' contention that the mobile scanner would simply serve the same population originally proposed for the fixed scanner is without merit. In the same manner that Petitioners anticipated that residents of Rowan County would travel to the fixed scanner in Forsyth County, it is reasonable to anticipate that locating a mobile scanner in Rowan County would extend the radius of potential patients beyond the borders of Rowan County into territory that was not included in Petitioners' original proposal.*

*Petitioners' proposal constitutes a material change in the physical location and scope of the project and must be denied.*

See Declaratory Ruling, pp. 3-4, Exhibit A hereto. Allowing the Petition would have the same result.

Further, while Petitioners may claim that a mobile PET/CT scanner acquired pursuant to the Policy would simply replace mobile PET/CT services currently provided by Alliance Imaging at their existing hospitals, nothing in the proposed language of the Policy would require that. Under the Policy as proposed, any hospital which meets its qualifications could provide mobile PET/CT services anywhere in the State, regardless of whether there already is adequate access to PET/CT services.

This issue was specifically discussed at the March 5, 2014 SHCC meeting. One of the SHCC members commented that any new Policy or methodology needs to provide some restraint on moving mobile PETs to counties with existing PET/CT sites. He believed that the SHCC had made a mistake in allowing the expansion of mobile MRI services without limiting that

expansion to rural counties where that service was not then available, resulting in extensive and unnecessary mobile MRI utilization in urban counties.

## **2. Petitioners' Current Mobile PET/CT Service Does Not Serve Rural Counties**

As previously noted, the general consensus among the PET Working Group was that the need for mobile PET/CT services is in rural, not urban counties. However, all of the existing Novant hospital sites referenced in the Petition are located in urban counties, as is evidenced by data from the North Carolina Rural Economic Development Center, Inc. (the "Rural Center").

The Rural Center is a nonprofit organization which develops, promotes and implements economic strategies to improve the quality of life in North Carolina's rural communities. The Rural Center serves North Carolina's 85 rural counties, focusing on individuals with low to moderate incomes and communities with limited resources.<sup>2</sup> The Rural Center focuses on population density in a given county to determine whether a county is considered rural or urban. If a county has a population density of 250 people per square mile or less, it is automatically considered rural. Of the 85 counties that the Rural Center serves, 80 qualify under that criterion. There are five rural transitional counties that have population densities in excess of 250 people per square mile, but those five counties still retain significant rural characteristics. A map of the entire state, identifying the counties designated by the Rural Center as rural and urban, is attached hereto as Exhibit B.

Petitioners' Petition proposes to serve four existing Novant Health hospital sites and two potential future sites. According to the Rural Center map and classifications, five of the combined six existing and potential sites in the Petition are located in urban areas. All four of the existing sites are in urban communities/counties and the potential Kernersville, Forsyth County site is in an urban community. The only site not in an urban community is the potential site of Louisburg, Franklin County<sup>3</sup>.

The purpose of expanding the mobile PET/CT services to rural communities is not met by the practical reality of the results achieved by the Petitioners' proposal. None of the existing sites shown in the proposal are in rural communities. One of the potential sites is even in an urban community. All of the existing hospitals using Alliance for mobile PET/CT service are in relatively close proximity to existing fixed PET/CT scanners in Forsyth, Guilford and Mecklenburg Counties. According to the 2014 SMFP, all of those PET/CT scanners are operating

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<sup>2</sup> Source: [http://www.ncruralcenter.org/index.php?option=com\\_content&view=article&id=66&Itemid=107](http://www.ncruralcenter.org/index.php?option=com_content&view=article&id=66&Itemid=107)

<sup>3</sup> See Petition, pp. 2-3.

at an average utilization below the 80% capacity threshold required to determine additional need in the HSA.<sup>4</sup>

And as noted below, the single potential future site that is in a rural community is within very close proximity to multiple providers that have PET/CT scanners with an average utilization below the 80% capacity threshold. For example, in HSA IV, four providers with six existing fixed dedicated PET/CT scanners<sup>5</sup> had an average utilization of 31.21% for 2012.<sup>6</sup> Further, the potential site in Louisburg, Franklin County is only 33 miles from the fixed dedicated PET/CT scanner at Nash General Hospital<sup>7</sup>, which had the third lowest utilization in the state at 14.73% in 2012.<sup>8</sup>

- Louisburg to Duke – 43.2 miles – 74.57% (2 scanners)
- Louisburg to WakeMed Cary – 44.1 miles – 22.7% (1 scanner)
- Louisburg to Rex – 35.2 miles – 57.63% (1 scanner)
- Louisburg to UNC – 56.6 miles – 32.33% (2 scanners)
- Louisburg to Nash General – 33.6 miles – 14.73% (1 scanner)

#### CONCLUSION

Wake Forest Baptist Health supports the SHCC's efforts to analyze current mobile PET/CT utilization and determine whether additional mobile PET/CT services are needed to serve patients residing in rural counties who do not have adequate access to PET/CT services. Petitioner's Petition does nothing to achieve that goal. The proposed Policy, as drafted, would allow an existing provider with two or more fixed PET/CT scanners to convert one of those fixed PET/CT scanners to a mobile PET/CT scanner, without any requirement to show that the areas to receive mobile PET/CT services actually need that service. That is not sound health planning, and could result in the unnecessary proliferation of PET/CT services in adequately served urban areas.

If the SHCC determines that conversion of some underutilized fixed PET/CT scanners to mobile PET/CT scanners makes sense, any provider proposing such conversion should be required to file a CON application and demonstrate to the CON Section that their specific proposal is needed. Further, the SHCC should limit such conversion to proposals seeking to provide mobile PET/CT services to underserved rural areas. Otherwise, the concerns raised at the March 5,

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<sup>4</sup> See 2014 SMFP at Table 9L, page 140.

<sup>5</sup> Duke University Hospital (2), UNC Hospitals (2), Rex Hospital (1), Wake PET Services/WakeMed (1).

<sup>6</sup> See 2014 SMFP at Table 9L, page 140.

<sup>7</sup> Franklin County and Nash County are contiguous counties, although they are located in HSA IV and HSA VI, respectively.

<sup>8</sup> See 2014 SMFP at Table 9L, page 140.

Mr. Parks  
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2014 SHCC meeting about the proliferation of unneeded mobile MRI scanners in urban areas will be repeated for PET/CT services.

Sincerely,

A handwritten signature in black ink, appearing to read "Lynn S. Pitman". The signature is written in a cursive style with a large initial "L".

Lynn. S. Pitman  
Associate Vice President, Strategic and Business Planning  
Wake Forest Baptist Health

NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES  
 DIVISION OF HEALTH SERVICE REGULATION  
 RALEIGH, NORTH CAROLINA

IN RE: REQUEST FOR DECLARATORY )  
 RULING BY NOVANT HEALTH, INC. AND )  
 FORSYTH MEMORIAL HOSPITAL, INC. ) DECLARATORY RULING  
 d/b/a FORSYTH MEDICAL CENTER. )  
 Project ID No. G-8129-08 )

I, Drexdal Pratt, as Director of the Division of Health Service Regulation, North Carolina Department of Health and Human Services ("Department" or "Agency"), do hereby issue this Declaratory Ruling pursuant to North Carolina General Statute § 150B-4 and 10A NCAC 14A .0103 under the authority granted me by the Secretary of the Department of Health and Human Services.

Novant Health, Inc. ("Novant") and Forsyth Memorial Hospital, Inc., d/b/a Forsyth Medical Center ("Forsyth") (collectively "Petitioners") have requested a declaratory ruling that would allow the acquisition of a mobile positron emission tomography ("PET") / computed tomography ("CT") scanner rather than the originally proposed fixed site PET scanner, contending that such acquisition would not constitute a change in scope for purposes of N.C. Gen. Stat. § 131E-181 of the certificate of need ("CON") law, and that the location change would not affect Forsyth's material compliance with representations made in the CON application or the conditions imposed upon the CON. The CON law would require a full review of Forsyth's proposal if it represented a material change in the physical location or scope of the project. N.C. Gen. Stat. § 131E-181(a). This ruling will be binding upon the Department and the entity requesting it, as long as the material facts stated herein are accurate. This ruling pertains only to the matters referenced herein. Except as provided by N.C.G.S. § 150B-4, the Department expressly reserves the right to make a prospective change in the interpretation of the

statutes and regulations at issue in this Declaratory Ruling. Denise M. Gunter of Nelson Mullins Riley & Scarborough, LLP has requested this ruling on behalf of Novant and Forsyth, and has provided the material facts upon which this ruling is based.

Comments in opposition to this request were received by the following:

- (1) Terrill Johnson Harris, of Smith Moore Leatherwood LLP, on behalf of Cone Health.
- (2) David J. French on behalf of Alliance Imaging Inc.

#### STATEMENT OF THE FACTS

The 2008 State Medical Facilities Plan ("SMFP") contained two need determinations for fixed site PET scanners: one for Health Service Area ("HSA") II and one for HSA III. On November 13, 2008, the CON section issued a CON to Novant and Forsyth to acquire a fixed site PET/CT scanner to be installed at the Forsyth facility located at 3333 Silas Creek Parkway, Winston-Salem, NC 27103, known as Project ID No. G-8129-08. According to Novant and Forsyth, this project has not yet been implemented. Carolinas Medical Center - Union ("CMC - Union") received the CON allowing acquisition of a fixed site PET scanner for HSA III. The 2008 SMFP concluded there was no need for any mobile PET scanners anywhere in the state.

Rather than acquire a fixed site PET/CT scanner, Petitioners seek to acquire a mobile PET/CT scanner that would be operated at Forsyth as authorized by the previously issued CON, but, in addition, would be operated at Thomasville Medical Center ("Thomasville") located in Davidson County, Rowan Regional Medical Center ("Rowan") located in Rowan County, and Kernersville Medical Center ("Kernersville") located in Forsyth County, each of which is owned by Novant.



## ANALYSIS

N.C. Gen. Stat. § 131E-181(a) provides that a CON "shall be valid only for the defined scope, physical location, and person named in the application." Petitioners' proposal to acquire a mobile PET/CT scanner must be denied based upon the provisions of N.C. Gen. Stat. § 131E-181(a).

The proposal constitutes a material change in the physical location and scope of the proposed project. As set forth in the factual statement above, Project ID No. G-8129-08 originally contemplated utilization of a fixed PET/CT scanner at the Forsyth facility located in Winston-Salem. Petitioners now propose utilization of a mobile scanner at the Forsyth facility in addition to the Thomasville, Rowan, and Kernersville facilities.

Pursuant to the 2008 SMFP, under which Petitioners originally acquired a fixed PET/CT scanner for HSA II, "there is no need for any additional mobile dedicated PET scanners anywhere in the state." 2008 SMFP at 117. In fact, there has not been a need for any additional mobile PET scanners anywhere in the state since Petitioners' application for the fixed PET/CT scanner. See 2009 SMFP at 133, 2010 SMFP at 139, 2011 SMFP at 143. Similarly, the proposed 2012 SMFP concludes there is no need for any additional mobile PET scanners in the state. In addition, CMC-Union was awarded the CON to acquire a fixed site PET scanner to serve the need identified in the 2008 SMFP for HSA III.

Not only does the methodology prevent additional acquisitions of mobile PET scanners, acquiring a mobile PET scanner would constitute a material change in the scope of the project as well as the physical location of the project given the proposed mobile sites. Petitioners' contention that the mobile scanner would simply serve the same population originally proposed for the fixed scanner is without merit. In the same manner that Petitioners anticipated that


residents of Rowan County would travel to the fixed scanner in Forsyth County, it is reasonable to anticipate that locating a mobile scanner in Rowan County would extend the radius of potential patients far beyond the borders of Rowan County into territory that was not included in Petitioners' original proposal.

Petitioners' proposal constitutes a material change in the physical location and scope of the project and must be denied.

#### CONCLUSION

For the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that the proposal to acquire a mobile PET/CT scanner rather than a fixed site PET/CT scanner constitutes a material change in the physical location and scope of the project, violates N.C. Gen. Stat. § 131B-181, and, therefore, must be denied.

This the 24 day of October, 2011.

  
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Drexel Pratt, Director  
Division of Health Service Regulation  
N.C. Department of Health and Human Services

**CERTIFICATE OF SERVICE**

I certify that a copy of the foregoing Declaratory Ruling has been served upon the agency party by facsimile and certified mail, return receipt requested, by depositing the copy in an official depository of the United States Postal Service in a first-class, postage pre-paid envelope addressed as follows:

**CERTIFIED MAIL**

Denise M. Gunter  
Nelson Mullins Riley & Scarborough LLP  
380 Knollwood Street, Suite 530  
Winston-Salem, NC 27103

Courtesy Copy:

David J. French  
Consultant to Alliance Imaging, Inc.  
Post Office Box 2154  
Reidsville, NC 27323-2154

Terrill Johnson Harris (for Cone Health)  
Smith Moore Leatherwood LLP  
Post Office Box 21927  
Greensboro, NC 27420

This the 24<sup>th</sup> day of October, 2011.



Jeff Horton  
Chief Operating Officer

