

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

**IN RE: REQUEST FOR DECLARATORY)
RULING BY ALLIANCE HEALTHCARE)
SERVICES, INC.) DECLARATORY RULING
Project I.D. No. F-6650-02)
Project I.D. No. H-6706-02)**

I, Mark Payne, 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 Statutes § 150B-4 and 10A NCAC 14A .0103, under the authority granted me by the Secretary of the Department of Health and Human Services.

Alliance Healthcare Services, Inc. (“Petitioner”) requests a declaratory ruling that the addition of three host sites to the route of either or both of its two mobile positron emission tomography (“PET”) scanners is consistent with the terms of the certificates of need (“CON”) previously issued to Petitioner. 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. David French, Consultant to Alliance Healthcare Inc., has requested this ruling on behalf of Petitioner and has provided the material facts upon which this ruling is based.

STATEMENT OF THE FACTS

The 2002 State Medical Facilities Plan (“SMFP”) included an adjusted need determination for two mobile PET scanners, one to serve host sites in PET Planning Region 1, which included Health Service Areas (“HSAs”) I, II, and III, and one to serve host sites in PET Planning Region 2, which included HSAs IV, V, and VI. Petitioner was issued a CON, effective October 13, 2003, for

Project ID #F-6650-02 to acquire a mobile PET scanner (FID #20756, Alliance I) to serve three hospitals in Rowan, Cabarrus, and Guilford counties in PET Planning Region 1. Petitioner was also issued a CON, effective May 1, 2003, for Project ID #H-6706-02 to acquire a mobile PET scanner (FID #21069, Alliance II) to serve five hospitals in Moore, Nash, Pasquotank, Robeson, and Wayne counties in PET Planning Region 2.

The 2015 SMFP, page 138, includes the following change in policy: “*A mobile PET scanner has a statewide service area.*” In March 2015, Petitioner obtained letters of material compliance for its mobile PET scanners to modify their service areas to the statewide mobile PET service area. In July 2015, Petitioner obtained a declaratory ruling that each of the two mobile PET scanners be allowed to serve any and/or all of Petitioner’s approved host sites in North Carolina to improve patient access, achieve operational efficiencies and provide cross-coverage on an as-needed basis.

As a result of subsequent declaratory rulings allowing changes in host sites, Project ID #F-6650-02 (Alliance I) currently serves Carolinas HealthCare System Cleveland, Watauga Medical Center, Caldwell Memorial Hospital, Carolinas HealthCare System Blue Ridge (Morganton and Valdese Campuses), Harris Regional Hospital (WestCare Health System), Novant Health Rowan Medical Center, Lake Norman Regional Medical Center, Margaret R. Pardee Hospital, Carolinas Healthcare System Stanly, Novant Health Matthews Medical Center, Novant Health Huntersville Medical Center, Randolph Hospital, Novant Health Thomasville Medical Center, Northern Hospital of Surry County, Rutherford Regional Medical Center, and Park Ridge Health in HSAs I, II, and III; and Project ID #H-6706-02 (Alliance II) currently serves Sentara Albemarle Medical Center, Carteret General Hospital, Duke Raleigh Hospital, Johnston Health, Lenoir Memorial Hospital, Onslow Memorial Hospital, The Outer Banks Hospital, Scotland Memorial Hospital, Southeastern Regional Medical Center, Wayne Memorial Hospital, LifePoint Wilson Medical Center, and Maria Parham

Hospital in HSAs IV, V, and VI. On April 17, 2017, Petitioner obtained a declaratory ruling adding Vidant Roanoke-Chowan Hospital in Ahoskie, Hertford County, HSA VI as an additional host site for either or both of its two mobile PET scanners.

Petitioner now requests, using either or both of its two mobile PET scanners, to be allowed to serve three additional host sites: (1) Duke LifePoint Haywood Regional Medical Center in Clyde, Haywood County, HSA I; (2) Carolinas Medical Center Lincoln in Lincolnton, Lincoln County, HSA III; and, (3) Vidant Duplin Hospital in Kenansville, Duplin County, HSA VI. Petitioner represents that the proposed sites each have an existing mobile pad that can accommodate mobile PET/CT services with no additional capital cost. The addition of the three proposed host sites will not change the scope of the approved projects or the costs and charges for the Petitioner or the public. The service agreement that will be used for the PET scanners at the Duke LifePoint Haywood Regional Medical Center, Carolinas Medical Center Lincoln, and Vidant Duplin Hospital host sites will be substantially similar to the services agreement that Petitioner has for its other host sites. Petitioner represents that it is committed to continue to comply with all applicable conditions of its CONs and all applicable regulations.

ANALYSIS

N.C.G.S. § 131E-181(a) provides that “[a] certificate of need shall be valid only for the defined scope, physical location, and person named in the application.” The recipient of the CON must also materially comply with the representations made in the CON application. N.C.G.S. § 131E-181(b). If Petitioner’s proposal were to represent a material change in the physical location or scope of the project, the CON law would require a full review of the proposal. N.C.G.S. § 131E-181(a).

Based on the facts as presented by Petitioner, Petitioner's proposal does not constitute a material change in the physical location or scope of the projects and is allowable. The two CONs, as issued, restricted the PET Planning Region and therefore the service area in which each mobile PET scanner could be utilized. However, subsequent declaratory rulings allowed the PET service area for the two PET scanners to be statewide and also allowed each of the two PET scanners to serve all of Petitioner's approved PET mobile host sites in North Carolina, as needed. The addition of the proposed host sites will not negatively impact the quality, scope, or availability of services provided by the mobile PET program, and will not increase costs or charges. Petitioner agrees to comply with all the material requirements and representations made in its original CON applications.

N.C. Gen. Stat. §131E-189(b) allows the Agency to withdraw Petitioner's CON if Petitioner either fails to develop the service in a manner consistent with the representations made in the Petitioner's application or with any conditions that were placed on the CON. Based upon the information provided by Petitioner, the proposed addition of Duke LifePoint Haywood Regional Medical Center, Carolinas Medical Center Lincoln, and Vidant Duplin Hospital as additional host sites for Project ID #H-6706-02 and Project I.D. # F-6650-02 will not be developing the projects in a manner that is materially different from the representations made in its application, nor will it be developing its project in a manner that is inconsistent with any of the conditions that were placed on its CONs.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that Petitioner's proposal will not violate N.C.G.S. § 131E-181, and will not constitute a failure to satisfy a condition of the certificate of need in violation of N.C.G.S. § 131E-189(b).

This the _____ day of May, 2017.

Mark Payne, Director
Division of Health Service Regulation
N.C. Department of Health and Human Services

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that I have this day served the foregoing Declaratory Ruling upon the PETITIONER by certified mail, return receipt requested, by causing a copy of same to be placed in the United States Mail, first-class, postage pre-paid envelope addressed as follows:

CERTIFIED MAIL

David J. French
Consultant to Alliance Healthcare Inc.
P.O. Box 2154
Reidsville, NC 27323

This the _____ day of May, 2017.

Cheryl Ouimet
Chief Operating Officer