

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

<b>IN RE: REQUEST FOR DECLARATORY</b>	)	
<b>RULING BY NASH IMAGING, L.L.C.</b>	)	<b>DECLARATORY RULING</b>
<b>AND</b>	)	
<b>NASH COMMUNITY HEALTH</b>	)	
<b>SERVICES, INC.</b>	)	
	)	

I, Jeff Horton, Acting Director of the Division of Health Service Regulation (the “Department” or the “Agency”), hereby issue this declaratory ruling to Nash Imaging, L.L.C. and Nash Community Health Services, Inc. (collectively, “Petitioners”) pursuant to N.C.G.S. § 150B-4, 10A NCAC 14A.0103, and the authority delegated to me by the Secretary of the North Carolina Department of Health and Human Services. Petitioners have filed a Declaratory Ruling Request (the “request”) asking the Department to issue a declaratory ruling that (1) there is good cause to transfer to Nash Hospitals, Inc. (the “Hospital”) the certificate of need (“CON”) issued to Nash Imaging, L.L.C. and Nash Community Health Services, Inc. for Project I.D. No. L-7499-06, in accordance with provisions in N.C. Gen. Stat. 131E-189(c); (2) the transfer will not constitute a failure to satisfy a condition of the CON in violation of N.C. Gen. Stat. 131E-189(b); and (3) changes in the project resulting from the transfer, which include a change in location, are in material compliance with the representations made in the CON application. If the transfer of the CON is not granted, Petitioners alternatively request that the Department issue a declaratory ruling permitting Petitioners to change the location of the MRI scanner to the proposed new site. For the reasons given below, I conclude that I must deny Petitioners’ requested ruling.

This ruling is binding on the Department and the person requesting it if the material facts stated in the request are accurate and no material facts have been omitted from the request. The ruling applies only to this request. Except as provided by N.C.G.S. § 150B-4, the Department

reserves the right to change the conclusions which are contained in this ruling. Robert L. Wilson, Jr. and Terrill Johnson Harris of Smith Moore Leatherwood LLP have requested this ruling on behalf of Petitioners and have provided the statement of facts upon which this ruling is based. The material facts are set out below.

### **STATEMENT OF THE FACTS**

On or about February 15, 2006, Nash Imaging, L.L.C. and Nash Community Health Services, Inc. applied for a certificate of need (“CON”) to acquire a fixed open magnetic resonance imaging (“MRI”) scanner and to develop a new diagnostic center in Nash County, Project I.D. No. L-7499-06, (the “project”). The project was proposed to be located on the Community Medical Plaza campus at 1051 Noell Lane in Rocky Mount, the site of LifeCare Hospitals of North Carolina, a long-term acute care hospital. The site is owned by Nash Community Health Services, Inc. and was proposed to be ground leased to Nash Imaging, L.L.C. for development of the diagnostic center. Nash Imaging, L.L.C. proposed to acquire the MRI scanner, construct a modular building to house the equipment and develop the new diagnostic center. Nash Health Care Systems is the ultimate parent of Nash Hospitals, Inc. (the “Hospital”) and Nash Imaging, L.L.C., and Nash Community Health Services, Inc. is a controlled affiliate of Nash Health Care Systems.

At the time Petitioners’ CON application for the project was filed, the Hospital was the sole member of Nash Imaging, L.L.C. However, in the CON application, Petitioners anticipated that the formation of Nash Imaging, L.L.C., would provide the opportunity for physician ownership in the company in the future. Additionally, Petitioners’ CON application represented that the Hospital would provide management services for the project and that staffing would be provided by the Hospital pursuant to a Management Services and Personnel Lease Agreement.

Petitioners' application was reviewed in a competitive review in which both applications were disapproved. In settlement, a CON was issued to Petitioners for the project with a condition that Nash Imaging, L.L.C. would purchase a fixed open bore MRI scanner.

Since issuance of the CON to Petitioners on March 1, 2007, Petitioners state there have been changes in the levels of reimbursement for a freestanding diagnostic center operating an MRI scanner. While Petitioners' CON application anticipated opportunities for offering physician ownership in the project, according to Petitioners, such opportunities have ceased to exist, primarily because a suitable business case could not be created for such investment by local physicians in the current reimbursement environment. Even so, Petitioners believe that the physician "joint venture" aspect of its original proposal is good for the patients in its service area and for the medical community.

Petitioners propose to convert the anticipated limited liability company "joint venture" to a "contractual joint venture" with the largest multi-specialty physician practice in the Rocky Mount area, Boice-Willis Clinic, P.A. ("Boice-Willis"). Petitioners propose to transfer the CON they were granted for the project to the Hospital which would operate it as a hospital outpatient department (HOPD) rather than a freestanding diagnostic center. The Hospital would contract with Boice-Willis to provide management services for the MRI scanner. Petitioners also propose to locate the MRI scanner on the property where Boice-Willis is located. Boice-Willis, who owns the property, would ground lease it to the Hospital, but the Hospital would own the building housing the MRI scanner.

Boice-Willis currently contracts with Alliance to provide mobile MRI services to patients served at its practice. However, in connection with the proposed "contractual joint venture," Boice-Willis would discontinue its contract for mobile MRI services. On May 7, 2009, Boice-Willis submitted a letter to the Department confirming its intent to discontinue its mobile MRI

service and its intent to provide management services for the proposed fixed MRI scanner if Petitioners' request is allowed.

### **ANALYSIS**

Petitioners received a CON for Project ID # L-7499-06 to acquire a fixed open MRI scanner and to develop a new diagnostic center in Nash County. The project has not yet been developed. Petitioners now propose to transfer the CON for the project to the Hospital and also change the scope and location of the project.

#### Transfer of CON for Good Cause

N.C.G.S. § 131E-189(c) states:

The Department may immediately withdraw any certificate of need if the holder of the certificate, before completion of the project or operation of the facility, transfers ownership or control of the facility, the project, or the certificate of need. Any transfer after that time will be subject to the requirement that the service be provided consistent with the representations made in the application and any applicable conditions the Department placed on the certificate of need. Transfers resulting from death or personal illness or other good cause, as determined by the Department, shall not result in withdrawal if the Department receives prior written notice of the transfer and finds good cause. Transfers resulting from death shall not result in withdrawal.

Petitioners assert that good cause exists for transfer to the Hospital of the CON that was issued to Nash Imaging, L.L.C. and Nash Community Health Services, Inc. for Project I.D. No. L-7499-06. As a result of the transfer, the Hospital would be permitted to acquire the MRI scanner, provide a building to accommodate it, and license and operate the MRI scanner as an outpatient department of the hospital, instead of operating it as a freestanding diagnostic center.

In the proposal outlined in the declaratory ruling request, Petitioners assert that both applicants in the CON application would transfer their interests in the project to the Hospital. However, in the CON application, Nash Community Health Services, Inc. owned the land on

which the project would be developed and proposed to ground lease it to Nash Imaging, L.L.C. for development of the facility. The new proposal indicates that the project will be developed on land owned by Boice-Willis and that Boice-Willis would ground lease the land to the Hospital for development of the project. Thus, Nash Community Health Service, Inc.'s role in the project as set forth in the CON application is being assumed by Boice-Willis, not the Hospital.

With regard to Nash Imaging, L.L.C., the Petitioners' assert that good cause exists for the transfer of Nash Imaging's interests in the CON to the Hospital because of changes in regulations and reimbursement affecting hospital-physician joint ventures. Nash Imaging's role in the project included the acquisition of an MRI scanner, the construction of a modular building for the equipment, and the establishment of a new diagnostic center. Petitioners contend that CMS is particularly concerned that physicians' ownership or investment interests in diagnostic services may influence their decisions to order tests or refer patients for those services. Yet Petitioners have not demonstrated that CMS will view its proposed "contractual joint venture" differently from the "joint venture" proposed in its application. In fact, Petitioners state that "[r]eplacing the idea of physician ownership in the 'joint venture' as proposed, with the opportunity for a 'contractual joint venture' with physicians may give the Hospital more leverage with payors . . ." [Emphasis added]. Thus, Petitioners do not affirmatively state that the proposed new "contractual joint venture" will solve the reimbursement issues it is facing.

Further, Petitioners state the Hospital would contract with Boice-Willis, a multi-specialty physician practice, to provide management services for the MRI scanner. The MRI scanner would be located on the same campus as Boice-Willis and Boice-Willis would terminate its current contract with Alliance for mobile MRI services. In FY2008 Boice-Willis performed 951 weighted MRI scans on a mobile MRI scanner. Based on these facts, it is reasonable to conclude that Boice-Willis will be referring its patients to the MRI scanner that it will operate

under the management agreement with the Hospital. Neither the terms of the management agreement nor the billing arrangements for the MRI services were provided in the declaratory ruling request. Thus, it is unclear how the proposed arrangement between the Hospital and Boice-Willis would be a satisfactory resolution to what Petitioners state is their intent, which is to address CMS' stated concern "about physicians' ownership or investment interests influencing their decisions to order or to refer for certain services or tests."

In addition, Petitioners state "joint venturing an imaging center with physicians (other than radiologists) under the current Medicare regulations and reimbursement schedule is becoming financially infeasible." Based on this statement it appears that it would not be a problem for a hospital to joint venture with a group of radiologists. The Petitioners did not provide any information in the request to show why it would not be commercially feasible for the Hospital and radiologists to participate together in ownership of Nash Imaging, L.L.C., instead of dissolving Nash Imaging, L.L.C. and transferring its interests in the CON and the project to the Hospital.

Petitioners assert that "recent changes in various Medicare regulations significantly impact reimbursement for imaging by a freestanding diagnostic center, which changes were not contemplated when Petitioners applied for the CON in 2006." The Deficit Reduction Act of 2005 ("DRA") was signed into law on February 8, 2006 and became effective January 1, 2007. The CON was not issued to the Petitioners until March 2, 2007 after negotiation of a settlement agreement between the parties in the contested case. Thus, the changes in reimbursement made by the DRA had been law for more than one year and were already in effect when the Petitioners signed the settlement agreement and agreed to comply with the representations made in their CON application.

Moreover, Petitioners state that the U.S. Department of Health and Human Services is establishing a new accreditation process for entities furnishing diagnostic procedures. Petitioners claim, “[Independent Diagnostic Testing Facilities] and physician practices providing imaging services will incur additional costs to comply with the standards.” Petitioners further state that because the Hospital already has Joint Commission accreditation, “Hospital ownership of the MRI scanner in this instance would make these functions less costly and more cost-effective than the original proposal.” However, the Petitioners do not provide any information about the difference in costs between the accreditation standards for the two types of facilities and, therefore, this assertion was unsupported.

The consequence of the proposed transfer of the CON and the project to the Hospital also results in multiple changes in the project that are not in material compliance with representations made in the CON application, as discussed below. In summary, for all of the above reasons the Agency concludes the Petitioners have not demonstrated that there is sufficient basis to establish good cause for the transfer of the CON or the project to the Hospital.

#### Material Compliance

The proposal described in the request for the declaratory ruling is materially different than the project described in Petitioners’ CON application. N.C.G.S. § 131E-181 provides in part:

- (a) A certificate of need shall be valid only for the defined scope, physical location, and person named in the application. A certificate of need shall not be transferred or assigned except as provided in G.S. 131E-189(c).
- (b) A recipient of a certificate of need, or any person who may subsequently acquire, in any manner whatsoever permitted by law, the service for which that certificate of need was issued, is required to materially comply with the representations made in its application for that certificate of need.

The consequence of the above statutory provisions is that the request must be denied, because either sufficient information was not provided to evaluate the assertions or the proposed changes in the project are not in material compliance with the representations made in the CON application for Project I.D. No. L-7499-06 regarding the proposed scope, location and persons, as discussed below.

For instance, instead of providing services in a freestanding diagnostic center the facility will be operated under the Hospital's license as a hospital outpatient department ("HOPD"). Also, as now proposed, management services for the MRI scanner would be provided by Boice-Willis rather than the Hospital.

Petitioners also state the proposed MRI scanner would not be located at the Community Medical Plaza campus on property owned by Nash Community Health Services, Inc., but instead on property owned by Boice-Willis on the campus of its existing medical practice. Thus, Boice-Willis, not Nash Community Health Services, Inc., would lease its property for development of the building that would house the MRI scanner. Consequently, the ground lease of the property would be between Boice-Willis and the Hospital instead of between Nash Community Health Services, Inc. and Nash Imaging L.L.C.

Petitioners state the capital expenditure for the new proposal is expected to be less than the capital expenditure approved by the Department. However, Petitioners do not provide any information about the building that will be used for the MRI scanner. In particular, it is not clear if an existing building will be up-fitted or if a new building will be constructed. Petitioners do not provide the size of the building or the capital cost to develop the building. Consequently, it is impossible to determine from the request, whether the change in location to the new site would result in a material change in the project's capital expenditure or any other representation made



by Petitioners in the CON application with regard to the building in which the MRI scanner would be located.

Petitioners assert the proposed changes will not result in any material changes in the costs, charges, or payor mix as proposed in its application. However, Petitioners do not quantify what the anticipated changes in costs, charges or payor mix would be. Thus, sufficient information was not provided for the Agency to make a determination if the resulting changes in costs, charges, or payor mix are material or not. Further, Petitioners do not make any representations regarding what impact, if any, the changes in the project would have on payments made by patients who receive MRI services at the new facility. Therefore, sufficient information was not provided in the request to determine if the new proposal would result in a material change in patient payments.

In addition, because Petitioners' proposed changes in the project that are material or because Petitioners failed to provide sufficient information to demonstrate that the proposed changes were not material, the Petitioners failed to satisfy the following condition on the CON:

*“Nash Imaging, LLC and Nash Community Health Services, Inc. shall materially comply with all representations made in the certificate of need application for Project I.D. No. L-7499-06 and in the supplemental information it submitted to the Certificate of Need Section dated February 8, 2007. In those instances in which any representations in these documents conflict, Nash Imaging, L.L.C. and Nasy Community Health Services, Inc. shall materially comply with the latter-made representation except as amended by the conditions of approval.”*

### **CONCLUSION**

For all of the foregoing reasons, I conclude that Petitioner's request for a declaratory ruling must be denied because:

(1) Petitioners did not establish good cause for the transfer of the CON issued to Nash Imaging, L.L.C. and Nash Community Health Services, Inc. for Project I.D. No. L-7499-06 to Nash Hospitals, Inc.;

(2) Petitioners did not demonstrate that changes in the project resulting from the transfer, including, among other things, locating the MRI scanner on the Boice-Willis campus and entering into a management agreement with Boice-Willis, are in material compliance with the representations made by Petitioners in the CON application for Project I.D. No. L-7499-06;

(3) Petitioners did not provide sufficient information to support all assertions regarding material compliance; and

(4) Petitioners failed to demonstrate that the changes in the project resulting from the transfer satisfy all conditions of the CON and thus, the proposed changes to the project would result in violation of N.C. Gen. Stat. 131E-189(c).

While Petitioners request, in the alternative, a declaratory ruling permitting Petitioners to change the location of the MRI scanner from the Community Medical Plaza campus to the campus of Boice-Willis, as discussed above, there is insufficient information in the request to determine whether the change in location is in material compliance with the representations in Petitioners' CON application. Therefore, for the foregoing reasons, I also conclude that Petitioners' request permitting Petitioners to develop its project on the campus of Boice-Willis must be denied.

This \_\_\_\_ day of June, 2009.

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Jeff Horton, Acting 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 nonagency party by certified mail, return receipt requested, by depositing the copy in an official depository of the United States postal service in a first class, postage prepaid envelope addressed as follows:

**CERTIFIED MAIL**

Robert L. Wilson, Jr.  
Terrill Johnson Harris  
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434 Fayetteville Street, Suite 2800  
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This \_\_\_\_\_ day of June, 2009.

\_\_\_\_\_  
Jeff Horton  
Acting Director