



North Carolina Department of Health and Human Services  
Division of Health Service Regulation

Pat McCrory  
Governor

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Ambassador (Ret.)  
Secretary DHHS

Drexdal Pratt  
Division Director

March 12, 2014

William R. Shenton & Pamela A. Scott  
301 Fayetteville Street, Suite 1900  
Raleigh, NC 27601

**Exempt from Review – Physician Office Renovation**

Provider: North Carolina Radiation Therapy Management Services, Inc.  
Project Description: Renovate portions of existing physician office building  
County: Buncombe

Dear Mr. Shenton and Ms. Scott:

In response to your letter of February 14, 2014, the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(9). Therefore, you may proceed to offer, develop or establish the above referenced project without a certificate of need.

It should be noted that this Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this Agency and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Julie Halatek  
Project Analyst

Martha J. Frisone, Interim Chief  
Certificate of Need Section

cc: Medical Facilities Planning Branch, DHSR



**Certificate of Need Section**

[www.ncdhhs.gov](http://www.ncdhhs.gov)

Telephone: 919-855-3873 • Fax: 919-733-8139

Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

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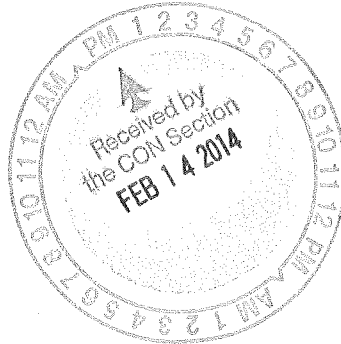


*WRS*

Poyner Spruill<sup>LLP</sup>

February 14, 2014

Via Hand Delivery



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Martha Frisone  
Interim Chief  
N.C. Certificate of Need Section  
809 Ruggles Drive  
Raleigh, NC 27603

RE: **Notice of Renovation of Exempt Physician Office Space at 20 Medical Park Drive, Asheville**

Dear Ms. Frisone:

We are writing on behalf of our firm's client, North Carolina Radiation Therapy Management Services, Inc. ("NCRTMS"), to provide notice to the Certificate of Need Section that, pursuant to N.C. Gen. Stat. § 131E-184(a)(9), NCRTMS plans to renovate one part of a physician office building at 20 Medical Park Drive, in Asheville, North Carolina (the "20 Medical Park Building" or "Building"). NCRTMS subleases this Building to Radiation Therapy Associates of Western North Carolina, PA ("RTAWNC"), as part of a management services arrangement. As described in more detail below, NCRTMS plans to renovate a small portion of the 20 Medical Park Building to create a more distinct and separate waiting area and entryway for one of the physician groups affiliated with RTAWNC which currently practices in the Building. No new institutional health service, as defined in N.C. Gen. Stat. 131E-176(16)(b), will be offered or developed in the renovated physician office space without first obtaining appropriate certificate of need approval.

The office space in the 20 Medical Park Building consists of physician and staff offices, patient examination rooms, and related support space. See 20 Medical Park Building Floor Plan (**Appendix A**). Several independent oncology physician groups utilize all of the medical office space in this Building for their respective practices. These physician groups, each of which is affiliated with RTAWNC, include a Gynecologic Oncology Group, a Radiation Oncology Group, and a Medical Oncology Group. The Gynecologic Oncology Group and Radiation Oncology Group use office space made available to them through RTAWNC under a lease with NCRTMS. The Medical Oncology Group provides services to patients under a professional services agreement with a local hospital, which subleases the medical oncology office space in the building from NCRTMS. Neither the Gynecologic Oncology Group nor the Radiation Oncology Group has such a professional services agreement with that hospital.

By way of background, in early 2012, NCRTMS and its parent company, Radiation Therapy Services (now 21st Century Oncology), acquired ownership interests in the corporate entities that owned and operated an oncology treatment center and associated medical equipment located at the 20 Medical Park Building. By letter dated January 6, 2012 (**Appendix B**), the CON Section confirmed that this transfer of ownership interests was not subject to CON review. Pursuant to the noticed transaction, the

Ms. Martha Frisone  
Interim Chief, N.C. CON Section  
February 14, 2014  
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Poyner Spruill<sup>LLP</sup>

20 Medical Park Building is now subleased by NCR TMS from AOR Management Company of Virginia, LLC which has a master lease with the property owner, CC Asheville MOB LLC.

The planned renovations of the 20 Medical Park Building include a total project zone of approximately 5,305 square feet. Most of the project work and expense will involve reconfiguring space to create a new waiting area and entryway for the Gynecologic Oncology Group's patients; and improving patient privacy and flow for the Group. The project also will include cosmetic updates such as new paint and flooring for some of the Gynecologic Oncology Group's designated office space, including rooms in which diagnostic medical equipment to be used by that Group will be located. None of the planned renovation and update work will be necessary for the installation or operation of that diagnostic equipment. The total cost of the planned renovations is estimated to be approximately \$250,000. This planned renovation will simply modify the layout of part of the Building and its interior office space and update the appearance of the space to allow the Gynecologic Oncology Group to better serve its patients.


The Certificate of Need Law provides that upon receiving prior written notice, the CON Section shall exempt from certificate of need review a proposal "to develop or acquire a physician office building regardless of cost, unless a new institutional health service other than defined in G.S. 131E-176(16)b is offered or developed in the building." N.C. Gen. Stat. § 131E-184(a)(9). This provision exempts from CON review any activities or costs associated with the development or acquisition of a physician office building, regardless of cost, so long as no new institutional health service (other than a capital expenditure exceeding \$2,000,000) is to be offered or developed in the building.

The information presented above establishes that NCR TMS' planned renovation of medical office space in the 20 Medical Park Building should be exempt from CON review under N.C. Gen. Stat. § 131E-184(a)(9). We request your confirmation of this exemption and thank you in advance for your prompt consideration of this request.

Please do not hesitate to contact us if you need any additional information or have any questions regarding this matter.

With best regards, we are

Very truly yours,

  
**William R. Shenton**

  
**Pamela A. Scott**

Enclosures





North Carolina Department of Health and Human Services  
 Division of Health Service Regulation  
 Certificate of Need Section  
 2704 Mail Service Center ■ Raleigh, North Carolina 27699-2704

Beverly Eaves Perdue, Governor  
 Lanier M. Cansler, Secretary

[www.ncdohhs.gov/dhsr](http://www.ncdohhs.gov/dhsr)

Craig R. Smith, Section Chief  
 Phone: 919-853-3875  
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January 6, 2012

William R. Shenton  
 Poyner Spruill  
 P.O. Box 1801  
 Raleigh, NC 27602-1801

RE: No Review:

- Transfer by Cancer Centers of North Carolina – Asheville, P.C. (CCNC Asheville) of 100% of its ownership interests in the existing oncology treatment center located at 20 Medical Park Drive, Asheville (Oncology Center) to AHLCC, LLC, a wholly-owned subsidiary of CCNC Asheville
- Transfer by AOR Management Company of Virginia, LLC (AOR) of 100% of its ownership interests in the Oncology Center to Asheville CC, LLC, a wholly-owned subsidiary of AOR
- Acquisition of 100% of AHLCC, LLC by North Carolina Radiation Therapy Management Services, LLC (NCR-TMS)
- Acquisition of 100% of Asheville CC, LLC by NCR-TMS  
 Buncombe County

Dear Mr. Shenton:

The Certificate of Need (CON) Section received your letter of September 26, 2011 and an email dated December 28, 2011 regarding the above referenced proposals. Based on the CON law in effect on the date of this response to your request, the proposals described in your correspondence are not governed by, and therefore, do not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposals would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposals when the new law becomes effective.

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the proposals or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Certificate of Need Section. Changes in a proposal include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

Please contact the CON Section if you have any questions. Also, in all future correspondence you should reference the Facility I.D.# (FID) if the facility is licensed.

Sincerely,

*Martha J. Frisone*  
 Martha J. Frisone  
 Assistant Chief

*Craig R. Smith*  
 Craig R. Smith, Chief  
 Certificate of Need Section

cc: Medical Facilities Planning Section, DHSR



September 26, 2011

William R. Shenton  
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**Via Hand Delivery**

Mr. Craig R. Smith, Chief  
Certificate of Need Section  
Division of Health Service Regulation  
North Carolina Department of Health and Human Services  
809 Ruggles Drive  
Raleigh, North Carolina 27603

**RE: Request for No Review Determination – Acquisition of Ownership Interests in Corporate Entities that Own Cancer Centers of North Carolina's Asheville Oncology Treatment Center**

Dear Mr. Smith:

We are submitting this letter on behalf of our client, Radiation Therapy Services, Inc. ("RTS"), as well as its wholly-owned subsidiary, North Carolina Radiation Therapy Management Services, LLC ("NCRRTMS"). RTS is a national provider of radiation oncology services which offers services at several locations in western North Carolina.

With this letter, NCRRTMS is requesting a no-review determination regarding its acquisition of the ownership interests in the corporate entities that own an existing oncology treatment center and the associated equipment located in Asheville, North Carolina. Consistent with the longstanding approach of the Agency in finding that purchases of corporate ownership interests are not events requiring a certificate of need, NCRRTMS now seeks confirmation that its acquisition of membership interests in the corporate entities owning the existing Asheville oncology treatment center, including a linear accelerator and computed tomography scanner, and its continued operation of that oncology treatment center and the same equipment, at the same site, may proceed without first obtaining a certificate of need.

**FACTUAL BACKGROUND**

***The Parties***

Since 2004, Cancer Centers of North Carolina – Asheville, P.C. ("CCNC-Asheville") and AOR Management Company of Virginia, LLC (f/k/a AOR Management Company of Virginia, Inc.) ("AOR"), an indirect, wholly-owned subsidiary of US Oncology, Inc. ("USON"), together have owned and operated an oncology treatment center that is located at 20 Medical Park Drive, Asheville, North Carolina (the "Oncology Center").<sup>1</sup> This Oncology Center uses a Varian 2100C linear accelerator (the "Linac") and a computed tomography scanner (the "CT Scanner") to provide radiation therapy services to patients. As discussed further below, the Linac and CT Scanner were acquired, and have been used to provide radiation therapy services, under an exemption from certificate of need ("CON") review that was recognized by the Certificate of Need Section ("CON Section"). After an appeal of this determination, the CON Section's decision to grant an exemption was upheld.

<sup>1</sup> CCNC-Asheville was formerly known as Asheville Hematology and Oncology Associates, P.A. ("AHO"). The corporate name was changed in 2009. See Exhibit 1. AOR was formerly a corporation, but has converted to a limited liability company. See Exhibit 2.

Mr. Craig R. Smith  
Chief, CON Section  
September 26, 2011  
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CCNC-Asheville is a professional corporation organized under the laws of the State of North Carolina with its principal place of business located at 20 Medical Park Drive, Asheville, North Carolina. It employs physicians licensed to practice medicine in the State of North Carolina, who provide oncology treatment services, including radiation oncology services through the use of the Linac and CT Scanner located at the Asheville Oncology Center on Medical Park Drive. CCNC-Asheville has served cancer patients in the Asheville area since 1982 when the practice (then AHO) was first formed and began providing medical oncology services. Its oncology treatment center is a "grandfathered" facility because it became operational before the CON Law was amended to apply to oncology treatment centers. See 2004 correspondence between AHO and CON Section (without exhibits) (Exhibit 3).

USON is a business corporation organized under the laws of the State of Delaware, with its principal place of business located at 10101 Woodloch Forest Drive, The Woodlands, Texas 77380. Through its subsidiaries, USON provides administrative support for oncology practices throughout the United States, and also furnishes medical equipment used by those practices. One of those subsidiaries is AOR, a Delaware limited liability company.

RTS (also known as 21<sup>st</sup> Century Oncology) operates several radiation therapy centers in western North Carolina, including one located in a medical office building in Asheville which was the site of a damaging fire that occurred on July 28, 2011, and which was reported to you in an earlier letter. Federal and State investigators have indicated they believe this fire may have been intentionally set; but because the investigation of the fire is still in process, RTS has not been able to access this center and assess the damage and determine when and how it might be re-opened. Once a damage assessment is completed, RTS will approach the CON Section about the status of the center, including any steps needed to repair or replace it. However, without a full assessment of the status of this site, RTS is uncertain at this point about the steps necessary to resume operations at that center.

Immediately following the fire, RTS successfully transitioned cancer patients who had been receiving treatment at its Asheville center to its other treatment centers in western North Carolina, where they are continuing to receive consultations and radiation therapy treatment. The transaction proposed in this letter would facilitate the resumption of RTS's provision of radiation therapy services to patients closer to Asheville, and accordingly RTS and NCRRTMS request that the Agency expedite its consideration of this no-review request.

NCRRTMS is a North Carolina limited liability company which is a wholly-owned subsidiary of RTS. NCRRTMS provides management and administrative support services for RTS's radiation therapy centers in North Carolina.

RTS, NCRRTMS, CCNC-Asheville and AOR (collectively, the "Parties") have discussed and reached agreement on a transaction that would involve the transfer of the membership interests in the corporate entities that own the Oncology Center and the equipment used to provide treatment for patients at the Oncology Center, including the Linac and CT Scanner (collectively, the "Equipment"). The transaction would be limited to a transfer of the underlying ownership interests in the corporate entities that own the Oncology Center and the Equipment (the "Proposed Transaction"). The Oncology Center and its Equipment will continue to serve patients at the same location, and there will be no change in the scope of services provided by the Oncology Center as part of the Proposed Transaction. The Proposed Transaction does not involve the offering or expansion of any new facility, service or equipment, and the State's inventory of linear accelerators will not change as a result of the transaction. Based upon prior

Mr. Craig R. Smith  
Chief, CON Section  
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declaratory rulings and "no review" determinations that have been issued by the Office of the Director of the Division of Health Services Regulation and by the CON Section, it is clear that the Proposed Transaction agreed upon by the Parties is not a "New Institutional Health Service," and should be permitted to proceed without first obtaining a certificate of need.

This letter describes the Proposed Transaction and identifies the grounds for a determination that the transaction is not subject to CON review.

#### *Background on the Oncology Center and Equipment*

In 2005, AHO (now CCNC-Asheville) relocated its Asheville offices to establish the current Oncology Center. AHO acquired the Linac and CT Scanner to provide radiation therapy services to patients. The Linac that has been operated at the Oncology Center is recognized in the Linac Inventory in the State Medical Facilities Plan. See Draft 2012 State Medical Facilities Plan, p. 147 (Exhibit 4). As you will recall, the present Oncology Center was developed under an exemption from CON review recognized by the CON Section. In February 2005, AHO sought "no review" determinations for a proposed relocation and expansion of its oncology treatment center and acquisition of medical equipment that would allow AHO to provide radiation therapy. See AHO No-Review Requests and Related Correspondence (without exhibits) (Exhibit 5). AHO presented four proposals: (1) acquisition of a linear accelerator, (2) acquisition of a CT scanner, (3) acquisition of treatment planning equipment, and (4) relocation of its oncology treatment center. On August 2, 2005, the CON Section issued four "no review" letters, confirming that none of the proposals required a certificate of need. See CON Section No-Review Determinations (Exhibit 6).

The CON Section's determinations were challenged and following a lengthy contested case and appeal, the North Carolina Court of Appeals ultimately affirmed the Final Agency Decision, entered by the Acting Director of the Division of Faculty Services (the "Division") that AHO's acquisition of the Linac and CT scanner and expansion of the oncology treatment center did not require a CON. See *Mission Hospitals, Inc. v. N.C. DHHS*, 696 S.E.2d 163 (N.C. Ct. App. 2010) (Exhibit 7).

At the heart of the appeal challenging the CON Section's no-review determinations were amendments to the CON Law which took effect in late August 2005. Before late August 2005, oncology treatment centers were among the services regulated by the CON Law, and a certificate of need was required to develop an oncology treatment center. But on August 26, 2005, the CON Law was amended by deleting the term "oncology treatment center" from the group of facilities defined as a "health service facility" under N.C. Gen. Stat. § 131E-176. Along with this change, the list of new institutional health services for which a certificate of need is required was amended to add any acquisition of a linear accelerator occurring on or after the effective date of the amendment. AHO's no-review requests and the CON Section's subsequent no-review determinations preceded the August 26, 2005 amendment that eliminated the concept of oncology treatment centers and established a requirement for a certificate of need to acquire a linear accelerator.

In its decision, the Court of Appeals recognized that AOR provided substantial administrative support for AHO's day-to-day operations under a Management Services Agreement which also authorized AOR to acquire equipment for AHO. The Court of Appeals concluded that: (1) AHO's February 2005 requests seeking CON determinations regarding its proposals were made in good faith reliance on the CON Law then in existence; (2) AHO had acquired vested rights to develop its proposed services under the prior version of the CON Law because of the building lease entered into by AHO's managing agent, and AHO's acquisition by comparable arrangement of the Linac through a purchase contract entered into by AOR; and (3) the CON Section had issued its no-review determinations prior to



the effective date of the amendment to the CON Law. Accordingly, the Court of Appeals held that the CON Section and the Division in its Final Agency Decision properly applied the CON Law as it existed when AHO submitted its no-review requests. The Court of Appeals also affirmed the Final Agency Decision's determinations that AHO's acquisition of the CT Scanner did not require a CON because the total costs to buy the CT Scanner and make it operational were below the threshold dollar amount for a diagnostic center, and that the relocation and expansion of AHO's oncology treatment center did not require a CON because the costs related to such relocation and expansion did not exceed \$2,000,000. Thus, the Court of Appeals conclusively determined that the relocation and expansion of AHO's (now CCNC-Asheville's) oncology treatment center and AHO's acquisition of the Linac and CT Scanner did not require a certificate of need.

#### ***The Proposed Transaction***

The Proposed Transaction to transfer the ownership interests in the corporate entities that own the Oncology Center and Equipment will proceed in two steps. First, CCNC-Asheville will transfer its interest in the Oncology Center and Equipment to a wholly-owned subsidiary ("CCNC Sub"), and AOR will transfer its interest in the Oncology Center and Equipment to a wholly-owned subsidiary (collectively with CCNC Sub, the "LLCs"). The transaction will be completed with NCR TMS purchasing all of the membership interests in those two LLCs as a second step.

After the Proposed Transaction is complete, the LLCs will continue to exist as legal business entities, and will continue to own the Oncology Center and Equipment, including the Linac and CT Scanner that the CON Section (and the Court of Appeals) determined were not subject to CON review. The Oncology Center and its Equipment will continue to serve patients at the same location at 20 Medical Park Drive in Asheville. There will be no purchase of additional equipment, nor will any new services be offered, as a result of the Proposed Transaction. The only change will be the membership composition of the corporate entities that own the Oncology Center and Equipment, with CCNC-Asheville and AOR initially transferring their ownership interests to the wholly-owned subsidiary LLCs, followed by a separate transaction in which NCR TMS will acquire all of the membership interests in the LLCs.

The LLCs will not offer any medical services. All medical services associated with oncology treatment at the center will be furnished by licensed physicians. The Parties anticipate that the radiation oncologists who have been practicing with CCNC-Asheville and have supervised the care of a significant majority of the patients receiving treatment at the Oncology Center in the past will continue to supervise and direct the treatment of patients under their care. Under an agreement that preserves the physicians' authority over all clinical and medical decisions, the LLCs will make the Linac and CT Scanner available for treatment of patients by the CCNC-Asheville radiation oncologists and other licensed physicians authorized to care for patients at the Oncology Center.

Based upon the long-standing approach that the Division and the CON Section have taken to the purchase of equity interests in existing North Carolina health care facilities when there is no change in the services offered or the equipment employed to offer the services, NCR TMS respectfully submits that none of these steps relating to the Proposed Transaction constitutes a New Institutional Health Service that requires a certificate of need.

#### **ANALYSIS**

The CON Law was enacted to prevent the development and operation of unneeded health services, equipment and facilities. This is made explicit in the very first section of the law, where the General Assembly finds: "That the proliferation of unnecessary health service facilities results in costly

duplication and underuse of facilities, with the availability of excess capacity leading to unnecessary use of expensive resources and overutilization of health care services." N.C. Gen. Stat. § 131E-175(4). The CON Law essentially focuses on the development and offering of those "new institutional health services" that would create additional capacity, and which are catalogued in N.C. Gen. Stat. § 131E-176(16). Each of these new institutional health services entails in some way the acquisition or establishment of a *new* health service, *new* equipment, *new* facilities, or expansions and relocations of existing facilities or services (which also would have an impact on how health services are deployed and utilized). In keeping with its fundamental goals, the CON Law expressly recognizes that certain activities are not subject to review. Based upon the clear terms of the CON Law and prior declaratory rulings by the Department, the Proposed Transaction does not require a certificate of need.

***The Proposed Transaction Will Not Result in a New Institutional Health Service***

The CON Law provides that no person shall offer or develop a "new institutional health service" without first obtaining a CON. N.C. Gen. Stat. § 131E-178. However, none of the components of the "new institutional health service" definition address, directly or indirectly, the acquisition of membership interests in an organization that already is operating a health service. This type of transaction is among the activities that are "administrative and other activities that are not integral to clinical management," and which are specifically excluded from the definition of "health service" in the CON Law. N.C. Gen. Stat. § 131E-176(9a). Therefore, an acquisition of corporate ownership interests, such as the Proposed Transaction at issue in this request, does not involve a new institutional health service at all and should not be subject to CON Review.

The list of new institutional health services does include "the acquisition by purchase, donation, lease, transfer or comparable arrangement" of a linear accelerator "by or on behalf of any person," N.C. Gen. Stat. § 131E-176(16)(f)5a, 9, and "the obligation by any person of a capital expenditure exceeding two million dollars (\$2,000,000) to develop or expand a health service or a health service facility, or which relates to the provision of a health service," N.C. Gen. Stat. § 131E-176(16)(b). However, neither of these definitions applies to the Proposed Transaction. In prior declaratory rulings and no review determinations, the Department and CON Section have consistently recognized that transactions which are limited to an acquisition of underlying corporate membership interests in an existing legal entity which owns and operates an existing oncology center and its associated equipment, such as the Proposed Transaction, fall within the above-referenced exclusion recognized in the definition of "health service" in the CON Law. Accordingly, the Department and CON Section have consistently determined that events such as the Proposed Transaction do not trigger certificate of need review under either the linear accelerator acquisition or the \$2,000,000 capital expenditure provision.

***The Department's Prior Declaratory Rulings Confirm the Transaction Does Not Require a CON***

This No-Review Request is consistent with the Department's prior declaratory rulings which have interpreted the applicability of the CON Law to the purchase of ownership interests in corporate entities that own existing health care facilities. Over the course of North Carolina's Certificate of Need program, there have been a number of declaratory rulings which confirmed that the acquisition of ownership interests in companies which own existing health care facilities that already are offering services does not constitute the offering of a new institutional health service because such transactions do not implicate the creation of additional capacity and health service facilities which might lead to the "unnecessary use and expense of resources and overutilization of healthcare services," detailed in the legislative findings. See N.C. Gen. Stat. § 131E-175(4). Several examples of declaratory rulings which have upheld this principle of no review for acquisitions of corporate ownership interests are discussed below.

In at least four rulings that were issued after the enactment of the August 2005 amendment to the CON Law, the Department has determined specifically that the transfer of ownership interests in organizations that own linear accelerators does not require a certificate of need.

- On August 18, 2011, the Department issued a declaratory ruling finding that Radiation Oncology Centers of the Carolinas, Inc.'s transfer of two CON-approved radiation oncology facilities to two wholly-owned subsidiaries did not constitute a new institutional health service or require a certificate of need. See *In re: Request for Declaratory Ruling by Radiation Oncology Centers of the Carolinas, Inc.* (Exhibit 8).
- On September 27, 2010, the Department issued a declaratory ruling confirming that the acquisition by Cancer Centers of North Carolina, P.C. of the majority of the membership interests in Wake Radiology Oncology Services and the continued operation of WROS's oncology treatment center did not require a certificate of need. See *In re: Request for Declaratory Ruling by Wake Radiology Oncology Services, PLLC, Cancer Centers of North Carolina, P.C., US Oncology, Inc. et al.* (Exhibit 9).
- On December 21, 2007, the Department issued a declaratory ruling finding that Rex Healthcare, Inc.'s acquisition of 100% of the membership interest of Smithfield Radiation Oncology, LLC, which owned and operated a linear accelerator, was not subject to CON review. See *In re: Request for Declaratory Ruling by Rex Healthcare, Inc. and Smithfield Radiation Oncology, LLC* (Exhibit 10).
- On September 14, 2007, the Department issued a declaratory ruling confirming that certificate of need review was not required for the sale to another entity of 100% of the issued and outstanding stock of a company that owned a linear accelerator. See *In re: Request for Declaratory Ruling by Radiation Therapy Services, Inc. and North Carolina Radiation Therapy Management Services, Inc.* (Exhibit 11).

At issue in the August 2011 declaratory ruling involving Radiation Oncology Centers of the Carolinas, Inc. ("ROCC"), was the proposed transfer of two existing oncology facilities owned by ROCC to two wholly-owned subsidiaries of ROCC. The two oncology facilities each operated a linear accelerator and CT simulator, the acquisition of which had previously been approved by the CON Section. The Department concluded that this transaction was not subject to CON review. As the Declaratory Ruling explained, "The entity that owns the linear accelerator and simulator will not change, and the same equipment will be used to provide the same radiation oncology services, in the same location. . . . The Proposed Transaction does not involve the offering or expansion of any new facility, service or equipment, and the state's inventory of linear accelerators and simulators will not change." The transaction at issue in the ROCC declaratory ruling is very similar to the first step of the Proposed Transaction at issue in this request, under which CCNC-Asheville and AOR will transfer their interests in the existing Oncology Center and its associated Equipment to two wholly-owned subsidiary LLCs.

In the September 2010 declaratory ruling involving Wake Radiology Oncology Services, the Department reviewed a proposed transaction under which WROS would be converted from a professional limited liability company to a limited liability company, followed immediately by the sale of the ownership interests in WROS to Cancer Centers of North Carolina, P.C. Subsequently, in a separate transaction, WakeMed proposed purchasing a minority membership interest in the renamed WROS entity. After the two transactions, the resulting LLC would continue to exist as a legal and business entity and would continue to own the oncology center and equipment that was authorized by a previously issued CON. The Department concluded that these proposed transactions did not require a certificate of need. In its

Declaratory Ruling, the Department noted that the entity which owned the Linac and Simulator would not change and the same equipment would continue to be used to provide the same radiation oncology services at the same location. The Declaratory Ruling explained that although the proposed transaction involved expenditures by CCNC and WakeMed, "these will be purchases of ownership interests in an existing limited liability company that owns the oncology treatment center. There will be no capital expenditure to develop or expand a health service or health service facility because the same equipment will continue to be operated at the same location, and no expansion of services is proposed." The transactions involved in the WROS declaratory ruling are analogous to the second step of the Proposed Transaction at issue in this request, under which NCRTMS will acquire ownership interests in two existing LLCs which own the Oncology Center and its associated Equipment which will continue to provide the same services to patients at the same location following the transaction.

In its September 2007 declaratory ruling involving NCRTMS, the Department reviewed a request that involved the purchase of all of the stock of Carolina Radiation and Cancer Treatment Center, Inc. ("CRTC"). In its declaratory ruling request, CRTC stated that it was operating one linear accelerator and simulator that were in the Department's equipment inventory reports, as well as an additional linear accelerator that was not listed in the inventory. After reviewing the proposed transaction, the Department concluded, as to the one linear accelerator and simulator that were in the equipment inventory reports, that the proposed stock purchase could proceed without a CON. The Declaratory Ruling stated: "The transaction described by Petitioners does not constitute the acquisition of a linear accelerator or a simulator by any person because ownership of the one reported linear accelerator and one reported simulator here will not change. CRTC will continue to be the owner of these two pieces of equipment, and CRTC's legal status as a corporate entity will not change." The Department's ruling permitted all of the stock of CRTC, which owned the linear accelerator and simulator, to be purchased without a certificate of need.

The purchase of LLC interests proposed by the Parties in this Request is analogous to the stock purchase that was proposed by CRTC. The Proposed Transaction will entail acquisition by NCRTMS of all of the ownership interests in the LLCs. Ownership of the Oncology Center and its associated Equipment, including the Linac and CT Scanner, will remain with the LLCs following the second step of the Proposed Transaction.

In the December 2007 declaratory ruling involving Smithfield Radiation Oncology, the Department reached a similar conclusion. In that situation, Rex Healthcare already had a 25% ownership interest in Smithfield Radiation Oncology, LLC ("SRO"), and proposed to acquire the remaining 75% of the ownership interests from the physician owners. The Department concluded that "[t]he transaction described by Petitioners does not constitute the acquisition of a linear accelerator by any person because ownership of the linear accelerator here will not change." Thus, the Department concluded that these purchases of the ownership interests of companies which own an operating linear accelerator did not require a CON.

The Department also issued a similar ruling with regard to acquisition of the stock of a company that owned heart lung bypass equipment. See *In re: Request for Declaratory Ruling by New Hanover Perfusionists, Inc.*, January 24, 2006 (Exhibit 12). Heart-lung bypass machines are another type of medical equipment for which a certificate of need is required under N.C. Gen. Stat. § 131E-175 (16) (f1), the same portion of the definition of new institutional health services that applies to purchases of linear accelerators. The Department focused on the fundamental fact that the ownership of the equipment would not change, and that there was no purchase of equipment, in ruling that this stock acquisition did not require a Certificate of Need. The Department's determination in these rulings is firmly founded on the express terms of the CON Law.

***The Proposed Transaction Is Not an Acquisition of a Linear Accelerator***

The proposed acquisition of 100% of the membership interests in the LLCs by NCR TMS does not constitute the acquisition of a linear accelerator. As explained above, the transaction is limited to the acquisition of the underlying ownership interests in the corporate entities that own the existing Oncology Center and its associated Equipment. The Linac will continue to be used to provide the same radiation oncology services, in the same location, and the entity that owns the Linac will not change as a result of Step 2 of the Proposed Transaction. The LLCs will continue to own the Linac and the CT Scanner as well as all the Oncology Center assets that were found to be exempt from CON review and have been used to furnish oncology treatments to patients. The LLCs' membership composition will change to a single member, NCR TMS, but their legal status as existing business entities will not change.

Since the LLCs will remain the same legal entities, the same "person" will own the equipment and operate the Oncology Center and its Equipment following the Proposed Transaction's second step. See N.C. Gen. Stat. § 131E-176(19) and 178. There will be no change in the operation of the Oncology Center. Accordingly, and consistent with the rulings issued since the August, 2005 amendment, there is no basis to require CON review of the Proposed Transaction as an acquisition of a linear accelerator under the provisions of N.C. Gen. Stat. § 131E-176(16)(f)5a.

***The Proposed Transaction Does Not Involve the Development or Expansion of a Health Service Facility***

The Proposed Transaction will involve expenditures by NCR TMS, but these will simply be purchases of ownership interests in existing LLCs that own the Oncology Center. They will not entail a capital expenditure to develop or expand a health service or health service facility because the same equipment will continue to be operated at the same location, and no expansion of services is proposed.

Likewise, the Proposed Transaction will not entail "a capital expenditure . . . which relates to the provision of a health service" under N.C. Gen. Stat. § 131E-176(16)(b). The only change that will result from the Proposed Transaction will be in the membership composition of the LLCs, and that change in ownership is not a health service.

As the Department must have determined in the prior declaratory rulings discussed above, the purchase of ownership interests in an existing enterprise, which already is lawfully operating the equipment and offering the services, is not a capital expenditure that "relates to the provision of a health service" under N.C. Gen. Stat. § 131E-176(16)(b). The definition of "health service" in the CON Law specifically excludes "administrative and other activities that are not integral to clinical management." N.C. Gen. Stat. § 131E-176(9a). The membership composition of the LLCs is not integral to the clinical management of the Oncology Center, and the Center's operations will not change as a result of the Proposed Transaction. Therefore, the purchase of membership interests in the LLCs is not an activity that is "integral to clinical management," and accordingly is not "a capital expenditure . . . which relates to the provision of a health service" within the meaning of N.C. Gen. Stat. § 131E-176(16)(b).

***Issuance of the No-Review Determination Is Consistent with the Purposes of the CON Law***

The CON Law is intended to regulate new institutional health services and is not intended to impede routine business transactions such as an acquisition of a limited liability company's ownership interests. The only point when the CON Law does limit changes in ownership is "before completion of the project or operation of the facility . . ." N.C. Gen. Stat. § 131E-189(c). CCNC-Asheville and AOR have operated the Oncology Center for more than a year<sup>2</sup>, so this restriction in the CON Law clearly does not apply.

The Proposed Transaction does not involve the offering or expansion of any new facility, service or equipment, and the State's inventory of linear accelerators will not change. The Oncology Center and its Equipment have been established and operating for years. No new, or additional equipment will be acquired or placed in operation in the State. No new facility will be established nor new services offered. As a result, the Proposed Transaction does not implicate the fundamental objective of the CON Law – to control the development and expansion of health service facilities. Although not applicable to the Parties' Proposed Transaction, in keeping with this overarching objective, the CON Law actually contains a provision, in N.C. Gen. Stat. § 131E-184(a)(8), which recognizes that an outright purchase of all the assets of an entire health service facility is exempt from the requirement of obtaining a CON, even if the purchased facility contains equipment that would otherwise be subject to CON review.

The purposes for which the CON Law was enacted are not served by regulating the purchase and sale of the underlying membership interests in corporate entities that own existing health service facilities or equipment which the CON Section has already determined to be needed. If membership interests in companies that own an existing health service facility are purchased, without any accompanying addition, expansion, reduction, or relocation of the services offered, then none of the underlying policy concerns that are the basis for the CON Law come into play.

**CONCLUSION**

For all of the foregoing reasons, the regulation of events like the Proposed Transaction, involving existing and previously reviewed and approved facilities and their associated equipment which do not otherwise implicate the fundamental purposes of the CON Law stated in N.C. Gen. Stat. § 131E-175, is beyond the scope of the CON Law, and should not require a CON. As stated above, since the expansion of the Oncology Center pursuant to the exemption recognized by the CON Section, the Linac, CT Scanner, and related equipment have been operated as part of an ongoing health care facility and that will continue after completion of the Proposed Transaction.

The North Carolina courts have recognized that because the CON Law interferes with the normal right to do business, it must be narrowly construed. See *HCA Crossroads Residential Centers, Inc. v. N.C. Dep't of Human Resources*, 327 N.C. 573, 579, 398 S.E.2d 466, 470 (1990) ("When viewed in its entirety, Article 9 of Chapter 131E of the General Statutes, the Certificate of Need Law, reveals the

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<sup>2</sup> As you may be aware, AHO (now CCNC-Asheville) operated the Oncology Center in 2006, but the operation of the Equipment was stayed after the initial Final Agency Decision on AHO's no review request reversed the CON Section's initial determination and the Recommend Decision. CCNC-Asheville was not able to fully reinstate operation of the Equipment until after the Court of Appeals' decision in 2010 affirming the second Final Agency Decision which upheld the CON Section's initial determination.

Mr. Craig R. Smith  
Chief, CON Section  
September 26, 2011  
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Norton Spruill

legislature's intent that an applicant's fundamental right to engage in its otherwise lawful business be regulated but not be encumbered with unnecessary bureaucratic delay.") Failure to issue the requested no-review determination would delay and impede the Parties that are requesting this determination in proceeding with a lawful business transaction.

We have enclosed a copy of the materials referenced in this letter (see attached Index). We request your earliest possible attention to this request and look forward to your confirmation that the Proposed Transaction is not a new institutional health service and may proceed without a certificate of need. Thank-you for your attention to this and if there is any additional information you may require, it will be expedited upon receipt of your request.

Sincerely,



William R. Shenton  
Partner

Enclosures

cc: Martha Frisone, Assistant Chief, CON Section  
Norton L. Travis, General Counsel for RTS  
S. Todd Hemphill, Counsel for CCNC-Asheville and AOR  
Jeremy C. Ouchley, Counsel for AOR

**Scott, Pamela**

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**From:** S. Todd Hemphill [Hemphill@bcs-law.com]  
**Sent:** December 28, 2011 9:57 AM  
**To:** Smith, Craig R.; Frisone, Martha  
**Cc:** Shenton, Bill; Ouchley, Jeremy C  
**Subject:** Request for No Review Determination - Asheville Oncology Treatment Center  
**Attachments:** North Carolina Qualification - Asheville CC.pdf; ART-ORG - AHLC.pdf; CERT ORG - Asheville CC.pdf

Dear Craig and Martha,

Following up on Bill Shenton's September 26, 2011 letter regarding the above matter, please find attached Articles of Organization for AHLC, LLC (the entity owned by the physicians), and the Certificate of Organization and Application for Certificate of Authority for Asheville CC, LLC (the entity owned by AOR Management). I believe this is all the information you need to complete your review of the request, but please feel free to contact me if I can be of further assistance.

Todd

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**S. Todd Hemphill**

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