



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

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt
Division Director

August 12, 2015

Maureen Demarest Murray
300 N. Greene Street, Suite 1400
Greensboro, NC 27401

Exempt from Review – Acquisition of Facility

Record #: 1688
Facility Name: McDowell MRI
Type of Facility: Diagnostic Center
FID #: 050741
Acquisition by: The McDowell Hospital, Inc.
Business #: 1800
County: McDowell

Dear Ms. Murray:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) determined that based on your letters of February 12, 2015; May 19, 2015; and August 10, 2015, the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-184(a)(8). Therefore, The McDowell Hospital, Inc. may proceed to acquire the above referenced health service facility without first obtaining a certificate of need. However, you need to contact the Agency's Acute and Home Care Licensure and Certification Section to obtain instructions for changing ownership of the existing facility. Note that pursuant to G.S. 131E-181(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."*

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,
Assistant Chief, Certificate of Need

cc: Acute and Home Care Licensure and Certification Section, DHSR
Assistant Chief, Healthcare Planning

Healthcare Planning and Certificate of Need Section

www.ncdhhs.gov

Telephone: 919-855-3873 • Fax: 919-715-4413

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

Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

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Halatek, Julie F

From: Maureen Demarest Murray <Maureen.Murray@smithmoorelaw.com>
Sent: Monday, August 10, 2015 10:55 AM
To: Halatek, Julie F
Cc: Allyson Labban
Subject: RE: Mission Exemption Notice regarding ARA Acquisition--Response to Request for Additional Information

Thanks, Julie.

-----Original Message-----

From: Halatek, Julie F [mailto:julie.halatek@dhhs.nc.gov]
Sent: Monday, August 10, 2015 10:54 AM
To: Maureen Demarest Murray
Cc: Allyson Labban
Subject: RE: Mission Exemption Notice regarding ARA Acquisition--Response to Request for Additional Information

Maureen,

Thanks! I'll review and let you know if I need anything else.

Julie Halatek

N.C. Department of Health and Human Services Project Analyst, Healthcare Planning and Certificate of Need
Section - Division of Health Service Regulation
809 Ruggles Drive
Raleigh, NC 27603
(Office) 919.855.3873
julie.halatek@dhhs.nc.gov
www.ncdhhs.gov/dhsr

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-----Original Message-----

From: Maureen Demarest Murray [mailto:Maureen.Murray@smithmoorelaw.com]
Sent: Monday, August 10, 2015 10:50 AM
To: Halatek, Julie F <julie.halatek@dhhs.nc.gov>
Cc: Allyson Labban <Allyson.Labban@smithmoorelaw.com>
Subject: RE: Mission Exemption Notice regarding ARA Acquisition--Response to Request for Additional Information

Julie,

So sorry for the delay in getting back to you about the Brevard and McDowell exemption requests. I thought that I had responded to you earlier and realized that I never sent the e-mail.

Attached are diagrams showing the before/former and after/current transaction picture for the Brevard and McDowell exemption requests. These are fairly straightforward. The assets and services remain in place.

The hospital in each circumstance is acquiring Asheville Radiology's interests in the diagnostic center joint venture and the name of the joint venture LLC is changing.

We have received the exemption letters from the CON Section regarding the other aspects of the transaction so I believe you found the information that you needed in the previous submittals.

If you have other questions or need other information, please let Allyson or me know.

Kind regards, Maureen

Maureen Demarest Murray, Esq.
Smith Moore Leatherwood LLP
300 North Greene Street, Suite 1400
Greensboro, NC 27401
Direct: 336.378.5258
www.smithmoorelaw.com

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-----Original Message-----

From: Halatek, Julie F [mailto:julie.halatek@dhhs.nc.gov]

Sent: Wednesday, July 01, 2015 3:45 PM

To: Maureen Demarest Murray

Cc: Allyson Labban

Subject: RE: Mission Exemption Notice regarding ARA Acquisition--Response to Request for Additional Information

Maureen and Alison,

After reviewing all the information, I am all set with the information needed for the exemption requests for Asheville Imaging and Asheville MRI. However, I am missing any information about the Brevard and McDowell requests. I need that before I can proceed with those requests. However, the format you gave me the information in works fine, so that should hopefully help in terms of preparing other information.

Additionally, in the attachments for the 222 Asheland Avenue transaction, there are two slides marked "Asheville MRI - AIOC" (the former and current slides). I didn't see any mention of either the C-Arm or the procedure table in either of the two Asheville requests. Am I missing something in my reading?

Thanks!

Julie Halatek

N.C. Department of Health and Human Services Project Analyst, Healthcare Planning and Certificate of Need
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-----Original Message-----

From: Halatek, Julie F
Sent: Tuesday, May 19, 2015 9:13 AM
To: Maureen Demarest Murray
Cc: Allyson Labban; Frisone, Martha
Subject: RE: Mission Exemption Notice regarding ARA Acquisition--Response to Request for Additional Information

Maureen, thanks so much! It may take me a few days to fully explore this - I have a few deadlines that are approaching - but it's been on the top of my list for whenever you were able to get me the information. I'll reach out if I have any questions and please don't hesitate to reach out to me with any questions or updates as well!

Julie Halatek
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-----Original Message-----

From: Maureen Demarest Murray [mailto:Maureen.Murray@smithmoorelaw.com]
Sent: Tuesday, May 19, 2015 12:16 AM
To: Halatek, Julie F
Cc: Allyson Labban; Frisone, Martha
Subject: RE: Mission Exemption Notice regarding ARA Acquisition--Response to Request for Additional Information

Hi Julie,

So sorry for the time it has taken us to complete our response to your request for additional information. Mission brought a new Executive Director of Radiology on board during this time and she had to transition into her role. I have also been tied up on an urgent matter.

Attached are charts illustrating the locations and equipment at each location before and after the transaction between Mission and ARA. We thought the chart approach would be most helpful to you.

If you have additional questions or would like to discuss this information, please let Allyson Labban (336-378-5261) or me know.

Kind regards, Maureen

Maureen Demarest Murray, Esq.
Smith Moore Leatherwood LLP
300 North Greene Street, Suite 1400
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Direct: 336.378.5258
www.smithmoorelaw.com

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-----Original Message-----

From: Halatek, Julie F [mailto:julie.halatek@dhhs.nc.gov]
Sent: Monday, April 27, 2015 7:53 AM
To: Maureen Demarest Murray
Subject: RE: Mission Exemption Notice regarding ARA Acquisition

Great - thanks Maureen!

-----Original Message-----

From: Maureen Demarest Murray [mailto:Maureen.Murray@smithmoorelaw.com]
Sent: Friday, April 24, 2015 4:25 PM
To: Halatek, Julie F
Subject: Mission Exemption Notice regarding ARA Acquisition

Dear Julie,

Just letting you know that we are still in the process of confirming some information with Mission to respond to your request for additional information. Mission has a new executive director of radiology so she is trying to get acclimated and has a number of items to address. It is taking a little longer than we expected.

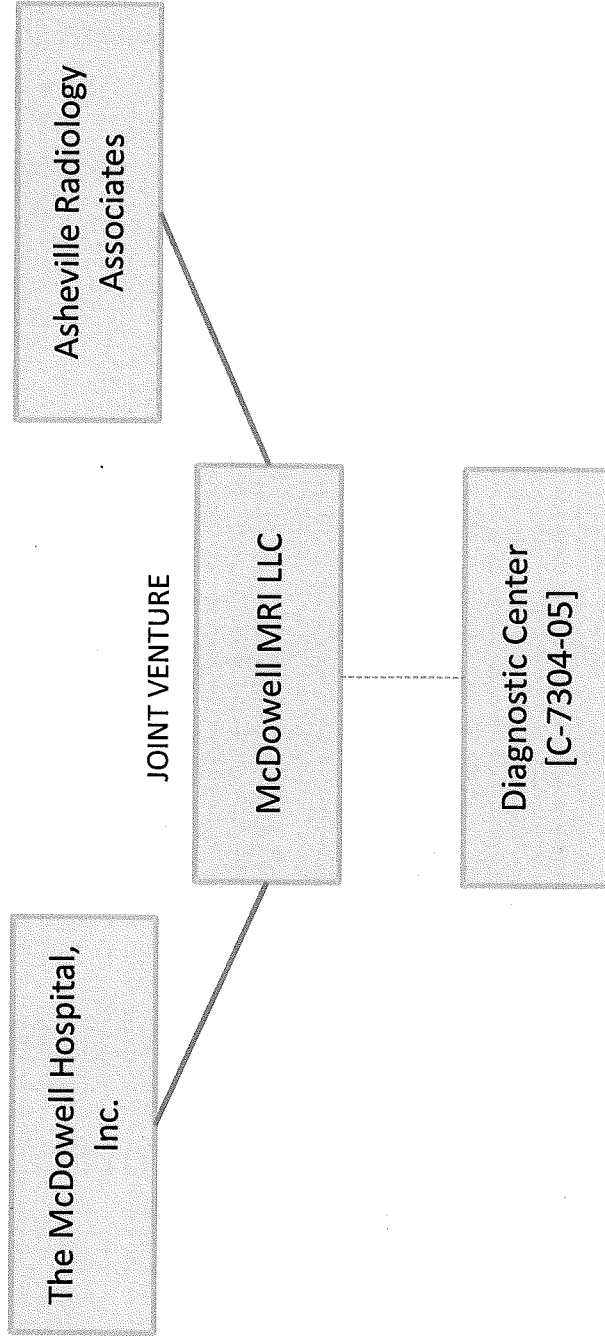
We plan to respond to you next week.

Have a great weekend.

Maureen

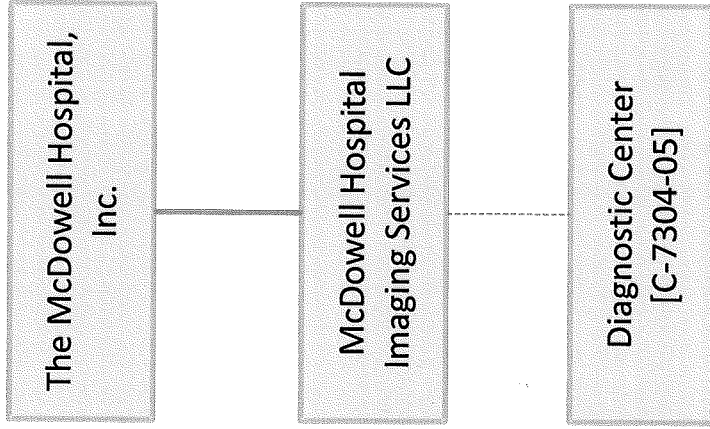
Maureen Demarest Murray
Smith Moore Leatherwood LLP
maureen.murray@smithmoorelaw.com

Former: 414 Rankin Drive, Marion (McDowell MRI LLC)



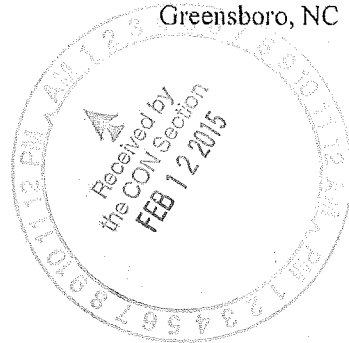
- MRI [C-7304-05]

Current: 414 Rankin Drive, Marion (McDowell Hospital Imaging Services LLC)



- MRI [C-7304-05]

February 12, 2015



Via E-Mail and U.S. Mail

Martha Frisone, Assistant Chief
Certificate of Need Section
Division of Health Service Regulation
NC Department of Health and Human Services
2704 Mail Service Center
Raleigh, North Carolina 27699-2704

Re: Corporate Reorganization and Acquisition of the Assets of McDowell MRI, LLC by McDowell Hospital Imaging Services, LLC and Acquisition of 100% Ownership Interest in McDowell Hospital Imaging Services, LLC by The McDowell Hospital, Inc.

Dear Ms. Frisone:

The purpose of this letter is to provide notice to the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Certificate of Need Section (the "Agency") of a corporate reorganization that will result in the acquisition of substantially all of the assets of McDowell MRI, LLC by McDowell Hospital Imaging Services, LLC, and the subsequent acquisition of 100% ownership interest in McDowell Hospital Imaging Services, LLC by The McDowell Hospital, Inc., which is exempt and not subject to review under the North Carolina Certificate of Need ("CON") law.

McDowell MRI, LLC currently provides a fixed MRI at a diagnostic center located on the campus of The McDowell Hospital in Marion. See Project I.D. No. C-7304-05. McDowell MRI, LLC is jointly owned by The McDowell Hospital, Inc. and Asheville Radiology Associates. The certificate of need for the diagnostic center located on the campus of The McDowell Hospital in Marion was issued in 2005. The application that resulted in issuance of the CON proposed that The McDowell Hospital, Inc. and McDowell MRI, LLC would jointly develop a fixed MRI scanner and develop a new diagnostic center on the campus of The McDowell Hospital. The application proposed that The McDowell Hospital would construct space for the diagnostic center and would own the facility and bill patients for the proposed fixed MRI services on behalf of McDowell MRI but that McDowell MRI would own the scanner and lease space to operate the equipment from The McDowell Hospital. (See Page 2 of enclosed CON Section's Findings).

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McDowell MRI, LLC proposes to form a new limited liability company, McDowell Hospital Imaging Services, LLC, that will also be jointly owned by The McDowell Hospital, Inc. and Asheville Radiology Associates. McDowell MRI, LLC. will then distribute substantially all of its assets to the new entity (McDowell Hospital Imaging Services, LLC). Subsequently, Asheville Radiology Associates will transfer its membership interest in McDowell Hospital Imaging Services, LLC to The McDowell Hospital, Inc., which will increase its ownership percentage of McDowell Hospital Imaging Services, LLC to one hundred percent. A chart illustrating the transaction is enclosed as Exhibit A.

The McDowell Hospital, Inc. will continue to own the CON diagnostic center, operate the facility and bill patients for MRI services. The diagnostic center, MRI and related assets will remain in operation at their current location. McDowell Hospital Imaging Services, LLC does not propose to offer or develop any new institutional health services or acquire any new major medical equipment or other reviewable equipment as part of this transaction. As you know, a diagnostic center is an existing health service facility and the acquisition of existing health service facilities is exempt pursuant to N.C. Gen. Stat. § 131E-184(a)(8). The McDowell Hospital, Inc.'s acquisition of 100% of the ownership interest in the reorganized legal entity and its assets is legally permissible by providing this prior written notice to the CON Section and does not require a CON.

The proposed transaction is similar to various corporate reorganization and restructuring transactions previously approved by the CON Section. For example, on August 27, 2013, the CON Section confirmed that the transfer of 100% of Roanoke Valley Cancer Center, P.A.'s ownership interests in a linear accelerator and other assets to a newly-formed LLC—and the subsequent acquisition of 100% of the ownership interest in the newly-formed LLC by NCRTMS—was exempt from review. See 08/27/13 No Review determination issued to North Carolina Radiation Therapy Management Services ("NCRTMS") (Exhibit B). Under the approved transaction, Roanoke Valley Cancer Center, P.A. formed a new LLC to which it transferred the linear accelerator and other associated operating assets. NCRTMS then acquired 100% ownership interest in the new LLC. In support of its exemption notice, NCRTMS cited to the August 18, 2011 Declaratory Ruling issued to Radiation Oncology Centers of the Carolinas, Inc., approving the petitioner's transfer of its ownership interests in existing oncology treatment centers and major medical equipment to two wholly-owned subsidiaries. (Exhibit C)

NCRTMS also cited to the September 27, 2010 Declaratory Ruling confirming that Wake Radiology Oncology Services, PLLC's change in business form from a PLLC to an LLC and sale of ownership interests in the new LLC did not require a CON, in which Drexdal Pratt stated: "Prior declaratory rulings show that the Department has already determined that these [CON]

February 12, 2015

Page 3

definitions do not require an entity to obtain a CON to acquire membership interests in an existing legal entity...The declaratory ruling requested by Petitioners is consistent with the Department's prior rulings that have interpreted the applicability of the CON Law to the purchase of ownership interests in health care organizations." Mr. Pratt also noted that while the acquisition of ownership interests in the LCC would involve expenditures, "[t]here 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." (Exhibit D) *See also* 04/02/12 No Review regarding transfer of membership interests and acquisition of ownership interests in entities that own Sampson Regional Cancer Center (Exhibit E); 12/20/12 Exempt from Review/Acquisition of substantially all the assets of Union Regional Home Care (HHA) by The Charlotte-Mecklenburg Hospital Authority (Exhibit F); 12/21/12 Exempt from Review/Acquisition of substantially all the assets of Chapel Hill Surgical Center, Inc. by The University of North Carolina Hospitals at Chapel Hill and the subsequent lease back of such assets by UNC Hospitals to Chapel Hill Surgical Center, Inc. (Exhibit G); 12/09/11 Exempt from Review/Transfer by CSA Medical Services, LLC of 100% ownership interests in existing heart-lung bypass machines to two wholly-owned subsidiaries, and 02/27/12 No Review/WakeMed/Acquisition of Ownership Interests in CSA-1 and 02/27/12 No Review/Rex Hospital/Acquisition of Ownership Interests in CSAMS Lake Boone (whereby equipment owner transferred assets to two wholly-owned subsidiaries, which subsidiaries were subsequently acquired by WakeMed and Rex) (Exhibit H).

Based on the information provided in this letter, we would appreciate the Agency's written confirmation that the proposal described above is not subject to CON review and does not require a CON. If you require additional information to consider this request, please let us know. We appreciate your consideration.

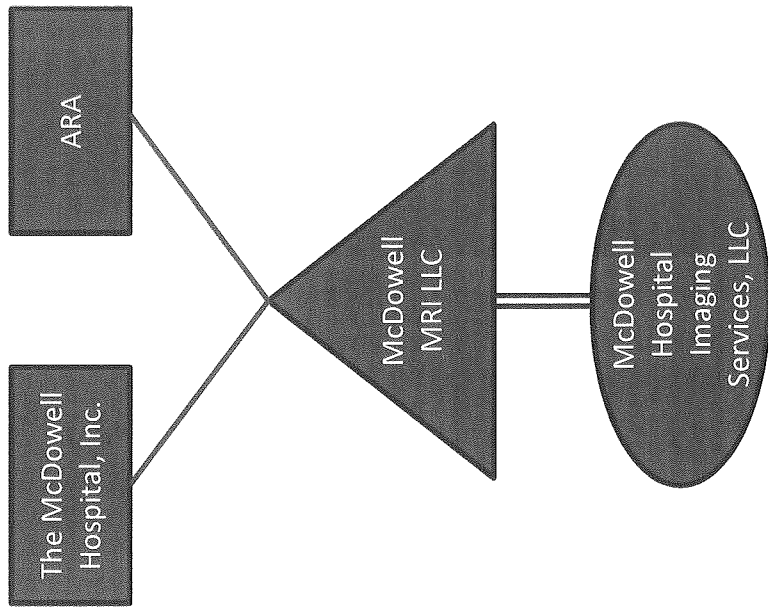
Sincerely,

SMITH MOORE LEATHERWOOD LLP

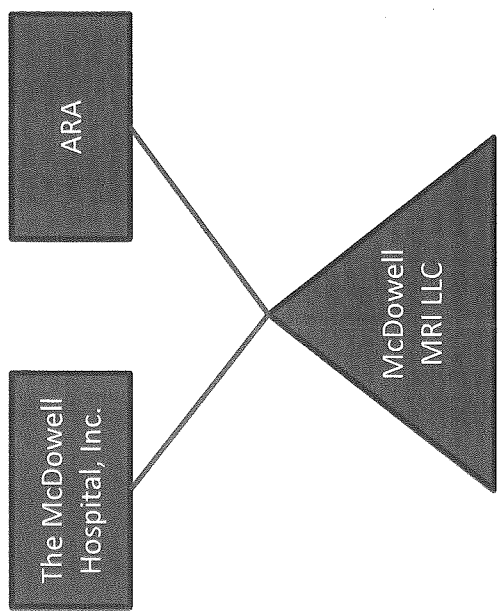
Maureen Demarest Murray
Maureen Demarest Murray (w/permission by
Allyson Jones Galbraith)

cc: Brian Moore

Creation of McDowell Hospital Imaging Services, LLC

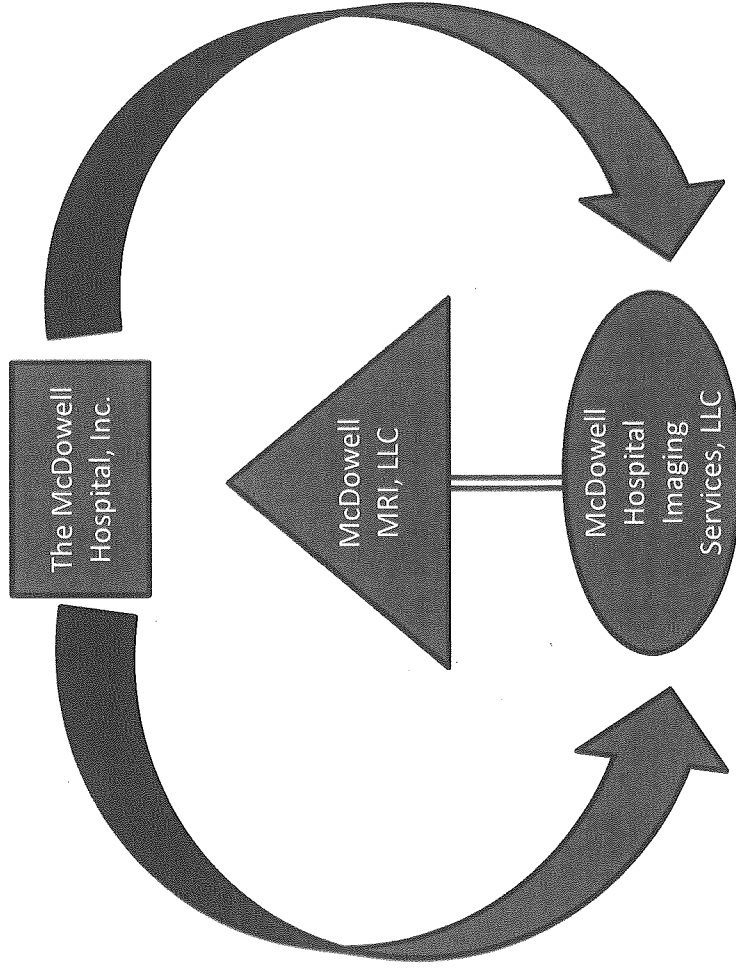


Current Structure



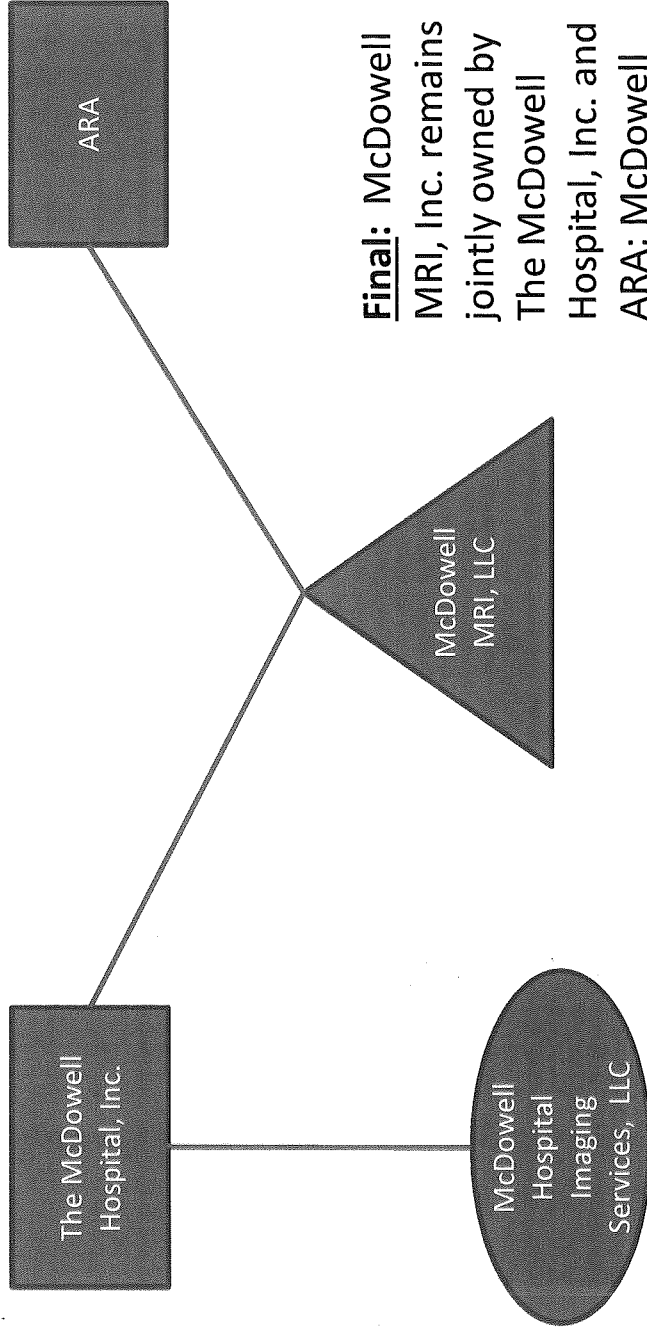
Step One:
McDowell MRI LLC forms McDowell Hospital Imaging Services LLC and distributes assets

Acquisition of Ownership Equity by The McDowell Hospital, Inc.



Step Two:
The McDowell Hospital, Inc. acquires 100% of McDowell Hospital Imaging Services, LLC

Final Structure



Final: McDowell MRI, Inc. remains jointly owned by The McDowell Hospital, Inc. and ARA; McDowell Hospital Imaging Services, LLC is a wholly-owned subsidiary of The McDowell Hospital, Inc.



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

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Drexdal Pratt
Division Director

August 27, 2013

William R. Shenton
Poyner Spruill
301 Fayetteville Street
Suite 1900
Raleigh, NC 27602

No Review

Facility or Business: Roanoke Valley Cancer Center

Project Description:

- o Transfer of 100% of Roanoke Valley Cancer Center, P.A ownership interests in the linear accelerator and other assets to New LLC
- o Acquisition of 100% of New LLC by NCRTMS

County: Halifax
FID #: 130385

Dear Mr. Shenton:

The Certificate of Need Section (CON Section) received your letter of July 25, 2013 regarding the above referenced proposal. Based on the CON law **in effect on the date of this response to your request**, the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

Moreover, you need to contact the Acute and Home Care Licensure and Certification Sections of the Division of Health Service Regulation to determine if they have any requirements for development of the proposed project.

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project 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 project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the

Certificate of Need Section

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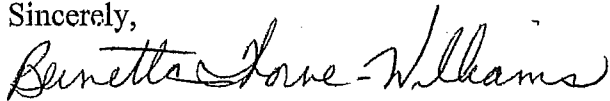
Exhibit B

Mr. Shenton
August 27, 2013
Page 2

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,



Bernetta Thorne-Williams, Project Analyst



Craig R. Smith, Chief
Certificate of Need Section

cc: Medical Facilities Planning Section, DHSR
Acute and Home Care Licensure and Certification Section, DHSR

Smith

Poyner Spruill^{LLP}

July 25, 2013

Received by
the CON Section
JUL 25 2013

William R. Shenton
Partner
D: 919.783.2947
F: 919.783.1075
wshenton@poynerspruill.com

VIA HAND DELIVERY

Craig R. Smith
Chief
CON Section
809 Ruggles Drive
Raleigh, NC 27603

Martha Frisone
Assistant Chief
CON Section
809 Ruggles Drive
Raleigh, NC 27603

RE: Acquisition of Linear Accelerator Operated by Roanoke Valley Cancer Center

Dear Mr. Smith and Ms. Frisone:

We are writing on behalf of North Carolina Radiation Therapy Management Services, Inc. ("NCRTMS"), to inform the Certificate of Need Section of its plans to purchase the ownership interests in an organization that operates a linear accelerator located at 212 Smith Church Road in Roanoke Rapids, North Carolina. As a result of the transaction described in this letter, NCRTMS will acquire ownership of the entity that now operates the linear accelerator. Based on the CON Section's treatment of similar arrangements in the past, the transaction described in this letter does not involve an activity for which a certificate of need should be required. In a separate letter to be submitted at a later date, NCRTMS will describe its plans to replace the current linear accelerator operated in Roanoke Rapids and present the basis for an exemption of that replacement from certificate of need review under NC 10 Stat. § 131E-184(a)(7) and 10A NCAC 14C .0303.

OVERVIEW

Roanoke Valley Cancer Center, P.A.

The current owner of the linear accelerator in operation in Roanoke Rapids is Roanoke Valley Cancer Center, P.A. This facility treated its first patient with a Cobalt 60 linear accelerator on April 8, 1988, and thus was in operation and became an "Oncology Treatment Center" before the Certificate of Need Law was amended in 1993 to require a certificate of need before an Oncology Treatment Center is established. **Exhibit 1** has excerpts from each State Medical Facilities Plan since 1997, the first SMFP that presented a linear accelerator inventory. This data shows that Roanoke Valley Cancer Center's linear accelerator has operated continuously throughout this period. We understand that late in 1995, it acquired the refurbished Varian Clinac 6/100 linear accelerator, which it operates now, at a total cost of \$295,000, which included all associated construction and upfit costs. Since the purchase of the Varian Clinac 6/100, the following additional equipment purchases associated with the operation of the linear accelerator have occurred, with the stated costs and dates of purchase, where available:

- Acrylic base plate with Silverman support (\$390.00)
- Breast boards (2 model MT-250WC) \$6,190.00
- Cassette holder model MT-300 (\$2,400.00 – May/1996)
- Crosshair laser (\$4,358.72 – July 31, 2001)
- Digital electro meter (\$1,200.00)
- Simulator manufactured by Cascade (\$59,000.00 – July 24, 1998)

Craig R. Smith
Martha Frisone
July 25, 2013
Page 2

Poyner Spruill^{LLP}

As best as can be presently determined, the purchase of the Varian 6/100 linear accelerator was not presented to the CON Section for consideration as a Replacement Equipment exemption under N.C. Gen. Stat. § 131E-184(a)(7). However, as already noted, the center already was in operation and was an established oncology treatment center before the statutory amendment, and so the purchase of the Varian machine did not constitute the initial development or establishment of an oncology treatment center that would require obtaining a certificate of need. In addition, the total cumulative expenditures for all of these equipment purchases, from acquisition of the Varian 6/100 linear accelerator forward to the present time, is \$368,538.72. Thus, the total cost of the current Varian Clinac 6/100 and all other equipment in place at the center since purchase of the Varian Clinac 6/100 falls well below the Major Medical Equipment threshold of \$750,000 defined in N.C. Gen. Stat. § 131E-176 (14o). Accordingly, none of the equipment purchases at the center to date have required a certificate of need.

The Transfer of Ownership Interest in Roanoke Valley Cancer Center, P.A.

The transaction presented in this letter will involve only a transfer of the underlying ownership interests of the center. As its name indicates, Roanoke Valley Cancer Center, P.A., is a professional association. The sole owner of its stock is Dr. C.A. Thannikkary, a licensed physician. Roanoke Valley plans to establish a limited liability company whose interests can be acquired by non-physicians. The linear accelerator and other associated operating assets would be transferred to this **NEW LLC**, and simultaneously with the transfer, NCRMS would acquire all of the ownership interests in the NEW LLC.

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 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). Accordingly, the CON Law essentially focuses on the development and offering of those "new institutional health services" that are listed in N.C. Gen. Stat. § 131E-176(16), and which would create additional health service capacity. Each of the listed new institutional health services entails the establishment of an additional health service or facility, the operation of additional equipment, or an expansion or relocation of existing services. Each of these events could have an impact on the capacity, or service area, of a type of health service and thereby affect how it is utilized. In keeping with its fundamental goals, the CON Law expressly recognizes that certain activities are not subject to review, such as purchases of existing health services, or the repair or replacement of existing facilities or equipment, since these actions do not change the overall capacity of the health care system. Based upon the clear terms of the CON Law and prior declaratory rulings by the Department that have recognized this fundamental principle, 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 addresses, directly or indirectly, the acquisition of ownership interests in an organization that already offers a health service. The CON Law also identifies changes in ownership among the "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, based on the text of the law, the acquisition of NEW LLC's ownership interests does not involve a new service at all and should not be subject to CON review.

The Proposed Transaction Does Constitute the Acquisition of a Linear Accelerator or Simulator Subject to Review Under N.C. Gen. Stat. § 131E-176(16)(f1).

The list of new institutional health services does include "the acquisition by purchase, donation, lease, transfer or comparable arrangement" of a linear accelerator or simulator "by or on behalf of any person," N.C. Gen. Stat. § 131E-176(16)(f1)5a, 9; but the proposed acquisition by NCRIMS of all the ownership interests of NEW LLC 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 entity owning the existing radiation center and its associated equipment. The ownership of the NEW LLC will change to NCRIMS, but its legal status as an existing business entity will not change. Since NEW LLC will remain the same legal entity, the same "person" will own and operate the linear accelerator and other equipment following the Proposed Transaction. See N.C. Gen. Stat. §131E-176(19). Accordingly, and consistent with the rulings issued since the August 2005 amendment, there is no basis to treat the Proposed Transaction as a purchase of a linear accelerator under the provisions of N.C. Gen. Stat. § 131E-176(16)(f1) 5a and to require a certificate of need before it may occur.

The Agency's Past Responses to Similar Transactions Confirm that This Does Not Require a CON.

This request follows prior declaratory rulings which have interpreted the applicability of the CON Law to the purchase of ownership interests in corporate entities that already are operating a health service. In at least four rulings that were issued after the enactment of the August 2005 amendment to the CON Law, the Department has determined 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 centers 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 2)*.
- 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 ownership interests in Wake Radiology Oncology Services 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 3)*.

In addition to the two rulings attached as exhibits, the Department also issued a declaratory ruling on December 21, 2007, finding that Rex Healthcare, Inc.'s purchase of the membership interests of Smithfield Radiation Oncology, LLC, was not subject to CON review; and a declaratory ruling on September 14, 2007, confirming that certificate of need review was not required for the sale to another entity of 100% of the stock of a company that owned a linear accelerator.

Finally, in transactions involving acquisitions by NCRTMS of ownership interest in entities that operated linear accelerators in Goldsboro and Clinton, the CON Section has issued no review letters confirming that transactions structured in a similar way to the one described in this letter may proceed without certificate of need review. Attached as **Exhibit 4** is the letter that was issued by the CON Section on April 2, 2012 with regard to the transactions involving the linear accelerator in Clinton.

Thus, the Department and CON Section have consistently determined that events such as the Proposed Transaction do not trigger certificate of need review. The transactions involved in the above-described declaratory rulings are exactly analogous to the Proposed Transaction at issue in this request. Under the Proposed Transaction, NCRTMS will acquire all of the ownership interests in NEW LLC, which will continue to own the Roanoke Valley Cancer Center and its associated equipment, including the Varian 6/100 Linac.

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

The Proposed Transaction 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 ownership of NEW LLC, 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 medical equipment and offering 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 ownership of the Roanoke Valley Cancer Center is not integral to its clinical management, and the center's operations will not change as a result of the Proposed Transaction. Therefore, the purchase of ownership interests in NEW LLC 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).

CONCLUSION

As explained above, since 1995, Roanoke Valley Cancer Center has been operated as a radiation oncology center for many years and that will continue after completion of the Proposed Transaction. The Proposed Transaction would only involve a transfer of the underlying ownership interests in the corporate entity that owns the linear accelerator. The equipment will continue to serve patients at the same location, and there will be no change in the scope of services provided by the Cancer Center as a result 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.

For all of the foregoing reasons, the regulation of events like the Proposed Transaction, involving an existing oncology center and its associated equipment, which does 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. 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*

Craig R. Smith
Martha Frisone
July 25, 2013
Page 5

Poyner Spruill^{LLP}

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 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 Exhibits 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 that it may proceed without a certificate of need. Thank-you for your attention to this matter, and please let me know if there is any additional information you may require.

Very truly yours,



William R. Shenton
Partner



North Carolina Department of Health and Human Services
 Division of Health Service Regulation
 Office of the Director
 2701 Mail Service Center • Raleigh, North Carolina 27699-2701
<http://www.ncdhhs.gov/dhsr>

Beverly Eaves Perdue, Governor
 Lanier M. Cantler, Secretary

Drexdal Pratt, Director
 Phone: 919-855-3750
 Fax: 919-733-2757

August 18, 2011

CERTIFIED MAIL

Bode Call & Stroupe, L.L.P.
 S. Todd Hemphill, Esquire
 Post Office Box 6338
 Raleigh, NC 27628-6338

RE: Declaratory Ruling for Radiation Oncology Centers of the Carolinas, Inc.

Dear Mr. Hemphill:

I am enclosing a Declaratory Ruling that you requested. If questions arise, do not hesitate to let me know.

Sincerely,

Drexdal Pratt

DP:JH:peb

Enclosure

- cc: Jeff Horton, Chief Operating Officer, DHSR
 Craig Smith, Chief, Certificate of Need Section
 Steven Lewis, Chief, Construction Section
 Azzie Conley, Chief, Acute and Home Care Licensure and Certification Section
 DHSR Medical Facilities Planning Section
 Marc Lodge, Special Deputy Attorney General, DOJ



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

**IN RE: REQUEST FOR DECLARATORY)
 RULING BY RADIATION ONCOLOGY) DECLARATORY RULING
 CENTERS OF THE CAROLINAS, INC.)**

I, Drexel 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.

Radiation Oncology Centers of the Carolinas, Inc. ("ROCC") has requested a declaratory ruling to confirm that the transfer of two CON-approved radiation oncology facilities to two wholly owned subsidiaries (the "Proposed Transaction") will not constitute a new institutional health service or require a CON. This ruling will be binding upon the Department and the entities 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. S. Todd Hemphill of Bode, Call & Stroupe, L.L.P. has requested this ruling on ROCC's behalf and have provided the material facts upon which this ruling is based.

STATEMENT OF THE FACTS

ROCC directly owns and operates two CON-approved radiation oncology facilities. University Radiation Oncology Center ("UROC"), located at 8310 University Executive Park, Suite 500, Charlotte, NC 28262, was acquired by ROCC in 1997 pursuant to an exemption.

Matthews Radiation Oncology Center ("MROC"), located at 1400 Matthews Township Parkway, Matthews, NC 28105, is a "grandfathered" facility, because it became operational in 1990, prior to the application of the CON law to oncology treatment centers or major medical equipment.

The radiation oncology equipment located at UROC includes a Varian 2100C linear accelerator and a GE Highspeed Advantage CT simulator. The radiation oncology equipment located at MROC includes a Varian 21Ex-d linear accelerator and a GE Brightspeed CT simulator. Acquisition of the linear accelerator and CT simulator equipment at each facility has been previously approved by the agency.

ROCC would like to transfer its interest in UROC and MROC to two wholly owned subsidiaries of ROCC.

ANALYSIS

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. The list of new institutional health services includes "the acquisition by purchase, donation, lease, transfer or comparable arrangement" of a linear accelerator or simulator "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).

Prior declaratory rulings show that the Department has already determined that these definitions do not require an entity to obtain a CON to acquire membership interests in an existing legal entity like ROCC which owns and operates a linear accelerator or simulator. The declaratory ruling requested by Petitioner is consistent with the Department's prior rulings that

have interpreted the applicability of the CON Law to the purchase of ownership interests in health care organizations, for the following reasons:


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 LLC will continue to own the linear accelerator, the simulator, and all the oncology treatment center assets that were authorized under the CON and have been used to furnish oncology treatments to patients.

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. No new, or additional equipment will be acquired or placed in operation in the State.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that the Petitioner does not require a certificate of need in order to proceed with the Proposed Transaction:

This the 18th day of August, 2011.


Drexal 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 nonagency 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

Bode Call & Stroupe, L.L.P.
S. Todd Hemphill, Esquire
Post Office Box 6338
Raleigh, NC 27628-6338

This the 18th day of August, 2011.



Jeff Horton
Chief Operating Officer



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

Office of the Director

2701 Mail Service Center • Raleigh, North Carolina 27699-2701

<http://www.ncdhhs.gov/dhsr>

Beverly Eaves Perdue, Governor
Lanier M. Cansler, Secretary

Drexdal Pratt, Director
Phone: 919-855-3750
Fax: 919-733-2757

September 27, 2010

CERTIFIED MAIL

William R. Shenton, Esquire
Poyner Spruill LLP
301 Fayetteville Street, Suite 1900
Raleigh, NC 27601

RE: Declaratory Ruling for Wake Radiology Oncology Services, PLLC, Cancer Centers of North Carolina, P.C., US Oncology, Inc., AOR Management Company of Virginia, LLC and WakeMed.

Dear Mr. Shenton:

I am enclosing a Declaratory Ruling that you requested. If questions arise, do not hesitate to let me know.

Sincerely,

Drexdal Pratt

DP:JH:peb

Enclosure

cc: Ronald I. Kirschbaum, Esq., Kirschbaum, Nanney, Keenan & Griffin, P.A.
Larry E. Robbins, Esq., Wyrick Robbins Yates & Ponton, LLP
Maureen Demarest Murray, Esq., Smith Moore Leatherwood LLP
✓ Jeff Horton, Chief Operating Officer, DHSR
Craig Smith, Chief, Certificate of Need Section
Steven Lewis, Chief, Construction Section
Azzie Conley, Chief, Acute and Home Care Licensure and Certification Section
Medical Facilities Planning Section
Marc Lodge, Special Deputy Attorney General, DOJ



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

IN RE: REQUEST FOR DECLARATORY)	
RULING BY WAKE RADIOLOGY)	
ONCOLOGY SERVICES, PLLC, CANCER)	DECLARATORY RULING
CENTERS OF NORTH CAROLINA, P.C.,)	
US ONCOLOGY, INC., AOR)	
MANAGEMENT COMPANY OF VIRGINIA,)	
LLC AND WAKEMED)	

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.

Wake Radiology Oncology Services, PLLC (hereinafter "WROS"); Cancer Centers of North Carolina, P.C. ("CCNC"); US Oncology, Inc. ("USON") and its subsidiary AOR Management Company of Virginia, LLC ("AOR"); and WakeMed have requested a declaratory ruling to confirm that the acquisition of the membership interests in WROS and the continued operation of the oncology treatment center may proceed without first obtaining a certificate of need. This ruling will be binding upon the Department and the entities 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. Attorneys for the Petitioners have requested this ruling on their behalf and have provided the material facts upon which this ruling is based.

STATEMENT OF THE FACTS

WROS is a North Carolina professional limited liability company presently owned by certain physician-members, each of whom owns a specific percentage of the total membership interests in WROS. WROS provides radiation oncology treatment services at 300 Ashville Avenue, Suite 110, Cary, North Carolina, based on a certificate of need that was issued in 1997 to own an oncology treatment center and to operate a linear accelerator and simulator and other equipment used in furnishing radiation oncology services.

CCNC is a professional corporation organized under the laws of the State of North Carolina. CCNC 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 a linear accelerator.

USON is a business corporation organized under the laws of the State of Delaware. Through its subsidiaries, US Oncology provides administrative support for, and furnishes medical equipment used by, oncology practices throughout the United States.

AOR is a limited liability company, a subsidiary of USON and was organized under the laws of the State of Delaware and authorized to do business in North Carolina. AOR provides administrative and other support services to CCNC under a Management Services Agreement with CCNC.

WakeMed is a North Carolina nonprofit corporation engaged in the provision of acute care services and other health care services in Wake County.

WROS established its oncology treatment center on or about July 17, 1998. Since the establishment of its oncology treatment center, WROS has continuously operated the oncology treatment center established pursuant to the CON it received in 1997.

When the CON Law was amended in 2005, WROS already was operating an existing oncology treatment center pursuant to the CON that it had obtained in 1997 and using a linear accelerator and simulator that had been recognized in the SMFP inventory for seven years. Since it already owned the equipment, it was not required to obtain a second CON to be able to continue to operate its linear accelerator and simulator.

Recently, WROS physician owners approved a conversion of WROS from a professional limited liability company to a limited liability company, to occur simultaneously with the sale of ownership interests to CCNC. It is likely that WROS will change its name after the sale. Subsequently, in a separate transaction, WakeMed anticipates purchasing a minority membership interest in the renamed WROS ("the LLC").

This change in the business form of WROS that has been approved by its physician owners will not constitute a change in or dissolution of WROS, the legal entity that received the CON in 1997 and has continuously operated the oncology treatment center and the linear accelerator and simulator since they became operational.

After these two transactions, the LLC will continue to exist as a legal and business entity, and will continue to own the oncology treatment center and the equipment that was authorized under the 1997 CON, including the linear accelerator and simulator. The oncology treatment center and its equipment will remain at the same location at 300 Ashville Avenue in Cary.

The LLC will not offer any medical services. Oncology treatment services will be furnished by physicians associated with CCNC.

ANALYSIS

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. The list of new

institutional health services includes “the acquisition by purchase, donation, lease, transfer or comparable arrangement” of a linear accelerator or simulator “by or on behalf of any person,” N.C. Gen. Stat. § 131E-176(16)(f1)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).

Prior declaratory rulings show that the Department has already determined that these definitions do not require an entity to obtain a CON to acquire membership interests in an existing legal entity like WROS which owns and operates a linear accelerator or simulator. The declaratory ruling requested by Petitioners is consistent with the Department’s prior rulings that have interpreted the applicability of the CON Law to the purchase of ownership interests in health care organizations, for the following reasons:

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 LLC will continue to own the linear accelerator, the simulator, and all the oncology treatment center assets that were authorized under the 1997 CON and have been used to furnish oncology treatments to patients. Its membership composition initially will change from the present physician members to a single member, CCNC, with the subsequent purchase of a minority interest by WakeMed.

The Proposed Transaction will involve expenditures by CCNC, and later by WakeMed, but 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 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. No new, or additional equipment will be acquired or placed in operation in the State.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that the Petitioners do not require a certificate of need in order to proceed with the Proposed Transaction.

This the 27th day of September, 2010.



Drexal 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 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 pre-paid envelope addressed as follows:

CERTIFIED MAIL


William R. Shenton, Esquire
Poyner Spruill LLP
301 Fayetteville Street, Suite 1900
Raleigh, NC 27601
Attorneys for U.S. Oncology, Inc. and AOR Management
Company of Virginia, LLC

Ronald I. Kirschbaum, Esquire
Kirschbaum, Nanney, Keenan & Griffin, P.A.
Post Office Box 19766
Raleigh, NC 27607
Attorneys for Wake Radiology Oncology, PLLC

Larry E. Robbins, Esquire
Wyrick Robbins Yates & Ponton, LLP
Post Office Drawer 17803
Raleigh, NC 27607
Attorneys for Cancer Centers of North Carolina, P.C.

Maureen Demarest Murray, Esquire
Smith Moore Leatherwood LLP
Post Office Box 21927
Greensboro, NC 27420
Attorneys for WakeMed

This the 27th day of September, 2010.



Jeff Horton
Chief Operating Officer



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
<http://www.ncdhhs.gov/dhsr/>

Drexdal Pratt, Director

Beverly Eaves Perdue, Governor
Albert A. Delia, Acting Secretary

Craig R. Smith, Section Chief
Phone: (919) 855-3873
Fax: (919) 733-8139

April 2, 2012

William R. Shenton
PoynerSpruill
301 Fayetteville Street
Suite 1900
Raleigh, NC 27601

RE: No Review

- Transfer By MV-Photon of its membership interest in Sampson Regional Cancer Center LLC to Sampson Regional Medical Center
- Transfer by Sampson Radiation Oncology, P.A. of its ownership interests in the Simulator currently located in the Sampson Regional Cancer Center LLC to a New LLC (a wholly owned subsidiary of Sampson Radiation Oncology, P.A.)
- Transfer by Sampson Regional Medical Center of its ownership interests in the Linac currently located in the Sampson Regional Cancer Center LLC to SRMC Sub (a wholly-owned subsidiary limited liability company)
- Acquisition of 100% of SRMC Sub by North Carolina Radiation Therapy Management Services, LLC
- Acquisition of 100% of New LLC by North Carolina Radiation Therapy Management Services, LLC

Sampson County

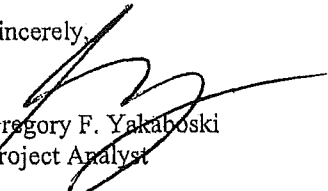
Dear Mr. Shenton:


The Certificate of Need (CON) Section received your letters of February 29, 2012 and March 23, 2012 regarding the above referenced proposal. Based on the CON law in effect on the date of this response to your request, the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal 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 project 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 project 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.

In addition, you should contact the Construction Section, DHSR to determine if they have any requirements for development of the proposed project. 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,


Gregory F. Yakaboski
Project Analyst


Craig R. Smith, Chief
Certificate of Need Section

cc: Medical Facilities Planning Section, DHSR

Exhibit E





Greg

Poyner Spruill^{LLP}

March 23, 2012

William R. Shenton
Partner
D: 919.783.2947
F: 919.783.1075
wshenton@poynerspruill.com

VIA HAND DELIVERY

Mr. Greg Yakaboski
Project Analyst
CON Section
801 Ruggles Drive
Raleigh, NC

RE: Request for No Review Determination – Acquisition of Ownership Interests in Corporate Entities that Own Sampson Regional Cancer Center

Dear Greg:

I am writing to follow up on our telephone conversation earlier this week and enclose a series of charts that depict the current relationships of the parties involved in the operation of the Sampson Regional Cancer Center, the nature of the transactions that are described in the letter that I sent to Craig Smith and Martha Frisone on February 29, and the end result of the transactions proposed.

I hope that this meets your needs in analyzing this matter, and please do not hesitate to contact me if you have any questions concerning the enclosures or any other aspect of the proposed transaction.

Thank you once again for your attention to this.

With best wishes, I am

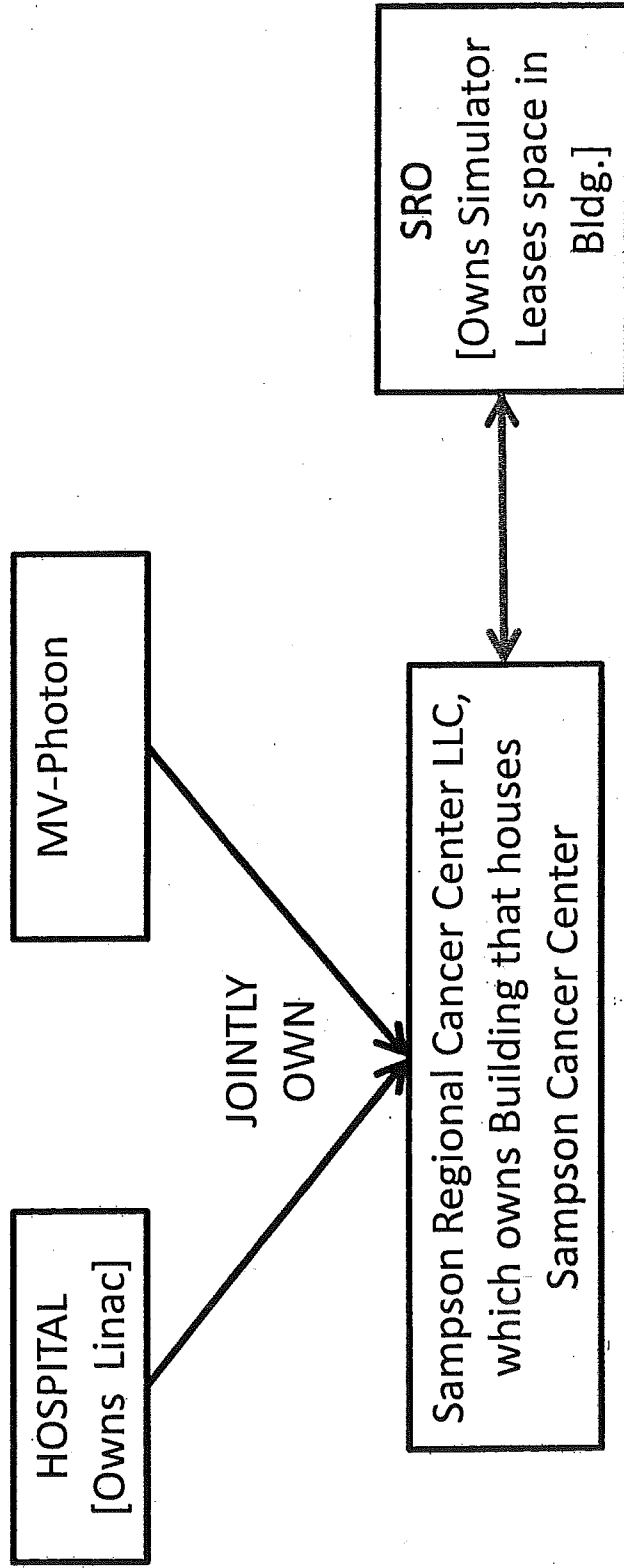
Very truly yours,

William R. Shenton
Partner

WRS:klh

Enc.

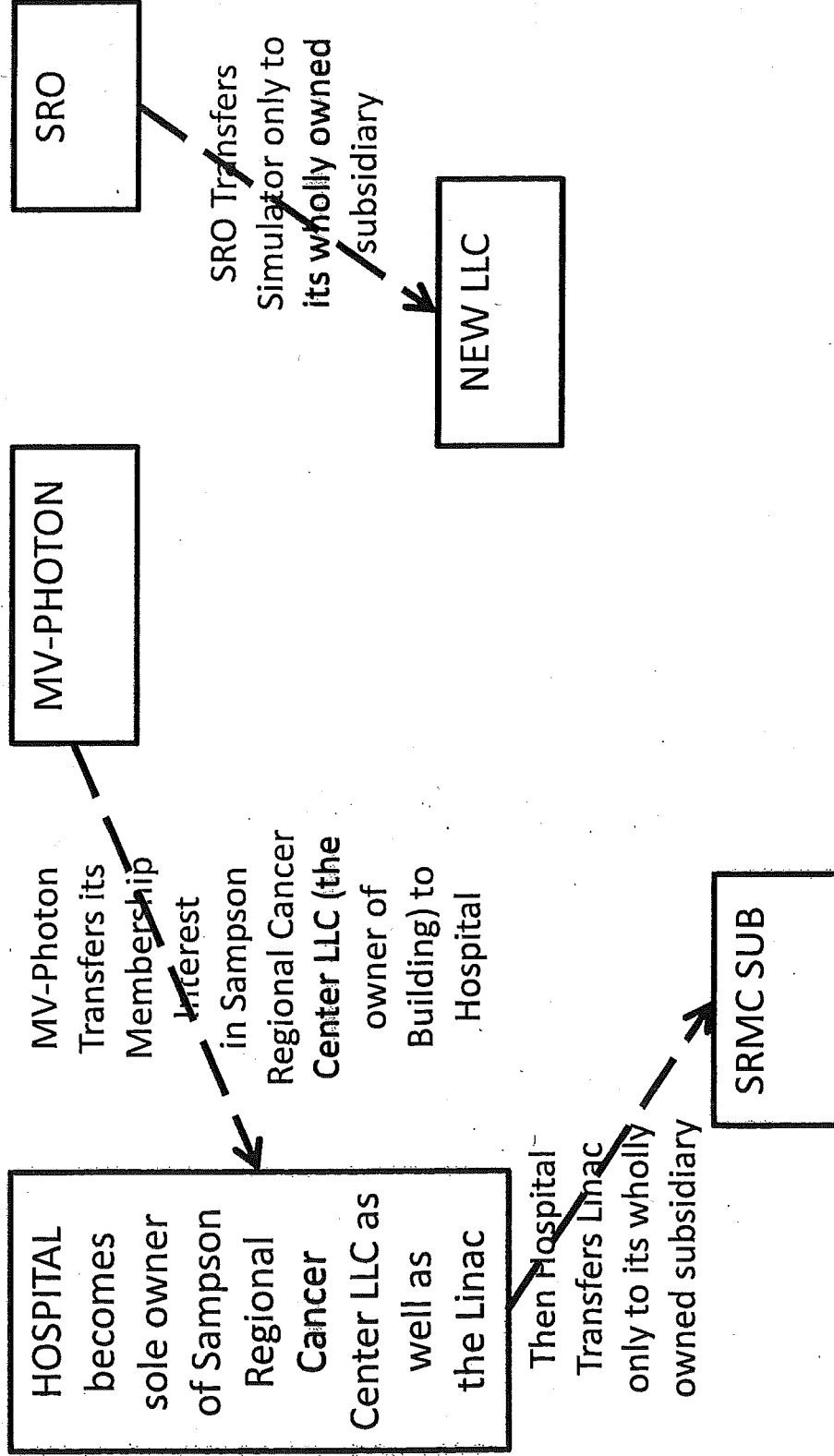
Current Ownership and Relationships to Sampson Cancer Center



Solid Blue Lines indicate an ownership relationship
Solid Green Lines indicate a lease relationship

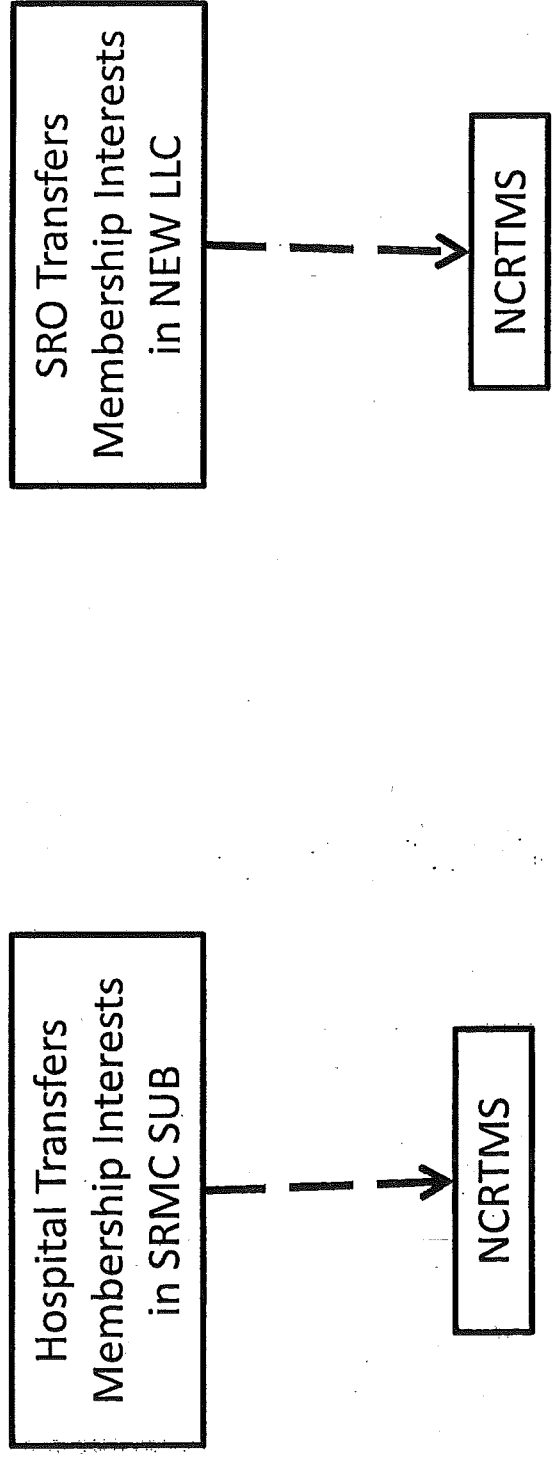
Transfer of Membership Interests

Phase 1



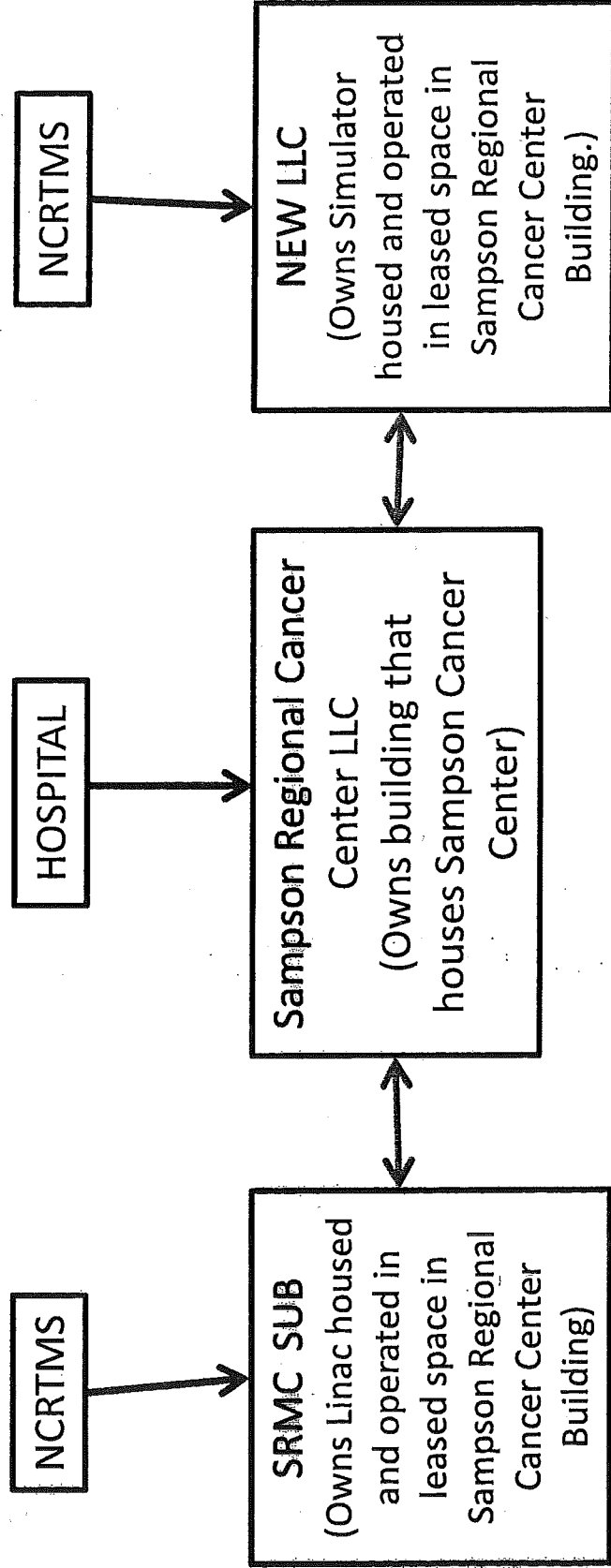
Dotted Red Lines indicate transfer

Transfer of Membership Interests Phase 2



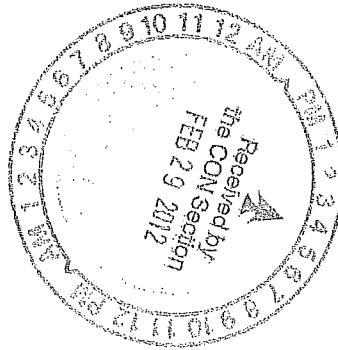
Dotted Red Lines indicate transfer

Resulting Ownership after Transfers



Solid Blue Lines indicate an ownership relationship
Solid Green Lines indicate a lease relationship

February 29, 2012



William R. Shenton
D: 919.783.2947
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Pamela A. Scott
D: 919.783.2954
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pascott@poynerspruill.com

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 Sampson Regional Cancer Center

Dear Mr. Smith:

We are submitting this letter on behalf of our client, Radiation Therapy Services, Inc. ("RTS") and its wholly-owned subsidiary, North Carolina Radiation Therapy Management Services, LLC ("NCRTMS"). RTS (also known as 21st Century Oncology) is a national provider of radiation oncology services, which operates a number of radiation therapy centers in North Carolina. NCRTMS is a North Carolina limited liability company which is a wholly-owned subsidiary of RTS. NCRTMS provides management and administrative support services for RTS's radiation therapy centers in North Carolina.

With this letter, NCRTMS is requesting a no-review determination regarding its acquisition of the ownership interests in the existing Sampson Regional Cancer Center located in Clinton, North Carolina and the associated equipment. Consistent with the longstanding approach of the CON Section in finding that other purchases of corporate ownership interests are not events requiring a certificate of need, NCRTMS now seeks confirmation that its acquisition of membership interests in the corporate entities involved in the existing Sampson Regional Cancer Center, and the continued operation of that center by NCRTMS at the same site, may proceed without first obtaining a certificate of need.

FACTUAL BACKGROUND

This request relates to the Sampson Regional Cancer Center ("Sampson Cancer Center"), which is located at 215 Beaman Street in Clinton, North Carolina, near the Sampson Regional Medical Center campus. The Sampson Cancer Center was established by Sampson Regional Medical Center, Inc. ("the Hospital"), MV-Photon, LLC ("MV-Photon") and Sampson Radiation Oncology, P.A. ("SRO") following a settlement agreement that was reached in contested cases arising from a 2003 linear accelerator review conducted by the North Carolina Certificate of Need Section. The Settlement Agreement was executed and approved by the Director of the North Carolina Division of Facility Services and the Chief of the Certificate of Need Section in May 2004; and it included no-review and exemption determinations pertaining to several aspects of the Sampson Cancer Center. See Global Settlement Agreement in Contested Cases Nos. 03 DHR 1710 and 03 DHR 1736 ("Settlement Agreement") (Exhibit 1).

Background on the Organizations Submitting this Request

The Hospital is a North Carolina non-profit corporation which has owned and operated an acute care hospital in Clinton for many years. In addition to acute care services, the Hospital offers a variety of outpatient services, including radiation therapy services provided for cancer patients on the Linac owned by the Hospital and operated at the Sampson Cancer Center as an outpatient department of the Hospital.

Sampson Regional Cancer Center, LLC is a North Carolina limited liability company whose members are the Hospital and MV-Photon. Sampson Regional Cancer Center, LLC owns the building in which the Sampson Cancer Center is located.

MV-Photon is a North Carolina limited liability company owned by Dr. Kevin J. Kerlin ("Dr. Kerlin"), a North Carolina licensed physician.

SRO is a professional corporation organized under the laws of the State of North Carolina, and its principal place of business is located at the Sampson Cancer Center. Its sole shareholder is Dr. Kerlin. SRO currently leases space in the Sampson Cancer Center from Sampson Regional Cancer Center, LLC. SRO and Dr. Kerlin have served cancer patients at the Sampson Cancer Center since it first opened in 2006.

Goldsboro Radiation Therapy Services, P.A. ("GRTS") was formed as a professional corporation under the laws of the State of North Carolina, with Dr. Kerlin as its sole shareholder, and its principal place of business located at 2802 McLamb Place, Goldsboro, North Carolina. Prior to the establishment of the Sampson Cancer Center, GRTS served Sampson County area patients at its Wayne Oncology Center located in Goldsboro, North Carolina. However, since establishment of the Sampson Cancer Center, Sampson County patients have received Dr. Kerlin's professional services through SRO. In connection with a separate transaction in December of 2011, GRTS converted to a business corporation, and it is now owned by NCRTMS.

Under a Professional Services Agreement with the Hospital, Dr. Kerlin has furnished professional services required to provide radiation therapy services, using the Linac, Simulator and other equipment in operation at the Sampson Cancer Center since the Center first opened. GRTS also has provided management and administrative support services for the Sampson Cancer Center. Currently, a Varian Clinac 2100C linear accelerator (the "Linac"), a Varian Ximatron CD-X CT Simulator (the "Simulator"), and other associated equipment are used to provide radiation therapy services to patients at the Sampson Cancer Center. The Linac was acquired by the Hospital following the CON Section's no-review determination, and the Simulator was acquired by SRO. SRO was formed so that Dr. Kerlin would have a separate professional corporation from GRTS through which he could furnish professional services to Sampson Cancer Center, and so SRO, rather than GRTS, acquired the Simulator.

The Proposed Transaction

RTS, NCRTMS, the Hospital, SRO, GRTS, and MV-Photon (collectively, the "Parties") have discussed and reached agreement in principle on a transaction (the "Proposed Transaction") that would involve the transfer of the ownership interests in the corporate entities that own interests in any facet of the Sampson Cancer Center and its associated equipment, including the Linac and Simulator (collectively, the "Equipment"). Ultimately, the Proposed Transaction (as more fully described on pages 3 and 4) would only involve the contribution of the Equipment to wholly owned subsidiaries followed by a transfer of the underlying ownership interests in the corporate entities that hold ownership interests in any facet of the Sampson Cancer Center and the Equipment. The Sampson Cancer 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 Sampson Cancer Center as a result 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 declaratory rulings and "no review" determinations that have been issued by the Office of the Director of the Division of Health Service Regulation ("DHSR") and by the CON Section, it is clear that the Proposed Transaction is not a "New Institutional Health Service," and should be permitted to proceed without first obtaining a CON. This letter describes the details of the Proposed Transaction and identifies the grounds for a determination that it is not subject to CON review.

Background on the Sampson Cancer Center and Equipment

As mentioned above, the Sampson Cancer Center was established following the execution and approval of the Settlement Agreement, in which the CON Section recognized that the following activities did not require a certificate of need:

- the Hospital's acquisition and installation of a linear accelerator and related items for less than the cost thresholds in the CON Law;
- Acquisition and installation of planning and simulation equipment and related items for less than \$250,000; and
- Development of medical office space exempt from CON review pursuant to N.C. Gen. Stat. § 131E-184(a)(9), by a joint venture between the Hospital and MV-Photon.

Settlement Agreement, p. 5, ¶¶ 3-5.

In accordance with the exemption recognized by the CON Section in the settlement, through a joint venture between the Hospital and MV-Photon, medical office space was constructed in a building located at 215 Beaman Street in Clinton, to be used in providing physician services to patients receiving treatment at the Sampson Cancer Center. Consistent with the no review determination recognized by the CON Section as part of the settlement, the Hospital acquired and installed the Linac at the Sampson Cancer Center in 2006.

The Linac and Simulator are the only oncology equipment that has been operated at the Sampson Cancer Center. The first treatment on the Linac was provided in October of 2006 over five years ago, and the Linac has been recognized each year in the linear accelerator inventory in the State Medical Facilities Plan. See State Medical Facilities Plan Excerpts for 2009-2012 (Exhibit 2).

The Proposed Transaction

The Proposed Transaction to transfer the ownership interests in the Sampson Cancer Center and the related Equipment will proceed in two phases, after receiving confirmation that no certificate of need is required for the Proposed Transaction. In the first phase, the Hospital will transfer its interest in the Linac to a wholly-owned subsidiary limited liability company ("SRMC Sub"). In addition, MV-Photon will transfer its interest in the Sampson Regional Cancer Center, LLC, which owns the building, to the Hospital, and SRO will transfer the simulator to a NEW LLC. In the final step of the transaction, NCRTMS will purchase all of the membership interests in SRMC Sub and NEW LLC.

After the Proposed Transaction is complete, the three LLCs, SRMC Sub, NEW LLC, and Sampson Regional Cancer Center LLC, all will continue to exist as legal business entities. Sampson Regional Cancer Center, LLC will continue to own the building that houses the Sampson Cancer Center, and will enter a long-term lease of the building to NCRTMS. Under an appropriate arrangement with NCRTMS that will be defined in writing, SRMC Sub and NEW LLC will continue to own and operate the equipment in the building, including the Linac and Simulator. It also is possible that at some point in the future, after the Proposed Transaction is complete, NCRTMS will determine that it is more convenient to merge SRMC Sub and NEW LLC into NCRTMS.

After all these steps, the Sampson Cancer Center and its Equipment will continue to serve patients at the same location at 215 Beaman Street in Clinton, in a manner that is the same in all material respects as the current operations of the Center and its associated Equipment. No additional equipment will be purchased as part of the Proposed Transaction, and no new services be offered as a result of the Proposed Transaction. The lease of Sampson Cancer Center to NCRTMS will not entail any new construction or associated capital expenditure, since the building already exists. Thus, the only change resulting from any aspect of the Proposed Transaction will be a change in the membership composition of the corporate entities that own the Sampson Cancer Center and Equipment.

Sampson Regional Cancer Center LLC, SRMC Sub and NEW LLC 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 SRO and GRTS and have supervised the care of a significant majority of the patients receiving treatment at the Sampson Cancer 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, SRMC Sub and NEW LLC will make the Linac and Simulator available for treatment of patients by Dr. Kerlin and other licensed physicians authorized to care for patients at the Sampson Cancer Center.

Based upon the longstanding approach by DHSR and the CON Section to the purchase of equity interests in existing health care facilities when there is no change in the services offered or the equipment employed to offer the services, NCRTMS respectfully submits that: 1) none of the steps in the Proposed Transaction constitutes a New Institutional Health Service requiring a CON; and 2) a subsequent merger of SRMC Sub and NEW LLC into NCRTMS also does not require a CON.

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). Accordingly, 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 regulated 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, such as acquisitions of existing facilities, or the repair or replacement of existing

facilities or equipment, since these actions do not change the overall capacity of the health care system. Based upon the clear terms of the CON Law and prior declaratory rulings by the Department that have recognized this fundamental principle, the Proposed Transaction does not require a CON.

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 addresses, directly or indirectly, the acquisition of ownership interests in an organization that already is operating a health service. Acquisitions of ownership interests are 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 or simulator "by or on behalf of any person," N.C. Gen. Stat. § 131E-176(16)(f1)5a, 9; as well as "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 other transactions with the same basic features as the Proposed Transaction, which involve only the acquisition of underlying corporate ownership interests in an existing legal entity which owns and operates an existing oncology center and its associated equipment, 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 Rulings Confirm the Transaction Does Not Require a CON

This No-Review Request is consistent with the Department's and the CON Section's prior 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. In at least five rulings issued after the enactment of the August 2005 amendment to the CON Law, which added acquisition of a linear accelerator to the definition of "new institutional health services" under N.C. Gen. Stat. § 131E-176, the Department has determined that the transfer of ownership interests in organizations that own and operate linear accelerators does not require a certificate of need.

- On January 6, 2012, the CON Section issued a no-review determination confirming that the transfer of ownership interests in Cancer Centers of North Carolina's Asheville radiation oncology treatment center to wholly-owned subsidiaries and the acquisition by NCRTMS of the membership interests in those subsidiaries did not require a CON. *See No-Review Determination Letter Re: Request by NCRTMS Pertaining to Cancer Centers of North Carolina Asheville Oncology Treatment Center* (Exhibit 3).
- 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 CON. See *In re: Request for Declaratory Ruling by Radiation Oncology Centers of the Carolinas, Inc.* (Exhibit 4).

- 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 CON. 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 5).
- 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 6).
- 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 7).

The August 2011 declaratory ruling relating to Radiation Oncology Centers of the Carolinas, Inc. ("ROCC"), involved a 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 the Hospital and MV-Photon will transfer their respective ownership interests in the existing Sampson Cancer Center and its associated Equipment to wholly-owned subsidiary LLCs.

The January 2012 no-review determination relating to Cancer Centers of North Carolina's Asheville oncology treatment center, involved a transaction very similar to the Proposed Transaction at issue in this request. CCNC and its management company proposed to transfer an existing oncology center and associated equipment to two wholly-owned subsidiary limited liability companies, and NCRTMS proposed to acquire 100% of the ownership interests in those subsidiaries. In their no-review request letter, the parties explained that the Asheville oncology center and its exempt linear accelerator and computed tomography scanner would continue to serve patients at the center's existing location. The structure and result of the Proposed Transaction at issue in this request mirror this Asheville oncology center transaction which the CON Section determined did not require a CON.

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. 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 treatment center and equipment that was authorized by a previously issued CON. The Department concluded that these proposed transactions did not require a CON. In its Declaratory Ruling, the Department noted that the entity which owned the linear accelerator 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 Sampson Cancer Center and its associated Equipment which will continue to provide the same services to patients at the same location following the transaction.

Similarly, 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 CON.

In the December 2007 declaratory ruling relating to 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 purchase of LLC interests proposed by the Parties in this Request is analogous to the transactions that were proposed by NCRTMS and Rex Healthcare in the above-described declaratory rulings and no-review determination. Under the Proposed Transaction, NCRTMS will acquire all of the ownership interests in the LLCs, and ownership of the Sampson Cancer Center and its associated Equipment, including the Linac and Simulator, will remain with the LLCs following the Transaction. The Sampson Cancer Center will continue to use the Equipment to provide the same radiation therapy services to patients at the same location following the Proposed Transaction.

The Proposed Transaction Is Not an Acquisition of a Linear Accelerator or Simulator

The proposed acquisition of 100% of the membership interests in the LLCs by NCRTMS does not constitute the acquisition of a linear accelerator or simulator. As explained above, the transaction is limited to the acquisition of the underlying ownership interests in the corporate entities that own the existing Sampson Cancer Center and its associated Equipment. The Linac and Simulator will continue to be used to provide the same radiation oncology services, in the same location, and the entity that owns the Linac and Simulator will not change as a result of Step 2 of the Proposed Transaction. The LLCs will continue to own the Linac and the Simulator as well as all the Sampson Cancer Center assets that have been used to furnish oncology treatments to patients. The LLCs' membership composition will change to a single member, NCRTMS, 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 Sampson Cancer 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 Sampson Cancer 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 and simulator under the provisions of N.C. Gen. Stat. § 131E-176(16)(f1)5a and 9.

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

The Proposed Transaction 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" within the meaning of N.C. Gen. Stat. § 131E-176(16)(b). The only change involved in the Proposed Transaction is the membership composition of the LLCs, and that change in ownership is not a health service.

As the Department and CON Section must have determined in the prior 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 Sampson Cancer 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).

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 does not implicate the fundamental purposes of the CON Law and should not require a CON. As stated above, since 2006, the Sampson Cancer Center and its associated Equipment have been operated as part of an ongoing health care facility and that will continue after completion of the Proposed Transaction. Similarly, a subsequent merger of SRMC Sub and NEW LLC into NCRTMS also should not require a CON.

Mr. Craig R. Smith
Chief, CON Section
February 29, 2012
Page 9

Poyner Spruill^{LLP}

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 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 Exhibits 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. The Parties are aiming to close on the Proposed Transaction within approximately 30 days, and accordingly, we request a response from you by March 2, 2012, if possible.

Thank you for your attention to this matter, and please let us know if there is any additional information you may require.

With best regards, we are

Very truly yours,



William R. Shenton



Pamela A. Scott

Enclosures

cc: Martha Frisone, Assistant Chief, CON Section
Norton L. Travis, General Counsel for RTS
Lee Spinks, Counsel for SRO, GRTS and MV-Photon
Lew Starling, Counsel for Sampson Regional Medical Center, Inc.



North Carolina Department of Health and Human Services
 Division of Health Service Regulation
 Certificate of Need Section

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Beverly Eaves Perdue, Governor
 Albert A. Delia, Acting Secretary

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 Phone: (919) 855-3873
 Fax: (919) 733-8139

December 20, 2012

Ms. Mary Beth Johnston
 K&L Gates, LLP
 430 Davis Drive, Suite 400
 Morrisville, North Carolina 27560

Exempt from Review – Acquisition of Facility

Facility: Union Regional Home Care (HHA)
 Acquisition by: Charlotte-Mecklenburg Hospital Authority (CMHA)
 County: Union
 FID #: 955428

Dear Ms. Johnston:

In response to your letter of November 28, 2012, the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(8). Therefore, Charlotte-Mecklenburg Hospital Authority (CMHA) may proceed to acquire substantially all of the assets of the above referenced health service facility without first obtaining a certificate of need. However, you need to contact the Acute and Home Care Licensure and Certification Section of the Division of Health Service Regulation to obtain instructions for changing ownership of the existing facility. Note that pursuant to N.C.G.S. §131E-181(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.”*

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,

Gloria C. Hale

Gloria C. Hale
 Project Analyst

Craig R. Smith

Craig R. Smith, Chief
 Certificate of Need Section

cc: Acute and Home Care Licensure and Certification Section, DHSR



Alona

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November 28, 2012

Mary Beth Johnston
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marybeth.johnston@klgates.com

Via Hand Delivery

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



RE: Exemption Notice for Union Memorial Regional Medical Center, Inc. d/b/a Union Regional Home Care (License No. HC1238)

Dear Craig:

We are writing on behalf of our clients, The Charlotte-Mecklenburg Hospital Authority ("CMHA") and Union Memorial Regional Medical Center, Inc. ("UMRMC"). UMRMC is the licensed operator of a Medicare-certified home health agency known as Union Regional Home Care (the "HHA") (License No. HC1238). The purpose of this letter is to provide notice to the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Certificate of Need Section (the "Agency") that CMHA will be acquiring substantially all of the assets of the HHA pursuant to a corporate reorganization, which transaction is exempt from certificate of need ("CON") review under N.C. Gen. Stat. § 131E-184(a)(8).

A. Factual Background

UMRMC is a wholly-owned controlled affiliate of CMHA. The HHA is a Medicare-certified home health agency licensed by the State and located in Monroe, Union County. UMRMC is currently the licensed operator of the HHA and holds a CON for the provision of home health services. CMHA and UMRMC seek to reorganize the HHA such that CMHA will acquire the assets of the HHA and become its licensed operator effective on or about January 1, 2013. The parties will be submitting a change of ownership application to the Division of Health Service Regulation, Acute and Home Care Licensure and Certification Section to effectuate the transfer of the license.

Craig R. Smith
November 28, 2012
Page 2

B. Exemption Notice

Under North Carolina law, a CON is required only prior to offering or developing a "new institutional health service." "New institutional health service" includes a variety of services and activities, including the establishment of a home health agency office.¹ However, the North Carolina General Assembly has exempted certain types of services or proposals from CON review under N.C. Gen. Stat. § 131E-184, including the acquisition of an existing health service facility, including equipment owned at the time of acquisition.²

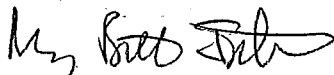
This transaction involves only the acquisition of the assets of an existing "health service facility," including all equipment owned at the time of acquisition. After the acquisition, CMHA will continue to operate this health service facility at its current location. Furthermore, the acquisition of the HHA does not entail the purchase of any major medical equipment or any *per se* reviewable equipment as defined in N.C. Gen. Stat. §§ 131E-176(14)(o) and (16)(f1). Likewise, the acquisition does not include the offering of any *per se* reviewable services.³ Thus, given that the transaction involves only the acquisition of an existing health service facility, it is exempt from CON review.

C. Conclusion

Based on the foregoing information, we hereby request the Agency's confirmation that the proposal described above is exempt from CON review under N.C. Gen. Stat. § 131E-184(a)(8). In the alternative, we request that the Agency confirm that the proposed transaction is not subject to CON review. If you require additional information, please contact us at the above number as soon as possible.

Thank you for your consideration of this request.

Sincerely,



Mary Beth Johnston

¹ See N.C. Gen. Stat. § 131E-176 (9b), (12), and (16)(a).

² See N.C. Gen. Stat. § 131E-184(a)(8).

³ See N.C. Gen. Stat. § 131E-176(16)(f).



North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section

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<http://www.ncdhhs.gov/dhsr/>

Drexdal Pratt, Director

Beverly Eaves Perdue, Governor
Albert A. Delia, Acting Secretary

Craig R. Smith, Section Chief
Phone: (919) 855-3873
Fax: (919) 733-8139

December 21, 2012

Gary S. Qualls
430 Davis Drive, Suite 400
Morrisville, NC 27560

Exempt from Review

Facility: Chapel Hill Surgical Center, Inc.
Project Description: University of North Carolina Hospitals at Chapel to acquire substantially all the assets of Chapel Hill Surgical Center, Inc. (a multispecialty ambulatory surgical facility) in Chapel Hill, Orange County, which transaction is exempt from Certificate of Need Review under N.C. General Statute § 131 E-184 (a)(8).
County: Orange
FID #: 923089

Dear Mr. Qualls:

The Certificate of Need Section (CON Section) received your letter on December 18, 2012 regarding the above referenced proposal. Based on the CON law in effect on the date of this response to your request, the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal 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 project 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 project include, but are not limited to: (1) increase in 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.

In addition, you should contact the Construction Section of the DHSR Section to determine if they have any requirements for development of the proposed project. 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.

Thank you for the opportunity to be of assistance.



Location: 809 Ruggles Drive, Dorothea Dix Hospital Campus, Raleigh, N.C. 27603
An Equal Opportunity/Affirmative Action Employer



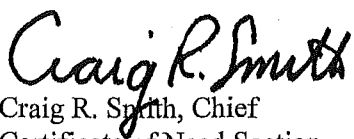
Exhibit G

Gary S. Qualls
December 21, 2012
Page 2

Sincerely,



F. Gene DePorter, Project Analyst
Certificate of Need Section



Craig R. Smith, Chief
Certificate of Need Section

cc: Construction Section, DHSR
Medical Facilities Section, DHSR

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December 18, 2012

Gary S. Qualls
D 919.466.1182
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gary.qualls@klgates.com

VIA HAND DELIVERY

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

Re: Exemption Notice for Chapel Hill Surgical Center, Inc.
License No. AS0010; Facility ID 923089

Dear Mr. Smith:

The purpose of this letter is to provide notice to the North Carolina Department of Health and Human Services, Division of Health Service Regulation ("DHSR"), Certificate of Need Section (the "CON Section") that our client, the University of North Carolina Hospitals at Chapel Hill ("UNC Hospitals"), a North Carolina governmental agency, is planning to acquire substantially all of the assets of Chapel Hill Surgical Center, Inc. ("Chapel Hill Surgical"), a licensed three (3) operating room multispecialty ambulatory surgical facility in Chapel Hill, Orange County (the "ASF"),¹ which transaction is exempt from certificate of need ("CON") review under N.C. Gen. Stat. § 131E-184(a)(8).

I. THE TRANSACTION

As of this date, Chapel Hill Surgical operates a three (3) operating room multispecialty ambulatory surgical facility, which is an existing "health service facility," as that term is defined in N.C. Gen. Stat 131E-176(9b). Effective on or about December __, 2012 (the "Effective Date"), UNC Hospitals will purchase substantially all of the assets of the ASF from Chapel Hill Surgical. On the Effective Date, UNC Hospitals will lease back to Chapel Hill Surgical substantially all of the assets of the ASF. Accordingly, Chapel Hill Surgical will remain the licensed operator after the Effective Date.

II. EXEMPTION NOTICE

Under North Carolina law, a certificate of need ("CON") is required only prior to offering or developing a "new institutional health service." "New institutional health service" includes a variety of services and activities, including the establishment of an ambulatory surgical facility or a capital expenditure exceeding \$2 million to develop a health service facility. N.C. Gen. Stat. § 131E-176(16)(a) & (b). However, the North Carolina General Assembly has exempted certain types of proposals from CON review, pursuant to N.C. Gen. Stat. § 131E-184, including the acquisition of an existing health service facility, including equipment owned by the health service facility at the time of acquisition.

¹ Note that Chapel Hill Surgical is currently not a certified supplier participating in Medicare.

Mr. Craig Smith, Chief
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This transaction involves only the acquisition of an existing ambulatory surgical facility, which falls within the purview of the statutory definition of "health service facility." UNC Hospitals' acquisition of the ASF from Chapel Hill Surgical does not entail the purchase of any major medical equipment or any *per se* reviewable equipment as defined in N.C. Gen. Stat. §§ 131E-176(14o) and (16)(f1). Likewise, the transaction does not include the offering of any *per se* reviewable services except those already licensed to be provided by the ASF. N.C. Gen. Stat. § 131E-176(16)(f). Thus, given that the transaction involves only the acquisition of an existing health service facility, it is exempt from CON review.

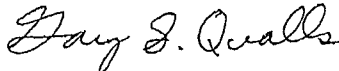
III. CONCLUSION

Based on the foregoing information, we are hereby providing notice that the transaction described above is exempt from CON review, pursuant to N.C. Gen. Stat. § 131E-184(a)(8).

Chapel Hill Surgical, represented by Steve Miller, Esq. and Dean McCord, Esq., has authorized the submission of this letter.

If you require additional information, please contact me at the above number.

Sincerely,



Gary S. Qualls

cc: Gina Bertolini, Esq., Assistant General Counsel, UNC Health Care System
Steve Miller, Esq., Alexander, Miller & Schupp, LLP
Dean McCord, Esq., Wyrick Robbins Yates & Ponton LLP



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.ncdhhs.gov/dhsr

Craig R. Smith, Section Chief
Phone: 919-855-3875
Fax: 919-733-8139

December 9, 2011

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

RE: No Review:

- Transfer by CSA Medical Services, LLC (CSA) of 100% of its ownership interests in five (5) existing heart lung bypass machines in use at WakeMed to CSAMS New Bern Avenue, LLC, a wholly-owned subsidiary of CSA
- Transfer by CSA Medical Services, LLC (CSA) of 100% of its ownership interests in three (3) existing heart lung bypass machines in use at Rex Hospital to CSAMS Lake Boone Trail, LLC, a wholly-owned subsidiary of CSA

Wake County

Dear Mr. Shenton:

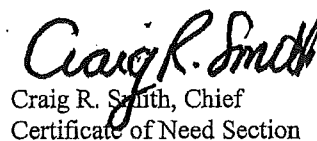
The Certificate of Need (CON) Section received your letter of November 21, 2011 regarding the above referenced proposals. Based on the CON law in effect on the date of this response to your request, the proposals described in your correspondence are not governed by, and therefore, do not currently require 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,

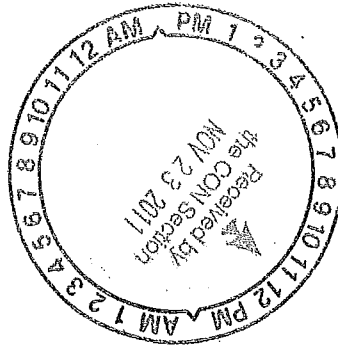

Martha J. Frisone
Assistant Chief


Craig R. Smith, Chief
Certificate of Need Section

cc: Medical Facilities Planning Section, DHSR



Martha



Poyner Spruill^{LLP}

November 21, 2011

Wilson Hayman
Partner
D: 919.783.1140
whayman@poynerspruill.com
William R. Shenton
Partner
D: 919.783.2947
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wshenton@poynerspruill.com

VIA U.S. MAIL AND E-MAIL/
Craig.smith@dhhs.nc.gov
Martha.frisone@dhhs.nc.gov

Mr. Craig R. Smith, Chief
Ms. Martha Frisone, Assistant Chief
Division of Health Service Regulation
Certificate of Need Section
2704 Mail Service Center
Raleigh, North Carolina 27696-2704

RE: CSA Medical Services, LLC; No Review Request regarding Transfer of Heart-Lung Bypass Machines to Wholly Owned Subsidiaries

Dear Mr. Smith and Ms. Frisone:

This letter is submitted on behalf of CSA Medical Services, LLC ("CSA"), and two subsidiary limited liability companies to be formed and wholly owned by CSA and to be named "CSAMS New Bern Avenue, LLC" (CSA New Bern), and "CSAMS Lake Boone Trail, LLC" (CSA Lake Boone), upon receipt of your approval of this request. CSA currently owns and operates eight (8) heart-lung bypass ("HLB") machines. Five (5) of the HLB machines are operated at WakeMed and three (3) of the HLB machines are operated at Rex Hospital, Inc. ("Rex"). The purpose of this letter is to provide notice to the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Certificate of Need Section (the "Agency"), and confirm that the transfer of CSA's interests in these eight (8) HLB machines and the operation of the same to two wholly owned subsidiaries of CSA is not reviewable as a new institutional health service under the North Carolina Certificate of Need ("CON") law.

The Agency has recently approved a similar transfer in an August 18, 2011 Declaratory Ruling regarding Radiation Oncology Centers of the Carolinas, Inc. ("ROCC"). That Declaratory Ruling concerned the transfer of interests in two radiation oncology facilities from ROCC to two wholly owned subsidiaries of ROCC. Attached hereto as Exhibits 1 and 2 are the ROCC Declaratory Ruling Request and the ROCC Declaratory Ruling. The ruling requested by CSA here is directly analogous to the ROCC ruling, the only difference being that ROCC involved the *per se* reviewable items of linear accelerators and simulators and CSA's request involves the *per se* reviewable items of heart-lung bypass machines.

I. BACKGROUND AND FACTS

CSA directly owns eight (8) Terumo Corporation Series 8000 HLB machines. Five (5) of these HLB machines are located and used by CSA to provide perfusion services at WakeMed, located at 3000 New Bern Avenue, Raleigh, NC 27620. Three (3) of these HLB machines are located and used by CSA to provide perfusion services at Rex, located at 4420 Lake Boone Trail, Raleigh, NC 27607. CSA also owns

Mr. Craig R. Smith, Chief
Ms. Martha Frisone, Assistant Chief
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Page 2

seven (7) cell saver machines located at WakeMed in Raleigh, and two (2) located at WakeMed-Cary. These cell saver machines are Baylor Rapid Autologous Transfusion (BRAT) machines manufactured by Sorin Corporation and are not subject to CON review. CSA does not own the BRAT machines at Rex, which are owned by the hospital. CSA also provides the hospitals with the services of seven (7) licensed perfusionists, who are employed by CSA's affiliate Carolina MSO, L.L.C. (MSO) but work for CSA pursuant to its Management Services Agreement with MSO.

The five (5) HLB machines at WakeMed are labeled A, B, C, D, and E, and the three (3) at Rex are labeled 1, 2, and 3. Each HLB machine consists of the following: (a) a four (4) or five (5) pump Terumo Base; (b) three (3) or four (4) Terumo 8000 roller pump modules (8000 roller pump modules); (c) one (1) Medtronic Bio-Medicus arterial pump series 550 (Bio pump); (d) one (1) Medtronic TX 50 Flowmeter (Flowmeter); and (e) one (1) Sechrist air/oxygen mixer (Sechrist). Similarly, the seven (7) BRAT machines at WakeMed in Raleigh are labeled A, B, C, D, E, F and G, and the two at WakeMed-Cary are labeled 1 and 2. Each HLB machine (and its components) and BRAT machine is identified by its serial numbers (SN), model numbers and the hospital where it is located, as described in Exhibit 3 to this letter.

The surgeons of Carolina Cardiovascular Surgical Associates, P.A. (Practice), started performing open heart surgery and providing their own perfusion services at WakeMed in 1979 and at Rex in 1989, through either the Practice itself or a perfusion company owned by the same physicians. Each of the eight (8) HLB machines currently owned by CSA is replacement equipment for a machine owned by CSA (or a predecessor entity) prior to the year 1993, when acquisition of an HLB machine became subject to CON review regardless of its cost. W. Charles Helton, M.D., founded the Practice in 1979 and Cardinal Bio-Medical Associates, Inc. (Cardinal Bio-Medical), in 1980. Cardinal Bio-Medical was the perfusion company predecessor to CSA that like CSA was owned by the shareholders of the Practice. The two hospitals have never owned the HLB machines used at their facilities. Before 1989, Cardinal Biomedical had acquired and operated three (3) HLB machines at WakeMed and two (2) at Rex. Another cardiothoracic surgery practice in Raleigh, Atkinson & Zeok, M.D., P.A., had two (2) additional HLB machines at WakeMed and one (1) additional HLB machine at Rex. Atkinson & Zeok, M.D., P.A. merged with the Practice in 1993, and its two (2) surgeon shareholders, Alvan W. Atkinson, M.D., and John V. Zeok, M.D., joined the Practice. At the same time their three (3) HLB machines were acquired by Cardinal Bio-Medical, and they become shareholders of that perfusion company. Cardinal Bio-Medical or its successor company has continued to own and operate these eight (8) HLB machines (or their replacements) at their same respective locations at WakeMed and Rex since that time. In 1997, the shareholders of Cardinal Bio-Medical reorganized the company by forming CSA and transferring the operations and all eight (8) machines to CSA, which was owned by the same surgeons.

By 2001, CSA needed to replace all eight (8) of its HLB machines. There was a fourth HLB machine at Rex owned by surgeons Abdul G. Chaudhry, M.D. and James H. Davis, M.D. This one (1) HLB machine had been loaned to them by the manufacturer in the late 1990's to replace one they had provided for use at Rex which had become obsolete. At that time, CSA bought this fourth loaned HLB machine, which had already been used at Rex, from the manufacturer to replace one of CSA's older machines at Rex. Thereafter, Drs. Chaudhry and Davis no longer provided perfusion services or a HLB machine for use at Rex. CSA's purchase of this machine thus resulted in a net decrease in useable HLB machines at Rex from four (4) to three (3).

The same year, CSA obtained replacement equipment for its other seven (7) HLB machines at WakeMed and Rex, at a total capital cost of \$322,695. CSA's obsolete machines were subsequently removed out of North Carolina. By letter dated June 25, 2004, the Agency approved CSA's acquisition of the seven (7)

Mr. Craig R. Smith, Chief
Ms. Martha Frisone, Assistant Chief
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new HLB machines at WakeMed and Rex as replacement equipment. The Agency's "no review" letter of that date is attached and labeled as Exhibit 4.

CSA would like to transfer its interest in the eight (8) HLB machines into two wholly owned subsidiary limited liability companies. The first wholly owned subsidiary will be named "CSAMS New Bern Avenue, LLC" and will own the five (5) HLB machines currently operated at WakeMed. The second wholly owned subsidiary will be named "CSAMS Lake Boone Trail, LLC" and will own the three (3) HLB machines currently operated at Rex. The transfer of CSA's interests in the eight (8) HLB machines into two (2) wholly owned subsidiaries is not a CON reviewable event because it will have the following results:

- (1) No increase in the HLB machine inventory in Wake County;
- (2) No physical relocation of any HLB machines in Wake County;
- (3) No creation of any new health service facilities; and
- (4) No asset purchases of any per se reviewable equipment, consistent with the ROCC Declaratory Ruling.

This letter requests your confirmation that such a proposed transfer of interests would not trigger any of the new institutional health service provisions in the CON statute, and the transaction may proceed without first acquiring a CON.

II. ANALYSIS

The CON law provides that the "acquisition by purchase, donation, lease, transfer or comparable arrangement" of an HLB machine constitutes a "new institutional health service" that is subject to CON review. N.C. Gen. Stat. § 131E-176(16)f1; § 131E-178(a). However, we believe the creation of these two wholly owned subsidiaries is not a reviewable event because CSA, the owner of the CON rights for the eight (8) HLB machines, is not undergoing any direct change in its ownership status. Rather, this is merely a type of reorganization in the nature of those which the CON rules recognize as non-reviewable.

Until 1993, the acquisition of an HLB machine was not regulated under the CON law unless it involved the obligation of a capital expenditure exceeding two million dollars (\$2,000,000), which far exceeds the cost of this equipment. See N.C. Sess. Laws 1993, c. 7, § 2 (adding the acquisition of HLB machines and any "major medical equipment" costing more than \$750,000 as "new institutional health services" requiring a CON). However, effective March 18, 1993, the General Assembly amended the CON law to make the acquisition of HLB machines constitute a "new institutional health service" requiring a CON regardless of its cost. N.C. Gen. Stat. § 131E-176(10a), (16)f1.5., as amended by N.C. Sess. Laws 1993, c. 7, § 2.

Under the CON law, transfer of ownership or control of a CON prior to completion of a project or operation of the facility constitutes grounds for withdrawal of a CON. N.C. Gen. Stat. § 131E-189. However, the Agency's rules provide that in that situation, neither ownership nor control of a CON is transferred when the holder of the certificate is a corporation and the identity of the holder changes because of corporate reorganization, including transferring ownership to wholly owned subsidiaries. 10A N.C.A.C. 14C.0502(b)(1) and (c).

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Specifically, the provisions of N.C. Gen. Stat. § 131E-189(c) state by analogy that the Department of Health and Human Services may immediately withdraw any CON 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." Further, the Agency's rules at 10A N.C.A.C. 14C.0502(b) state as follows:

Ownership of a certificate of need is transferred when any person acquired a certificate from the holder by purchase, donation, lease, trade, or any comparable arrangement, except that ownership of a certificate of need is not transferred when:

- (1) the holder of the certificate is a corporation and the identity of the holder changes because of a corporate reorganization; or
- (2) the holder of the certificate is a partnership and the identity of the holder changes because the same partners reorganize as a new partnership.

10A N.C.A.C. 14C.0502(b) (emphasis added).

Here, CSA's right to own and operate the HLB machines is not a CON project that is not yet completed or operational. Nonetheless, if the CON law permits the transfer of a CON for an undeveloped project to a subsidiary of the applicant without a new CON or other sanction, then it would make no sense to interpret the law to prevent an existing provider from transferring a service to a wholly-owned subsidiary after the project has been developed. This principle has been affirmed by the Agency on a very similar set of facts in the ROCC Declaratory Ruling referenced above and attached as Exhibit 2.

Moreover, N.C. Gen. Stat. § 131E-189(c) acknowledges that completed projects may be transferred without CON review. It states that "[a]ny transfer after [the project is completed or becomes operational] will be subject to the requirement that the service be provided consistent with the representations made in the application and any applicable conditions." That statute does not require that a CON first be acquired before such a transfer takes place. Clearly, the reorganization of CSA's assets and CON exemption into two wholly owned subsidiaries would not constitute the "offering or development of a new institutional health service" within the definition of N.C. Gen. Stat. § 131E-178(a).

III. CONCLUSION

Based on the foregoing information, we hereby request the Agency's confirmation that the following transactions are not subject to CON review as a new institutional health service:

- (1) CSA's proposed transfer of its ownership interest in, and operation of, five (5) HLB machines, operated at WakeMed, to CSA Lake Boone, a wholly owned subsidiary of CSA; and
- (2) CSA's proposed transfer of its ownership interest in, and operation of, three (3) HLB machines, operated at Rex, to CSA New Bern, a wholly owned subsidiary of CSA.

If you require additional information to consider this request, please contact us as soon as possible. We thank you for consideration of this request.

Poyner Spruill^{LLP}

Mr. Craig R. Smith, Chief
Ms. Martha Frisone, Assistant Chief
November 21, 2011
Page 5

Very truly yours,

A handwritten signature in black ink, appearing to read "Wilson Hayman", with a long horizontal line extending to the right.

Wilson Hayman
Partner

William R. Shenton
Partner

Attachments



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
<http://www.ncdhhs.gov/dhsr/>

Drexdal Pratt, Director

Beverly Eaves Perdue, Governor
Albert A. Delia, Acting Secretary

Craig R. Smith, Section Chief
Phone: (919) 855-3873
Fax: (919) 733-8139

February 27, 2012

Maureen Demarest Murray
Smith, Moore, Leatherwood
300 N. Greene Street, Suite 1400
Greensboro, NC 27401

RE: No Review / WakeMed / Acquisition of ownership interests of CSA-1, owners of five heart-lung bypass machines located at WakeMed / Wake County
FID #: 943528

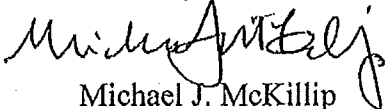
Dear Ms. Murray:

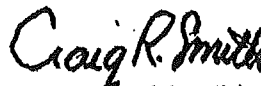
The Certificate of Need (CON) Section received your letter of February 8, 2012 regarding the above referenced proposal. Based on the CON law in effect on the date of this response to your request, the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal 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 project 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 project 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.

Sincerely,


Michael J. McKillip
Project Analyst


Craig R. Smith, Chief
Certificate of Need Section





North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section

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Drexdal Pratt, Director

Beverly Eaves Perdue, Governor
Albert A. Delia, Acting Secretary

Craig R. Smith, Section Chief
Phone: (919) 855-3873
Fax: (919) 733-8139

February 27, 2012

Gary S. Qualls
K & L Gates, LLP
P.O. Box 14210
Research Triangle Park NC 27709-4210

RE: No Review / Rex Hospital, Inc. / Acquisition of ownership interests of CSAMS Lake Boone, LLC, owners of three heart-lung bypass machines located at Rex Hospital / Wake County
FID #: 953429


Dear Mr. Qualls:

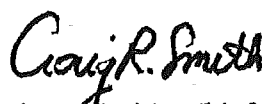
The Certificate of Need (CON) Section received your letter of February 9, 2012 regarding the above referenced proposal. Based on the CON law **in effect on the date of this response to your request**, the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal 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 project 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 project 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.

Sincerely,


Michael J. McKillop
Project Analyst


Craig R. Smith, Chief
Certificate of Need Section

