

JOSH STEIN • Governor

DEVDUTTA SANGVAI • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY CORRECTED

March 25, 2025

Denise Gunter

denise.gunter@nelsonmullins.com

Exempt from Review - Acquisition of Facility

Record #: 4729

Date of Request: February 25, 2025 Facility Name: OrthoCarolina, PA

Type of Facility: Mobile diagnostic program, including two mobile MRI scanners, trailers and

related equipment

Acquisition by: Novant Health Enterprises Imaging, LLC and Novant Health, Inc.

Business #: 3934

County: Forsyth and Mecklenburg

Dear Denise Gunter

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) determined that the project described above is exempt from certificate of need (CON) review in accordance with G.S. 131E-184(a)(8). Therefore, the above referenced business may proceed to acquire the health service facility identified above without first obtaining a CON. The Agency's determination is limited to the question of whether the above referenced business would have to obtain a CON if the current owners of the health service facility do in fact sell it to the business listed above. 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."

If the business listed above does acquire the facility, you should contact the Agency's & (Section Name) Section to obtain instructions for changing ownership of the existing facility.

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 regarding whether a certificate of need would be required. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Chaline L. Masse

Chalice L. Moore, Project Analyst

Micheala Witchell

Micheala Mitchell, Chief

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603

MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704

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February 25, 2025

Via E-mail Only

Micheala Mitchell, Chief
Healthcare Planning and Certificate of Need Section
North Carolina Department of Health and Human Services
Division of Health Service Regulation
micheala.mitchell@dhhs.nc.gov
cc: tiffany.stancil@dhhs.nc.gov

RE: Acquisition of Membership Interests and A Mobile Diagnostic Program

Dear Ms. Mitchell:

On behalf of Foundation Health Systems, LLC (a Novant Health affiliate) and Novant Health, Inc. (collectively, "Novant Health"), I am writing to provide the Agency with prior written notice of the following transaction (the "Transaction"). The Transaction has two components: 1) the acquisition of membership interests in a limited liability company; and 2) the acquisition of a mobile diagnostic program, which is considered a "diagnostic center" pursuant to N.C. Gen. Stat. § 131E-176(7a). Accordingly, with respect to the acquisition of membership interests, this letter seeks a determination that the CON Law, N.C. Gen. Stat. § 131E-175 et seq., does not apply. With respect to the mobile diagnostic program, this letter seeks an exemption from the CON Law pursuant to N.C. Gen. Stat. § 131E-184(a)(8).

Facts

OrthoCarolina, PA ("OrthoCarolina") is a physician-owned and physician-led independent orthopedic practice. OrthoCarolina operates 17 imaging facilities across 11 different counties with both fixed and mobile MRI units. In order to focus its growth efforts on its core service lines, OrthoCarolina has made the strategic decision to divest its diagnostic imaging business (the "Business") to Novant Health. As shown in the table below, the Business consists of two fixed MRI scanners and two mobile MRI scanners. Pursuant to services agreements, OrthoCarolina also receives mobile MRI service from Alliance HealthCare Services, Inc. ("Alliance"), using four Alliance mobile scanners. This Transaction does not involve the acquisition of any mobile MRI scanners owned by Alliance. Rather, OrthoCarolina intends to assign its rights under its Alliance services

agreements to Novant Health. For the sake of completeness, the Alliance mobile MRI scanners are also listed in the table below.¹

MRI Scanner	Туре	Location	Owner	Status
Project I.D. No. J-06698-02; Serial No. R6645	Fixed; GE Signa HDX 1.5T	OrthoCarolina Spine Center, 2001 Randolph Rd., Charlotte, North Carolina 28207	OrthoCarolina	In operation
Project I.D. No. F-10287-14; Serial No. HM1228	Fixed; GE Optima MR450W	OrthoCarolina Ballantyne, 15825 Ballantyne Medical Pl., #100 Charlotte, NC 28277	OrthoCarolina	In operation
Project I.D. No. F-7987-07; Serial No. RD 1384	Mobile; GE Signa Voyager 1.5T	OC Spine Center, 2001 Randolph Rd., Charlotte, NC 28207; 10315 Hamptons Park Dr., Huntersville, NC 28078; 710 Park Center Dr., Matthews, NC 28105	OrthoCarolina	In operation
Project I.D. No. G-7723-06	Mobile; GE HDxt 1.5T	170 Kimel Park Dr, Winston- Salem, NC 27103;	Alliance (Service Agreement)	In operation

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¹ As the Agency is aware, Alliance was acquired by Akumin® on September 1, 2021. For ease of reference, this letter uses the name Alliance.

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MRI Scanner	Туре	Location	Owner	Status
(Alliance 483) ² ; Serial No. R3177		3311 Jessie Village Dr., Clemmons, NC 27012; 45 Pineview Dr., Suite 220, Kernersville, NC 27284		
Legacy (Alliance 273): Serial No. R2443	Mobile; GE EchoSpeed HDxt 1.5T	354 Copperfield Blvd NE, Concord, NC 28025; 124 Welton Way, Mooresville, NC 28117; 870 Summit Crossing Pl., Gastonia, NC 28054; 540 Mount Holly Medical Pkwy, Belmont, NC 28012	Alliance (Service Agreement)	In operation
Legacy (Alliance 457); Serial No. R6033	Mobile; GE Signa HDX 1.5T	OC Spine Center, 2001 Randolph Rd., Charlotte, NC 28207; 101 Delta Park Dr., Shelby, NC 28150;	Alliance (Service Agreement)	In operation

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² OrthoCarolina fulfilled this CON via a contract with Alliance instead of acquiring an MRI unit directly. Novant Health is acquiring OrthoCarolina's rights in this CON as part of the Transaction. In the future, Novant Health may decide to fulfill this CON in a different way that does not involve a contract with Alliance. Novant Health will advise the Agency should it decide to change the current arrangement.

MRI Scanner	Туре	Location	Owner	Status
		9848 N. Tryon St., Charlotte, NC 28262; 1604 Medical Dr., Laurinburg, NC 28352		
Legacy (Alliance 461); Serial No. R6498	Mobile; GE Signa Excite HDX 1.5T	214 18 th Street SE, Hickory, NC 28602; 703 Comfort Ln., Monroe, NC 28112	Alliance (Service Agreement)	In operation

The Transaction

With respect to the fixed scanners, OrthoCarolina plans to form a new, wholly owned subsidiary ("Newco, LLC") and will drop the two fixed MRI scanners (and the related equipment necessary for the operation thereof) into Newco, LLC. Novant Health will then acquire 100% of the membership interests in Newco, LLC. The fixed scanners will continue to be used at their current locations.

With respect to the mobile diagnostic program, Novant Health intends to acquire the entirety of OrthoCarolina's mobile diagnostic program, including the equipment and all rights related thereto. This includes OrthoCarolina's right, title, and interest in two existing mobile MRI scanners, trailers, and related equipment. There are no plans at this time to change host site locations for the OrthoCarolina-owned mobile MRI scanner or the Alliance-owned mobile MRI scanners.

For a period up to one year after closing, Novant Health and OrthoCarolina will operate under a Resource Services Agreement ("RSA"). Pursuant to the RSA, OrthoCarolina will continue to be the MRI service provider and bill patients and payors for MRI services under OrthoCarolina's name and billing number. When the RSA expires, Novant Health will become the billing provider and will sublease space from OrthoCarolina in the locations where the fixed scanners are currently located, as well as the pads upon which the mobile MRI trailers are parked. There are no plans at this time to move the fixed MRI scanners to new locations or to change the host site locations for the mobile MRI scanners.

The number of existing fixed and mobile MRI scanners in North Carolina will not change as a result of the Transaction. (The Transaction does not involve any approved but not yet operational MRI scanners.) The existing MRI scanners described in this letter will continue to be operated just as they have always been operated. Other than as described herein, the Transaction does not contemplate acquiring any equipment that is regulated by the CON Law, incurring any capital costs that are regulated by the CON Law or otherwise developing any "new institutional health services" that are regulated by the CON Law.

Analysis with respect to Membership Interests

With respect to the fixed scanners, the Transaction involves the acquisition of membership interests, not the acquisition of MRI scanners. The Agency has repeatedly recognized that acquisitions of membership interests are not regulated by the CON Law. For example, in 2015, the Agency concluded that Vidant's acquisition of 100% of the membership interests in Newco Cancer Services, LLC ("Newco"), a 50/50 joint venture ("JV") between Vidant and ECU Brody School of Medicine that owned and operated two linear accelerators and CT simulators, did not require a CON. See **Exhibit A**. After Vidant became the sole owner of Newco, Vidant and North Carolina Radiation Therapy, another company that owned linear accelerators in Pitt County, contributed their respective linear accelerators to a new JV limited liability company, Vidant Radiation Oncology. Again, the Agency determined that no CON was required as only membership interests in an LLC were being acquired. *Id.*

The Agency has also issued declaratory rulings establishing that acquisitions of membership interests in LLCs are not regulated by the CON Law. See, e.g., **Exhibit A**, including pp. 3-4 and attachments therein. The same reasoning applies here. There is nothing in the CON Law that regulates acquisitions of membership interests in limited liability companies. See N.C. Gen. Stat. § 131E-176(16)a.-v.(definition of new institutional health services); In re Miller, 357 N.C. 316, 325, 584 S.E.2d 772, 780 (2003)(according to the doctrine of expressio unius est exclusio alterius, the expression of one thing means the exclusion of others; thus, "when a statute lists the situations to which it applies, it implies the exclusion of situations not contained on the list.").

In 2011, the Agency issued a declaratory ruling to Radiation Oncology Centers of the Carolinas, Inc. ("ROCC") as to ROCC's proposal to transfer its interest in two oncology treatment centers which operated linear accelerators and CT simulators to two wholly owned subsidiaries of ROCC. See **Exhibit B**. Similar to **Exhibit A** and the declaratory rulings cited therein, the Agency determined no CON review was required for the ROCC transaction.

More recently, in yet another transaction analogous to the ROCC transaction, , Novant Health, Inc. and Novant Health New Hanover Regional Medical Center, LLC ("Novant") proposed the acquisition of membership interests in South Atlantic Radiation Oncology, LLC ("SARO"). Coastal Carolina Radiation Oncology, PA ("CCRO") dropped

its linear accelerators into HoldCo, LLC, a wholly owned subsidiary of CCRO. SARO then acquired the membership interests in HoldCo, LLC and Novant acquired the remaining 50% interest in SARO from the CCRO shareholders. At the conclusion of the transaction, just as in the proposed Transaction, Novant owned 100% of the membership interests in SARO and the Agency determined that the CON Law did not regulate the transaction. See **Exhibit C**.

Analysis with respect to Mobile Diagnostic Program

With respect to the mobile diagnostic program, the CON Law expressly exempts from CON review the acquisition of an existing "health service facility, including equipment owned by the health service facility at the time of acquisition," upon prior written notice to the Agency. N.C. Gen. Stat. § 131E-184(a)(8). The term "health service facility" is defined to include a "diagnostic center." *Id.* § 131E-176(9b). In turn, a "diagnostic center" is defined to include a "mobile diagnostic program." *Id.* § 131E-176(7a). Hence, the acquisition of an existing mobile diagnostic program, including the equipment it owns upon the acquisition, is exempt from CON review as the acquisition of an existing health service facility.

The OrthoCarolina mobile MRI scanners, together with the equipment and services these two scanners provide to multiple sites, constitute a "mobile diagnostic program." Consequently, the mobile diagnostic program is a "diagnostic center" and, hence, an existing "health service facility." For these reasons, Novant Health's proposed acquisition of OrthoCarolina's mobile diagnostic program, including the two mobile MRI scanners, trailers, and associated equipment owned by OrthoCarolina at the time of acquisition, is exempt from CON review.

Prior decisions by the Agency confirm this conclusion. On November 15, 2017, the Agency determined that an almost identical acquisition by Rex Hospital, Inc. was exempt from CON review. See **Exhibit D**. FirstHealth of the Carolinas, Inc. ("FirstHealth") owned a mobile cardiac catheterization unit that was grandfathered because the unit was originally acquired and placed into service before March 18, 1993 (the "Mobile Cath Unit"). The Agency determined that the grandfathered Mobile Cath Unit constituted a grandfathered mobile diagnostic program, which in turn constituted a grandfathered diagnostic center. Consequently, the Agency determined that Rex Hospital could acquire this grandfathered health care facility, including the Mobile Cath Unit, from FirstHealth, without first obtaining a CON. More recently, , the Agency determined that Novant Health-Norfolk, LLC's acquisitions of two grandfathered mobile diagnostic programs from Kings Medical Company were also exempt from CON review. See **Exhibit E**.3

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³ While not considered by the Agency in its prior determinations, Novant Health notes that OrthoCarolina's mobile diagnostic program meets the CON Law definition of a diagnostic center in that the medical diagnostic equipment utilized by the program, which costs ten

Conclusion

For the foregoing reasons, we respectfully request the Agency's written determination that the Transaction described in this letter does not require a CON. If you have any questions or need further information, please let me know. Thank you for your time and consideration.

Sincerely,

Denise M. Gunter

Enclosures



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

Gary S. Qualls K&L Gates, LLP Post Office Box 14210 Research Triangle Park, North Carolina 27709-4210

William R. Shenton Poyner Spruill Post Office Box 1801 Raleigh, North Carolina 27602-1801

Exempt from Review

Record #:

1689

Business Name:

Vidant Radiation Oncology

Business #:

2249

Project Description:

Acquisition by Vidant Radiation Oncology of the linear accelerators and other equipment owned by NewCo Cancer

Services, LLC and North Carolina Radiation Therapy Management

Services, LLC (NCRT)

County:

Pitt

Dear Messrs. Qualls and Shenton:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of July 31, 2015, the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-184(a)(8). Therefore, you may proceed to offer, develop or establish the above referenced project without a certificate of need.

However, you need to contact the Agency's Construction and Acute and Home Care Licensure and Certification Sections to determine if they have any requirements for development of the proposed project.



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
An Equal Opportunity/ Affirmative Action Employer

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 Agency. 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.

If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Jane Rhoe-Jones

Project Analyst

Martha J. Frisone

Assistant Chief, Certificate of Need

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

Construction Section, DHSR

Assistant Chief, Healthcare Planning

K&L GATES

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July 31, 2015

Received by the CON Section JUL 31 2015

Via Hand Delivery

Shelley Carraway

Chief

Department of Health and Human Services Division of Health Service Regulation Health Planning and Certificate of Need Section 809 Ruggles Drive Raleigh, North Carolina 27603 Martha Frisone
Assistant Chief, Certificate of Need
Department of Health and Human Services
Division of Health Service Regulation
Health Planning and Certificate of Need
Section
809 Ruggles Drive
Raleigh, North Carolina 27603

RE: No Review Request - Joint Venture between Vidant and 21st Century Oncology Affiliate

Dear Ms. Carraway and Ms. Frisone:

On behalf of our client, Pitt County Memorial Hospital, Incorporated, d/b/a Vidant Medical Center ("Vidant"), along with William Shenton, who is counsel for 21st Century Oncology and its North Carolina affiliate, North Carolina Radiation Therapy Management Services, LLC ("NCRT"), enclosed please find an attachment describing a No Review Request for a potential joint venture between Vidant and NCRT.

As indicated in the No Review Request, we do not believe that this joint venture is subject to certificate of need review. Thank you in advance for your attention, and please let me know if you have any questions.

Sincerely,

Bary B. Quella Gary S. Qualls

cc: William Shenton

Attachments

RT-3042393

Poyner Spruill[™]

July 31, 2015

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

Shelley Carraway Chief Healthcare Planning and Certificate of Need Section Certificate of Need NC Department of Health and Human Services 2704 Mail Service Center Raleigh, NC 27699-2704

Martha Frisone Asst. Chief NC Department of Health and Human Services 2704 Mail Service Center Raleigh, NC 27699-2704

RE: No Review Request - Joint Venture between Vidant and 21st Century Oncology Affiliate

Dear Ms. Carraway and Ms. Frisone:

William a Sharton

I am writing as counsel for 21st Century Oncology and its North Carolina affiliate, North Carolina Radiation Therapy Management Services, LLC ("NCRT"), to transmit, along with Gary Qualls and Colleen Crowley, who are counsel for Vidant Medical Center, a No-Review request for your consideration. Vidant and NCRT are planning to implement a joint venture which will entail the combination of their respective freestanding radiation equipment and services in the Greenville area into a new limited liability company, called Vidant Radiation Oncology.

The enclosed document describes the steps in the transaction, and as we indicate this joint venture should not be subject to certificate of need review. We appreciate your attention to this request and please feel free to contact counsel for either of the parties if you should have any questions or need further clarification.

Very truly yours,

William R. Shenton

Partner

No Review Request for Joint Venture between Vidant Health and 21st Century Oncology

The purpose of this request is to inform the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (the "Agency") of a planned joint venture between Pitt County Memorial Hospital, Incorporated, d/b/a Vidant Medical Center ("Vidant") and North Carolina Radiation Therapy Management Services, LLC ("NCRT"), involving the combination of their existing, freestanding radiation oncology equipment and services into a single joint venture limited liability company to be named Vidant Radiation Oncology ("VRO"). We ask that the Agency confirm that this joint venture is not reviewable as a new institutional health service under the North Carolina Certificate of Need ("CON") law.

STATEMENT OF FACTS

By way of background, NewCo Cancer Services LLC ("NewCo"), d/b/a Leo Jenkins Cancer Center ("Cancer Center"), a 50/50 joint venture between East Carolina University Brody School of Medicine ("ECU") and Vidant, owns and operates two existing linear accelerators ("linacs") and CT simulators, pursuant to CON Project I.D. Q-8562-10. See Certificate of Need attached as Exhibit 1 and Exemption Request and Approval to Replace a CT Simulator attached as Exhibit 2. Vidant also owns and operates a Cyberknife linac, which is operated as a freestanding radiation treatment service at the Cancer Center, pursuant to CON Project I.D. Q-8558-10 and Material Compliance letter dated May 19, 2011. See Certificate of Need attached as Exhibit 3 and Material Compliance Letter attached as Exhibit 4.

NCRT owns and operates two existing linacs as part of NC Radiation Therapy-Greenville. See Declaratory Ruling and Exemption attached as Exhibits 5 and 6.

¹ NCRT is a controlled affiliate of 21st Century Oncology.

First, Vidant seeks to obtain full ownership of the two linacs and CT simulators currently owned by NewCo and located at the Cancer Center. NewCo will continue to exist after Vidant obtains 100% ownership of the linacs and simulators. Once Vidant obtains full ownership, the same equipment will be used to provide the same radiation oncology services, in the same location.

Second, as part of a joint venture, Vidant and NCRT will be combining and contributing their existing freestanding radiation oncology services, medical equipment (including the 5 linacs, one of which is a Cyberknife linac) and related assets to the newly created VRO. After the joint venture transaction occurs, all of the equipment will continue to be operated in the same two locations as described above.² Therefore, as a result of these two steps (collectively, the "Transaction"), no linacs will be relocated or added to Linear Accelerator Service Area 27, as defined by the 2015 State Medical Facilities Plan ("SMFP").

DISCUSSION

I. Obtaining NewCo's Interest in the Equipment Does Not Require a CON.

As Step #1 to the Transaction, Vidant seeks to acquire 100% ownership of the two linacs and simulators currently owned by NewCo. A separate, third party will not be obtaining ownership of the linacs and simulators. Instead, Vidant, the 50% owner of the equipment, will now become the 100% owner. The linacs and simulators will continue to be operated at the Cancer Center in the same manner they are currently being operated.

The purchase of NewCo's interest in the two linacs and simulators does not involve the offering or expansion of any new facility, service or equipment, and the State's inventory of linacs will not change. No new or additional linacs will be acquired or placed in operation in the

² While at some point in the future VRO may seek to relocate equipment, it would not do so unless and until all necessary approvals are obtained from the Agency.

State. As detailed below in Section II, this is similar to membership change in the ownership of regulated equipment and a CON is not required.

II. Creating VRO as a Conduit for Ownership is Not Regulated Under CON Law.

Likewise, Step 2 in the Transaction -- Vidant and NCRT contributing their respective linacs to VRO -- does not require a CON. The CON statute provides a lengthy and exclusive list of activities that constitute development of a new institutional health service, requiring a CON. The joint venture of two existing entities that already actively provide health services is not included on that list. Pursuant to a well-established maxim of statutory construction, *expressio unius est exclusio alterius*, those transactions not included in N.C. Gen. Stat. § 131E-176(16) do not require a CON. *See, e.g., In re Miller,* 357 N.C. 316, 325, 584 S.E.2d 772, 780 (2003) (stating that "[u]nder the doctrine of *expressio unius est exclusio alterius*, when a statute lists the situations to which it applies, it implies the exclusion of situations not contained in the list"); *see also Jackson v. A Woman's Choice, Inc.,* 130 N.C. App. 590, 594, 503 S.E.2d 422, 425 (1998) (internal citations omitted) ("Where a statute is explicit on its face, the courts have no authority to impose restrictions that the statute does not expressly contain.").

Here, Vidant and NCRT will place the ownership rights of all five linacs into the joint venture, VRO. NCRT will own 50% of VRO and Vidant will own 50% of VRO. Therefore, both Vidant and NCRT will continue to own the linacs through their respective ownership of VRO.

Previous Declaratory Rulings and No Review Decisions demonstrate that the Agency and the Division of Health Service Regulation have already determined that a CON is not required for similar membership interest changes pertaining to CON regulated equipment. See Id., attached as Exhibit 7; In re: Request for Declaratory Ruling by Wake Radiology Oncology

Services, PLLC, et al., attached as Exhibit 8; In re: Request for Declaratory Ruling by Radiation Therapy Services, Inc. et. al., attached as Exhibit 9; No Review/WakeMed/Acquisition of Ownership Interest of CSA-1, Owners of Five Heart-Lung Bypass Machines Located in WakeMed/Wake County attached as Exhibit 10; and 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 attached as Exhibit 11.

Likewise, here, Vidant and NCRT's joint venture does not constitute the acquisition of a linac. In fact, the underlying linac ownership will be essentially the same. Unlike some of the prior situations referenced above that were determined not to be subject to CON review, Vidant and NCRT will still retain an ownership interest in the linacs. No separate third party will be acquiring any ownership interest in the equipment. The same parties will retain ownership of all five linacs (now through the joint conduit of VRO); and the linacs will remain in the same location, and will still be used to serve patients in the same manner.

A "new institutional health service" includes "the acquisition by purchase, donation, lease, transfer, or comparable arrangement . . . by or on behalf of any person" a linear accelerator and simulator. N.C. Gen. Stat. § 131E-176(16)(f1)(5a) and (f1)(9). However, the transaction contemplated here will not constitute the acquisition of a linear accelerator as defined by N.C. Gen. Stat. § 131E-176(16). Ownership of the radiation therapy equipment will largely be unaffected by this transaction. That equipment will continue to be owned, in part, by the same entities both before and after this transaction. VRO will be owned by Vidant and NCRT. VRO will merely be the new ownership conduit through which NCRT and Vidant continue to own the radiation oncology treatment equipment.

A fundamental concept of corporate law is that the owners of corporate stock are distinct from the corporation itself. *See* Robinson on North Carolina Corporate Law, § 2.08 ("A corporation is a legal entity separate and distinct from its shareholders.") By design, LLC members also stand in a position similar to corporate shareholders. *Id.* at § 34.03[3]. Consequently, under the general principles of business organizations law governing LLC membership interests, the members of an LLC are legally distinct from the LLC itself. *Id.* at § 34.05[1] ("A membership interest may be acquired directly from the LLC or by assignment from another holder").

Vidant and NCRT are merely placing their collective ownership interests into one joint venture and will then each retain a percentage share of the ownership of the joint venture. Therefore, this transaction cannot constitute the acquisition of a linear accelerator because Vidant and NCRT will retain ownership of their respective equipment through the VRO.

CONCLUSION

Based on the discussion herein, Vidant and NCRT request that the Agency provide confirmation that no CON is required for the proposed Transaction described above.

EXHIBITS

- 1. Certificate of Need CON Project I.D. Q-8562-10
- 2. Exemption Request (without exhibits) and Approval to Replace CT Simulator
- 3. Certificate of Need CON Project I.D. Q-8558-10
- 4. Material Compliance Letter dated May 19, 2011
- 5. NC Radiation Therapy-Greenville 2007 Declaratory Ruling
- 6. NC Radiation Therapy-Greenville's 2009 Certificate of Need Exemption
- 7. Declaratory Ruling for the Charlotte-Mecklenburg Hospital Authority d/b/a/Carolinas Healthcare System, November 4, 2011
- 8. In re: Request for Declaratory Ruling by Wake Radiology Oncology Services, PLLC, et al.
- 9. In re: Request for Declaratory Ruling by Radiation Therapy Services, Inc. et. al.
- 10. No Review/WakeMed/Acquisition of Ownership Interest of CSA-1, Owners of Five Heart-Lung Bypass Machines Located in WakeMed/Wake County
- 11. 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



CERTIFICATE OF NEED

Project Identification Number #Q-8562-10

FID #100878

NewCo Cancer Services, LLC ISSUED TO:

P.O. Box 6028

Greenville, NC 27835

Pursuant to N.C. Gen. Stat. § 131E-175, et. seq., the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the "certificate holder") to develop the certificate of need project identified above. The certificate holder shall develop the project in a manner consistent with the representations in the project application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by N.C. Gen. Stat. § 131E-176(16)e. The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. § 131E-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to N.C. Gen. Stat. § 131E-189 for any of the reasons provided in that law.

SCOPE: NewCo Cancer Services shall acquire two existing linear accelerators, CT simulator, and related equipment, and multispecialty oncology physician practices from East Carolina University Brody School of Medicine/ Pitt County

CONDITIONS:

See Reverse Side

PHYSICAL LOCATION: Pitt County Memorial Hospital

600 Moye Boulevard Greenville, NC 27834

MAXIMUM CAPITAL EXPENDITURE: \$9,700,000

TIMETABLE:

See Reverse Side

FIRST PROGRESS REPORT DUE:

May 1, 2011

This certificate is effective as of the 30th day of December, 2010

Chief, Co fificate of Need Section Division of Health Service Regulation

CONDITIONS:

- 1. NewCo Cancer Services, LLC shall materially comply with all representations made in its application.
- 2. NewCo Cancer Services, LLC shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application or which would otherwise require a certificate of need.
- 3. NewCo Cancer Services, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to the issuance of the certificate of need.

A letter acknowledging acceptance of and agreeing to comply with all conditions stated in the conditional approval letter was received by the Certificate of Need Section on December 6, 2010.

THE PARTY OF THE P	
TIMETABLE:	



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

September 13, 2013

Jeffrey Shovelin, Director of Corporate Planning Vidant Health Post Office Box 2068 Greenville, North Carolina 27835-6028

Exempt from Review - Replacement Equipment

Facility or Business:

Vidant Medical Center

Project Description:

Replace CT Scanner and CT Simulator at the Leo Jenkins Cancer Center

County:

Pitt

FID #:

933410

Dear Mr. Shovelin:

In response to your letter of August 14, 2013, the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, the GE Optima CT580 16 Slice CT Simulator to replace the existing Siemens SimView CT Scanner. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need. Further please be advised that as soon as the replacement equipment is acquired, you must provide the CON Section and the Medical Facilities Planning Section with the serial number of the new equipment to update the inventory, if not already provided.

Moreover, you need to contact the Acute and Home Care Licensure and Certification Section and the Construction Section to determine if they have any requirements for development of the proposed project.

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.



Certificate of Need Section

www.ncdhhs.gov
Telephone: 919-855-3873 • Fax: 919-733-8139
Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603
Mailing Address: 2704 Mail Service Center •Raleigh, NC 27699-2704
An Equal Opportunity/ Affirmative Action Employer

Jeffrey Shovelin September 13, 2013 Page 2

Sincerely,

Project Analyst

Craig R. Smith, Chief Certificate of Need Section

cc:

Acute and Home Care Licensure and Certification, DHSR Construction Section, DHSR

Medical Facilities Planning Branch, DSHR





August 29, 2013

Ms. Jane Rhoe-Jones Certificate of Need Section Division of Health Service Regulation NC Department of Health and Human Services 2704 Mail Service Center Raleigh, NC 27699-2704



Dear Ms. Rhoe-Jones:

NewCo Cancer Services, LLC (NewCo), a joint venture between Vidant Medical Center and ECU's Leo Jenkins Cancer Center, plans to replace an existing CT simulator with new equipment. NewCo believes that the proposed equipment replacement is not subject to review under North Carolina's Certificate of Need (CON) laws.

The proposed project includes the replacement of a Siemens SimView CT scanner with a GE Optima CT580 16 slice CT simulator (see Appendix A for vendor quotes and Appendix B for equipment comparison table and brochure). The equipment will be secured through accumulated reserves. The reason for this replacement is due to age and the need for upgraded technology to provide optimal care. Only minor renovations are needed for the existing CT simulator suite (See Appendix C for drawings and construction estimate). The total capital costs for the proposed replacement is estimated to be \$ 1,147,781 (see Appendix D for the Capital Cost Sheet). These costs include all expenses associated with the equipment and minor renovations. After the new scanner is operational, the existing equipment will be permanently removed from the facility and will no longer be exempt from CON law (see Appendix E for required documentation of equipment removal).

NewCo's proposed project meets the definition of replacement equipment found in G.S. 131E-176(22a). The total capital expenditure for the equipment is less than \$2,000,000 and the equipment being purchased is for the sole purpose of replacing comparable medical equipment. Since NewCo's proposal meets the definition of "replacement equipment", G.S. 131E-184(a)(7) exempts this project from review. Therefore, NewCo requests approval of a no review status for the proposed project.

If you require additional information or clarification, please contact me at (252)-847-3631.

Jeffrey Shovelin

Director of Corporate Planning

Vidant Health



CERTIFICATE OF NEED

for Project Identification Number #Q-8558-10

FID #933410

ISSUED TO: Pitt County Memorial Hospital, Inc.

P.O. Box 6028

Greenville, NC 27835

Pursuant to N.C. Gen. Stat. § 131E-175, et. seq., the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the "certificate holder") to develop the certificate of need project identified above. The certificate holder shall develop the project in a manner consistent with the representations in the project application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by N.C. Gen. Stat. § 131E-176(16)e. The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. § 131E-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to N.C. Gen. Stat. § 131E-189 for any of the reasons provided in that law.

SCOPE: Pitt County Memorial Hospital shall acquire a CyberKnife radiosurgery system and related equipment from East Carolina University Brody School of Medicine/Pitt County

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: Pitt County Memorial Hospital

600 Moye Boulevard Greenville, NC 27834

MAXIMUM CAPITAL EXPENDITURE: \$4,750,000

TIMETABLE:

See Reverse Side

FIRST PROGRESS REPORT DUE:

May 1, 2011

This certificate is effective as of the 30th day of December, 2010

Chief, Certificate of Need Section Division of Health Service Regulation



CERTIFICATE OF NEED

for Project Identification Number #Q-8558-10

FID #933410

Pitt County Memorial Hospital, Inc. ISSUED TO:

P.O. Box 6028

Greenville, NC 27835

Pursuant to N.C. Gen. Stat. § 131E-175, et. seq., the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the "certificate holder") to develop the certificate of need project identified above. The certificate holder shall develop the project in a manner consistent with the representations in the project application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by N.C. Gen. Stat. § 131E-176(16)e. The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. § 131E-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to N.C. Gen. Stat. § 131E-189 for any of the reasons provided in that law.

SCOPE: Pitt County Memorial Hospital shall acquire a CyberKnife radiosurgery system and related equipment from East Carolina University Brody School of Medicine/ Pitt County

CONDITIONS:

See Reverse Side

PHYSICAL LOCATION: Pitt County Memorial Hospital

600 Moye Boulevard Greenville, NC 27834

MAXIMUM CAPITAL EXPENDITURE: \$4,750,000

TIMETABLE:

See Reverse Side

FIRST PROGRESS REPORT DUE:

May 1, 2011

This certificate is effective as of the 30th day of December, 2010

Division of Health Service Regulation

CONDITIONS:

- 1. Pitt County Memorial Hospital, Incorporated shall materially comply with all representations made in its application.
- 2. Pitt County Memorial Hospital, Incorporated shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application or which would otherwise require a certificate of need.
- 3. Pitt County Memorial Hospital, Incorporated shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to the issuance of the certificate of need.

A letter acknowledging acceptance of and agreeing to comply with all conditions stated in the conditional approval letter was received by the Certificate of Need Section on December 6, 2010.

Occupancy/Offering of service(s)		January 1, 2011
TIMETABLE:		
DESCRIPTION A PROPERTY	* 1	

A

1



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: 919-855-3873

Fax: 919-733-8139

May 19, 2011

Mr. Jeff Shovelin, Director of Corporate Planning Pitt County Memorial Hospital 2100 Stantonsburg Road Greenville, NC 27835

RE:

Material Compliance/ Project I.D. # Q-8558-10 Pitt County Memorial Hospital shall acquire a CyberKnife radiosurgery system and related equipment from East Carolina University Brody School of Medicine/ Change from operating the CyberKnife as a hospital-based service to a freestanding radiation treatment center/ Pitt County

FID # 933410

Dear Mr. Shovelin:

In response to your correspondence dated April 18, 2011 regarding the above referenced project, the Certificate of Need Section has determined that the proposed change is in material compliance with representations made in the application. These changes include obtaining an additional NPI number and new Medicare and Medicaid identification numbers to operate the CyberKnife service as a freestanding radiation treatment center at the same location in the Leo W. Jenkins Cancer Center. This change in operating status does not constitute a change in the equipment to be acquired from East Carolina University Brody School of Medicine. However, you should contact the Construction Section of the Division of Health Service Regulation to determine if they have any requirements pertinent to the proposed change.

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. Please refer to the Project I.D.# and Facility I.D.# (FID) in all correspondence.

Bernetta Thorne-Williams, Project Analyst

Certificate of Need Section

cc:

Medical Facilities Planning Section, DHSR

Construction Section, DHSR

Acute Care Licensure and Certification Section, DHSR





April 18, 2010

Mr. Craig Smith, Chief Certificate of Need Section, Division of Health Service Regulation North Carolina Department of Health and Human Services 2704 Mail Service Center Raleigh, NC 27699-2704

Re: Notification of a minor project change to Project ID #Q-8558-10 / Pitt County Memorial Hospital, Inc. / Acquire CyperKnife (linear accelerator) from Brody School of Medicine / Pitt County FID#933410

Dear Mr. Smith:

This letter serves as notification of a minor project change in approved Project ID #Q-8558-10 / Pitt County Memorial Hospital, Inc. / Acquire CyperKnife (linear accelerator) from Brody School of Medicine / Pitt County. We believe the change outlined below does not constitute a material difference in the representations made in the original CON. The change was necessary to comply with the new CMS Life Safety Code Requirements effective February, 2011.

Specifically, in the original application, Pitt County Memorial Hospital, Inc. (PCMH) stated the CyberKnife would be operated in its existing location in the existing Leo W. Jenkins Cancer Center (LWJCC) as a hospital-based service under the hospital's existing provider numbers. As a result of new CMS Life Safety Code Requirements effective February, 2011, the LWJCC does not meet the requirements for institutional space. Therefore, in its existing location, the CyberKnife cannot be operated as a hospital-based service without first incurring significant capital improvements.

To address this issue, PCMH will operate the CyberKnife in its current location, but instead of operating as a hospital-based service, PCMH will obtain an additional NPI number and new Medicare and Medicaid identification numbers to operate CyberKnife services as a freestanding radiation treatment center, doing business as "UHS CyberKnife". PCMH believes this change has not materially altered the approved CON as these changes do not require modifications to ownership, need, services to be provided, patients to be served, capital costs, staffing, time lines, or financial projections.

If you need additional information or have any questions, please do not hesitate to call me at (252) 847-3631 or email me directly at jshoveli@uhseast.com.

Sincerely,

Jeff Shovelin

Director of Corporate Planning,

University Health System of Eastern Carolina



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

Michael R. Easley, Governor Dempsey Benton, Secretary

Robert J. Fluzgerald, Director Phone: 919-855-3750 Fax: 919-733-2757

September 18, 2007

CERTIFIED MAIL

Susan H. Hargrove, Esquire Smith, Anderson, Blount, Dorsett Mitchell & Jernigan, L.L.P. P.O. Box 2611 Raleigh, NC 27602-2611

Declaratory Ruling for Radiation Therapy Services, Inc. and North Carolina Radiation RE: Therapy Management Services, Inc.

Dear Ms. Hargrove:

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

Sincerely

RJF:JH:peb

Enclosure

Jeff Horton, Chief Operating Officer, DHSR cc:

Lee Hoffman, Chief, Certificate of Need Section, DHSR

Azzie Conley, Chief, Acute and Home Care Licensure and Certification Section, DHSR

Marc Lodge, Special Deputy Attorney General, DOJ





Fax:9197332757

P, 02

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

IN RE: REQUEST FOR)	
DECLARATORY RULING BY RADIATION)	
THERAPY SERVICES, INC. AND NORTH)	DECLARATORY RULING
CAROLINA RADIATION THERAPY)	
MANAGEMENT SERVICES, INC.)	•

I, Robert J. Fitzgerald, Director of the Division of Health Service Regulation (the "Department"), hereby issue this declaratory ruling to Radiation Therapy Services, Inc. d/b/a/ 21st Century Oncology ("RTS") and North Carolina Radiation Therapy Management Services, Inc. ("NC Radiation") (collectively "Petitioners") pursuant to N.C.G.S. § 150B-4, 10A NCAC 14A.0103, and the authority delegated to me by the Secretary of the North Carolina Department of Health and Human Services. Petitioners have filed a Declaratory Ruling Request (the "Request") asking the Department to issue a declaratory ruling that they may acquire all of the stock of Carolina Radiation and Cancer Treatment Center, Inc. ("CRTC") without certificate of need ("CON") review.

This ruling is binding on the Department and the person requesting it if the material facts stated in the Request are accurate and no material facts have been omitted from the request. The ruling applies only to this request. Except as provided by N.C.G.S. § 150B-4, the Department reserves the right to change the conclusions which are contained in this ruling. Susan H. Hargrove, Sean A. Timmons, and Jennifer B. Markhan of Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan, L.L.P., counsel for Petitioners, have requested this ruling on behalf of Petitioners and have provided the statement of facts upon which this ruling is based. The material facts as provided by counsel for Petitioners are set out below.

STATEMENT OF THE FACTS

Except as noted, the following statement of the facts is based on the representations of Petitioners in the Request.

Petitioner RTS is a Florida corporation. NC Radiation is a North Carolina corporation that is a wholly-owned subsidiary of RTS. Both have their principal business address in Fort Myers, Florida.

Petitioners wish to acquire 100% of the issued and outstanding stock of CRTC, which they state is a North Carolina corporation owned by Dr. Gordon Koltis that operates a radiation therapy facility for cancer patients. Petitioners describe CRTC as an oncology treatment center that, prior to 26 August 2005, would have been a "health service facility" as defined in N.C.G.S. § 131E-176(9b). S.L. 2005-325 eliminated oncology treatment centers from the category of "health service facilities," effective 26 August 2005.

Petitioners also state that CRTC "owns and operates two linear accelerators" and "one simulator." Request, p. 3. Footnote 1 to the Request states:

CRTC has represented to Petitioners that it entered into binding obligations to acquire the second linear accelerator prior to August 26, 2005, and that the acquisition of the second linear accelerator cost less than \$750,000, including the cost of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the second linear accelerator.

I note from the files of the Department that the inventory report of linear accelerator equipment submitted by Carolina Radiation Medicine, P.A., certified and dated by Gordon G. Koltis on April 6, 2007, identifies only one linear accelerator owned by CRTC. The Department files do not contain any information concerning the purported second linear accelerator.

Petitioners represent that they have executed a stock purchase agreement by which NC Radiation will acquire 100% of the issued and outstanding capital stock of CRTC from Dr. Koltis. After closing the transaction, Petitioners state that CRTC will remain a separate corporate entity that is a wholly-owned subsidiary of NC Radiation. They state that CRTC will continue to operate its freestanding radiation therapy facility at the same location in Greenville, Pitt County, North Carolina, in the same manner in which it operated prior to the transaction in all material ways. Petitioners will pay more than two million dollars to purchase the CRTC stock. The closing of the transaction is conditioned on receiving confirmation from the Department that acquisition of the stock will not require a certificate of need.

<u>ANALYSIS</u>

N.C.G.S. § 131E-178 provides that no person shall offer or develop "a new institutional health service" without first obtaining a CON. N.G.C.S. § 131E-176(16) defines "new institutional health service" to include: (1) "The acquisition by purchase, donation, lease, transfer, or comparable arrangement" of a linear accelerator "by or on behalf of any person," N.G.C.S. § 131E-176(16)f1.5a, and (2) "The obligation by any person of a capital expenditure exceeding two million dollars (\$2,000,000) to develop or expand a heath service or a health service facility, or which relates to the provision of a health service," N.C.G.S. § 131E-176(16)b.

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.

Similarly, the transaction is not an obligation to develop or expand a health service or a health service facility, since Petitioners represent that CRTC will continue to operate at the same

location in a manner that is the same in all material respects as it operated prior to the transaction. In addition, pursuant to S.L. 2005-325, oncology treatment centers are not "health service facilities" for purposes of the CON law.

Finally, on the specific facts of this case, the transaction proposed by Petitioners is not "a capital expenditure... which relates to the provision of a health service" within the meaning of N.C.G.S. § 131B-176(16)b. The definition of "health service" specifically "does not include administrative and other activities that are not integral to clinical management." Petitioners' representations indicate that stock ownership of CRTC is not integral to the clinical management of CRTC, because in all material respects the operations of CRTC will not change.

I specifically except from this Ruling any conclusions as to the status or legality of the ownership of a purported second linear accelerator by CRTC. The Department has no notice of the existence or ownership of the second linear accelerator, and I make no finding that CRTC may acquire or operate, or has properly acquired and operated, a second linear accelerator without CON review.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the Request to be true, I conclude that the acquisition by Petitioners of 100% of the outstanding and issued stock of CRTC, in the manner represented by Petitioners in the Request, is not subject to CON review.

This ruling is subject to the condition that, after the transaction, CRTC continues to operate its freestanding radiation therapy facility at the same location in Greenville, Pitt County, North Carolina, in the same manner in which it operated prior to the transaction in all material ways.

This ruling is not intended to address, expand or validate any activities or status of CRTC with respect to the requirements of the CON law as it relates to CRTC. The ruling is limited to the specific facts presented in the Request. It specifically does not address the status of any linear accelerator that CRTC may own or claim to own.

This // day of 5/1/2 2007.

Robert J. Fitzgeries, Director

Division of Highth 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

Susan H. Hargrove, Esq. Smith, Anderson, Blount, Dorsett Mitchell & Jernigan, L.L.P. P.O. Box 2611 Raleigh, NC 27602-2611

This the 14th day of September, 2007.

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

Beverly Eaves Perdue, Governor Lanier M. Cansler, Secretary

www.ncdhhs.gov/dhsr

Lee Hoffman, Section Chief Phone: 919-855-3873

Fax: 919-733-8139

June 29, 2009

Renee J. Montgomery, Partner Parker Poe Adams and Bernstein LLP Post Office Box 389 Raleigh, NC 27602-0389

RE: Exempt from Review - Replacement Equipment/ Radiation Therapy Services, Inc. d/b/a 21st Century Oncology, North Carolina Radiation Therapy Management Services, Inc. and Carolina Radiation and Cancer Treatment Center, Inc./ Acquire a replacement linear accelerator for the second linear accelerator located at CRCTC in Greenville/ Pitt County

Dear Ms. Montgomery:

In response to your letters of June 23, 2009, November 18, 2008, and July 29, 2008, the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, the Varian 2100C, s/n 1167, to replace the existing Varian 2100C, s/n 527. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need.

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

Sincerely

F. Gene DePorter, Project Analyst

Certificate of Need Section

Medical Facilities Planning Section, DHSR



cc:



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

November 4, 2011

CERTIFIED MAIL & FACSIMILE

William W. Stewart, Esq. **K&L Gates LLP** 430 Davis Drive, Suite 400 Morrisville, NC 27560

RE:

Declaratory Ruling for The Charlotte-Mecklenburg Hospital Authority

d/b/a Carolinas Healthcare System

Dear Mr. Stewart:

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)	
THE CHARLOTTE-MECKLENBURG)	DECLARATORY RULING
HOSPITAL AUTHORITY D/B/A)	
CAROLINAS HEALTHCARE SYSTEM)	

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.

The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Healthcare System ("CMHA") has requested a declaratory ruling to confirm that its acquisition of the membership interests of University Radiation Oncology Center, LLC ("UROC") and its continued operation of that facility may proceed without first obtaining a Certificate of Need ("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. William W. Stewart of K&L Gates LLP has requested this ruling on CMHA's behalf and has provided the material facts upon which this ruling is based.

STATEMENT OF THE FACTS

UROC, which is located at 8310 University Executive Park, Suite 500, Charlotte, NC 28262, is a limited liability company which provides radiation therapy treatment. UROC was

acquired by Radiation Oncology Centers of the Carolinas, Inc. ("ROCC") pursuant to an exemption in August 1997. Currently, UROC operates a Varian 2100C linear accelerator and a GE Highspeed Advantage CT simulator, which the CON Section previously approved.

On August 18, 2011, the Department issued a Declaratory Ruling determining that ROCC could transfer, without a CON, its interest in UROC and Matthews Radiation Oncology Center ("MROC") to two wholly owned subsidiaries of ROCC. Once that transaction is consummated, ROCC will be the sole member of UROC. ROCC will then transfer its entire membership interest in UROC to CMHA and CMHA will become UROC's sole member. Thus, UROC will remain intact as the same LLC, but with a different membership composition.

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 UROC which owns and operates a linear accelerator or simulator. The declaratory ruling requested by CMHA is consistent with the Department's prior rulings that

Exhibit A

have interpreted the applicability of the CON Law to the purchase of ownership interests in

health care organizations, for the following reasons:

CMHA's acquisition of the membership interests in UROC does not constitute the

acquisition of a linear accelerator or a simulator because the ownership of the equipment will not

change, and the same equipment will be used to provide the same radiation oncology services, in

the same location. UROC will continue to own the two pieces of equipment and UROC's legal

status as a corporate entity will not change.

The purchase of ROCC's membership interests in UROC 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 CMHA does not require a certificate of need in order to proceed with the purchase

of ROCC's membership interests in UROC.

This the 44 day of November, 2011.

Drexdal 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

William W. Stewart K&L Gates LLP 430 Davis Drive, Suite 400 Morrisville, NC 27560

This the 4th day of November, 2011.

Chief Operating Officer

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 _____ day of September, 2010.

Drexdal 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 first-class, postage pre-paid envelope addressed as follows:

CERTIFIED MAIL

Ronald I. Kirschbaum KIRSCHBAUM, NANNEY, KEENAN & GRIFFIN, P.A. P.O. Box 19766 Raleigh, North Carolina 27607 Attorneys for Wake Radiology Oncology, PLLC

William R. Shenton
POYNER SPRUILL LLP
301 Fayetteville Street, Suite 1900
Raleigh, North Carolina 27601
Attorneys for U.S. Oncology, Inc. and AOR Management
Company of Virginia, LLC

Larry E. Robbins WYRICK ROBBINS YATES & PONTON, LLP P.O. Drawer 17803 Raleigh, North Carolina 27607 Attorneys for Cancer Centers of North Carolina, P.C.

Maureen Demarest Murray SMITH MOORE LEATHERWOOD LLP P.O. Box 21927 Greensboro, North Carolina 27420 Attorneys for WakeMed

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		To SE I Louton
		Jeff Horton Chief Operating Officer

day of September, 2010.

This the

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

IN RE: REQUEST FOR)	
DECLARATORY RULING BY RADIATION)	
THERAPY SERVICES, INC. AND NORTH)	DECLARATORY RULING
CAROLINA RADIATION THERAPY)	
MANAGEMENT SERVICES, INC.)	

I, Robert J. Fitzgerald, Director of the Division of Health Service Regulation (the "Department"), hereby issue this declaratory ruling to Radiation Therapy Services, Inc. d/b/a/ 21st Century Oncology ("RTS") and North Carolina Radiation Therapy Management Services, Inc. ("NC Radiation") (collectively "Petitioners") pursuant to N.C.G.S. § 150B-4, 10A NCAC 14A.0103, and the authority delegated to me by the Secretary of the North Carolina Department of Health and Human Services. Petitioners have filed a Declaratory Ruling Request (the "Request") asking the Department to issue a declaratory ruling that they may acquire all of the stock of Carolina Radiation and Cancer Treatment Center, Inc. ("CRTC") without certificate of need ("CON") review.

This ruling is binding on the Department and the person requesting it if the material facts stated in the Request are accurate and no material facts have been omitted from the request. The ruling applies only to this request. Except as provided by N.C.G.S. § 150B-4, the Department reserves the right to change the conclusions which are contained in this ruling. Susan H. Hargrove, Sean A. Timmons, and Jennifer B. Markhan of Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan, L.L.P., counsel for Petitioners, have requested this ruling on behalf of Petitioners and have provided the statement of facts upon which this ruling is based. The material facts as provided by counsel for Petitioners are set out below.

STATEMENT OF THE FACTS

Except as noted, the following statement of the facts is based on the representations of Petitioners in the Request.

Petitioner RTS is a Florida corporation. NC Radiation is a North Carolina corporation that is a wholly-owned subsidiary of RTS. Both have their principal business address in Fort Myers, Florida.

Petitioners wish to acquire 100% of the issued and outstanding stock of CRTC, which they state is a North Carolina corporation owned by Dr. Gordon Koltis that operates a radiation therapy facility for cancer patients. Petitioners describe CRTC as an oncology treatment center that, prior to 26 August 2005, would have been a "health service facility" as defined in N.C.G.S. § 131E-176(9b). S.L. 2005-325 eliminated oncology treatment centers from the category of "health service facilities," effective 26 August 2005.

Petitioners also state that CRTC "owns and operates two linear accelerators" and "one simulator." Request, p. 3. Footnote 1 to the Request states:

CRTC has represented to Petitioners that it entered into binding obligations to acquire the second linear accelerator prior to August 26, 2005, and that the acquisition of the second linear accelerator cost less than \$750,000, including the cost of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the second linear accelerator.

I note from the files of the Department that the inventory report of linear accelerator equipment submitted by Carolina Radiation Medicine, P.A., certified and dated by Gordon G. Koltis on April 6, 2007, identifies only one linear accelerator owned by CRTC. The Department files do not contain any information concerning the purported second linear accelerator.

Petitioners represent that they have executed a stock purchase agreement by which NC Radiation will acquire 100% of the issued and outstanding capital stock of CRTC from Dr. Koltis. After closing the transaction, Petitioners state that CRTC will remain a separate corporate entity that is a wholly-owned subsidiary of NC Radiation. They state that CRTC will continue to operate its freestanding radiation therapy facility at the same location in Greenville, Pitt County, North Carolina, in the same manner in which it operated prior to the transaction in all material ways. Petitioners will pay more than two million dollars to purchase the CRTC stock. The closing of the transaction is conditioned on receiving confirmation from the Department that acquisition of the stock will not require a certificate of need.

ANALYSIS

N.C.G.S. § 131E-178 provides that no person shall offer or develop "a new institutional health service" without first obtaining a CON. N.G.C.S. § 131E-176(16) defines "new institutional health service" to include: (1) "The acquisition by purchase, donation, lease, transfer, or comparable arrangement" of a linear accelerator "by or on behalf of any person," N.G.C.S. § 131E-176(16)f1.5a, and (2) "The obligation by any person of a capital expenditure exceeding two million dollars (\$2,000,000) to develop or expand a heath service or a health service facility, or which relates to the provision of a health service," N.C.G.S. § 131E-176(16)b.

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.

Similarly, the transaction is not an obligation to develop or expand a health service or a health service facility, since Petitioners represent that CRTC will continue to operate at the same

location in a manner that is the same in all material respects as it operated prior to the transaction. In addition, pursuant to S.L. 2005-325, oncology treatment centers are not "health service facilities" for purposes of the CON law.

Finally, on the specific facts of this case, the transaction proposed by Petitioners is not "a capital expenditure . . . which relates to the provision of a health service" within the meaning of N.C.G.S. § 131E-176(16)b. The definition of "health service" specifically "does not include administrative and other activities that are not integral to clinical management." Petitioners' representations indicate that stock ownership of CRTC is not integral to the clinical management of CRTC, because in all material respects the operations of CRTC will not change.

I specifically except from this Ruling any conclusions as to the status or legality of the ownership of a purported second linear accelerator by CRTC. The Department has no notice of the existence or ownership of the second linear accelerator, and I make no finding that CRTC may acquire or operate, or has properly acquired and operated, a second linear accelerator without CON review.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the Request to be true, I conclude that the acquisition by Petitioners of 100% of the outstanding and issued stock of CRTC, in the manner represented by Petitioners in the Request, is not subject to CON review.

This ruling is subject to the condition that, after the transaction, CRTC continues to operate its freestanding radiation therapy facility at the same location in Greenville, Pitt County, North Carolina, in the same manner in which it operated prior to the transaction in all material ways.

This ruling is not intended to address, expand or validate any activities or status of CRTC with respect to the requirements of the CON law as it relates to CRTC. The ruling is limited to the specific facts presented in the Request. It specifically does not address the status of any linear accelerator that CRTC may own or claim to own.

This		day	of	,	2007.
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Robert J. Fitzgerald, Director Division of Health Service Regulation N.C. Department of Health and Human Services

CERTIFICATE OF SERVICE

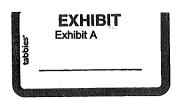
I certify that a copy of the foregoing Declaratory Ruling has been served upon the nonagency party by certified mail, return receipt requested, by depositing the copy in an official depository of the United States postal service in a first class, postage prepaid envelope addressed as follows:

CERTIFIED MAIL

Susan H. Hargrove Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan, L.L. P P.O. Box 2611 Raleigh, NC 27602-2611

nıs	$_{-}$ day of $_{-}$, 2007.	
		0	
			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

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 Rosmith, Chief
Certificate of Need Section



Location: 809 Ruggles Drive, Dorothea Dix Hospital Campus, Raleigh, N.C. 27603 An Equal Opportunity/Affirmative Action Employer February 8, 2012

Via E-Mail and U.S. Mail

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

Re: WakeMed Acquisition of Ownership Interests in CSA-1

Dear Mr. Smith and Ms. Frisone:

We represent WakeMed. 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 WakeMed's acquisition of the ownership interests of CSA-1 is not reviewable as a new institutional health service under the North Carolina Certificate of Need ("CON") law. CSA-1 is a wholly owned sub of CSA Medical, LLC ("CSA") and owns five (5) heart lung bypass ("HLB") machines that have been and are operated at WakeMed. WakeMed would acquire the membership interests in CSA-1, which would continue to exist as a legal entity and to own the five (5) HLB machines that would remain located and operated at WakeMed.

The Agency has issued numerous declaratory rulings and no review letters that acknowledge that acquisition of ownership interests in a legal entity does not constitute a reviewable acquisition of the medical equipment owned by that legal entity. For example, in a declaratory ruling issued to New Hanover Perfusionists, Inc., the Agency determined that the purchase of stock did not constitute the acquisition of a heart-lung bypass machine because ownership of the regulated heart-lung bypass equipment would not change. The Agency also determined that the transaction was not an obligation to develop or expand a health service or health service facility because the equipment company was not a health service facility. The stock purchase transaction proposed also was 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). The definition of "health service" specifically "does not include administrative and other activities that are not integral to clinical management." Stock or membership interest ownership is not integral to clinical management. In re: Request for Declaratory Ruling by New Hanover Perfusionists, Inc., January 24, 2008.

Mr. Craig R. Smith, Chief Ms. Martha Frisone, Assistant Chief February 8, 2012 Page 2

Similarly, the Department approved the sale of 100% of the issued and outstanding stock of a company that owned a linear accelerator to another entity. Linear accelerators are regulated in the same manner as heart-lung bypass equipment. The Department held that certificate of need review was not required for the stock purchase transaction. See Declaratory Ruling, In re: Request for Declaratory Ruling by Radiation Therapy Services, Inc. and North Carolina Radiation Therapy Management Services, Inc., September 14, 2007.

We would appreciate written confirmation from you that the anticipated transaction does not require CON review. If you require additional information to consider this request, please contact us. We appreciate your consideration.

Sincerely yours,

SMITH MOORE LEATHERWOOD LLP

Maureen Demarest Murray

cc: Stan Taylor, WakeMed



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

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,

MihAm Ed

Michael J. McKilly

Project Analyst

Craig R. Smith, Chief Certificate of Need Section



K&L GATES



K&L Gates LLP
Post Office Box 14210
Research Triangle Park, NC 27709-4210
430 Davis Drive, Suite 400

Morrisville, NC 27560 T 919.466.1190

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Gary S. Qualls
D 919.466.1182
F 919.516.2072
gary.qualls@klgates.com

February 9, 2012

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

Re: Rex Acquisition of Ownership Interests in CSAMS Lake Boone Trail, LLC

Dear Mr. Smith and Ms. Frisone:

We represent 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 Rex's acquisition of the ownership interests of CSAMS Lake Boone Trail, LLC ("CSA Lake Boone") is not reviewable as a new institutional health service under the North Carolina Certificate of Need ("CON") law. CSA Lake Boone is a wholly owned sub of CSA Medical, LLC ("CSA") and owns three (3) heart-lung bypass ("HLB") machines that have been and are operated at Rex. Rex would acquire the membership interests in CSA Lake Boone, which would continue to exist as a legal entity and to own the three (3) HLB machines that would remain located and operated at Rex.

The Agency has issued numerous declaratory rulings and no review letters that acknowledge that acquisition of ownership interest in a legal entity does not constitute a reviewable acquisition of the medical equipment owned by that legal entity. For example, in a declaratory ruling issued to New Hanover Perfusionists, Inc., the Agency determined that the purchase of stock did not constitute the acquisition of a heart-lung bypass machine because ownership of the regulated heart-lung bypass equipment would not change. The Agency also determined that the transaction was not an obligation to develop or expand a health service or health service facility because the equipment company was not a health service facility. The stock purchase transaction proposed also was 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). The

K&L GATES

Mr. Craig R. Smith, Chief Martha Frisone, Assistant Chief February 9, 2012 Page 2

definition of "health service" specifically "does not include administrative and other activities that are not integral to clinical management." Stock or membership interest ownership is not integral to clinical management. In re: Request for Declaratory Ruling by New Hanover Perfusionists, Inc., January 24, 2008.

Similarly, the Department has recently approved the sale of 100% of the membership interests in a company that owned a linear accelerator to another entity. Linear accelerators are regulated in the same manner as heart-lung bypass equipment. The Department held that certificate of need review was not required for the LLC membership purchase transaction. See Declaratory Ruling, In re: Request for Declaratory Ruling by The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Healthcare, November 4, 2011 (attached as Exhibit 1).

We would appreciate written confirmation from you that the anticipated transaction does not require CON review. If you require additional information to consider this request, please contact us. We appreciate your consideration.

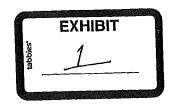
Sincerely yours,

K&L GATES LLP

Fany S. Qualle

Gary S. Qualls





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

November 4, 2011

CERTIFIED MAIL & FACSIMILE

William W. Stewart, Esq. K&L Gates LLP 430 Davis Drive, Suite 400 Morrisville, NC 27560

RE: Declaratory Ruling for The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Healthcare System

Dear Mr. Stewart:

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)	
THE CHARLOTTE-MECKLENBURG)	DECLARATORY RULING
HOSPITAL AUTHORITY D/B/A)	
CAROLINAS HEALTHCARE SYSTEM)	

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.

The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Healthcare System ("CMHA") has requested a declaratory ruling to confirm that its acquisition of the membership interests of University Radiation Oncology Center, LLC ("UROC") and its continued operation of that facility may proceed without first obtaining a Certificate of Need ("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. William W. Stewart of K&L Gates LLP has requested this ruling on CMHA's behalf and has provided the material facts upon which this ruling is based.

STATEMENT OF THE FACTS

UROC, which is located at 8310 University Executive Park, Suite 500, Charlotte, NC 28262, is a limited liability company which provides radiation therapy treatment. UROC was

acquired by Radiation Oncology Centers of the Carolinas, Inc. ("ROCC") pursuant to an exemption in August 1997. Currently, UROC operates a Varian 2100C linear accelerator and a GE Highspeed Advantage CT simulator, which the CON Section previously approved.

On August 18, 2011, the Department issued a Declaratory Ruling determining that ROCC could transfer, without a CON, its interest in UROC and Matthews Radiation Oncology Center ("MROC") to two wholly owned subsidiaries of ROCC. Once that transaction is consummated, ROCC will be the sole member of UROC. ROCC will then transfer its entire membership interest in UROC to CMHA and CMHA will become UROC's sole member. Thus, UROC will remain intact as the same LLC, but with a different membership composition.

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 UROC which owns and operates a linear accelerator or simulator. The declaratory ruling requested by CMHA 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:

CMHA's acquisition of the membership interests in UROC does not constitute the

acquisition of a linear accelerator or a simulator because the ownership of the equipment will not

change, and the same equipment will be used to provide the same radiation oncology services, in

the same location. UROC will continue to own the two pieces of equipment and UROC's legal

status as a corporate entity will not change.

The purchase of ROCC's membership interests in UROC 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 CMHA does not require a certificate of need in order to proceed with the purchase

of ROCC's membership interests in UROC.

This the 44 day of November, 2011.

Drexdal Pratt, Director

Division of Health Service Regulation

N.C. Department of Health and Human Services

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, 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.

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)(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 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

Exhibit B

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 _____ day of August, 2011.

Drexdal Pratt, Director

Division of Health Service Regulation

N.C. Department of Health and Human Services

3

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 first-class, postage pre-paid envelope addressed as follows:

CERTIFIED MAIL

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

This the day of A	August, 2011.
	Jeff Horton Chief Operating Officer



KODY H. KINSLEY • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

October 15, 2024

Denise M. Gunter

denise.gunter@nelsonmullins.com

No Review

Record #: 4609

Date of Request: September 24, 2024 Business Name: Novant Health, Inc.

Business #: 1341

Project Description: Acquisition by Novant Health, Inc. of membership interests in South Atlantic

Radiation Oncology, LLC (SARO) from Coastal Carolina Radiation Oncology, PA

(CCRO)

County: New Hanover

Dear Ms. Gunter:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the project described above. Based on the representation in your request and the CON law **in effect on the date of this response to your request**, the project as described is not governed by, and therefore, does not currently require a certificate of need. 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.

This determination is binding only for the facts represented in your correspondence. If changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office. As a reminder, it is unlawful to offer or develop a new institutional health service without first obtaining a certificate of need. The Department reserves the right to impose sanctions, including civil penalties and the revocation of a license, upon any entity that offers or develops a new institutional health service without first obtaining a certificate of need.

Please do not hesitate to contact this office if you have any questions.

Sincerely,

Ena Lightbourne Project Analyst

Micheala Mitchell

Micheala Mitchell Chief

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION



Denise M. Gunter Attorney T: (336) 774-3322 denise.gunter@nelsonmullins.com **NELSON MULLINS RILEY & SCARBOROUGH LLP** ATTORNEYS AND COUNSELORS AT LAW

380 Knollwood Street Suite 530 Winston-Salem, NC 27103 T: (336) 774-3300 F: (336) 774-3299

nelsonmullins.com

September 24, 2024

Via E-mail

Micheala Mitchell. Chief Healthcare Planning and Certificate of Need Section North Carolina Department of Health and Human Services Division of Health Service Regulation 809 Ruggles Drive Raleigh, North Carolina 27699

RE: No Review Novant Health New Hanover Regional Medical Center, LLC Linear Accelerator Service Area 19 (New Hanover, Brunswick, Pender, and Columbus Counties)

Dear Ms. Mitchell:

On behalf of Novant Health, Inc. and Novant Health New Hanover Regional Medical Center, LLC ("NHNHRMC" and collectively, "Novant"), I am writing to request that the Agency issue a written determination that the CON Law, N.C. Gen. Stat. § 131E-175 et seq., does not apply to the following transaction (the "Transaction").

Facts:

As shown in the table below, there are four linear accelerators currently operating in Service Area 19. A fifth linear accelerator is scheduled to open in 2025.

Linear Accelerator	Location	Owner	Status
1	Novant Health Cancer Institute - New Hanover Radiation Oncology 1988-A S. 16 th Street, Wilmington, NC 28401	Coastal Carolina Radiation Oncology, PA ("CCRO")	In operation

Micheala Mitchell September 24, 2024 Page 2

Linear Accelerator	Location	Owner	Status
2	Novant Health Cancer Institute - New Hanover Radiation Oncology 1988-A S. 16 th Street, Wilmington, NC 28401	CCRO	In operation
3	Novant Health Cancer Institute - New Hanover Radiation Oncology 1988-A S. 16 th Street, Wilmington, NC 28401	NHNHRMC	In operation
4	Novant Health Cancer Institute Radiation Oncology – Supply 545 Ocean Hwy W, Supply, NC 28462	South Atlantic Radiation Oncology, LLC ("SARO")	In operation
5	NHNHRMC Scotts Hill, 151 Scotts Hill Medical Dr, Wilmington, NC 28411	SARO (Novant Health and NHNHRMC are the two other parties listed on the CON)	In development; CON issued in Project I.D. No. O-12110-21

CCRO is a radiation oncology practice that provides professional and clinical services. Certain physician shareholders of CCRO and NHNHRMC jointly formed SARO; currently, NHNHRMC owns 50% of SARO, and the four current physician shareholders of CCRO (the "CCRO Shareholders") collectively own the remaining 50% of SARO. For many years, CCRO and NHNHRMC have worked collaboratively under a Resource Services Agreement to provide outstanding radiation oncology care to patients in Service Area 19 and adjacent areas. To further enhance quality and access to radiation oncology services in Service Area 19 and adjacent areas, Novant and CCRO have been discussing the Transaction, as described below.

The Transaction:

CCRO plans to form a new, wholly owned subsidiary ("HoldCo, LLC") and will drop the two linear accelerators (and the related equipment necessary for the operation thereof) CCRO owns into HoldCo, LLC. SARO will then acquire the membership interests in HoldCo, and Novant will then acquire the remaining 50% interest in SARO from the

Micheala Mitchell September 24, 2024 Page 3

CCRO Shareholders. At the conclusion of the Transaction, Novant will own 100% of the membership interests in SARO. To effectuate the Transaction, CCRO and Novant will enter into various agreements, including real estate leases, a Professional Services Agreement pursuant to which CCRO will be the exclusive provider of professional radiation oncology services in the area, and a Radiation Oncology Co-Management Agreement for CCRO to provide non-billable management services and advisory services for the radiation oncology service line of NHNHRMC.

The Transaction does not contemplate acquiring any equipment that is regulated by the CON Law, incurring any capital costs that are regulated by the CON Law or otherwise developing any "new institutional health services" that are regulated by the CON Law. The number of existing and approved linear accelerators and their locations in Service Area 19 will not change as a result of the Transaction. The linear accelerators will continue to be operated just as they have always been operated.

Analysis:

The Transaction involves the acquisition of membership interests, not the acquisition of linear accelerators. The Agency has repeatedly recognized that the acquisition of membership interests is not regulated by the CON Law. For example, in 2015, the Agency concluded that Vidant's acquisition of 100% of the membership interests in Newco Cancer Services, LLC ("Newco"), a 50/50 JV between Vidant and ECU Brody School of Medicine that owned and operated two linear accelerators and CT simulators did not require a CON. See **Exhibit A**. The same is true here as Novant, the 50% owner of SARO, will become the 100% owner of SARO. **Exhibit A** also describes that after Vidant became the sole owner of Newco, Vidant and North Carolina Radiation Therapy, another company that owned linear accelerators in Pitt County, planned to contribute their respective linear accelerators to a new joint venture limited liability company, Vidant Radiation Oncology ("VRO"). Again, the Agency determined that no CON was required as the only thing being acquired was membership interests in an LLC.

Exhibit A also cites and attaches numerous declaratory rulings establishing that the acquisition of membership interests in an LLC is not regulated by the CON Law. See **Exhibit A**, pp. 3-4 and attachments therein. The same reasoning applies here. There is nothing in the CON Law that regulates the acquisition of membership interests in limited liability companies. See N.C. Gen. Stat. § 131E-176(16)a.-v.(definition of new institutional health services); *In re Miller*, 357 N.C. 316, 325, 584 S.E.2d 772, 780 (2003)(according to the doctrine of *expressio unius est exclusio alterius*, the expression of one thing means the exclusion of others; thus, "when a statute lists the situations to which it applies, it implies the exclusion of situations not contained on the list.").

Exhibit B is a declaratory ruling issued in 2011 to Radiation Oncology Centers of the Carolinas, Inc. ("ROCC"), in which ROCC proposed to transfer its interest in two oncology treatment centers which operated linear accelerators and CT simulators to two wholly owned subsidiaries of ROCC. This is analogous to CCRO moving its linear

Micheala Mitchell September 24, 2024 Page 4

accelerators into HoldCo, LLC, a wholly owned subsidiary of CCRO. Similar to **Exhibit A** and the declaratory rulings cited therein, the Agency determined no CON was required.

We further note with respect to the approved but not yet operational linear accelerator at Scotts Hill, Novant Health, Inc., SARO, and NHNHRMC were all applicants for that CON and the parties to which the CON was issued. See Findings for Project I.D. No. O-12110-21; see also N.C. Gen. Stat. § 131E-181(a)(a CON is valid only for the defined scope, physical location, and person named in the application). None of the persons named in the application for Project I.D. No. O-12110-21 will change as a result of the Transaction. As described above, SARO remains intact as an LLC with a different membership composition. Accordingly, we do not believe it is necessary to request a good cause transfer of that CON pursuant to N.C. Gen. Stat. § 131E-189(c). If, however, the Agency believes otherwise, we respectfully request that the Agency find good cause on the grounds that the Transaction merely contemplates the reconfiguration of membership interests in a limited liability company.

For the foregoing reasons, we respectfully request the Agency's written determination that the Transaction described in this letter does not require a CON. If you have any questions or need further information, please let me know. Thank you for your time and consideration.

Sincerely,

Denise M. Gunter

Enclosures



DEPARTMENT OF HEALTH AND HUMAN SERVICES DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE DIRECTOR

November 15, 2017

Gary S. Qualls K & L Gates 430 Davis Drive, Suite 400 Morrisville NC 27560

Exempt from Review – Acquisition of Facility

Record #: 2439

Facility Name: FirstHealth of the Carolinas, Inc.

Type of Facility: Diagnostic center (Grandfathered mobile cardiac catheterization unit)

Acquisition by: UNC Rex Hospital

FID#: 953429 Business #: 1554 County: Wake

Dear Mr. Qualls:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) determined that based on your letter of November 9, 2017, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(a)(8). Therefore, UNC Rex Hospital 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 N.C. Gen. Stat. §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.

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

WWW.NCDHHS.GOV TELEPHONE 919-855-3873 Sincerely,

Michael J. McKillip Project Analyst

Martha J. Frisone

Chief, Healthcare Planning and Certificate of Need Section

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

Sharetta Blackwell, Program Assistant Healthcare Planning, DHSR







November 9, 2017

Gary S. Qualls
D 919.466.1182
F 919.516.2182
gary.qualls@klgates.com

Via Hand Delivery

Martha Frisone Chief, Certificate of Need Department of Health and Human Services Division of Health Service Regulation Health Planning and Certificate of Need Section 809 Ruggles Drive Raleigh, North Carolina 27603

RE: Rex Hospital, Inc. – Exemption Notice for Acquisition of Replacement Cardiac Catheterization Equipment at Rex Hospital's Main Campus, Wake County

Dear Ms. Frisone:

Our client, Rex Hospital, Inc. d/b/a UNC REX ("Rex"), seeks to acquire a Mobile Cardiac Catheterization Unit from FirstHealth of the Carolinas, Inc. ("FirstHealth"). This Mobile Cardiac Catheterization Unit is grandfathered under the Certificate of Need ("CON") law because it was in use in the State prior to March 18, 1993 and has been in use continuously. See Exhibits 1 and 2, Exempt from Review Letters dated October 29, 1998 and November 9, 1998. Thus, this "Grandfathered Cath Unit" is also considered a grandfathered mobile Diagnostic Center under N.C. Gen. Stat. § 131E-176(7a) because it is a grandfathered mobile diagnostic program. Currently this Grandfathered Cath Unit is serving Rex two days a week through a contract between FirstHealth and Rex.

Rex intends to:

- (1) acquire the Grandfathered Cath Unit from FirstHealth as an exempt acquisition of an existing grandfathered mobile Diagnostic Center pursuant to N.C. Gen. Stat. §§ 131E-184(a)(8) and 131E-176(7a);
- then replace the Grandfathered Cath Unit (also referred to herein as the "Existing Equipment") with a different cardiac cath unit (the "Replacement Equipment") and will house the Replacement Equipment in Rex Hospital rather than in the mobile coach that currently houses the Grandfathered Cath Unit.

I. Step #1: Acquire the Grandfathered Cath Unit as an Exempt Diagnostic Center

As a first step, Rex will acquire the Grandfathered Cath Unit from FirstHealth as an exempt acquisition of an existing grandfathered mobile Diagnostic Center pursuant to N.C. Gen. Stat. §§ 131E-184(a)(8) and 131E-176(7a). Exhibits 1 and 2 are attached as proof of grandfathered status. As referenced above, FirstHealth's Grandfathered Cath Unit is a grandfathered mobile Diagnostic Center under N.C. Gen. Stat. § 131E-176(7a). The Section 176(7a) definition of Diagnostic Center specifically includes mobile diagnostic programs.

II. Step #2: Replacement Equipment Exemption

After the acquisition in Step #1 above, Rex intends to then replace the Grandfathered Cath Unit (also called the "Existing Equipment") with a different cardiac cath unit (the "Replacement Equipment") and will house the Replacement Equipment in Rex Hospital's Heart Tower on its Main Campus¹ rather than in the mobile coach which currently houses the Grandfathered Cath Unit.

Instead of acquiring a new piece of cardiac cath equipment, Rex will instead denominate a unit of existing vascular equipment at Rex as the "Replacement Equipment" and will convert that Replacement Equipment to cardiac cath use by adding software to enable that use. The Replacement Equipment is identified by serial number in Exhibit 3, which is the CON Replacement Equipment Comparison Form ("Comparison Form"). The Replacement Equipment will be located in the same location where it is currently used as a vascular unit.

This letter is to provide the Agency with notice and to request confirmation that:

- Rex may acquire the Grandfathered Cath Unit from FirstHealth as an exempt acquisition of an existing grandfathered mobile Diagnostic Center pursuant to N.C. Gen. Stat. §§ 131E-184(a)(8) and 131E-176(7a);
- 2) Rex's Replacement Equipment described herein is exempt from CON review pursuant to N.C. Gen. Stat. § 131E-184(a)(7); and
- Rex will have the right to reconvert the grandfathered Replacement Equipment to mobile use again without a CON so long as no relevant cost thresholds or other CON new institutional health service definitions are triggered in the process.

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¹ Even though this equipment replacement will be on Rex's Main Campus, Rex does not need to invoke the main campus replacement equipment provisions contained in N.C. Gen. Stat. § 131E-184(f) because the costs for the Replacement Equipment here do not exceed \$2 Million.

The General Assembly has chosen to exempt certain, otherwise reviewable events from CON review. Among those exemptions is the acquisition of "replacement equipment," defined as follows in the CON law:

"Replacement equipment" means equipment that costs less than two million dollars (\$2,000,000) and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced.

See N.C. Gen. Stat. § 131E-176(22a).

In addition to the foregoing, to qualify for this exemption, the replacement equipment must be "comparable" to the equipment it replaces and must be "sold or otherwise disposed of when replaced." Rex's proposal qualifies for this exemption.

A. Cost of the Replacement Equipment

The total cost to acquire, install, and make operational the Replacement Equipment is \$13,000. See Exhibit 4 (this shows the costs to upgrade the Existing Equipment -- vascular equipment -- to cardiac cath use). No additional capital costs will be expended regarding the Replacement Equipment because Rex already owns it, having purchased the Replacement Equipment in 2015, where it has since been used as non-cardiac cath vascular equipment.

B. Comparable Equipment

The CON rule codified as 10A N.C.A.C. 14C.0303 (the "Regulation") defines "comparable medical equipment" in subsection (c) as follows:

"Comparable medical equipment" means equipment which is functionally similar and which is used for the same diagnostic or treatment purposes.

10A N.C.A.C. 14C.0303(c).

Rex intends to use the Replacement Equipment for substantially the same types of services for which the Existing Equipment it currently used. The Existing Equipment (i.e., the Grandfathered Cath Unit) performs a wide range of cardiac cath procedures, as will the Replacement Equipment.

The Replacement Equipment will perform all procedures currently performed on the Existing Equipment. Although it possesses some expanded capabilities due to technological improvements, the Replacement Equipment will perform the same general range of

procedures as the Existing Equipment. <u>See</u> Exhibit 3, Comparison Form. The Replacement Equipment is therefore "comparable medical equipment" as defined in Subsection (c).

Furthermore, Rex does not intend to increase patient charges or per procedure operating expenses more than 10% within the first 12 months after its acquisition. For further equipment comparison, please refer to Exhibit 3, the Comparison Form.

Subsection (d) of the Regulation further provides that the Replacement Equipment must meet the following tests:

- it has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements; and
- (2) it is functionally similar and is used for the same diagnostic or treatment purposes as the equipment currently in use and is not used to provide a new health service; and
- (3) the acquisition of the equipment does not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.

10A N.C.A.C. 14C.0303(d).

The Replacement Equipment will meet all three of the tests set out in Subsection (d). The Replacement Equipment satisfies the technology and functionality tests in Subsection (1) and (2) as discussed above and identified in the Comparison Form See Exhibit 3. Moreover, Rex represents that use of the Replacement Equipment will not result in the types of expense or charge increase described in Subsection (d)(3).

D. Disposition of Existing Equipment

As part of the proposal, Rex will decommission the Existing Equipment acquired from FirstHealth and put it in storage. Rex will not operate the Existing Equipment without further authorization from the Agency.

CONCLUSION

Based on the foregoing information, Rex provides exemption notices under N.C. Gen. Stat. §§ 131E-184(a)(7) and (a)(8), and hereby requests that the Agency provide a written response confirm the following:

- Rex may acquire the Grandfathered Cath Unit from FirstHealth as an exempt acquisition of an existing grandfathered mobile Diagnostic Center pursuant to N.C. Gen. Stat. §§ 131E-184(a)(8) and 131E-176(7a);
- 2) Rex's Replacement Equipment described herein is exempt from CON review pursuant to N.C. Gen. Stat. § 131E-184(a)(7); and
- Rex will have the right to reconvert the grandfathered Replacement Equipment to mobile use again without a CON so long as no relevant cost thresholds or other CON new institutional health service definitions are triggered in the process.

If the Agency needs additional information to assist in its consideration of this request, please apprise us as soon as possible. We thank you for your consideration of this notice.

Sincerely,

Lay S. Qualla Gary S. Qualls

Exhibits

- 1. Notice of Exempt Acquisition by FirstHealth of the Carolinas, Inc. dated October 29, 1998
- 2. Exempt from Review Letter dated November 9, 1998
- 3. CON Equipment Comparison Form
- 4. Documentation of Purchase Price of Replacement Equipment (software upgrades to existing equipment)



KILPATRICK STOCKTON LLP

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4101 Lake Boone Trail
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NOAH H. HUFFSTETLER, III E-mail: nhuffstetler@kilstock.com Direct Dial: 919.420.1812

October 29, 1998

HAND DELIVERED

Ms. Lee B. Hoffman, Chief North Carolina Department of Health and Human Services Division of Facilities Management Certificate of Need Section 701 Barbour Drive - Council Bldg. Raleigh, NC 27602-0629

Re: Notice of Exempt Acquisition by FirstHealth of the Carolinas, Inc.

Dear Ms. Hoffman:

As we have discussed by telephone, Riverside Health System of Newport News, Virginia, currently owns and operates a mobile cardiac catheterization laboratory which was located and in use in North Carolina prior to March 18, 1993, and has been continuously located and utilized in North Carolina to the present date. At the present time this laboratory is used by Riverside to provide services at Roanoke-Chowan Hospital, in Ahoskie, North Carolina. Riverside plans to create a new wholly-owned corporate subsidiary to be known as Riverside North Carolina Catheterization Services, Inc. ("the Provider"). The above-referenced cardiac catheterization laboratory, which is the only equipment of this kind that Riverside currently operates in North Carolina, will be owned by the Provider and any contracts for its use by North Carolina hospitals will be assigned to the Provider. Our client, FirstHealth of the Carolinas, Inc., ("FirstHealth") will purchase the Provider from Riverside and will locate its mobile cardiac catheterization laboratory on the campus of FirstHealth Moore Regional Hospital in Pinehurst, North Carolina. The Provider will thereafter be a wholly owned corporate subsidiary of FirstHealth. At some time in the future, FirstHealth may elect to merge the Provider into FirstHealth or one of its other corporate subsidiaries.

The purposes of this letter are as follows:

 to notify the Department of Human Resources ("Department") of the transaction described above, as provided in N.C.G.S. § 131E-184(a);

KILPATRICK STOCKTON LLP

Ms. Lee B. Hoffman, Chief October 29, 1998 Page 2

- (2) to explain briefly the reasons for the transaction; and
- (3) to request that the Department confirm that the transaction is exempt from certificate of need review under N.C.G.S. § 131E-184(a)(8).

FirstHealth desires to acquire the Provider from Riverside in order to increase patient access to cardiac catheterization services in its service area. Utilization of cardiac catheterization equipment as a diagnostic and interventional tool continues to increase. As the only tertiary facility in a six county service area, the demand for cardiac catheterization services at FirstHealth Moore Regional Hospital has continued to see significant increases approximately 17% per year over the past four years.

FirstHealth believes that this transaction should not require it to first obtain a certificate of need, as provided in N.C.G.S. § 131E-178. As you know, N.C.G.S. § 131E-184(a)(8) provides an exemption from certificate of need review for a proposal to "acquire an existing health service facility, including equipment owned by the health service facility at the time of acquisition." Under N.C.G.S. § 131E-176(9b), the term "health service facility" is defined to include a "diagnostic center." In turn, the term "diagnostic center" is defined by N.C.G.S. § 131E-176(7a) to mean "a freestanding facility, program, or provider, including, but not limited to . . . mobile diagnostic programs, in which the total cost of all the medical diagnostic equipment utilized by the facility which cost ten thousand dollars (\$10,000) or more exceeds five hundred thousand dollars (\$500,000)." Because this transaction involves the acquisition of a mobile diagnostic program in which the total cost of the medical diagnostic equipment utilized by the facility which costs ten thousand dollars (\$10,000) or more is \$1,124,554, this transaction qualifies for the above-referenced exemption.

This notice is timely, because FirstHealth has not yet incurred "an obligation for a capital expenditure which is a new institutional health service," as that term is defined in N.C.G.S. § 131E-178(c), with respect to the proposed acquisition. However, FirstHealth and Riverside hope to conclude the transaction described in this notice on or before December 1, 1998. Therefore, pursuant to this prior written notice, FirstHealth requests the Department to confirm as soon as possible that the proposed acquisition is exempt from certificate of need review under N.C.G.S. § 131E-184(a). Also, please let us know as soon as possible if you need additional information to assist in your consideration of this request.

KILPATRICK STOCKTON LLP

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Ms. Lee B. Hoffman, Chief October 29, 1998 Page 3

Thank you for your prompt consideration of this matter. To confirm the timely submission of this notice, we would appreciate your returning to us the enclosed copy of this letter, stamped with the date of its filing. With best regards, we are

Very truly yours,

KILPATRICK STOCKTON LLP

Noah H. Huffstetler, III

cc: Ms. Lynn DeJaco

Ms. Caroline Martin

Mr. Peter S. Brunstetter

RALLIB01;484444.02





North Carolina Department of Health and Human Services Division of Facility Services

701 Barbour Drive - Post Office Box 29530 Raleigh, N.C. 27626-0530 Courier Number 56-20-05

James B. Hunt, Jr., Governor H. David Bruton, M.D., Secretary

Lynda D. McDaniel, Director

Certificate of Need Section Phone: (919) 733-6360 Fax: (919) 733-8139

November 9, 1998

Noah H. Huffsteler, III Kilpatrick Stockton LLP Attorneys at Law 4101 Lake Boone Trail, Suite 400 Raleigh, NC 27607-6519

RE: Exempt from Review/ Acquisition by Riverside North Carolina Catheterization Services, Inc. ("Riverside NC"), of Riverside Health System's mobile diagnostic cardiac catheterization program/ Hertford County

RE: Exempt from Review/ Acquisition by FirstHealth of the Carolinas, Inc. ("FirstHealth"), of Riverside North Carolina Catheterization Services, Inc. ("Riverside NC"), including all equipment owned by Riverside NC/ Moore County

Dear Mr. Huffstetler:

In response to your letter of October 29, 1998, the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(8). Therefore, FirstHealth may proceed to acquire Riverside Health System's entire cardiac catheterization program in North Carolina, including all cardiac catheterization equipment owned by Riverside Health System that is operated in North Carolina, without first obtaining a certificate of need. This determination is based on the following findings and conclusions:

- 1. Riverside Health System is located in Virginia and has a mobile diagnostic cardiac catheterization program in North Carolina. The mobile cardiac catheterization equipment currently operated by Riverside Health System is not a "mobile diagnostic program" or a "diagnostic center". Rather, Riverside Health System's entire mobile cardiac catheterization program in North Carolina is the "diagnostic center" as defined in N.C.G.S. 131E-176(7a), which would also be the case if Riverside Health System had more than one piece of mobile cardiac catheterization equipment in North Carolina.
- 2. Riverside Health System proposes to create a wholly-owned subsidiary to be known as Riverside North Carolina Catheterization Services, Inc. This company will own all cardiac catheterization equipment operated by Riverside Health System in North Carolina. Further, all contracts for

Noah Huffstetler Page 2 November 9, 1998

> provision of cardiac catheterization services between Riverside Health System and North Carolina Hospitals will be assigned to Riverside NC. Therefore, Riverside Health System will no longer be a diagnostic center in North Carolina. Rather, Riverside North Carolina Catheterization Services, Inc. will acquire Riverside Health System's entire mobile cardiac catheterization program in North Carolina and consequently, will become the diagnostic center.

- 3. There will be no net increase in the number of diagnostic centers in North Carolina because Riverside Health System's diagnostic center in North Carolina, is being acquired by Riverside North Carolina Catheterization Services, Inc., which will become the new diagnostic center.
- 4. After Riverside NC becomes a diagnostic center, FirstHealth will acquire Riverside NC, including all equipment owned by Riverside NC. Riverside NC will become a wholly owned corporate subsidiary of FirstHealth.

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,

Lee B. Hoffman, Chief

Certificate of Need Section

cc: Section Chief, Licensure and Certification Section, DFS

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Type of Equipment (List Each Component) Manufacturer of Equipment Tesla Rating for MRIs Model Number Serial Number Specify if Mobile or Fixed Mobile Traiter Serial Number/VIN # Mobile Tractor Serial Number/VIN #	Floor Mounted Single Floor Mounted Single Plane X-ray Siemens n/a Axiom Artis 7412807 35610 Room Number Location Mobile 1TKH05126XB027601	EQUIPMENT Ceiling Mounted Single Plane X-ray Philips n/a Allura Xper FD20 71267710 Room Number Location Fixed n/a
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	Not Yet Acquired	Not Yet Acquired
Jease?	Yes	Yes
Specify if Equipment Was/Is New or Used When Acquired	Used	New
Total Capital Cost of Project (Including Construction, etc.) <use attached="" form=""></use>	n/a	n/a
·	<\$50,000	\$13,000.00
Fair Market Value of Equipment	n/a	
Net Purchase Price of Equipment	n/a	
Locations Where Operated UNC RE	UNC REX Healthcare	UNC REX Healthcare
Number Days In Use/To be Used in N.C. Per Year	365	365
Percent of Change in Patient Charges (by Procedure)	n/a	n/a
Percent of Change in Per Procedure Operating Expenses (by Procedure)	n/a	n/a
Type of Procedures Currently Performed on Existing Equipment	Cardiac Catheterization	n/a
	and Vascular Imaging	
Type of Procedures New Equipment is Capable of Performing	n/a	Cardiac Catheterization
		and Vascular Imaging



Page: 1 of 1

EXHIBIT
Exhibit D

PO DATE: 10/17/2017

Acknowledge by email to <u>purchase@unchealth.unc.edu</u> (preferred) or fax 919-957-5786 with availability, Ship date, and Reference Nbr upon receipt of this PO.

If shipping charges contractually apply, ship Bill 3rd Party via FedEx account # 321417647, FOB Destination. If weight exceeds 150lbs, call 888-457-5851 for instructions.

PHILIPS MEDICAL SYSTEMS
CONTRACTS ADMINISTRATION
22100 BOTHELL-EVERETTE HWY
BOTHELL WA 98041-3003
ACCOUNT:

Contact Susan Phillippi (Agent)
Phone 984-974-6590

PRODUCT TOTAL: \$13,000.00

PURCHASE ORDER NUMBER

95100004687-0-9

SHOW PO NUMBER ON ALL SHIPPING LABELS, INVOICES, PACKING LIST, BILLS OF LADING. COPIES OF PACKING LIST MUST ACCOMPANY ALL SHIPMENTS. FAILURE TO COMPLY WILL RESULT IN REJECTION OF SHIPMENTS AND NONPAYMENT OF INVOICES.

REX Healthcare

MAIL Accounts Payable Department

INVOICE 4400 Emperor Boulevard

TO: Suite 100 Durham, NC 27703

SHIP TO: REX HEALTHCARE

4420 LAKE BOONE TRAIL

REX HEART & VASCULAR TOWER ATTN JASON DUBRAY 919.357.7154

PO 95100004687-0-9 RALEIGH NC 27607

TOTAL

\$13,000.00

	SHIP 7	TERMS: F	ree On	Board Destination SHIP VIA: INSTALLED		
Purchase Order Currency: US Dollars Invoice by mail QUOTE 1-1085JCP DATED 9.23.2017 ATTN: BETHANN GRIFFITH-SUBIK 18-241500.01 101000-200700-510018241500.01-15002 1 1.0000 LO NCVA VENTRICULAR QUANT SW PKG Deliver on November 3, 2017	TERM	S: NET 3	0	FREIGHT TERMS: Vendor Expense	PRICE	TOTAL
Invoice by mail QUOTE 1-1085JCP DATED 9.23.2017 ATTN: BETHANN GRIFFITH-SUBIK 18-241500.01 101000-200700-510018241500.01-15002 1 1.0000 LO NCVA VENTRICULAR QUANT SW PKG Deliver on November 3, 2017	LINE	QTY	UOM	DESCRIPTION		
				Purchase Order Currency: US Dollars Invoice by mail QUOTE 1-1085JCP DATED 9.23.2017 ATTN: BETHANN GRIFFITH-SUBIK 18-241500.01 101000-200700-510018241500.01-15002 NCVA VENTRICULAR QUANT SW PKG Deliver on November 3, 2017	13,000.0000	13,000.00



ROY COOPER • Governor

KODY H. KINSLEY • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

March 14, 2023

Denise M. Gunter denise.gunter@nelsonmullins.com

Exempt from Review - Acquisition of Facility

Record #: 4154

Date of Request: March 6, 2023

Facility Name: Kings Medical Group

Type of Facility: Diagnostic Center (grandfathered mobile MRI unit, serial #31472)

Acquisition by: Novant Health-Norfolk, LLC

Business #: 3863

County: Mecklenburg

Dear Ms. Gunter:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) determined that the project described above is exempt from certificate of need (CON) review in accordance with G.S. 131E-184(a)(8). Therefore, the above referenced business may proceed to acquire the health service facility identified above without first obtaining a CON. The Agency's determination is limited to the question of whether the above referenced business would have to obtain a CON if the current owners of the health service facility do in fact sell it to the business listed above. 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 regarding whether a certificate of need would be required. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Julie M. Faenza Project Analyst

Micheala Mitchell

Micheala Mitchell

Chief

cc: Acting Assistant Chief, Healthcare Planning

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION
HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION



Denise M. Gunter T: 336.774.3322 F: 336.774.3372 denise.gunter@nelsonmullins.com

NELSON MULLINS RILEY & SCARBOROUGH LLP ATTORNEYS AND COUNSELORS AT LAW

The Knollwood, 380 Knollwood Street Suite 530 Winston-Salem, North Carolina 27103 T: 336.774.3300 F: 336.774.3299 nelsonmullins.com

March 6, 2023

VIA EMAIL ONLY

Micheala Mitchell, Chief
North Carolina Department of Health and Human Services
Division of Health Service Regulation
Healthcare Planning and Certificate of Need Section
809 Ruggles Drive
Raleigh, North Carolina 27603

RE: Acquisition of Existing Grandfathered Diagnostic Centers

Dear Ms. Mitchell:

On behalf of Novant Health-Norfolk, LLC¹ ("Novant"), I am writing to request the Agency's written confirmation that the acquisition of the existing grandfathered diagnostic centers described in this letter is exempt from Certificate of Need review pursuant to N.C. Gen. Stat. § 131-184(a)(8).

I. Details Related to the Diagnostic Centers

Novant intends to acquire two grandfathered diagnostic centers owned by Kings Medical Company ("Kings"). These diagnostic centers are known as Kings I and Kings II. Each of the diagnostic centers is a "mobile diagnostic program" that consists of a grandfathered mobile MRI scanner and related equipment, such as trailer, to pull the scanner. Kings acquired the original mobile MRI scanners and placed them in operation in North Carolina prior to March 18, 1993, when North Carolina's CON Law began specifically regulating MRI scanners and diagnostic centers. See N.C. Gen. Stat. § 131E-176(7a), (16)f1.7. Subsequently, Kings replaced those scanners by acquiring new MRI scanners that qualified as "replacement equipment" exempt from CON review and as grandfathered MRI scanners. For this reason, Kings mobile MRI scanners are currently identified as "legacy" (or grandfathered) scanners in Column C, Table 17E-1 of the 2023 State Medical Facilities Plan (see, e.g., page 346). The Agency's letters approving the acquisition of the existing MRI scanners as replacement equipment for grandfathered MRI

¹ Novant Health, Inc. owns a controlling interest in Novant Health-Norfolk, LLC.

Micheala Mitchell, Chief March 6, 2023 Page 2

scanners are attached as Exhibit A and Exhibit B. Kings I and Kings II have been in continuous use in North Carolina as grandfathered diagnostic centers with grandfathered MRI scanners since the original acquisitions and have been made available to various host sites in North Carolina via services agreements.

As you may recall from prior correspondence, the MRI scanner used for Kings I was damaged beyond repair in a fire in late 2021, and the Agency authorized Kings to place into operation temporary replacement MRI scanners, pending approval and acquisition of a permanent replacement MRI scanner. The correspondence concerning the temporary scanners is attached as Exhibit C. In addition, as shown on page 1 of **Exhibit C**, on February 13, 2023, the Agency authorized Kings to acquire a permanent replacement MRI scanner for the scanner damaged by fire. Kings expects the permanent replacement scanner will be delivered and placed into operation soon.²

II. Overview of CON Law Applicable to the Acquisition

The CON Law expressly exempts from CON review the acquisition of an existing "health service facility, including equipment owned by the health service facility at the time of acquisition", upon prior written notice to the Agency. N.C. Gen. Stat. § 131E-184(a)(8). The term "health service facility" is defined to include a "diagnostic center." Id. § 131E-176(9b). In turn, a "diagnostic center" is defined to include a "mobile diagnostic program." Id. § 131E-176(7a). Hence, the acquisition of an existing mobile diagnostic program. including the equipment it owns upon the acquisition, is exempt from CON review as the acquisition of an existing health service facility.

Each of the Kings mobile MRI scanners, together with the services each scanner provides to its multiple sites, constitutes a "mobile diagnostic program." Consequently, each mobile diagnostic program is a "diagnostic center" and, hence, an existing "health service facility." For these reasons, Novant's proposed acquisition of the two mobile diagnostic programs, including the mobile MRI scanners and trailers, is exempt from CON review.

Prior decisions by the Agency confirm this conclusion. On November 15, 2017, the Agency determined that an almost identical acquisition by Rex Hospital, Inc. was exempt from CON review. See Exhibit D. The decision concerned a mobile cardiac catheterization unit that was grandfathered because the unit was originally acquired and placed into service before March 18, 1993 (the "Mobile Cath Unit"). The Agency agreed with Rex Hospital and determined that the grandfathered Mobile Cath Unit constituted a grandfathered mobile diagnostic program, which in turn constituted a grandfathered diagnostic center. Consequently, the Agency determined that Rex Hospital could acquire

² Kings Medical Company, the owner of Kings I and Kings II, is a wholly owned subsidiary of Kings Medical Group, Inc. ("KMG"). Certain past correspondence to the Agency concerning Kings I and/or Kings II was submitted by KMG as the parent entity.

Micheala Mitchell, Chief March 6, 2023 Page 3

this grandfathered health care facility, including the Mobile Cath Unit, without first obtaining a CON.

This notice of exempt acquisition is intended to apply to the entirety of Kings I and Kings II, including their equipment, and all rights related thereto. Consequently, the notice applies (without limitation) to King's right, title, and interest in (a) the existing MRI scanners, trailers, and related equipment, (b) the temporary MRI scanner previously approved for use until the permanent replacement MRI scanner is approved and acquired, (c) the permanent replacement MRI scanner for the MRI scanner that was damaged by fire, and (d) the grandfathered status of Kings I and Kings II and the two MRI scanners. It is Novant's understanding that upon the Agency's approval of this notice and the closing the acquisition by Novant, all such rights, title, and interest, including the grandfathered statuses, shall continue in effect and belong to Novant under the CON Law.

This transaction does not involve any other health services that are regulated by the CON Law.

As the parties would like to close this transaction shortly, we would appreciate your prompt response to this letter.

Thank you for your time and consideration. Please do not hesitate to let me know if you have any questions or need additional information.

Sincerely,

Denise M. Gunter

DMG:pfb Enclosures

cc: Forrest Campbell, Esq. (with enclosures)(via email)

From: <u>Denise Gunter</u>

To: Stancil, Tiffany C; Waller, Martha K; Hale, Gloria; Mckillip, Mike; Jackson, Yolanda W; Moore, Chalice L

Subject: [External] No Review/Exemption for Novant Health (Health Service Areas II and III)

Date: Tuesday, February 25, 2025 10:10:18 AM **Attachments:** Feb 25 2025 Exemption letter.pdf

> Exhibit A.pdf Exhibit B.pdf Exhibit C.pdf Exhibit D.pdf Exhibit E.pdf

CAUTION: External email. Do not click links or open attachments unless verified. Report suspicious emails with the Report Message button located on your Outlook menu bar on the Home tab.

Good morning,

I hope everyone is doing well. Attached for processing is a no review/exemption letter for Novant Health. This relates primarily to Mecklenburg and Forsyth Counties, so I am copying the team that covers those areas.

Please confirm that you have received this.

Thanks.



Confidentiality Notice

This message is intended exclusively for the individual or entity to which it is addressed. This communication may contain information that is proprietary, privileged, confidential or otherwise legally exempt from disclosure. If you are not the named addressee, you are not authorized to read, print, retain, copy or disseminate this message or any part of it. If you have received this message in error, please notify the sender immediately either by phone (800-237-2000) or reply to this e-mail and delete all copies of this message.