

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

ROY COOPER • Governor KODY H. KINSLEY • Secretary MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

December 21, 2023

Jeffrey Shovelin jshoveli@ecuhealth.org

No Review	
Record #:	4344
Date of Request:	December 12, 2023
Business Name:	Pitt County Memorial Hospital, Inc.
Business #:	1443
Project Description:	Change in membership interest in Vidant Radiation Oncology, LLC
Counties:	Pitt, Halifax, Hertford

Dear Mr. Shovelin:

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 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.

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

Sincerely,

Gregory F. Yakaboski Project Analyst

Micheala Mitchell

Micheala Mitchell Chief

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

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 https://info.ncdhhs.gov/dhsr/ • TEL: 919-855-3873

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December 12, 2023

Ms. Michaela Mitchell, Chief Healthcare Planning and Certificate of Need Section Division of Health Service Regulation NC Department of Health and Human Services 2704 Mail Service Center Raleigh, NC 27699-2704

RE: Notice of Change in Membership Interest in Vidant Radiation Oncology, LLC. / Request for "No Review" Status

Dear Ms. Mitchell,

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This letter shall serve as notice that Pitt County Memorial Hospital, Inc. d/b/a/ ECU Health Medical Center ("EHMC") intends to acquire 100% of the membership interest in Vidant Radiation Oncology, LLC ("VRO"), which owns three (3) freestanding radiation oncology centers located in Greenville, NC (Pitt County), Roanoke Rapids, NC (Halifax County), and Ahoskie, NC (Hertford County). VRO is an existing joint venture between EHMC and North Carolina Radiation Therapy Management Services, LLC ("NCRT"), a controlled affiliate of GenesisCare, a worldwide provider of radiation oncology centers and services. Currently, EHMC owns 50% of the membership interest and NCRT owns the remaining 50% membership interest.

GenesisCare is presently under bankruptcy proceedings that are ultimately resulting in the company selling North American assets. As a controlled affiliate of GenesisCare, NCRT's assets, including the membership interest in VRO, are included in the bankruptcy proceedings to be sold. EHMC intends to purchase NCRT's membership interest at the fair market value of \$11 million and obtain full membership interest in VRO.

EHMC believes the acquisition of NCRT's membership interest of VRO is not considered a new institutional health service and is therefore not subject to Certificate of Need (CON) review since:

- General Statute (GS) 131E-176.16(a) that defines a new institutional health service as "the construction, development, or other establishment of a new health service facility" does not apply. This statute does not apply because freestanding radiation oncology centers are not listed in the definition of a "health service facility" as defined in GS 131E-176.9a. Even if it was, VRO is an existing entity, and purchasing additional membership in an existing entity would not constitute developing or establishing a new health service facility.
- 2) GS 131E-176.16(b) that defines a new institutional health service as "the obligation by any person of a capital expenditure exceeding four million dollars (\$4,000,000) to develop or expand a health service or a health service facility, or which relates to the provision of a health service" does not apply. This statute does not apply because, even though the capital investment to acquire NCRT's 50% membership of VRO exceeds \$4 million, the expenditure is not to develop or expand a health service or a health service facility. VRO is an existing entity with three existing locations. EHMC intends to keep VRO's legal entity as it exists today, as well as continue to provide the same services (radiation oncology) on the same existing equipment (linear accelerator) in the same locations as it is operating today. The purchase of NCRT's membership interest in VRO is a related-party transaction and is not considered a change in ownership. In addition, it will have no impact on the linear accelerator inventory in any of the linear accelerator service areas.
- 3) GS 131E-176.16(f1) that defines a new institutional health service as "the acquisition by purchase, donation, lease, transfer, or comparable arrangement of any of the following equipment by or on behalf of any person: (5a) linear accelerator" does not apply. This statute does not apply as there will not be an acquisition of any new or existing linear accelerators. Today, VRO owns and operates 5 linear accelerators (including a CyberKnife) in Pitt County, 1 linear accelerator in Halifax County, and 1 linear accelerator in Hertford County. EHMC's purchase of NCRT's membership interest in

December 12, 2023

Notice of Change in Membership Interest in VRO. Page 2

VRO will not change the ownership of the existing linear accelerators. VRO will continue to own and operate this equipment in the exact same manner and locations as they exist today. Exhibit 1 provides the No Review request and approval for the original acquisition/contribution of the linear accelerators to VRO. CON Project ID Q-11292-17 (certificate attached) is provided in Exhibit 2 to provide evidence the subsequent replacement linear accelerators in Greenville, NC were issued to VRO.

- 4) GS 131E-176.16(I) that defines a new institutional health service as "the purchase, lease, or acquisition of any health service facility, or portion thereof, or a controlling interest in the health service facility or portion thereof, if the health service facility was developed under a certificate of need issued pursuant to G.S. 131E-180" does not apply. This statute does not apply because freestanding radiation oncology centers are not listed in the definition of a "health service facility" as defined in GS 131E-176.9a. In addition GS 131E-180 was repealed August 26, 2005. Even if VRO met the definition of a health service facility and GS 131E-180 was still active, the statute would still not apply. EHMC already owns a controlling interest in VRO (50%). The purchase of NCRT's 50% membership does not change the fact EHMC will still maintain a controlling interest. Therefore, the purchase of membership interest in an entity that EHMC is already a major part of would constitute a related-party transaction and not considered a change in ownership. VRO would still be the legal entity.
- 5) GS 131E-176.16(p) that defines a new institutional health service as "the acquisition by purchase, donation, lease, transfer, or comparable arrangement by any person of major medical equipment" does not apply. This statute does not apply for the same reasons stated in #3 above.
- 6) All other definitions of new institutional health services presented in GS 131E-176.16 are not applicable.
- 7) Since the original formation of VRO and contribution of the Greenville, NC equipment from its members in 2015 and the subsequent expansion of VRO and contributed equipment from its members for the Roanoke Rapids, NC and Ahoskie, NC in 2019 was granted a No Review Decision Approval (Exhibit 1), it is reasonably assumed that shifts in membership percentage among the original members of VRO would not require CON approval. In this case, EHMC is shifting to 100% and NCRT is shifting to 0%.

For the reasons stated above, EHMC is requesting that the CON Section issue a letter determining EHMC's acquisition of NCRT's membership interest in VRO and the subsequent provision of radiation oncology services is not a new institutional health service and is therefore exempt from CON review.

If there are any questions regarding this response, please contact me at (252) 847-3631 or jshoveli@ecuheaith.org.

Sincerely,

Jeffrey Shovelin VP Business Planning & Strategy ECU Health PO Box 6028 Greenville, NC 27835-6028

Exhibit 1



NC DEPARTMENT OF HEALTH AND HUMAN SERVICES ROY COOPER • Governor MANDY COHEN, MD, MPH • Secretary MARK PAYNE • Director, Division of Health Service Regulation

October 9, 2019

Gary Qualls	
430 Davis Drive	
Suite 400	
Morrisville, NC 27560	
-	

No Review	
Record #:	3078
Business Name:	Vidant Radiation Oncology, LLC
Business #:	2324
Project Description:	Vidant Radiation Oncology, LLC (VRO) acquisition of two Linacs and one CT scanner from VRO's current members, Vidant Medical Center and North
	Carolina Radiation Therapy Management Services, LLC
County:	Pitt

Dear Mr. Qualis:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence 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 that correspondence 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.

You may need to contact the Agency's Acute and Home Care Licensure and Certification Section to determine if they have any requirements for development of the proposed project.

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.

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

Sincerely Gregory F. aboski Project **Malyst**

cc:

Fusone Martha J. Frisone

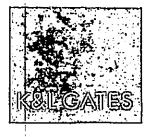
Martha J. Frisor Chief

Acute and Home Care Licensure and Certification Section, DHSR.

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

LOCATION: 809 Ruggles Drivo, Edgerton Bullding, Raleigh, NC 27603 MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704 https://info.ncdhhs.gov/dhsr/ - TEL: 919-855-3873

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Gary S. Qualls D 919,466,1182 F 919.516.2072 gary.qualls@klgates.com

August 22, 2019

<u>Via Hand Delivery</u> Martha J. Frisone, Chief Healthcare Planning and Certificate of Need Section Division of Health Service Regulation N.C. Department of Health and Human Services 809 Ruggles Drive Raleigh, NC 27603

Re: <u>No Review Request for VRO's Acquisition of Additional Linear Accelerators and a CT</u> <u>Scanner from Current Members</u>

Dear Ms. Frisone:

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 Certificato of Need Section (the "Agency") of the contribution of existing radiation oncology equipment and services by the two existing members of Vidant Radiation Oncology ("VRO") into VRO.

As you know from a prior No Review Decision approval (Exhibit A), VRO is an existing joint venture between Pitt County Memorial Hospital, Incorporated, d/b/a Vidant Medical Center ("Vidant") and North Carolina Radiation Therapy Management Services, LLC ("NCRT"). NCRT is a controlled affiliate of 21st Century Oncology. We ask that the Agency confirm that Vidant's and NCRT's respective contributions of two existing linear accelerators ("linacs"), and NCRT's contribution of a CT scanner, to VRO are not reviewable as a new institutional health service under the North Carolina Certificate of Need ("CON") law.

I. <u>Prior CON Approval for VRO.</u>

By letter dated August 12, 2015, the Agency approved Vidant's and NCRT's initial contribution of linacs and related radiation oncology assets to VRO ownership (the "Original VRO Transaction"). See Exhibit A (Agency's August 12, 2015 VRO No Review Decision Approval and July 31, 2015 Request, and related exhibits thereto). VRO has now operated those assets for a number of years.

II. Obtaining VRO's Interest in the Equipment Does Not Require a CON.

VRO now seeks to acquire 100% ownership of two additional linacs and one CT scanner (collectively the "New VRO Equipment") currently owned by VRO members, Vidant and NCRT, respectively. Specifically, the New VRO Equipment is comprised of:

- 1. A linear accelerator operated by a Vidant-related entity¹ in Ahoskie (the "Ahoskie Equipment"); and
- 2. A linear accelerator and CT scanner operated by NCRT in Roanoke Rapids (the "Roanoke Rapids Equipment").

This is a related-party transaction. In other words, a separate, third party will not be obtaining ownership of the New VRO Equipment. Instead:

- 1. For the Ahoskie Equipment, Vidant, the Ahoskie Equipment 100% owner, will become the 50% owner. NCRT will become the other 50% owner through VRO ownership.
- 2. Likewise, for the Roanoke Rapids Equipment, NCRT, the Roanoke Rapids Equipment 100% owner, will become the 50% owner. Vidant will become the other 50% owner through VRO ownership.

The New VRO Equipment will continue to be operated at the same locations at which they are currently being operated. VRO's ownership of the New VRO Equipment does not involve the offering or expansion of any new health service facility, service or equipment, and the State's inventory of linacs and CT scanners will not change. No new or additional linacs (or other regulated equipment) will be acquired or placed in operation in the State. As detailed below in Section III below, this is similar to other membership changes in regulated equipment ownership, which did not require a CON.

¹ Ahoskie Imaging, LLC and Radiation Services of North Carolina, LLC (the "Vidant Affiliates") collectively own the Ahoskie Linac a/k/a the Ahoskie Equipment. Those Vidant Affiliates are controlled affiliates of East Carolina Health. In turn, East Carolina Health and Vidant are both part of the Vidant Health System as related entities. The Vidant Affiliates currently allow the Ahoskie Equipment to be operated by its affiliate East Carolina Health d/b/a Vidant Roanoke-Chowan Hospital, pursuant to a service agreement, in separate business occupancy physical space from the main hospital building.

III. <u>Continuing to Use VRO as a Conduit for Linac Ownership is Not Regulated Under</u> <u>CON Law</u>.

Vidant and NCRT contributing their respective equipment 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 contribution of equipment by a joint venture member to its own joint venture that already actively provides 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.").

Via their initial joint venture established by the Original VRO Transaction, Vidant and NCRT placed ownership rights of five (5) of their collective linacs into the joint venture, VRO. Vidant and NCRT each own 50% of VRO. As we observed in that Original VRO Transaction Request (which the Agency approved), Vidant and NCRT continued to own those five (5) linacs through their respective ownership of VRO. See Exhibit A.

Now, Vidant and NCRT, through their VRO venture, wish to add the New VRO Equipment (i.e., the Ahoskie Equipment and Roanoke Rapids Equipment) to that same venture and each VRO member will continue to own a 50% interest in their newly contributed equipment.

IV. Prior Analogous Precedent.

The most relevant precedent for this approval is the initial establishment of VRO and the contribution of the five (5) linacs discussed in Part III above. <u>See</u> Exhibit A, pp. 1-10. However, many other previous Declaratory Rulings and No Review Decisions demonstrate that a CON is not required for similar membership interest changes pertaining to CON regulated equipment or there is no CON policy advanced by a review where:

- 1. All of the regulated equipment or other items (and associated space) to be part of the redesignation transaction at issue already exists and is currently being operated (particularly when the existing owner will continue to have an ownership role in the future).
- 2. No regulated equipment will be added to or removed from the site at issue.
- 3. No new service lines will be added to the site at issue.

4. No regulated equipment or services will be relocated to or otherwise added to the relevant State Medical Facilities Plan ("SMFP") service area.

In those instances, the Agency and Division have reasoned that the CON law is not intended to result in unnecessary CON reviews when the existing regulated asset or service will continue to serve the same patient base in the same location, albeit through a different ownership structure. See HCA Crossroads Residential Centers, The North Carolina Department of Human Resources, 327 N.C. at 579, 398 S.E. 2d at 470.

A. <u>Original VRO Transaction Approval and Other Radiation Therapy Facility</u> <u>Analogues.</u>

In addition to the approval establishing VRO and the contribution of the five (5) linacs discussed in Part III above (Exhibit A, pp. 1-10), the remainder of Exhibit A consists of numerous Declaratory Rulings and No Review Determinations from the Division and the Agency approving, without CON review, ownership structure changes to *per se* reviewable linear accelerators and related assets, <u>See</u> N.C. Gen. Stat. § 131E-176(16)(f1)(5a).

B. <u>Heart Lung Bypass Equipment Analogues</u>

Another category of relevant precedent is found at pages 56-68 of Exhibit A.² Those No Review Decision approvals pertained to WakeMed's and Rex's acquisition of heart-lung bypass machines through ownership of the physician-owned entities that owned the equipment. Like linear accelerators, the acquisition of a heart-lung bypass machine is technically *per se* CON-reviewable. See N.C. Gen. Stat. § 131E-176(16)(f1)(5). However, as in other examples cited throughout this Part IV, the Agency concluded that the CON law is not intended to be implicated when existing equipment (otherwise *per se* reviewable) changes ownership, yet is already counted in the CON and SMFP inventory and simply remains in the same place serving the same patient base.

C. <u>Nursing Facility Analogues</u>

Another category of such precedent is found in Exhibit B to this Request. Exhibit B consists of Agency No Review Decision approvals for Rex Hospital (Ex. B, pp. 1-5) and Hugh Chatham Memorial (Ex. B, pp. 6-18). See Agency's April 7, 2014 Rex Hospital No Review Decision Approval and March 24, 2014 Request to Obtain Separate License for Rex Rehabilitation Center of Raleigh (and exhibits thereto).

² These examples are contained in Exhibit A because they were cited in support of, and attached to, the Original VRO Transaction No Review Request.

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In both instances, the Agency found that no CON review was required where a skilled nursing facility was removed from its associated hospital license and the nursing facility obtained its own separate license from the hospital. Even though a new licensed health service facility was technically created in both situations,³ the Agency made the non-reviewability determination. In these nursing facility examples, as in the instant request, the CON law is not intended to result in unnecessary CON reviews when the existing CON-regulated equipment, beds, or services will continue to serve the same patient base, in the same location. *See HCA Crossroads Residential Centers, The North Carolina Department of Human Resources*, 327 N.C. at 579, 398 S.E. 2d at 470 ("[w]hen viewed in its entirety . . . the Certificate of Need Law reveals the legislature's intent that an applicant's fundamental right to engage in its otherwise lawful business be regulated but not be encumbered with unnecessary bureaucratic delay").

In both transactions, the CON and SMFP inventory of nursing home beds remained the same, and those beds remained in the same place serving the same patient base. In the High Chatham Memorial example, the ownership structure was also changing.

D. <u>Hospital Splits</u>

Exhibits C and D to this Request catalogue yet another area of similar agency interpretations. Those Division Declaratory Rulings involved The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System and Mercy Hospital, Inc. (collectively "CHS") and WakeMed, and their respective requests to change the licensure status of hospital segments. In CHS's November 2, 2012 Declaratory Ruling, the Division approved, without a CON, the redesignation of the Mercy Vail Avenue Campus to be relicensed from the Mercy Hospital license (License # H0042) to the Carolinas Medical Center license (License # H0071). See Exhibit C, Declaratory Ruling for the Charlotte-Mecklenburg Hospital Authority d/b/a/Carolinas Healthcare System and Mercy Hospital, Inc., November 2, 2012.

In the CHS Ruling, the Division cited a July 15, 2002 WakeMed Declaratory Ruling (Exhibit D), in which the Division determined that no CON was required for WakeMed to split the WakeMed Raleigh and WakeMed Cary campuses into two separate licensed hospitals, where those facilities had previously operated under a single license. That was true even though the WakeMed transaction technically constituted the creation of a newly licensed health service facility. See N.C. Gen. Stat. §§ 131E-176(9b) and 176(16)(a). In the WakeMed Declaratory Ruling, the Division reasoned that requiring a CON "would be an overly technical interpretation of the Certificate of Need law and not in furtherance of any statutory purpose."

³ See N.C. Gen. Stat. §§ 131E-176(9b) and 176(16)(a).

E. <u>Applying Prior Analogous Precedent</u>

Likewise, here, Vidant and NCRT's contributions of the New VRO Equipment do not constitute the acquisition of a linac or major medical equipment. In fact, the underlying equipment ownership will be essentially the same. Unlike some of the prior situations referenced above that were determined not to be subject to CON review, but similar to the initially approved VRO contributions in 2015, Vidant and NCRT will still retain an ownership interest in the linacs and the CT scanner. No separate third party will be acquiring any ownership interest in the equipment. The same parties will retain ownership of the New VRO Equipment -- just as with all five linacs in the original approval establishing VRO -- and the New VRO Equipment 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. See 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). As with the Original VRO Transaction:

- 1. ownership of the radiation therapy equipment will largely be unaffected by this transaction;
- 2. that equipment will continue to be owned, in part, by the same entities both before and after this transaction; and
- 3. VRO will merely be the new ownership conduit through which NCRT and Vidant continue to own the New VRO 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 VRO.

CONCLUSION

Based upon the foregoing information, we request that the Agency:

- 1. confirm that contribution of the New VRO Equipment into VRO by its members is not reviewable as a new institutional health service under the CON law because it is simply a related entity transaction; or
- 2. in the alternative, confirm that the New VRO Equipment contributions into VRO are exempt from review under the CON law's exemption provisions in N.C. Gen. Stat. § 131E-184(a)(8).

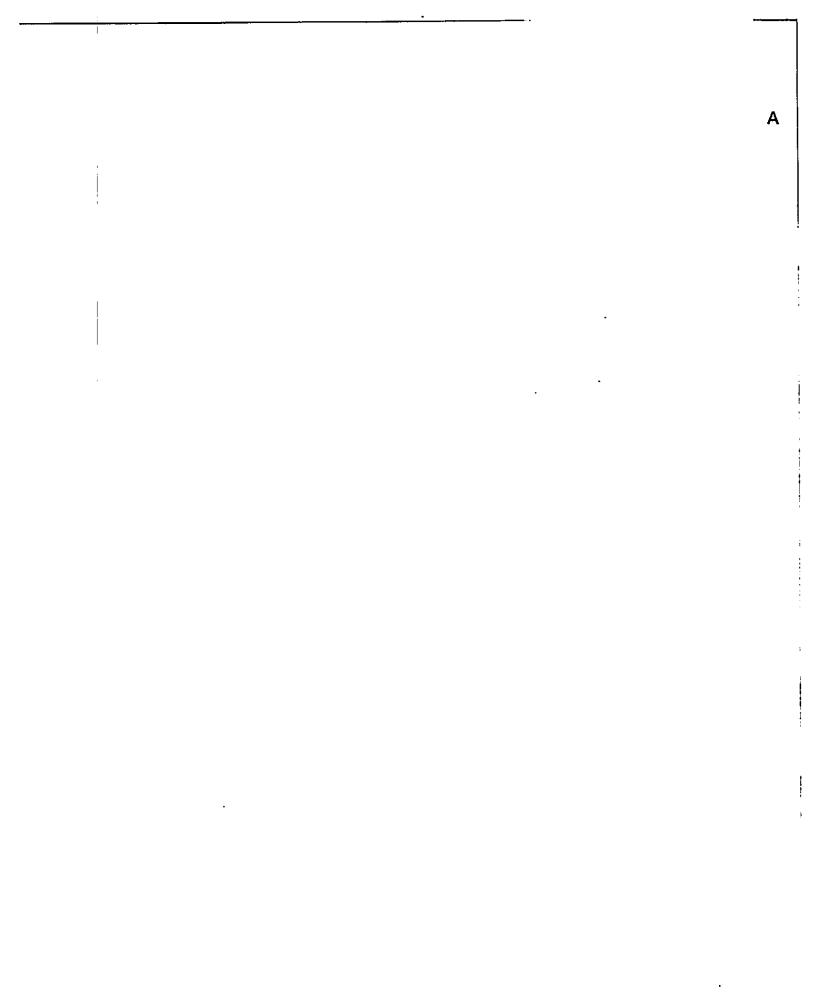
Thank you for your assistance in regard to this matter. Please feel free to contact me at the number above if you have any questions or need further information.

Sincerely,

Sang S. Qually Gary S. Qualls

EXHIBITS

- A. Agency's August 12, 2015 VRO No Review Decision Approval and July 31, 2015 Request, and related exhibits thereto (all Bates Stamped)
 - 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
 - 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
- B. Agency's April 7, 2014 Rex Hospital No Review Decision Approval and March 24, 2014 Request to Obtain Separate License for Rex Rehabilitation Center of Raleigh
- C. Declaratory Ruling for the Charlotte-Mecklenburg Hospital Authority d/b/a/Carolinas Healthcare System and Mercy Hospital, Inc., dated November 2, 2012
- D. Declaratory Ruling for WakeMed, dated July 15, 2002





EXHIBIT

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

1683
Vidant Radiation Oncology
2249 .
Vidant Medical Center becoming 100% owner of NewCo Cancer
Services, LLC
Pitt

Dear Messrs. Qualls and Shenton:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your letter of July 31, 2015 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.

However, you need to contact the Agency's Construction and Acute and Home Care Licensure and Certification Section, DHSR 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: Edgetton Building • 809 Ruggles Drive • Raleigh, NC 27603 Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704 An Equal Opportunity/ Affirmative Action Employer

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Gary S. Qualls and William R. Shenton August 12, 2015 Page 2

It should be noted that this determination is binding only for the facts represented in your correspondence. 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 this office. 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 this office if you have any questions. Also, in all future correspondence you should reference the Business # if the facility is licensed.

Sincerely,

Jane Rhoe-Jones Project Analyst

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Martha J. Frison¢ 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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shellev Car

Chief Nd

Section

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K&L Gates LLP Post Office Box 14210 Research Triangle Park, KC ⁵27709-4210

430 Davis Drive, Suite 400 Morrisville, NG 27560

r 919.466.1190 www.kigates.com

Gary S. Qualls D 919,466,1182 F 919,516,2072 gary,qualls@klgates.com

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:

Department of Health and Human Services

Health Planning and Certificate of Need

Division of Health Service Regulation

Raleigh, North Carolina 27603 .

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,

Davij &. Quella

Gary S. Qualls

cc: William Shenton

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Attachments

RT-3042393

Poyner Spruill[™]

July 31, 2015

William R. Shenton Partner D: 919,783.2947 F: 919.783,1075 wshanton@poynerspruill.com

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

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

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

Dear Ms. Carraway and Ms. Frisone:

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 Qualis 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 Shenta

William R. Shenton Partner

WWW.POWNERSPRUILL.COM

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RALEIGH / CHARLOTTE / ROCKY MOUNT / SOUTHERN PINES

301 Feyelleville Strael, Suite 1900, Roleigh, NC 27601 P.O. Ooz 1901, Releigh, NC 27602-1901

P.919,783,6400

<u>No Review Request for Joint Venture between</u> <u>Vidant Health and 21st Century Oncology</u>

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"),¹ 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. <u>See</u> 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. <u>See</u> 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. <u>See</u> Declaratory Ruling and Exemption attached as Exhibits 5 and 6.

RT-3036021 v9

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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

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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. <u>See Id.</u>, attached as Exhibit 7; In re: Request for Declaratory Ruling by Wake Radiology Oncology

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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.

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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.

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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

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- 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

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STATE OF NORTH CAROLIA

Department of Health and Human Services Division of Health Service Regulation

OATE OF

Project Identification Number #Q-8562-1

ED #100878

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ISSUED TO: New Co Cancel Services, LI P.O. Box 6028 Greenville, NC 27835

Pursuant to N.C. Gen. Stat, 5"131E-175; ef. sed., the North Garolina 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 mainter consistent with the representations in the project application and with the conditions contained herein and shall make good faith efforts to meet the finisfable 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 holden shall not transfer or assign this dertificate to any other person except as provided in N.C. Gen. Start § 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, Star § 131E-189 for any of the reasons provided in that law,

SCOPE: New Co Gancer Sorvices shall acquire two existing migar accelerators, CT simulator, and rented lequipment, and imultispecialty oucology physician prabtices from East Carolina University Brody School of Viedicine/ Pitt County. المجرد والتيديو الجديد

CONDITIONS () See Reverse Side.

33° F PHYSICAL LOCATION: Pilt County Memorial Hospital 600 Moye Bouleyard Greenville, NC 27834

MAXIMUM CAPITAL EXPENDITURE \$9,700,000

See Reverse Side TIMETABLE:

May 1, 201 TIRST PROGRESS REPORT DUE;

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

Chief, Certificate of Need Section ______ Division of Health Service Regulation

CONDITIONS:

.1. NewCo Cancer Services, LEC shall materially comply with all representations made in its application.

2. NewCo Cances. Services, ILC 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 Contlicate of Need Section in writing pittor 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.

TIMETABLE;

Occupancy/Offering of service(s) ______ April 1, 2011

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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

Ex	empt fi	rom	Review -	Re	pla	ce	men	tΕ	qui	pmen	t

 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 GB 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.

dhhs Titas	

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

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Jeffrey Shovelin September 13, 2013 Page 2

Sincerely, ·

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Stere 1 Jane Rhoe-Jones

Project Analyst

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Craig R. Smith, Chief Certificate of Need Section

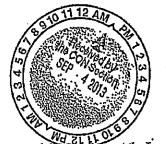
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cc: Acute and Home Care Licensure and Certification, DHSR Construction Section, DHSR Medical Facilities Planning Branch, DSHR



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



RE: Request for "No Review" for Replacement CT Scanner and CT Simulator at the Leo Jenkins Cancer Center

Dear Ms. Rhoe-Jones:

NewCo Cancer Services, LLC (NewCo), a joint venture between Vidant Medical Center and BCU'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.

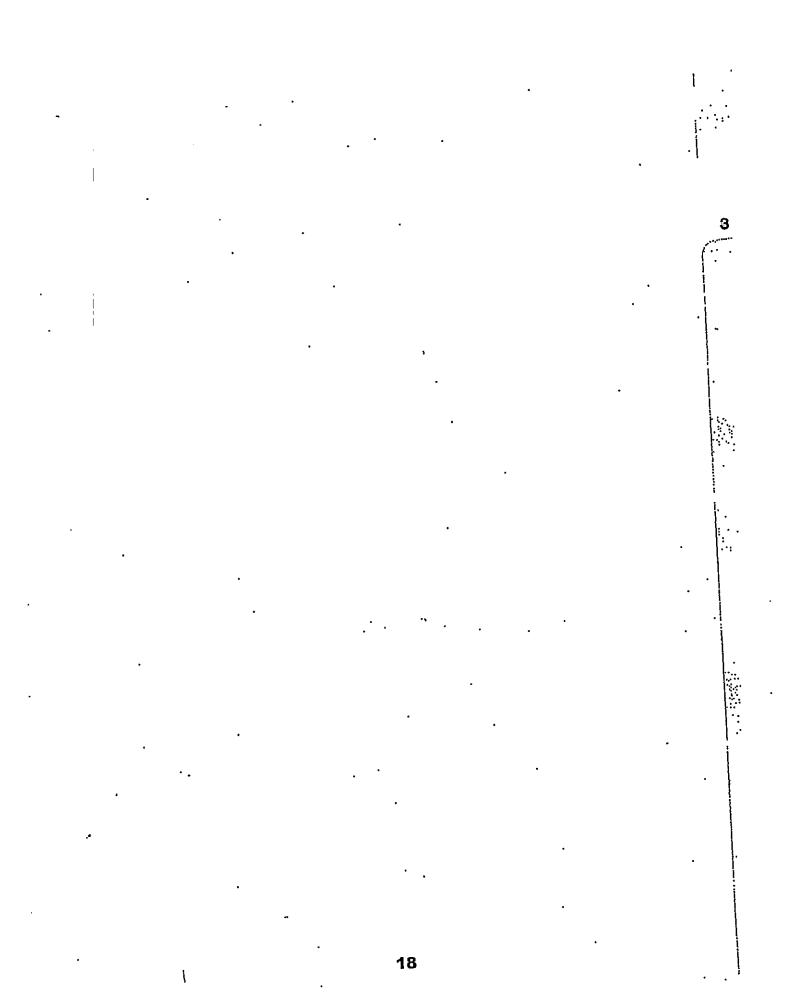
The proposed project includes the replacement of a Siemens SimView CT scanner with a GE Optima CT580 16 slice CT simulator (see Appendix A for vendor quotes and Appendix B for equipment comparison table and brochure). The equipment will be secured through accumulated reserves. The reason for this replacement 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 B 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 dofinition 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

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STATE OF NORTH CAROLING Department of Health and Human Services Division of Health Service Regulation

CERTIFICATE OF NEED

for

Project Identification Number #Q-8558-10

FID #933410

ISSUED TO: Pitt County Memorial Hospital, Inc.

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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 time able 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 fastion 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: Ritt County, Memorial Hospital shall acquire a CyberKuife radiosurgery system and related equipment from East Carolina University Brody School of Medicine/ Pitt County

CONDITIONS: See Reverse Side

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PHYSICAL LOCATION: Pitt County Memorial Hospital

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, Ceyfficate of Need Section Division of Health Service Regulation

STATE OF NORTH CAROLIN Department of Health and Human Services Division of Health Service Regulation

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

CONDITIONS: See Reverse Side

Pitt County

PHYSICAL LOCATION: Pitt County Memorial Hospital

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, Ceptificate of Need Section Division of Health Service Regulation

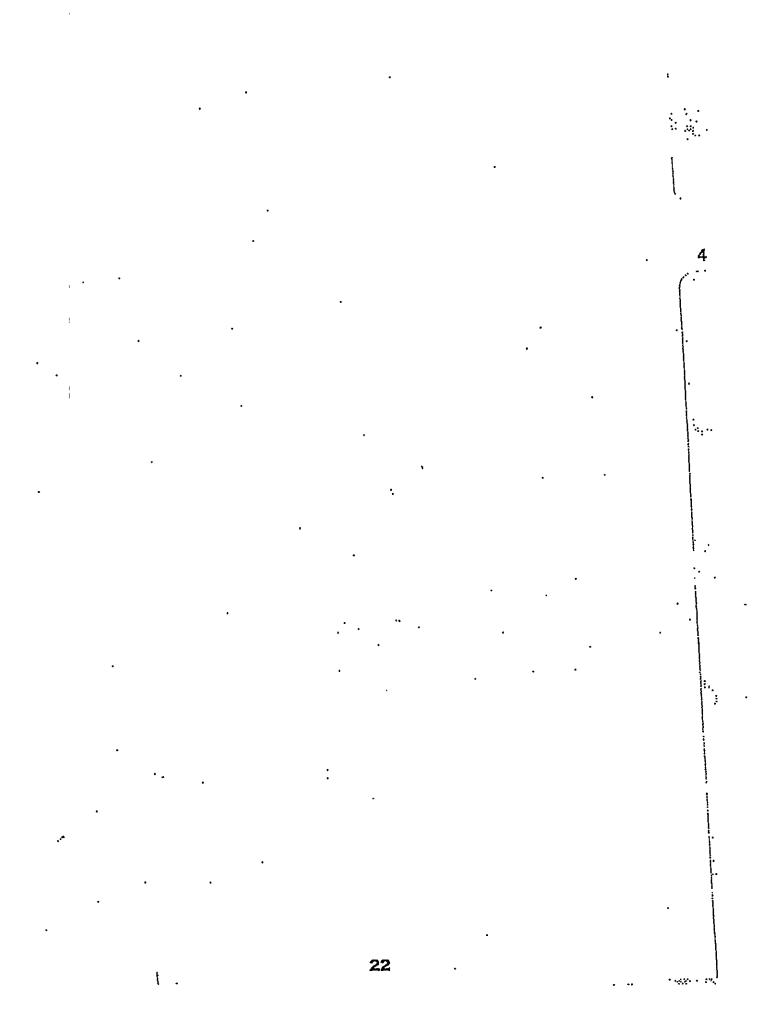
CONDITIONS:

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- 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.

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TIMETABLE:		·	• * *	•	
Occupancy/Offering of service(s)			•		January 1, 2011
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North Carolina Department of Health and Human Services Division of Health Service Regulation Certificate of Necd Section 2704 Mail Service Center , Ralelgh, 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

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 Faoility I,D,# (FID) in all correspondence.

Sincerely

Bernetta Thorne-Williams, Project Analyst

Craig R. Smith, Chief

Cortificate of Need Section

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

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Location: 701 Barbour Drive = Dorothea Dix Hospital Campus = Raleigh, N.C. 27603 An Equal Opportunity / Affirmative Action Employer

PITT COUNTY MEMORIAL HOSPITAL University Health Systems of Eastern Carolina...

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 Mall 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. Smlth:

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, Ino. (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 Medicald Identification numbers to operate CyberKnife services as a freestanding radiation freatment 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 jshovell@uhseast.com.

Sincerely,

Jeff Shovelin Director of Corporate Planning, University Health System of Eastern Carolina

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North Carolina Department of Health and Human Services Division of Health Service Regulation Office of the Director 2701 Mail Service Center • Releigh, North Catoline 27699-2701

Michael F. Estley, Governor Dempsey Beston, Secretary

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Robert J. Flizgerald, Director Phonet ,919-555-3750 Fax: 919-735-2757

September 18, 2007

CERTIFIED MAIL

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

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

Dear Ms. Hargrovel

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

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RJF:JH:peb

Enclosure

ec: Jeff Horton, Chief Operating Officer, DHSR Lee Hoffman, Chief, Certificate of Need Section, DHSR Azzie Conley, Chief, Acute and Home Care Licensure and Certification Section, DHSR. Maro Lodge, Special Deputy Attorney General, DOJ



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Lochtion: 701 Barbour Drive a Dorothen Dix Hospital Campus & Raleigh, N.C. 27603: An Equal Opportunity / Affirmalive Aeilon Employer

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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 CAROLINA, RADIATION THERAPY MANAGEMENT SERVICES, INC.

' DECLARATORY RULING

I, Robert J. Fitzgerald, Director of the Division of Health Service Regulation (the "Department"), hereby issue-this declaratory utiling to Radiation Therapy Services; Inc. d/b/a/ 2'1" 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.

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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 with to acquire 100% of the issued and outstanding stoole 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. § 191B-175(9b). S.L. 2005-325 eliminated oncology treatment centers from the category of "health service facilities," offective 26 August 2005.

Petitioners also state that CRTO "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 onfered 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 Medicina, 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.

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Petitioners represent that they have executed a stock purchase agreement by which NC. Radiation will acquire 100% of the lasued 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. Retilioners 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 davelop "a new institutional healthi 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 Patitioners 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

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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, encology 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 ORTC 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.

<u>CONCLUSION</u>

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.

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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 H day of Signature 2007. Robert F. Litzgennet, Director Division of Health Service Regulation N.C. Department of Health and Human Services.

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CERTIFICATE OF SERVICE

I certify that a copy of the foregoing Declaratory Ruling has been served upon the nonagency party by certified mall, 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 & Jemigan, L.L.P. P.O. Box 2611 Raleigh, NC 27602-2611

This the 14th day of September, 2007.

Chief Operating Officer

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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

www.ncdhhs.gov/dhsr

Beverly Eaves Perdue, Governor Lanler M. Cansler, Secretary Leo 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.

Sind DePorter, Project Analyst F. Gene

Les B. Hoffman, Chief Certificate of Need Section

cc: Medical Facilities Planning Section, DHSR

Location: 701 Barbour Drive = Dorothica Dix Hospital Campus = Raleigh, N.C. 27603 An Baual Opportunity / Affirmative Action Employer

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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 <u>http://www.nedhhs.gov/dhsr</u>

Beverly Baves Perdae, Governor Lanier M. Cansler, Secretary

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Drexdal Pratt, Director Phone: 919-855-3750 Fue 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:pcb

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



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

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

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IN RE: REQUEST FOR DECLARATORY RULING BY THE CHARLOTTE-MECKLENBURG HOSPITAL AUTHORITY D/B/A CAROLINAS HEALTHCARE SYSTEM

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DECLARATORY RULING

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 entitics 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

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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

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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:

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CERTIFIED MAIL

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

This the 4th day of November, 2011.

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Chief Operating Officer

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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 CENTERS OF NORTH CAROLINA, P.C., US ONCOLOGY, INC., AOR MANAGEMENT COMPANY OF VIRGINIA, LLC AND WAKEMED

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DECLARATORY RULING

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.

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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

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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

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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.

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Drexdal Pratt, Director Division of Health Service Regulation N.C. Department of Health and Human Services

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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

This the _____ day of September, 2010.

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Jeff Horton Chief Operating Officer

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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 CAROLINA RADIATION THERAPY MANAGEMENT SERVICES, INC.

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DECLARATORY RULING

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 piecess 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

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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

This _____ day of _____, 2007.

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Jeff Horton Chief Operating Officer

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EXHIBIT



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 <u>http://www.nedbhs.gov/dist/</u>

Drexdal Pratt, Director

Beverly Eaves Perdue, Governoz 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 heartlung 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 Ro Smith, Chief

Certificate of Need Section

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Location: 809 Ruggles Drive, Dorothea Dix Hospital Campus, Raleigh, N.C. 27603

An Equal Opportunity/Affirmative Action Employer

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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. \cdot 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

Maurien Semanot Surray

Maureen Demarest Murray

cc: Stan Taylor, WakeMed

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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.ncihha.gov/dhur/

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. Qualis:

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,

Minsma Michael J. McKil Project Analyst

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Craig R&mith, Chief Certificate of Need Section



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

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K&L Gates ttr Post Office Box 14210 Research Triangie Park, NC 27709-4210 سكربل

430 Davis Drive, Solte 400 Norvisville, NG 27560

r \$19.486.1190 nvr.klgates.com

Gary S. Qualls D 919,466,1182 F 919,516,2072 gary,qualis@klgates.com

February 9, 2012

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K&L GATES

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. Frisono:

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

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

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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

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Gary S. Qualls

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	EXHIBIT	١
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North Catolina Department of Health and Human Services Division of Health Service Regulation Office of the Director 2701 Mali Service Center • Raleigh, North Catolina 27699-2701 <u>http://www.nedbhs.gov/dhsr</u>

Beverly Enves Perdue, Governor Lunler M. Cantler, Secretary Drexdal Frate, 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, Chlef 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



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Location: 809 Ruggics Drive a Dorothea Dix Hospital Campus a Raielgh, N.C. 27603 An Equal Opportunity / Affirmative Action Employer ÷

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 HOSPITAL AUTHORITY D/B/A CAROLINAS HEALTHCARE SYSTEM

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DECLARATORY RULING

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.

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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

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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 conjclude 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 ______ day of November, 2011.

Drexdal Pratt, Director

Division of Health Service Regulation N.C. Department of Health and Human Services

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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.

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Jeff/Horton // Chief Operating Officer

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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

April 7, 2014

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

No Review	
Facility:	Rex Hospital
Project Description:	Obtain a separate license for Rex Rehabilitation and Nursing Center of
2 -	Raleigh
County:	Wake
FID #:	953429

Dear Mr. Qualls:

The Certificate of Need Section (CON Section) received your letter of March 24, 2014 regarding the above referenced proposal. Based on the CON law in effect on the date of this response to your request, the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

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

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Certificate of Need Section. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the 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.



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

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Mr. Quells April 7, 2014 Page 2

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

Sincerely,

Midguitz

Michael J. McKillip, Project Analyst

YI 7. Frisone Jaitha (

Martha J. Frisone, Interim Chief Certificate of Need Section

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

K&L|GATES



K&L Gates ur Post Office Box 1421D Research Triangle Perk, NG 27709-421D

430 Davis Drive, Suite 400 Norrievme, KO 27560

1 919.466.1190 www.klgates.com

Gary S. Qualls D 919.466.1182 F 919.516.2072 gary.qualis@kigates.com

March 24, 2014

<u>VIA HAND DELIVERY</u> Martha Frisone, Chief, Certificate of Need Section Division of Health Service Regulation North Carolina Department of Health & Human Services 809 Ruggles Drive Raleigh, North Carolina 27603

> RE: Rex Hospital, Inc. (License No. H0065)
> No Review Request To Independently License Rex Rehabilitation & Nursing Center of Raleigh

Dear Ms, Frisone:

We are writing on behalf of our client Rex Hospital, Inc. ("Rex"). Rex owns and operates Rex Rehabilitation & Nursing Center of Raleigh (the "Nursing Center"), a nursing home with 120 nursing beds under the Rex Hospital license. Rex has decided to obtain an independent license for the Nursing Center in order to promote operational efficiencies. We are requesting confirmation from the Department of Health and Human Services, Division of Health Service Regulation, Certificate of Need Section (the "Agency") that this proposal is not subject to certificate of need review.

In this instance, the entity (Rex) that owns the Nursing Center will not change, and the same building, staff and equipment will be used to provide the same services at the same location. Rex will continue to own the CON-authorized Nursing Center assets that have been used to furnish skilled nursing care to the Nursing Center's residents. The proposed transaction does not involve the offering or expansion of any new facility, service or equipment, and the State's inventory of nursing beds will not change. No new or additional nursing home beds will be acquired or placed in operation in the State. The Nursing Center already has its own

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K&L|GATES

Martha Frisone, Chief, Certificate of Need Section March 24, 2014 Page 2

distinct Medicare provider number (Medicare #345369), which is separate from Rex Hospital's Medicare provider number (Medicare #340114).

This proposal is similar to other proposals that the Agency has found to be non-reviewable. For example, the Agency recently determined that no CON review was necessary for Hugh Chatham Memorial Hospital, Inc. to independently license a nursing home that historically operated under its hospital license. See Exhibit 1.

We believe that the CON law allows the independent licensing of the Nursing Center without the requirement of a CON because such an event does not constitute the development or acquisition of a new facility or services, within the meaning of N.C. Gen, Stat. § 131E-176(16). The beds already exist in the State Medical Facilities Plan inventory and there is no new facility constructed. Thus, there has been no action which constitutes the offering or development of a new institutional health service within the meaning of N.C. Gen. Stat. § 131E-178(a), and no CON is therefore required.

We request that you provide a no review letter confirming that our interpretation of the CON law is correct and that this proposal is not subject to certificate of need review.

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

Sincerely,

Dary S. Quale

Gary S. Qualls



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Martha Frisone, Chief, Certificate of Need Section March 24, 2014 Page 3

<u>Exhibits</u>

1. Hugh Chatham Memorial Hospital, Inc. No Review Request and Response



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New York		ļ

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 Fratt Division Director

March 11, 2014

S. Todd Hemphill 3105 Glenwood Avenue, Suite 300 Raleigh, North Carolina 27612

No Review

Facility: Project Description:	Hugh Chatham Memorial Nursing Center Transfer by Hugh Chatham Memorial Hospital, Inc. (HCMH) of 100% of its ownership interests in Hugh Chatham Memorial Nursing Center to Hugh Chatham Nursing Center, LLC, a wholly-owned subsidiary of HCMH and license it separately from the hospital
County:	Surry .
FID #:	955375

Dear Mr. Hemphill:

The Certificate of Need Section (CON Section) received your letter of February 18, 2014, regarding the above referenced proposal. Based on the CON law in effect on the date of this response to your request, the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

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

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Certificate of Need Section. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the 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.



Certificate of Need Section www.nodhbs.gov Telephone: 919-855-3873 • Fox: 919-733-\$139 Location: Edgerton Building • 809 Ruggles Drive • Rateigh, NC 27693 Mailing Address: 2704 Mail Service Center • Releigh, NC 27699-2704 An Equal Opportunity/ Affirmative Action Employer

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S. Todd Hemphill March 11, 2014 Page 2

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

Sincerely,

M [Kim Randolph, Proje nalyst

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Martha J. Frisone, Interim Chief Certificate of Need Section

cc: Acute and Home Care Licensure and Certification Section, DHSR Nursing Home Licensure and Certification Section, DHSR Medical Facilities Planning Branch, DHSR Iohn T. Bóde S. Tond Hemphill Matthew A. Fisher David R. Broyles



BODE HEMPHILL, L.L.P. Attorneys at law 3105 Glenwood Avenue, Suite 300 Raleigh, North Carolina 27612

T'ELEPHONE (919) \$81-0338

FACSIMILE (919) 881-9548

MAILING ADDRESS .

POST OFFICE ROX 6335 RALEIGH, NORTH CAROLINA 27628-6335

WWW.BCS-LAW.COM

Writer's E-mail: HEAPHILL@BCS-LAW.COM

February 18, 2014

<u>VIA HAND DELIVERY</u> Martha J. Frisone, Interim Chlef Kim Randolph, Project Analyst Certificate of Need Section N.C. Department of Health and Human Services Division of Health Service Regulation 809 Ruggles Drive Raleigh, North Carolina 27603

> Re: Hugh Chatham Memorial Hospital, Inc. (License No. H0049) No review request to transfer control of Hugh Chatham Nursing Center to wholly owned-subsidiary

Dear Ms. Frisone and Ms. Randolph:

We are writing you on behalf of our client, Hugh Chatham Memorial Hospital, Inc. ("HCMH"), a North Carolina non-profit corporation. HCMH owns and operates Hugh Chatham Nursing Center (the "Nursing Center"), a combination facility with 99 nursing beds and 28 assisted living beds (20 Alzheimer's or special care unit beds and 8 general beds), under the hospital's license. HCMH has determined that it is in its best interest to transfer ownership of the Nursing Center to a wholly-owned subsidiary which it has created, Hugh Chatham Nursing Center, LLC, a North Carolina limited liability company ("HCNC"). HCMH is the sole member of HCNC. See HCNC Articles of Organization, <u>Exhibit 1</u> hereto.

We also understand that as part of this transfer, the Nursing Center will need to be operated as a separately-licensed nursing facility. I have already spoken about this subject with Becky Wertz, Nurse Consultant with the Nursing Home Licensure and Certification Section, and our client is in the process of preparing the Nursing Home Licensure Application and other related documentation which she has provided. However, before that documentation can be filed, we first need to confirm with your office that this proposal is not subject to certificate of need review. Ms. Frisone and Ms. Randolph February 18, 2014 Page 2

The CON law provides that transfer of ownership or control of a CON would constitute grounds for withdrawal of the CON if it occurs during the course of development of a project before the project is complete. N.C.G.S. § 131E-189. There is no CON project under development at the Nursing Center. Furthermore, Agency rules provide that neither ownership nor control of a certificate of need is transferred when the holder of the certificate is a corporation and the identity of the holder changes because of a corporate reorganization, such as transferring ownership to a wholly-owned subsidiary. 10A N.C.A.C. 14C.0502(b)(1) and (c).

In this instance, the entity that owns the Nursing Center will not change, and the same building, staff and equipment will be used to provide the same services at the same location. HCMH will continue to own the Nursing Center assets that were authorized under the CON and have been used to furnish skilled nursing care to the Nursing Center's residents. The proposed transaction does not involve the offering or expansion of any new facility, service or equipment, and the State's inventory of nursing home beds will not change. No new or additional nursing home beds will be acquired or placed in operation in the State. The Nursing Center already has its own separate NPI number and Medicare number.

This proposal is similar to other proposals involving transfer of assets to wholly owned subsidiaries that the CON Section has found in the past did not require CON review. For example, the CON Section determined that a perfusion company could hold heart-lung bypass equipment in two separate wholly owned subsidiaries without undergoing CON review. See enclosed <u>Exhibit 2</u> (without exhibits to original request letter).

For these reasons, we believe that the CON law allows the transfer of the Nursing Center to a wholly-owned subsidiary of HCMH, without the requirement of a CON, because such a transfer does not constitute the development or acquisition of a new facility or services by the subsidiary, within the meaning of G.S. 131E-176(16) or 10A N.C.A.C. 14C.0502. The subsidiary has no control over those services independent of its parent entity. The ultimate ownership and control of the service does not change. The beds already exist in the inventory in the State Medical Facilities Plan and there is no new facility constructed. Thus, there has been no action which constitutes the offering or development of a new institutional health service within the meaning of G.S. 131E-178(a), and no CON is required.

We request that you provide a letter of no review confirming that our interpretation of the CON law and applicable rules is correct and that this proposal is not subject to certificate of need review.

Ms. Frisone and Ms. Randolph February 18, 2014 Page 3

Please let us know if you need further information or it there are questions we can answer.

Very truly yours,

BODE HEMPHILL, L.L.P.

S. Todd Hemphill

STH:sh

Enclosure cc w/enc.:

Becky Wertz, Nurse Consultant (via hand delivery) Paul Hammes/Don Trippel (via e-mail only)

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		SOSID: 1361794 Date Filed: 2/14/2014 5:00:00 PM Elaine F. Marshall North Carolina Secretary of State C2014 043 00481
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	State of North Carolina Department of the Secretary of St	lais
	Limited Lighlity Company ARTICLES OF ORGANIZATION	· ·
Articles	to \$57D-2-20 of the General Statutes of North Carolins, the unders of Organization for the purpose of forming a limited liability comprise	ny,
1. 7	the name of the limited liability company ist Hugh Chatham N	ursing Center, LLC
2, 7	The name and address of each person extening these process of org whother each series is executing these prices of organization in th or both. Note: This documentation be signed by all persons list	anizaila i sa followa (Sialo 19 ospacity of a memba, organizar
	Post Office Box 6338, Raleigh, NC 27628	······································
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3,	The name of the initial registered agent is: Raymond A. Parka	
4. 1	the street redecase and county of the initial registered agent office of	the limited liability company is:
	Number and Street 131 Colony Lane	
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5.	The mailing address, if different from the street eddress, of the in Number and Street	lilel registered symptofiles is:
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G.	Principal office informations (Select either a or b.)	
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CORPO (Revise	orations division P.D. Box 25522 ad Junuary 2014) 1	HALEIOH, NC 27626-0522 (Form L-01)
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This mailing address. If different from the street address, of the principal office of the company is:

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	Number and Street Post Office Box 6	80		<u>.</u>
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ATTACHMENT TO ARTICLES OF ORGANIZATION HUGH CHATHAM NURSING CENTER, ILO

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NAME AND ADDRESS OF INITIAL MEMBER

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The sole member of Hugh Chalhum Nursing Center, LLC is Hugh Chaiham Morriorial Hospital, Ina.

Rugh Chaiham Mamorlal Hospital, Inc.'s address is 180 Parkwood Drive, Bildn, NC 28621



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

Beverly Eaves Pordus, Governar Lapier M. Caosler, Scoretary	www.nodhhs.gov/dhst	Craig R. Smith, Section Chief Phone: 919-855-3875 Fax: 919-733-8139
December 9, 2011		
William R. Shenton Poyner Spuill P.O. Box 1801 Releigh, NC 27602-1801		· .
lung bypass mechines in of CSA	al Services, LLC (CSA) of 100% of its own a use at WakeMed to CSAMS Naw Born A cal Services, LLC (CSA) of 100% of its times in use at Rox Hospital to CSAMS L	averable laterests in three (3) existing
Dear Mr. Shenton:		• •
proposals. Based on the CON law i your correspondence are not governe note that if the CON law is subseque need, this determination does not au becames effective.	in client of the case of this response to 2. by, and therefore, do not currenly requi- ally emended such that the above rolerence thorize you to proceed to develop the abov	1, 2011 regarding the above referenced your request, the proposals described in ice a certificate of need. However, please ed proposals would require a certificate of so referenced proposals when the new law
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Wartha Poyner Spruill



November 21, 2011

Pattnor . D: 019.783.1140 wheyman@poynstsprika.com William R. Shoriton

Wisson Hayman

Portner D: 010.783.2047 P: 019.783.1075 wahanlon@poynareproll.com

VIA U.S. MAIL AND E-MAIL/ Craig.smilh@dhhs.nc.gov Manha.filsone@dhhs.nc.gov

Mr. Cralg R. Smith, Chief Me. Manha Frizono; Assistant Chief Division of Health Service Regulation Certificate of Need Section 2704 Mail Service Center -Releigh, North Carolina 27698-2704

RE: CBA Medical Services, LLC; No Review Request regarding Transfer of Heart-Lung Bypase Machines to Wholly Owned Subsidiaties

Dear Mr. Smith and Ms. Frisone:

This letter is submitted on behalf of CSA Medical Services, LLO (*CSA*), and two subsidiary limited tability companies to be formed and wholly owned by CSA and to be named *CSAMS New Barn Avenue, LLO" (CSA New Born), and *CSAMS Lake Boone Trail, LLO" (CSA Lake Boone), upon receipi of your approval of tide request, CSA currently owns and operates eight (8) heart-lung bypass (*HLB*) matchines, Five (6) of the HLB matchines are operated at WakeMed and three (3) of the HLB matchines are operated at Rex Hospital, Inc. (*Rex*). The purpose of this letter is to provide notice to the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Carlineate of Need Section (the "Agency"), and confirm that the transfer of CSA's interests in these eight (8) HLB matchines and the operation of the same to two wholly owned subsidiaries of CSA is not reviewable as a new institutional health service under the North Carolina Certificate of Need (*CON*) faw.

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

BACKGROUND AND FACTS ł.

CSA directly owns eight (8) Terumo Corporation Sarlas 6000 HLB machines. Five (5) of these HLB machines are located and used by CSA to provide perfusion services at WokeMed, located at 3000 New Bern Avenue, Raiolgh, NC 27620. Three (3) of these HLB machines are located end used by OSA to provide perfusion services at Rex, located at 4420 Lake Boone Trail; Raiolgh, NC 27607, CSA also owns

NALEIGH / CHARLOTTE / ROCKYISOURT / SOUTHERHPINES WWW.POYNERSPAULLCOM

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Mr. Cralg R. Smilh, Chief Ms. Matha Edsone, Aselstant Chief November 21, 2011 Page 2

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

The five (5) HLB machines at WakeMod are labeled A, B, C, D, and E, and the three (3) at Rox are labeled 1, 2, and 3. Each HLB machine consists of the following: (a) a four (4) or five (5) pump Terumo Base; (b) three (3) or four (4) Terumo 8000 roller pump modules (8000 roller pump modules); (c) one (1) Mediconic Bio-Medicus antenial pump schos 560 (Bid pump); (d) one (1) Mediconic TX 60 Flowmater (Flowmeter); and (a) one (1) Sachriet alr/oxygen mixer (Sachriet). Similarly, the saven (7) BRAT machines of WakeMed In Réleigh are labeled A, B, C, D, E, F and G, and the two at WakeMed-Gary ore labeled 1 and 2. Each HLB machine (end its components) and BRAT machine is identified by its serial numbers (SN), model numbers and the hospital where it is located, as described in Exhibit 3 to this letter.

numbers (SN), model numbers and the nospitel where it is located, as described in Exhibit 3 to this letter. The surgeons of Carolina Cardiovascular Surgical Ansociates, P.A. (Praolice), started performing open heart surgery and providing their own perfusion company owned by the same physicians. Each of the eight (a) HLB machines currently owned by CSA is replacement equipment for a machine owned by CSA (or a predecessor ontily) prior to the year 1993, when acquisition of an HLB machine became subject to CON review regardless of its cost. W. Charles Hellon, M.D., bounded the Practice in 1979 and cardinal Bio-Midical Associates, inc. (Cardinal Bio-Medical), In 1980. Cardinal Bio-Medical was the perfusion company predecessor on CSA that like CSA was owned by the shareholders of the Practice. The two hospitals have never owned the HLB machines used at their facilities. Before 1989, Cardinal Biomedical and operated three (3) HLB machines used at their facilities. Before 1989, Cardinal Biomachines at WekeMed and one (1) additional HLB machine at New, Atkinson & Zeok, M.D., P.A., marged with the Practice in 1989, and its two (2) surgion shareholders, Alvan W. Atkinson, M.D., and John V. Zeok, M.D., Joined the Practice. At the same time that three (3) HLB machines were acquired by Cardinal Bio-Medical, and they become shareholders of that perfusion (2) additional HLB machines at WekeMed and the Practice. At the same time that three (3) HLB machines were acquired by Cardinal Bio-Medical, and they become shareholders of that perfusion (2). Addinal Bio-Medical or its supersor company has continued to own and operate heat effect (8) HLB machines (6) HLB machines (6) their replacements) at their amor repeated to own and operate heat eight (8) HLB machines (6) their shareholders of Cardinal Bio-Medical reorganized the company by forming CSA and transferring the operations and all eight (8) machines to CSA, which was owned by the same surgeone.

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

The same year, CSA obtained replacement equipment for its other saven (7) HLB machines at WakeMed and Rek, at a total capital cost of \$322,699. CSA's obsolete machines were subsequently removed out of North Carolina. By letter dated Juno 25, 2004, the Agency approved CSA's acquisition of the seven (7)

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Mr. Craig R. Smith, Chief Ms. Matha Frisone, Assistent Chief November 21, 2011 Page 3

now HLB machines at WakeMed and Rox as replacement equipment. The Agency's "no review" letter of that date is allached and labeled as Exhibit 4.

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

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

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

IL ANALYSIS

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The CON law provides that the "acquisition by purchase, donation, lease, transfer or comparable errangement" of an HLB machine constitutes a "new institutional health service" that is subject to CON review. N.C. Gen. Stat. § 13/1E-176(16)/1; § 13/1E-176(a). However, we believe the creation of these two wholly owned subsidiaries is not a reviewable event because CSA, the owner of the CON rights for the eight (8) HLB machines, is not undergoing any direct change in its ownership status. Rather, this is merely a type of reorganization in the nature of these which the CON rules recognize as non-reviewable.

Until 1899, the acquiation of an HLB trachine was not regulated under the CON law unlass it involved the obligation of a capital expanditure exceeding two million dollars (\$2,000,000), which far exceeds the cost of this equipment. See N.C. Sess, Laws 1993, c. 7, § 2 (adding the acquisition of HLB machines and any 'major medical equipment' costing more than \$760,000 as 'new insilultional health services' regulated to the CON law to make the acquisition of HLB machines constitute a 'new institutional health services' regulated to the CON law to make the acquisition of HLB machines constitute a 'new institutional health services' regulated to CON regardless of lis cost. N.C. Gen. Stat. § 131E-176(10a), (15)[1.5., as amonded by N.C. Sess, Laws 1993, c. 7, § 2,

Under the CON law, transfer of ownership or control of a CON prior to completion of a project or operation of the facility constitutes grounds for withdrawal of a CON. N.C. Gen. Stat. § 131E-189. However, the Agency's rules provide that in this elluation, neither ownership nor control of a GON is (ransferred when the holder of the certificate is frequentiate and the identity of the holder changes because of corporate reorganization, including transferring ownership to wholly owned aubsidiaties. 10A N.C.A.C. 14C.0602(b)(1) and (0).

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Mr. Cralg R. Smilh, Chief Ms. Martha Frisone, Assistant Chief November 21, 2011 Page 5

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EXHIBIT

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 HOSPITAL AUTHORITY D/B/A CAROLINAS HEALTHCARE SYSTEM AND MERCY HOSPITAL, INC.

DECLARATORY RULING

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.

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The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas. HealthCare System ("CMHA") and Mercy Hospital, Inc. ("Mercy") (collectively "CHS") has requested a declaratory ruling as to the applicability of Chapter 131E, Article 9 of the North Carolina General Statutes, and of the Department's rules, to the facts described below. Specifically, CMHA and Mercy request a Declaratory Ruling allowing the hospital facilities situated on the "Mercy Vail Avenue Campus," at 2001 Vail Avenue, Charlotte, NC 28207 (License # H0042), as well as some specific off-campus outpatient services, to be relicensed as part of Carolinas Medical Center's license (License # H0071) without first obtaining a Certificate of Need ("CON"), and allowing the good cause transfer of any outstanding CONs issued to Mercy-related CON projects. This ruling will be binding upon the Department and the entity 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. Gary S. Qualls of K&L Gates LLP has requested this ruling on behalf of CHS and has provided the material facts upon which this ruling is based.

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STATEMENT OF THE FACTS

Mercy owns and operates two separate hospital campuses which are operated under the single "Mercy/Pineville License" (License # H0042). One Mercy Hospital campus, the "Mercy Vail Avenue Campus," is located at 2001 Vail Avenue, Charlotte, NC 28207. Another Hospital campus, the "Pineville Campus," is located at 10628 Park Road, Pineville, NC 28210. CMHA owns and operates, among other hospitals, Carolinas Medical Center ("CMC") at 1000 Blythe Blvd., Charlotte, NC 28232 (License # H0071). CMHA is also the parent company for Mercy.

CMHA and its controlled affiliate Mercy have determined that operational and clinical efficiencies will be gained by shifting the Mercy Vail Avenue Campus, and some off-campus outpatient services, from the Mercy/Pineville License (License # H0042) to the CMC license (License # H0071). The off-campus outpatient services that will move from the Mercy/Pineville license are: (1) Carolinas Sleep Services-Mercy, (2) Carolinas Wound Care Center, (3) SEPC at Museum Medical Plaza.

CHS also requests a transfer of good cause of any outstanding CONs issued to Mercy. The change in outstanding Mercy/Pineville-related projects includes: (1) F-8771-12 CMC-Mercy MRI Replacement (will be licensed as part of CMC after the licensure change), (2) F-8763-11 CMC-Mercy 38 Acute Care Beds (will be licensed as part of CMC after the licensure change), (3) F-8704-11 CMC-Mercy 66 Bed Behavioral Health Hospital (will be licensed as part of CMC after the licensure change), (4) F-8640-11 and F-8764-11 Relocate LTACH beds to Pineville (will still be licensed under the Mercy/Pineville License on the Pineville campus), (5) F-8740-11 CMC-Providence Satellite ED (will still be licensed under the Mercy/Pineville License) and (6) F-7979-07 CMC-Pineville Phase II (will still be licensed under the Mercy/Pineville License on the Pineville campus).

ANALYSIS

The CON statute sets forth the following definitions of new institutional health services:

- (16) "New institutional health services" means any of the following:
 - a. The construction, development, or other establishment of a new health service facility.
 - c. Any change in bed capacity as defined in G.S. 131-176(5)

N.C. Gen. Stat. § 131E-176(16) (a) and (c).

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On July 15, 2002, the Department issued a Declaratory Ruling to WakeMed to split the WakeMed Raleigh and WakeMed Cary campuses into two separately licensed hospitals, where those facilities had previously operated under a single license. Since the WakeMed transaction, which created a new license did not require a CON, it can be assumed that the Mercy relicensing transaction requested herein which does not create a new license should not require a CON. The placing of Mercy Vail Avenue Campus under the CMC license does not involve any new institutional health service definitions requiring a CON. The relicensing transaction does not constitute the construction, development, or establishment of a new health service facility. The proposed transaction does not constitute a change in bed capacity as defined by N.C. Gen. Stat. § 131B-176(16)(c) and 176(5) in that no beds are being relocated from one licensed facility or campus to another, no health service facility bed capacity is being redistributed among the .categories of health service facility beds and there are no increases in the number of health service facility beds, which would require CON review.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that Carolinas HealthCare System and Mercy Hospital, Inc. be allowed to relicense hospital facilities situated on the Mercy Vail Avenue Campus and some specific off-campus outpatient services from the Mercy Vail Avenue Campus license (License # H0042) to the Carolinas Medical Center's license (License # H0071) including a transfer of good cause for any undeveloped CONs issued to Mercy/Pineville. The proposed licensure change has been determined to be in material compliance with representations in the respective applications.

This the $2^{\mu^{\mu}}$ day of November, 2012.

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 electronic 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

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

This the 2^{nd} day of November, 2012.

Cherry Ourer

Cheryl Ouimet, Chief Operating Officer

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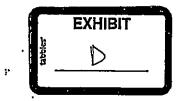
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North Carolina Department of Health and Human Services Division of Facility Services Office of the Director

2701 Mail Service Center • Raleigh, North Carolina 27699-2701 Robert J.

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

July 15, 2002

Robbië Röberts, Manager Market Planning WakeMed Post Office Box 14465

Raleigh, North Carolina 27620-4465

Re: Declaratory Ruling for WakeMed

Wake County

Dear Mr. Roberts:

Michael F. Easley, Governor Carmon Hooker Odom, Secretary

> I am enclosing a Declaratory Ruling that you requested in your letter received on May 15, 2002. If questions arise, do not besitate to let me know.

> > Sincerely,

Nobert A. F. Fran Robert J. Fitzgerald

. RJF:JR5:cjp

Enclosure .

cc: Jackie R. Sheppard, Chief Operating Officer, DFS Steve White, Chief, Licensure and Certification Section Lee Hoffman, Chief, Certificate of Need Section William Warren, Chief, Construction Section James Wellons, Attorney General's Office



Location: 701 Barbour Drive & Dorothea Dix Hospital Campus & Raleigh, N.C. 27603 . An Equal Opportunity / Affirmative Action Employer 踏

NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES DIVISION OF FACILITY SERVICES RALEIGH, NORTH CAROLINA

IN RE: REQUEST FOR DECLARATOR: RULING BY WAKEMED

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DECLARATORY RULING

I, Robert J. Fitzgerald, Director of the Division of Facility Services ("Agency"), do hereby issue this Declaratory Ruling pursuant to GiSz Sil SOB-4 and 10 NCAC 3B .0310, and the authority delegated to me by the Secretary of the Department of Health and Human Services. WakeMed asked the Agency to issue a ruling as to the applicability of the Certificate of Need Statute contained in G.S. §131E-176(16)(a) and G.S. §131E-178(a) to the facts described below. For the reasons given below I conclude that these portions of the Statute are not applicable with regard to WakeMed's intent to separately license its New Bern Avenue Campus ("Main Campus") and Western Wake Medical Center ("WWMC") facilities. Furthermore, I conclude that historical acute care utilization data for the last five years for the two hospitals be separately included in the *State Medical Facilities Plan* ("SMFP").

STATEMENT OF THE FACTS

WakeMed is licensed by the Department of Health and Human Services, Division of Facility Services, Licensure and Certification Section, Acute Care and Home Care Branch, as one facility with multiple sites.

WakeMed is licensed for a total of 629 acute care beds. These beds are contained on two separate locations – the Main Campus in Raleigh, with 515 acute care beds, and WWMC ' in Cary, with 114 acute care beds. Both facilities are located in Wake County:

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rable 2 – Acute Care Utilization at WWMC Since December	1991
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		· Percent
Fiscal Year "	: Patient Days	Utilization
1.992 (10 months)	6,078	20.8%
1993	10,511	. 36.0%
1994	11,508	· · · 39.4%.
1995	13,352	45.7%
1996	13,030	44.6%
1997 : .	13,640	· · 46.7%
1998	16;492	
1999 .	18,161	<u>: - · · 62.2%</u>
2000	: 20,432	59.6%
2001	24,945	. 72:7%
2002 (6 months prorated)	25,910	75.5%

:(Source of FYs 1992-2001 data: Annual License Renewal Applications on file with the Agency; Source of FY 2002 data: WakeMed. Please note that WakeMed's fiscal year is October 1-September 30.)

(11)

WakeMed wishes to license the Main Campus and WWMC under separate hospital

licenses for reporting and other internal administrative purposes. No changes in services,

staffinig, administration or other aspect of management, costs or charges would result

from licensing these two hospitals separately. However, doing so might technically be

interpreted as the offering of a new institutional health service, via provisions in the

Certificate of Need Statute contained in G.S. §131E-178(a), as follows:

(a) No person shall offer or develop a new institutional health service without first obtaining a certificate of need from the Department; provided, however, no hospital licensed pursuant to Article 5 of this chapter that would serve a minority population that would not otherwise have been served and that continues to serve a minority population may be required to obtain a certificate of need for transferring up to .65 beds to nursing care facility beds.

G.S. §131E-176(16) defines à "new institutional health service", in part, as follows:

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a. The construction, development or other establishment of a new health service facility.

In this request, WakeMed maintains that separate licensure of WWMC would not constitute a "change in bed capacity", as defined by G.S. §131E-176(5). No licensed beds would be relocated, nor would this proposal result in any change in the number of health service facility beds in the WakeMed system or in the Wake County Multi-Hospital Service System.

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WakeMed's request that the Agency issue a Declaratory Ruling described above is based upon the following: (1) Neither the WakeMed Main Campus nor WWMC are new health service facilities for

ANALYSIS

Certificate of Need law purposes The Main Campus opened in 1961; WWMC opened in . 1991. At the time of the opening of WWMC, it could have been separately licensed from the Main Campus without further certificate of need review.

Separate licensure of the Main Campus and WWMC would not affect government reimbursement, because both facilities currently maintain; and will continue to maintain; separate Medicare and Medicaid provider numbers.

Separate licensure of the Main Campus and W.WMC would not impact medical staff organization and composition at either facility, because these facilities have, and have always had, separate medical staffs. Separate licensure of the Main Campus and WWMC would not impact accreditation, because both facilities are separately surveyed and accredited by the JCAHO.

(4)

(5)

(6)

(7)

(8)

Separate licensure of the Main Campus and WWMC would not affect the governance of either facility, because there would be no resultant change in ownership from this proposal.

Separate licensure of the Main Campus and WWMC would not change the inventory of licensed acute care beds, either in the WakeWied system or in the Wake County Multi-Hospital Service System.

Separate licensure of the Main Campus and WWMC would not impact the reporting of acute care bed utilization data, as this data would continue to be reported to the Agency annually.

Any future capital expenditures and/or services requiring a CON pursuant to G.S. §131E-175 et seq. at either the Main Campus or WWMC would continue to be obtained through the CON process.

CONCLUSION For the reasons stated above and specific facts presented, I conclude that the separate licensure of Western Wake Medical Center from the WakeMed Main Campus does not

constitute a new institutional health service or otherwise require a certificate of need under the

applicable portions of the Certificate of Need Statute, specifically G.S. §131E-176(16)(a) and

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G.S. §131E-178(a). In particular, I find persuasive the facts and circumstance that, other than the common licensure, these two hospitals were organized and have historically functioned as separate facilities. Moreover, since the only change resulting from this separate licensure status is the separation of utilization data and operating statistics on the annual License Renewal.

Application submitted to the Agency, I have determined that requiring a certificate of need in this instance would be an overly connected and not not in the Agency should recognize the historical utilization data for the past five years by licensed hospital in the SMIFP; i.e., recognize utilization data for the Main Campus and for WWMC as separate hospitals under

common ownership.

WakeMed's acute care, rehabilitation, outpatient and skilled nursing facilities shall be

· licensed as follows:

Table 3: Licensure of WakeMed Facilities

Licensed Under Main		Licensed Under ···	· · · · · · · · · · · · · · · · · · ·
Campus:	Location	WWMC: .	Location
.WakeMed New Bern	3000 New Bern Ave	WakeMed Western	1900 Kildaire Farm Rd,
Avenue Campus	Raleigh, NC 27610	Wake Medical Center	Cary, NC 27511
WakeMed Rehab	3000 New Bern Ave.	WakeMed Fuquay-	400 W. Ransom St.
	Raleigh, NC 27610	Varina	Fuquay-Varina, NC 27526
	-535 W. Gannon Ave.		
Zebulon/Wendell	Zebulon, NC 27597		
WakeMed North	10000 Falls of Neuse Rd.	(· ·	
	Raleigh, NC 27614	· · · · · · · · · · · · · · · · · · ·	

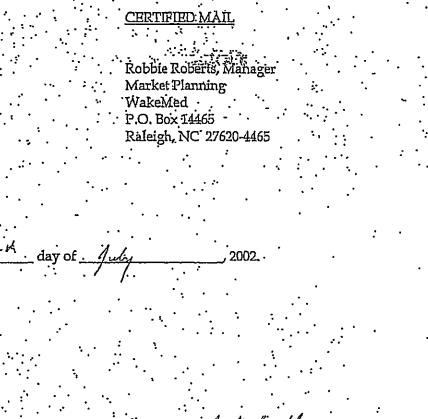
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This is the

Robert J. Fitzgerald, Director Division of Facility 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:



This the

Jackie R. Sheppard Chief Operating Officer

Exhibit 2

STATE OF NORTH CAROLING Department of Health and Human Services Division of Health Service Regulation

CERTIFICATE OF NEED

for Project ID #: 0-11292-17 FID #: 170020

ISSUED TO: Vidant Radiation Oncology, LLC P.O. Box 6028 Greenville, NC 27835-6028

Pursuant to N.C. Gen. Stat. §131E-175, 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, as documented by the periodic progress reports required by 10A NCAC 14C .0209. 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: Relocate five existing linear accelerators, two from NC Radiation Therapy Center and three from Leo Jenkins Cancer Center (replacing four) to a new outpatient cancer center at Vidant Medical Center which is currently under construction for a total of five linear accelerators upon project completion/ Pitt County

CONDITIONS: ' See Reverse Side

PHYSICAL LOCATION: Vidant Radiation Oncology Center at Vidant Medical Center 2100 Stantonsburg Road Greenville, NC 27834

MAXIMUM CAPITAL EXPENDITURE: \$24,159,964

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: November 1, 2017

This certificate is effective as of the 25th day of April. 2017

CONDITIONS:

- 1. Vidant Radiation Oncology, LLC shall material comply with all representation made in the certificate of need application.
- 2. Vidant Radiation Oncology, LLC shall acquire no more than four linear accelerators, including a CyberKnife, to replace four of the existing five linear accelerators being relocated to Vidant Radiation Oncology Center at Vidant Medical Center. The applicant shall dispose of the four existing linear accelerators being replaced by removing them from North Carolina.
- 3. Vidant Radiation Oncology, LLC shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditures in Section F of the application and that would otherwise require a certificate of need.
- 4. Vidant Radiation Oncology, LLC shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.
- 5. Vidant Radiation Oncology, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to 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 Agency on April 5, 2017.

TIMETABLE:

Phase 1 (Replace and Relocate Four Linear Accelerators, Inclu	uding the CyberKnife)
Equipment Ordered	August 5, 2017
Construction Contract Executed/Contract Award	November 1, 2017
25% Completion of Construction	December 1, 2017
50% Completion of Construction	January 1, 2018
75% Completion of Construction	February 1, 2018
Completion of Construction	March 15, 2018
Occupancy/Offering of Services	April 1, 2018
Phase 2 (Relocate the Fifth Linear Accelerator)	
Construction Contract Executed/Contract Award	May 1, 2019
25% Completion of Construction	June 1, 2019
50% Completion of Construction	July 1, 2019
75% Completion of Construction	August 1, 2019
Completion of Construction	September 1, 2019
Occupancy/Offering of Services	October 1, 2019

From:	<u>Waller, Martha K</u>
То:	<u>Stancil, Tiffany C</u>
Cc:	Shovelin, Jeffrey
Subject:	FW: [External] Letter of No Review Request - Vidant Radiation Oncology, LLC
Date:	Tuesday, December 12, 2023 11:36:09 AM
Attachments:	VRO Letter of No Review (Final Submitted).pdf

Hey Tiffany...for processing...

Martha Waller

Administrative Specialist 1 Division of Health Service Regulation, Certificate of Need Section North Carolina Department of Health and Human Services

Main: 919-855-3873 Office: 919-855-3885 martha.waller@dhhs.nc.gov

Help protect your family and neighbors from COVID-19. <u>Know the 3 Ws. Wear. Wait. Wash.</u> #StayStrongNC and get the latest at <u>nc.gov/covid19</u>

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From: Shovelin, Jeffrey <JShoveli@ecuhealth.org>
Sent: Tuesday, December 12, 2023 11:09 AM
To: Waller, Martha K <martha.waller@dhhs.nc.gov>
Subject: [External] Letter of No Review Request - Vidant Radiation Oncology, LLC

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Ms. Waller,

Attached is a Letter of No Review request for our planned acquisition of 100% membership interest in Vidant Radiation Oncology. Please confirm receipt and if anything else is needed. Thank you!

Jeff Shovelin VP - Business Planning & Strategy ECU Health PO Box 6028 Greenville, NC 27835-6028 Office: (252) 847-3631 / Cell: (252) 714-5156 jshoveli@ecuhealth.org