



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

Pat McCrory  
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Secretary DHHS

Mark Payne  
Assistant Secretary for Audit and  
Health Service Regulation

**VIA HAND DELIVERY**

March 8, 2016

Gary S. Qualls  
K&L Gates

**Exempt from Review – Acquisition of Facility**

**Record #:** 1886  
**Facility Name:** The Prostate Health Center  
**Type of Facility:** Diagnostic Center  
**FID #:** 070602  
**Acquisition by:** Rex Radiation Oncology, LLC  
**Business #:** 2359  
**County:** Wake

Dear Mr. Qualls:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) determined that based on your letter of March 7, 2016, the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-184(a)(8). Therefore, Rex Radiation Oncology, LLC may proceed to acquire the above referenced health service facility without first obtaining a certificate of need. Note that pursuant to G.S. 131E-181(b): *“A recipient of a certificate of need, or any person who may subsequently acquire, in any manner whatsoever permitted by law, the service for which that certificate of need was issued, is required to materially comply with the representations made in its application for that certificate of need.”*

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

Sincerely,

Martha J. Frisone,  
Assistant Chief, Certificate of Need

cc: Kelli Fisk, Program Assistant, Healthcare Planning, DHSR



**Healthcare Planning and Certificate of Need Section**

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March 7, 2016

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**VIA HAND DELIVERY**

Ms. Martha Frisone, Assistant Chief Certificate of Need  
Healthcare Planning and Certificate of Need Section  
Division of Health Service Regulation  
Department of Health and Human Services  
809 Ruggles Drive  
Raleigh, NC 27603



Re: No-Review Request and Exemption Notice for Rex Radiation Oncology, LLC to acquire the Prostate Health Center, Wake County

Dear Martha:

We are writing on behalf of our client Rex Radiation Oncology, LLC (“RRO”). RRO is a wholly owned subsidiary of Rex Hospital, Inc. The purpose of this letter 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” or “CON Section”) of RRO’s planned acquisition of The Prostate Health Center (the “Center”), a multi-disciplinary prostate care center demonstration project, currently owned and operated by Carolina Specialty Oncology, P.A., *formerly named* Parkway Urology, P.A (“Carolina Specialty” or “Parkway”). We ask that the Agency confirm that this transaction (the “Transaction”) is exempt and/or not reviewable as a new institutional health service under the North Carolina Certificate of Need (“CON”) law.

**I. BACKGROUND**

By way of background, Carolina Specialty currently operates the Center pursuant to a CON for Project I.D. No. J-8331-09 to develop and operate a diagnostic and therapeutic multi-disciplinary prostate health demonstration project, including a linear accelerator (“linac”) and computerized tomography (“CT”) simulator. See The Prostate Health Center CON, attached as Exhibit 1.<sup>1</sup> RRO seeks to obtain full ownership of the operational assets of the Center, including its existing linear accelerator and CT simulator. After the Transaction, RRO will continue to

<sup>1</sup> On the CON, The Prostate Health Center’s physical location was listed as “Waverly Drive,” the location used in its CON Application. Subsequently, through a Declaratory Ruling, dated August 2011, a site composed of three contiguous parcels of land located at 117 Sunnybrook Road (PIN 1723397021), 0 Carl Sandberg Court (PIN 1723399011), and 200 Michael J. Smith Lane (PIN 1723482960) in Raleigh, NC 27610 was approved as a new location. The Prostate Health Center uses 117 Sunnybrook Road, Raleigh, NC as its address.

operate the Center in material compliance with requirements of its CON, including providing diagnostic, planning, and therapeutic services, in the same location.<sup>2</sup>

## II. EXEMPTION NOTICE

The proposed Transaction involves RRO acquiring the entire Center. Due to the dual diagnostic and therapeutic functions of the Center, it serves as both a freestanding diagnostic center and a freestanding oncology treatment center. As “an existing health service facility,” this project is exempt from CON review.

Under North Carolina law, a CON is required only prior to offering or developing a “new institutional health service.” The North Carolina General Assembly saw fit to exempt certain types of services or proposals from CON review, pursuant to N.C. Gen. Stat. § 131E-184. One such exempt service or proposal includes the acquisition of “an existing health service facility, including equipment owned by the health service facility at the time of acquisition.” N.C. Gen. Stat. § 131E-184(a)(8).

The proposed Transaction involves the acquisition of an existing diagnostic center, which falls within the purview of the statutory definition of “health service facility.” See N.C. Gen. Stat. § 131E-176(9b). A “diagnostic center” is defined as:

a freestanding facility, program, or provider, including **but not limited to**, physicians' offices, clinical laboratories, radiology centers, and mobile diagnostic programs, in which the total cost of all the medical diagnostic equipment utilized by the facility which cost ten thousand dollars (\$10,000) or more exceeds five hundred thousand dollars (\$500,000). In determining whether the medical diagnostic equipment in a diagnostic center costs more than five hundred thousand dollars (\$500,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater.

N.C. Gen. Stat. § 131E-176(7a).

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<sup>2</sup> After the Transaction, Carolina Specialty will continue to own the building housing The Prostate Health Center, which will be leased to RRO.

The Center's multidisciplinary nature provides both diagnostic and therapeutic services. One service component of the Center is cancer diagnosis and clinical staging to determine the extent of a disease and determine appropriate treatment. Diagnostic and planning services are also provided by radiation oncologists working with the interdisciplinary team. The diagnostic and planning services include use of a CT simulator to evaluate the size of the tumor, take measurements, assess where the cancer is likely to spread, and identify normal tissues in the treatment area. See Excerpts of Parkway's CON Application for The Prostate Health Center, attached as Exhibit 2. The Prostate Health Center includes a Siemens Somatom Emotion 6 CT simulator, which costs \$555,000. See Quotation for Siemens Somatom Emotion 6 CT simulator, attached as Exhibit 3.

The linear accelerator also has planning and diagnostic functions, as it includes an add-on Varian On-Board Imager. The imager allows the radiation therapist to take high-definition digital images of the patient prior to treatment. This serves diagnostic and planning purposes, allowing the physician to clearly view the treatment area, diagnose and plan the treatment margins, and appropriately position the patient for treatment. The cost of the Varian On-Board Imager was \$348,518. See Invoice for Varian On-Board Imager, attached as Exhibit 4.

Equipment	Cost
<i>Siemens Somatom Simulator</i>	\$555,000
<i>Varian On-Board Imager</i>	\$348,518
Total	\$ 903,518

The cost of these two pieces of medical diagnostic equipment thus exceeds the diagnostic center threshold of \$500,000. Note that these costs do not include costs of construction, installation, and other activities essential to acquiring or making the equipment operational. When those costs are considered, the total cost further exceeds the diagnostic center threshold. Thus, because this Transaction involves the acquisition of an existing health service facility, it is exempt from CON review.

### **III. THE PROPOSED TRANSACTION IS NOT SUBJECT TO CON REVIEW**

The proposed Transaction is not subject to CON review for additional reasons. Prior to August 26, 2005, the acquisition of an oncology treatment center was exempt from CON review, because oncology treatment centers were "health service facilities" as defined in N.C.G.S. § 131E-176(9b). As discussed in Section II above, the acquisition of a health service facility is exempt from CON review under N.C. Gen. Stat. § 131E-184(a)(8). Session Law 2005-325 de-regulated oncology treatment centers, eliminating them from the category of health service facilities, effective August, 26 2005. Since buying an entire oncology treatment center was previously exempt from CON review, and the legislature subsequently acted to further de-regulate those facilities, the logical conclusion is that the acquisition of such a center today does not require CON review.



The proposed Transaction is consistent with prior Declaratory Rulings and No Review Decisions that found no CON was required for a new entity assuming ownership of an oncology center and/or CON regulated equipment therein, including linacs.<sup>3</sup> Although the Transaction is structured somewhat differently from prior rulings (being an asset purchase instead of a purchase of membership interest in the existing entity), the end result is the same. Specifically, the proposed Transaction does not involve the offering or expansion of any new facility, service, or equipment, and the State's and service area's linac inventory will not change. No new or additional linacs will be acquired or added to Linear Accelerator Service Area 20, as defined by the State Medical Facilities Plan ("SMFP"). The Prostate Health Center will continue to operate in the same location and in the same manner as it did prior to the Transaction. RRO will be bound by the same terms of the demonstration project that Carolina Specialty was bound to under CON #J-8331-09.

In this regard, this proposal is similar to prior Agency decisions finding that no CON review is required when a facility obtains a separate, independent license. Like in this case, in those requests and decisions, the location, services, and inventory of CON regulated items did not change, which rendered the addition of a new facility license immaterial. See No Review Request to Independently License Rex Rehabilitation & Nursing Center of Raleigh, attached as Exhibit 10; No Review Request to Transfer Control of Hugh Chatham Nursing Center to Wholly Owned-Subsidiary, attached as Exhibit 11. Here, we request that the Agency find that the transfer of the Center from Carolina Specialty to RRO is likewise not a CON reviewable activity, based on the same logic that the Transaction will not result in any change in the location, inventory, or services provided on CON regulated items.

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<sup>3</sup> See Declaratory Ruling for The Charlotte-Mecklenburg Hospital Authority, attached as Exhibit 5; In re: Request for Declaratory Ruling by Wake Radiation Oncology Services, PLLC, et al., attached as Exhibit 6; In re: Request for Declaratory Ruling by Radiation Therapy Services, Inc., et al., attached as Exhibit 7; 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 8; 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 9.

Ms. Martha Frisone, Assistant Chief, Certificate of Need Section  
March 7, 2016  
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**IV. CONCLUSION**

Based on the foregoing information, we hereby request the Agency's written confirmation that the proposed Transaction described above does not require CON review, and/or is exempt from CON review, pursuant to N.C. Gen. Stat. § 131E-184(a)(8).

If you require any additional information regarding this request, please contact us. We appreciate your consideration of this request.

Sincerely,



Gary S. Qualls

## EXHIBITS

1. CON for Project I.D. No. J-8331-09
2. Excerpts from Parkway's CON Application for The Prostate Health Center
3. Invoice for Siemens Somatom Emotion 6 CT simulator
4. Invoice for Varian On-Board Imager
5. *Declaratory Ruling for The Charlotte-Mecklenburg Hospital Authority,*
6. *In re: Request for Declaratory Ruling by Wake Radiation Oncology Services, PLLC, et al.*
7. *In re: Request for Declaratory Ruling by Radiation Therapy Services, Inc., et. al.*
8. *No Review/WakeMed/Acquisition of Ownership Interest of CSA-1, Owners of Five Heart-Lung Bypass Machines Located in WakeMed/Wake County*
9. *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*
10. *No Review Request to Independently License Rex Rehabilitation & Nursing Center of Raleigh*
11. *No Review Request to Transfer Control of Hugh Chatham Nursing Center to Wholly Owned-Subsidiary*



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

**CERTIFICATE OF NEED**

for

Project Identification Number #J-8331-09

FID #090277

**ISSUED TO: Parkway Urology, PA d/b/a Cary Urology, PA**  
**105 SW Cary Parkway, Suite 300**  
**Cary, NC 27511**

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

**SCOPE: Parkway Urology, PA d/b/a Cary Urology, PA shall acquire a linear accelerator and develop a multidisciplinary prostate health center demonstration project in Raleigh/ Wake County**

**CONDITIONS: See Reverse Side**

**PHYSICAL LOCATION: The Prostate Health Center**  
**Waverly Drive**  
**Raleigh, NC 27610**

**MAXIMUM CAPITAL EXPENDITURE: \$9,771,773**

**TIMETABLE: See Reverse Side**

**FIRST PROGRESS REPORT DUE: July 1, 2011**

This certificate is effective as of the 23<sup>rd</sup> day of February, 2011.

*Craig R. Smith*

Chief, Certificate of Need Section  
 Division of Health Service Regulation

**CONDITIONS:**

1. Parkway Urology, PA, d/b/a Cary Urology, PA shall materially comply with all representations made in the certificate of need application.
2. Parkway Urology, PA, d/b/a Cary Urology, PA shall acquire no more than one linear accelerator, one computed tomography (CT) simulator, one digital ultrasound unit, and one brachytherapy unit as part of this project.
3. Parkway Urology, PA, d/b/a Cary Urology, PA shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditures in Section VII of the application or that would otherwise require a certificate of need.
4. Parkway Urology, PA, d/b/a Cary Urology, PA shall develop an organized African American Prostate Cancer Education/Outreach Program that partners with and complements existing initiatives, such as the NC Minority Prostate Cancer Awareness Action Team.
5. Parkway Urology, PA, d/b/a Cary Urology, PA shall develop an Advisory Board composed of representatives of prostate cancer advocacy groups, prostate cancer patients and survivors that meets regularly and provides feedback about effective practices or changes that need to be made.
6. Parkway Urology, PA, d/b/a Cary Urology, PA shall prepare an annual report at the end of each of the first three operating years, to be submitted to the Medical Facilities Planning Section and the Certificate of Need Section, that shall include:
  - The total number of patients treated;
  - The number of African-Americans treated;
  - The number of other minorities treated; and
  - The number of insured, underinsured and uninsured patients served by type of payment category.
7. Parkway Urology, PA, d/b/a Cary Urology, PA shall make arrangements with a third party researcher (preferable a historically black university) to evaluate the efficacy of the model during the fourth operating year of the Center and develop recommendations whether or not the model should be replicated in other parts of the State. The report and recommendations of the researcher shall be provided to the Medical Facilities Planning Section and the Certificate of Need Section in the first quarter of the fifth operating year of the project.
8. Parkway Urology, PA, d/b/a Cary Urology, PA 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 Certificate of Need Section on October 2, 2009.

**TIMETABLE:**

Completion of Final Drawings and Specifications	September 1, 2011
Approval of Site by Construction Section, DHSR	February 1, 2012
25% completion of Construction	August 1, 2012
75% completion of Construction	February 1, 2013
Occupancy/Offering of Service(s)	June 1, 2013



II. SCOPE OF SERVICES/QUALITY OF CARE

- 1. (a) Describe each service component included in the proposed project (e.g., acute care beds, Emergency Department, Radiology, Laboratory, MRI scanner, CT scanner, operating rooms, etc.).

Proposed Project

Cary Urology is proposing to expand its urological health services by development of The Prostate Health Center. The Prostate Health Center will involve medical, research, therapy and social service disciplines in detection, treatment and aftercare management of people with or at risk of prostate cancer. Cary Urology proposes to house the multidisciplinary services in a newly constructed 12,315 square foot facility located in Raleigh, North Carolina. The proposed sites are easily accessible to residents of the service area, participating team member clinicians, other health care providers and minority communities. Part of the center will be a medical office building intended to house offices of clinicians and other specialists

The applicant has identified several suitable properties in Raleigh near WakeMed-Raleigh hospital. Please see Exhibits 4, 5 and 6 for a map showing locations for Wake County urologists, a map showing relationship to Raleigh African-American communities, and for transportation routes that serve the proposed locations. These maps support the suitable proposed locations.

The Prostate Health Center will be a state-of-the art ambulatory care facility primarily for treatment of men with prostate cancer. The center will also treat some patients who have urologic cancers. Male urologic cancers include prostate, bladder, kidney and male sexual organs. The Prostate Health Center will be dedicated to developing leading-edge care for persons with and at risk of prostate cancer.

The multidisciplinary Prostate Health Center will include programs designed to increase awareness about factors associated with maintaining healthy prostate organs, cancer prevention, early detection and post-treatment lifestyle management. It will also include cancer staging, prostate treatment, and continuing care. Clinicians from the fields of urology, medical oncology, radiation oncology and counseling/therapy will collaborate, bringing patients the most promising advances in medical, radiation and surgical treatments, including targeted therapies, chemotherapy, hormone therapy, radiation



therapy and minimally invasive and ablative surgery. These diverse expert disciplines will engage in the patient care as a team, often consulting together with the patient or in team conferences.

One goal of The Prostate Health Center's multidisciplinary team is to bring resources to the patient as much as possible. For services the center cannot provide, the center will employ trained clinicians to act as journey coordinators; they will be assigned to specific patients and will function as a single point of contact for patients and a communicator with other providers in the care continuum, including the patients' primary care providers. The intent is to maintain continuous connection between patient and providers throughout the care process.

Another goal is to consolidate / connect elements of the patient's medical record. Electronic medical records, web conferencing and face to face consults will be employed to share information on diagnostic tests, procedures, and therapeutic regimens among participating clinicians in the fields of urology, radiation, chemotherapy, nursing, biofeedback therapy, counseling and after care. This will contribute to clear communication among specialists, better care coordination, improved communication with patients and their support networks, with the goal of better overall outcomes.

Treatment of prostate cancer can involve brachytherapy, hormone therapy with testosterone suppression, surgical removal of the prostate, external beam radiation and chemotherapy, or combinations of these treatments. Each patient has different clinical conditions and each requires an understanding of the options and sufficient guidance to participate in making informed choices.

### Equipment

#### *Linear Accelerator*

The applicant proposes to acquire the Varian Clinac "iX" with On Board Imager (OBI) and RapidArc linear accelerator (or equipment that is equivalent at time of acquisition). See Exhibit 7 for the vendor quote and specifications. The Clinac® iX, an innovative platform for today and a solid foundation for the future, is capable of providing patients with today's most advanced treatments and adapting to tomorrow's advances.

With a streamlined workspace and true hardware and software integration, the Clinac iX has efficiency, quality and customization built in. This efficiency allows delivery of more exacting treatments faster, using image guidance every step of the way. The combination of quality and customization ensures that future technological breakthroughs and upgrades are more convenient and affordable.

The proposed system includes:

- 120 Leaf Millennium Multileaf Collimator and collimator accessory system-adjusts the size and shape of the computer-determined radiation beams. The collimator, a computer-controlled mechanical device, consists of 120 individually adjusted metal leaves. These leaves move across the irradiated tissue while the beam is on, blocking out some areas and filtering others to vary the beam intensity and precisely distribute the radiation dosage. Conformity and precision of the block is increased by a collimator with the higher number of smaller leaves.
- PortalVision aS500-II for high performance, high resolution, high contrast images with the MV treatment beam using less dose to the patient for both simple and complex treatments including IMRT.
- On-Board Imager to provide high quality kV images of real-time accurate anatomical detail for target localization, patient positioning and motion management in the treatment room. Cone-beam CT acquires a volumetric CT dataset, while the patient is on the treatment couch, and allows the patient to be repositioned - by comparing the locations of soft-tissue and bony anatomy visible in the cone-beam CT images with the locations of the same anatomy in the planning (reference) CT images. The OBI is a necessary component for IGRT.
- RapidArc delivery for a single linear accelerator provides the Varian accelerator with the capability to simultaneously modulate aperture shape, dose rate, and gantry speed continuously through 360 degrees of gantry rotation, during an arc beam delivery. It provides the capability to generate IMRT-quality dose distributions in a single, optimized arc around the patient.

- 4D Integrated Treatment Console gX – provides a streamlined front end to the treatment delivery process. The 4D console integrates the user controls of the linear accelerator, multi-leaf collimator and electronic portal imager into one application on a single workstation and provides the imaging control to manage advanced treatment processes such as 3D CRT, IMRT and Dynamic targeting IGRT.
- Portal Dosimetry – provides capability to perform pre-treatment IMRT quality assurance. It aids in immediate and confident setup verification for both simple and complex treatments including IMRT. High resolution images allow the oncologist and dosimetrist to view treatment field edges and included anatomy and surrogate targets more easily. With this feature, systematic errors may be calculated and later eliminated or reduced, which in turn helps to speed the delivery and improve the accuracy of conformal and IMRT treatment delivery.
- Eclipse Treatment Planning System – Treatment planning software which includes multi-modality image support, image registration and blending, clinical protocols, advanced segmentation, virtual simulation, beam placement, plan evaluation, electronic plan approval, electronic chart and configurable printing of plan documentation which 2D and 3D dose calculation on a distributed calculation framework including beam configuration, IRREG, 3D conformal and field in field planning using Anisotropic Analytical Algorithm (AAA) or pencil beam convolution, and electron calculation using Generalized Gaussian Pencil Beam. It also features 2D BrachyVision for film based brachytherapy planning.
- IMRT Planning package including beam angle optimization, Interactive IMRT optimization, electronic surface compensation and planar compensation. Support either split carriages or large-field IMRT.
- ARiA Database – maintains patient records system, and stores clinical patient information, and communicates with the linear accelerator
- Additional software, Servers, workstation and monitors

New clinical capabilities of the system include:

- IMRT and IGRT
- Versatility to offer treatment protocols tailored to the individual patient's biologic model, including high-dose-rate therapy for hypofractionation or to provide high doses to small treatment areas or
- Low-dose-rate therapy to minimize patient side effects when large volumes are treated
- Exact alignment
  - Tight isocenter alignment of gantry, couch, collimator, and imagers
  - Reproducible, stable, and accurate positioning
- Automated Imaging
  - Automated image acquisition
  - Reproducible online image matching
  - Remote control of imager position

Convenience and efficiency details include:

- Exact Couch treatment table
  - Robust, advanced carbon fiber composite construction optimized for IMRT and IGRT
  - Ultra precise imaging and patient positioning
- Workstations
  - At-a-glance system monitoring
  - Easy upgrades
- Efficient command center
  - Fewer controls to manage
  - Designed to follow workflow
  - Ergonomically designed for therapist comfort
  - Packaged for easy installation

In addition, Clinac iX offers all the features needed to achieve an image guided platform:

- Exact alignment between imaging and treatment isocenters
- Exact™ Couch positioning accuracy
- Best-in-industry beam delivery performance

The quote includes a tuition paid education course for one person to either a four-day course geared toward radiation therapists and radiation oncologists or a three-day course designed for those personnel responsible for the equipment maintenance, physicists and biomedical engineers. It also includes on-site Clinac iX Operations training for up to eight users. The applications training includes up to a two-day clinical training focusing on operations of the Clinac, Exact couch and Millennium MLC, Portal Varian Image acquisition and treatment methodologies to promote safe clinical operation of the Clinac.

OBI training is also provided for the physicist and radiation therapist. A four and a half-day course provides initial training for the physicist on implementation and departmental training of the OBI system. A three-day program is provided for the radiation therapist as an overview of the OBI system Clinac communication and verification system. In addition, on-site training includes a 2-day clinical training program for up to four users.

The quote also includes a five-day tuition-paid course for IMRT/RapidArc Administration and Physics which will cover IMRT planning with the Eclipse system and the delivery of IMRT using Varian dMLC, including integration into the ARIA system.

#### *CT Simulator*

Treatment planning and simulation are critical first steps in the radiation therapy process. In cancer treatment, a radiation oncologist, dosimetrist and physicist use a simulator to coordinate unique aspects of patient anatomy and tumor characteristics with the linear accelerator so that the target area is precisely located.

After the initial consultation, the radiation oncologist will formulate a treatment plan. Here, the patient comes to the radiation department and lies down on a table under a machine, called a simulator. Various immobilization devices may be necessary, such as a head rest or a face mask, in order to make sure the patient is positioned correctly and in the same way for each treatment. Various markings will be made on the skin and various images taken to assure accuracy of actual treatments.

Simulation is very important, because it is the step that allows for proper planning and delivery of the actual treatment. After simulation, there is a lot of behind-the-scenes work. Here the medical physicist and dosimetrist are involved.

The applicant proposes to acquire a Siemens Somatom Emotion 6 CT-Oncology scanner for simulation. See quote in Exhibit 7. Somatom Emotion is a state-of-the-art spiral whole-body computed tomography scanner with an air-cooled high-speed gantry. The system configuration is designed to produce optimum image quality with the lowest possible radiation exposure.

Features of the Emotion 6 CT scanner include:

- Radiation Treatment Planning (RTP) enhancement package hardware and software
- CARE Dose for real-time dose modulation yielding up to 68 percent dose savings with no compromise in image quality
- SureView™ – multi-slice image reconstruction system keeps image quality constant at any scan speed
- Fast 3D processing tools for effective visualization, analysis, quantification and documentation of clinical structures
- High speed and detail - fast image acquisition and real-time display for conspicuous visualization of fine bone and soft tissue structures
- High efficiency air cooled system – no water chiller required
- Siemens Remote Service (SRS) resulting in increased system availability and efficiency

### *Ultrasound*

The Prostate Health Center proposes to purchase a GE Logiq 200 Ultrasound. The all-digital Logiq 200 system is a superior, cost-effective solution for urological ultrasound. The system features advanced imaging technology designed to deliver powerful urological imaging capabilities. Its 48-channel, wide-aperture architecture supports wide-band, multi-frequency imaging at faster frame rates, for optimized resolution. It is compact and mobile and equipped with:

- A wideband 7.0 MHz endo-rectal probe for superb prostate imaging
- Sophisticated computational software for precise volume calculations
- An easy-to-use needle-biopsy guide.

### *Brachytherapy*

The leased brachytherapy equipment includes a Varian Vari-Seed TPS 7.1 and a Siemens Adara ultrasound.

The Varian Vari-Seed TPS brachytherapy is a comprehensive workstation that fully supports brachytherapy treatment planning needs, including rules-based dose optimization, unprecedented conformal dose capabilities and image-based planning. Varian's recent addition of dynamic dosimetry to its VariSeed software makes delivering the intended dose easier. Vari-Seed 7.1 offers a common interface and tools for users of Varian Systems, as well as having the advantage of being able to access existing patient records and images from the shared database. The VariSeed provides an editable longitudinal representation of the selected needle on the source placement tab.

The Adara ultrasound is a highly mobile system that offers premium grayscale imaging with enhanced image quality. It provides reduced image noise, improved image contrast and resolution and better penetration with higher frequency transducers.

can be involved in every aspect of the patient's cancer treatment program. Second, primary care physicians are responsible for coordination care that their patients receive from other physicians. To coordinate care of patients, physicians must coordinate with a large number of other physicians. "The typical primary care physician has 229 other physicians working in 117 practices with which care must be coordinated, equivalent to an additional 99 physicians and 53 practices for every 100 Medicare beneficiaries managed by the primary care physician."<sup>2</sup>

### **Radiation Oncology**

#### **Overview**

Radiation therapy, also radiotherapy or radiation oncology, is the medical use of ionizing radiation as part of cancer treatment to control malignant cells. Radiotherapy is used for the treatment of malignant tumors (cancer), and may be used as the primary therapy. It is also common to combine radiotherapy with surgery, chemotherapy, hormone therapy or some mixture of the three.

Radiotherapy may be used for curative or adjuvant cancer treatment. It is used as palliative treatment, where cure is not possible and the aim is for local disease control or symptomatic relief, or as therapeutic treatment, where the therapy has survival benefit and it can be curative. The precise treatment intent (curative, adjuvant, neoadjuvant, therapeutic, or palliative) will depend on the tumor type, location, and stage, as well as the general health of the patient. Approximately half of prostate cancer patients are treated with radiation therapy.

Two main divisions of radiotherapy are external beam radiotherapy (EBRT) and brachytherapy or sealed source radiotherapy. EBRT involves a radiation source outside the body; brachytherapy uses sealed radioactive sources placed inside the body, precisely in the area under treatment. Approximately 75 percent of radiation therapy patients are treated with EBRT, 20 percent are treated with brachytherapy and five (5) percent are treated with a combination of the two.

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<sup>2</sup> <http://www.annals.org/cgi/content/abstract/150/4/236>



### External Beam Radiotherapy (EBRT)

EBRT will be provided by a linear accelerator. Simulation, the imaging and positioning of the patient relative to the linear accelerator beam will be precisely calibrated on a CT simulator whose data will be electronically transmitted to the linear accelerator. Dosimetry and physics calculations will be planned on Eclipse Treatment Planning software that is designed to integrate specifically with the Varian linear accelerator and the Siemens CT simulator.

Within EBRT, intensity-modulated radiation therapy (IMRT) is an advanced mode of high-precision radiotherapy that utilizes computer-controlled x-ray accelerators to deliver precise radiation doses to a malignant tumor or specific areas within the tumor. IMRT allows for the radiation dose to conform more precisely to the three-dimensional (3-D) shape of the tumor by modulating—or controlling—the intensity of the radiation beam. IMRT also allows higher radiation doses to be focused to regions within the tumor while minimizing the dose to surrounding normal critical structures. Treatment is carefully planned by using 3-D computed tomography (CT) images of the patient in conjunction with computerized dose calculations to determine the dose intensity pattern that will best conform to the tumor shape. Typically, combinations of several intensity-modulated fields coming from different beam directions produce a custom tailored radiation dose that maximizes tumor dose while also protecting adjacent normal tissues.

Because the ratio of normal tissue dose to tumor dose is reduced to a minimum with the IMRT approach, higher and more effective radiation doses can safely be delivered to tumors with fewer side effects compared with conventional radiotherapy techniques. IMRT also has the potential to reduce treatment toxicity, even when doses are not increased.

Conventional IMRT does require longer daily treatment times and delivers a low dose to larger volumes of normal tissue than conventional radiotherapy.

### IGRT and RapidArc

The prostate is a soft and flexible glandular organ that moves easily in the body. Consequently, it can shift during EBRT treatment. Varian has introduced a new technology, Rapid Arc, which can deliver treatment two to eight times as fast as conventional IMRT. A Rapid Arc-equipped linear accelerator delivers treatments in one 360° gantry rotation. Treatments can be complete in 70 seconds. This compares to a conventional IMRT treatment of seven to 10 minutes.

Rapid Arc uses a treatment planning algorithm that simultaneously changes the rotation speed of the gantry, the delivery dose rate and the shape of the treatment aperture using the movement of multileaf collimator leaves. Reports from users indicate a correlation between treatment accuracy and the speed of the Rapid Arc treatment. For billing and coding purposes, the Rapid Arc is treated as intensity-gated radiation therapy (IGRT).

### EBRT Team

The center will involve a team specially trained for external beam and IMRT delivery to the prostate. This team includes the radiation oncologist, urologist, medical radiation physicist, dosimetrist, radiation therapist and radiation therapy nurse. The urologist role in prostate cancer EBRT is particularly important because of the complex nature of the anatomy of the prostate and the delicate nature of interconnected tissues, nerves and vessels in and around it.

A radiation oncologist specializes in the treatment of cancer patients, using radiation as the main modality of treatment. The radiation oncologist specializes in knowledge of the impact of radiation energy on normal and tumor cells. Whilst most oncologists will treat a selection of common general oncology cases, there is increasing specialization, with the expectation that consultants will specialize in one or two subsets.

John Leung, MD, a Radiation Oncologist who has deep expertise in external and internal radiation of the prostate, will be the Medical Director and provide clinical supervision for radiation oncology. Another radiation oncologist, Connie Nguyen, MD has expressed willingness to return to North Carolina and work full time in the center. One radiation oncologist will either lease professional space at the Center and provide full time physician coverage for

the linear accelerator or be an employee of Cary Urology and provide such services full time at the Center. For purposes of proformas in this application, the radiation oncologist has been treated as an independent practitioner. Proformas include only technical fees.

See resumes in Exhibit 2 for extensive experience of the radiation oncologists. Because the prostate anatomy is so complex, planning and positioning are critical to effective external beam radiation. Urologists in The Prostate Health Center will work directly with the radiation oncologist on the treatment plans. A urologist will also review patient status and progress throughout the radiation treatment program. This is a critical feature of the proposed center. Drs. Leung and Khoudary have successfully demonstrated the value of such a team relationship in the brachytherapy program at Cary Urology. The goal is to minimize and eliminate side effects of the radiation treatment.

#### Effectiveness of external beam radiation therapy

Success rates for EBRT can range from 19 to 86 percent. Studies have shown success rates between 81 to 86 percent for low-risk disease; 26 to 60 percent for moderate-risk disease; and 19 to 25 percent for high-risk disease. To improve the success rate, EBRT is often used in conjunction with other therapies. EBRT is an option when the cancer is confined to the prostate gland, it may be used alone or combined with medications or surgery. External beam radiation therapy can be curative if the cancer has not gone beyond the prostate gland.<sup>3</sup>

Patients undergoing EBRT generally receive treatment at an outpatient center five days a week for six to eight consecutive weeks.

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<sup>3</sup> Stokes SH: Comparison of biochemical disease-free survival of patients with localized carcinoma of the prostate undergoing radical prostatectomy, transperineal ultrasound-guided radioactive seed implantation, or definitive external beam irradiation. *Int J Radiat Oncol Biol Phys* 2000, 47:129-136.

Martinez AA, Gonzalez JA, Chung AK, et al.: A comparison of external beam radiation therapy versus radical prostatectomy for patients stages with low risk prostate carcinoma diagnosed, stages, and treated at a single institution. *Cancer* 2000, 88:425-432.

Zagars GK, Pollack A, von Eschenbach AC: Prognostic factors for clinically localized prostate carcinoma. *Cancer* 1997, 79:1370-1380.

Perez CA, Michalski JM, Purdy JA, et al: Three-dimensional conformal therapy or standard irradiation in localized carcinoma of prostate: preliminary results of a nonrandomized study. *Int J Radiat Oncol Biol Phys* 2000, 47:629-637.

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### Risks of external beam radiation therapy

External beam radiation therapy damages both cancer cells and normal cells. However, normal cells are usually able to better repair themselves and function properly more quickly than the cancer cells.

If the radiation damages nerves that control erections, the patient may lose his ability to get or keep an erection. Occasionally bowel function will not return immediately after treatment ends.



### Recovery time for EBRT

Side effects (see below) usually disappear shortly after the 7 to 8 week therapy regimen ends. The patient usually can keep to daily activities during the treatment.

### Side effects of EBRT<sup>4</sup>

External beam radiation therapy can lead to a variety of side effects. Most are minor and disappear after therapy ends. They include:

- Diarrhea
- Rectal irritation or bleeding
- Fatigue
- Frequent and painful urination
- Blood in the urine
- Possible fistulas
- Secondary tumors as a result of irradiation

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<sup>4</sup> (Int. J. Radiation Oncology Biol. Phys., Vol. 54, No. 4, pp. 1063-1068, 2002) EBRT reference material explained on website for Prostate Cancer Institute <http://www.prostate-cancer-institute.org/prostate-cancer-treatment/external-beam-radiation.html>

### Planning

The process of planning radiation therapy is complex and may take several days to complete. Treatments are designed to give the strongest dose of radiation to the cancer while sparing as much normal tissue as possible, resulting in fewer side effects. The first part of treatment planning is called simulation. In simulation, the physician checks the size of the tumor, identifies where it is more likely to spread, identifies normal tissues that are in the treatment area, takes measurements, and develops the treatment plan. The amount of radiation depends on the size of the tumor, how sensitive the tumor is to radiation, and the ability of the normal tissue to tolerate the radiation.

Special CT scans may be used to produce a three-dimensional image of the tumor to help in planning. This complex planning procedure is called dosimetry or determining the dose that will be delivered to normal structures in order to deliver the prescribed dose to the cancer. Radiation therapy physicians also provide consultative, evaluative, and diagnostic services to a wide range of programs within the continuum of cancer care services.

External beam radiation services available at The Prostate Health Center will include:

- Linear accelerator with IMRT and Rapid Arc capability. Specifically a Clinac iX with OBI and RapidArc
- CT simulator, a Siemens Somatom Emotion 6 CT, with wide open bore, which has capacity to support the wide girth of patients who may weigh up to 350 pounds
- Planning software Eclipse
- Picture Archiving Computer System (PACS) for storing image data
- Mold room to provide block capacity for simple treatments, or in the event of collimator down time
- Dosimetry
- Physics calibration of equipment and patient dosing

**VIII. CAPITAL COSTS AND FINANCING**

**1. Estimated Capital Costs of Proposed Project**

- (a) Both the lessor and the lessee, as applicable, shall individually complete Application Section VIII.**
- (b) Provide all assumptions and the specific methodology used to project capital costs.**

**Capital Cost Assumptions**

- Purchase price of the land is based on the land purchase asking price of the primary site as documented in Exhibit 72.
- Site preparation costs are based on the Architect's cost estimate for site preparation of the primary site in Exhibit 13.
- Total site costs (land purchase and site preparation) associated with the primary site were used because they are higher than total site costs associated with the secondary site. See the Architect's cost estimate in Exhibit 13.
- Costs of materials and labor are based on the Architects cost estimate in Exhibit 13.
- Equipment and furniture costs are based on fair market value for all equipment needed for the project. Please see Exhibit 7 for quotes of all medical equipment valued at over \$10,000.
- Brachytherapy equipment (to be leased) fair market value is based on the quote in Exhibit 8.
- Commissioning costs of the CON are based on conservative market estimates.
- A/E fees are based on the professional fees associated with the primary site listed on the Architect's cost estimate in Exhibit 13. (This is more expense than the professional fees associated with the secondary site.)
- CON consulting fees are based on conservative market estimates.
- Interest during construction is based on the interest paid during construction in accordance with the bank letter in Exhibit 73.
- Additional contingency was added to ensure capital cost estimates remain conservative.

**PROJECT CAPITAL COST****A. Site Costs**

(1)	Full purchase price of land	\$ 700,000
	# Acres _____ Price per Acre \$ _____	
(2)	Closing costs	_____
(3)	Site Inspection and Survey	_____
(4)	Legal fees and subsoil investigation	_____
(5)	Site Preparation Costs [include]	
	Soil Borings	
	Clearing and Grading	
	Roads and Parking	
	Sidewalks	
	Water and Sewer	
	Excavation and Backfill	
	Termite Treatment	
	<b>Sub-total Site Preparation Costs</b>	<b>\$ 467,125</b>
(6)	Additional Contingency	\$ 58,356
(7)	<b>Sub-total Site Costs</b>	<b>\$ 1,225,481</b>

**B. Construction Contract**

(8)	Cost of Materials [include]	
	General Requirements	
	Concrete/Masonry	
	Woods/Doors & Windows/Finishes	
	Thermal & Moisture Protection	
	Equipment/Specialty Items	
	Mechanical/Electrical	
	<b>Sub-total Cost of Materials</b>	_____
(9)	Cost of Labor	
	Cost of Materials and Labor	\$ 3,065,431
(10)	Additional Contingency	\$ 153,272
(11)	<b>Sub-total Construction Contract</b>	<b>\$ 3,218,703</b>

**C. Miscellaneous Project Costs**

(12) Building Purchase	
(13) Fixed Equipment Purchase/Lease	
(14) Movable Equipment Purchase/Lease	
Total Equipment Purchase	\$ 4,164,860
Brachytherapy Equipment Fair Market Value	\$ 79,014
(15) Furniture	\$ 100,000
Commissioning Costs	\$ 75,000
(16) Landscaping	
(17) Consultant Fees	
Architect/Engineering Fees	\$ 194,290
Legal Fees	
Market Analysis	
CON Consultant Fees	\$ 40,000
Total Consultant Fees	
(18) Financing Costs (e.g., Bond, Loan, etc.)	\$ 188,700
(19) Interest During Construction	\$ 336,032
(20) Additional Contingency	\$ 228,707
(21) Sub-total Miscellaneous	\$ 5,406,603

**D. Total Capital Cost of Project (Sum A-C above)** \$ 9,850,787



2. (a) Provide an itemized list of all medical equipment, which is valued at more than \$10,000, that is included in the proposed project, regardless of whether the equipment will be leased or purchased. Provide the estimated cost or fair market value of each item of medical equipment valued at more than \$10,000.

Equipment	Cost
Linear Accelerator -Varian iX with Rapid Arc	\$2,354,000
Eclipse Treatment Planning	\$401,250
ARiA Database	\$214,000
Siemens CT Simulator	\$418,771
GE Logic 200 Ultrasound	\$33,812
Block Cutter	\$12,332
Brachytherapy (Fair Market Value)	\$79,014

Please note, seven percent sales tax was included above the quotes in Exhibit 7 for all items listed above that will be purchased.

See Exhibit 8 for Fair Market Value of the leased brachytherapy equipment.

The above does not include estimates for miscellaneous medical equipment under \$10,000 to be purchased, office equipment and computers, and electronic medical records system.

- (b) Indicate if the equipment is replacement equipment or additional equipment.

The Prostate Health Center does not yet exist. All equipment to be purchased or leased as part of this project is additional equipment. All equipment except brachytherapy is new. Brachytherapy is a part-time lease of existing equipment.



# SIEMENS

## FINAL INVOICE

Siemens Medical Solutions USA Inc.  
51 Valley Stream Parkway, Malvern PA 19355

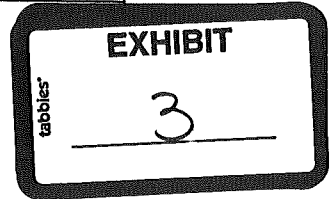
INVOICE NUMBER	90297417
INVOICE DATE	02/20/2013
CUSTOMER NO.	213033
SALES ORDER NO.	30159823
DISTRICT	26
DIVISION	03

**BILL TO:**

PARKWAY UROLOGY LLC  
105 SW CARY PKWY STE 300  
CARY NC 27511-5600

**SHIP TO:**

SHIPPED ON: 02/20/2013  
PARKWAY UROLOGY LLC  
117 SUNNYBROOK RD  
RALEIGH NC 27610



**YOUR PURCHASE ORDER**

NUMBER: 1-7N77-189      DATE: 09/12/2012

PAGE 1 of 1

FOB POINT FOB - Destination		CARRIER'S NAME, FREIGHT REMARKS	SHIPPED VIA
TERMS OF PAYMENT 00/80/20		TAX STATE NC	
DESCRIPTION/SERIAL NO.			TOTAL PRICE
Equipment Contract Total			555,000.00
EQUIPMENT TYPE: SOMATOM Definition AS(Open 20Slice)			
Portion Billed Previously			443,999.00-
20.00 % Final Amount Due			111,001.00
Taxes for Equipment Contract Total			36,088.88
<b>AMOUNT DUE NOW:</b>			<b><u>147,089.88</u></b>
<p>PLEASE DIRECT ANY INQUIRIES REGARDING THIS BILLING TO: csgsbillinginquiriesoutheast.healthcare@siemens.com</p>			

**PLEASE REMIT TO:**

**Siemens Medical Solutions USA, Inc. PO Box 120001 - Dept. 0733, DALLAS, TX 75312-0733**

The customer is hereby informed that section 1128B(b) of the Social Security Act requires that discounts and other reductions in price or the existence of discount programs be properly disclosed and reflected in the costs claimed or charges made by a provider under Medicare or a State Health Program.

NOTICE: COMPLIANCE WITH LEGAL AND INTERNAL REGULATIONS IS AN INTEGRAL PART OF ALL BUSINESS PROCESSES AT SIEMENS. POSSIBLE INFRINGEMENTS CAN BE REPORTED TO OUR HELPDESK "TELL US" AT WWW.SIEMENS.COM/TELL-US  
PAST DUE INVOICES ARE SUBJECT TO A SERVICE CHARGE OF 1 1/2% PER MONTH, EQUAL TO 18% PER YEAR APPLICABLE.  
GOODS HAVE BEEN CAREFULLY CHECKED AND SAFELY PACKED. NO RETURN OF MECHANDISE WILL BE ACCEPTED UNLESS PREVIOUSLY APPROVED. EQUIPMENT ORDERED IN COLORS OTHER THAN STANDARD COLORS CANNOT BE CHANGED WITHOUT PRIOR WRITTEN CONSENT OF SIEMENS MEDICAL SOLUTIONS USA, INC. ALL MERCHANDISE REMAINS THE PROPERTY OF SIEMENS MEDICAL SOLUTIONS USA, INC. UNTIL PAID FOR IN FULL. CLAIMS MUST BE MADE WITHIN SEVEN (7) DAYS AFTER RECEIPT OF SHIPMENT.  
THIS INVOICE IS FOR PAYMENT DUE PURSUANT TO THE TERMS OF THE EQUIPMENT SALES AGREEMENT BETWEEN SIEMENS AND CUSTOMER. PLEASE REFER TO THAT AGREEMENT FOR ALL APPLICABLE TERMS AND CONDITIONS OF SALE AND THE SOFTWARE LICENSE SCHEDULE.



Quotation For:

Kevin Khoudary, MD  
Parkway Urology Associates  
117 Sunnybrook Rd  
Raleigh, NC 27610  
(919) 467 - 3203

Please address inquiries and replies to:

Susan Thomas  
Varian Medical Systems  
2250 Newmarket Parkway  
Suite 120  
Marietta, GA 30067  
(770) 955 - 1367 FAX: (678) 255 - 3850  
susan.thomas@varian.com

Your Reference:	Quotation Firm Until: <b>May 13, 2015</b>
FOB Point: <b>US1 FOB: Origin Inc. Freight &amp; Ins.</b>	Shipping Allocation: <b>180 DAYS ARO</b>
Payment Terms: <b>10%/85%/5%</b>	Varian Terms and Conditions of Sale <b>1652U Attached</b>

**Parkway Urology Associates**

**Clinac iX with OBI, CBCT and RapidArc  
Expansion of Eclipse**

<p><b>Parkway Urology Associates</b></p> <p>Quotation Total of: USD <b>\$2,262,053</b> Accepted by:</p> <p>Signature: _____</p> <p>Name: _____</p> <p>Title: _____</p> <p>Date: _____</p> <p>For this purchase, we designate <u><b>FREESTANDING</b></u> as our Institution's Primary Group Purchasing Organization affiliation. Any change will be indicated below:</p> <p> <input type="checkbox"/> AmeriNet   <input type="checkbox"/> Aptium   <input type="checkbox"/> BJC   <input type="checkbox"/> Broadlane  <input type="checkbox"/> CHW   <input type="checkbox"/> Consorta/HPG   <input type="checkbox"/> KP Select   <input type="checkbox"/> Magnet  <input type="checkbox"/> Matrix   <input type="checkbox"/> MedAssets   <input type="checkbox"/> Novation   <input type="checkbox"/> Premier  <input type="checkbox"/> ROI   <input type="checkbox"/> USO   <input type="checkbox"/> VA Gov   <input type="checkbox"/> None         </p>	<p><b>Varian Medical Systems</b></p> <p>Submitted by:</p> <p>_____</p> <p>(Signature)</p> <p>Name: <b>Susan Thomas</b></p> <p>Title: <b>District Manager</b></p> <p>Date: <b>May 13, 2014</b></p>
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Item	Qty	Product Description	Offer Price
<b>Section 1 Clinac iX with OBI, CBCT and RapidArc</b>			
1.01	1	IX Package	Included
1.02	1	High Energy Clinac IX	540,619.00
1.03	1	INCL ED: CL100 Clinac Basic Operations	Included
1.04	1	STD TRNG: Clinac IX Ops	Included
1.05	1	INCL ED: HEC100 High-Energy Clinac Support	Included
1.06	1	Dual Photon Energy: 6/10 MV	99,093.00
1.07	1	Display of Photon Energy: BJR11	Included
1.08	1	Photon Dose Rate: 600 MU/Min	19,819.00
1.09	1	5 Electrons; Grp 4: 4,6,9,12,16 MeV	11,010.00
1.10	1	Electron Dose Rate: 400 MU/Min Maximum	8,808.00
1.11	1	Size of Electron Applicators: 6cm x 6cm	Included
1.12	1	Upper Wedges: 30cm x 40cm	Included
1.13	1	Energy of Spec Electron Procedures: 6MeV	Included
1.14	1	Scale Convention: Varian IEC 60601-2-1	Included
1.15	1	Counterweight	Included
1.16	1	Three Piece Breakdown	Included
1.17	1	New Universal Baseframe 52" Fixed Floor	9,229.00
1.18	1	Exact Couch with IGRT Couch Top	52,658.00
1.19	1	20" LCD Monitor (4:3)	653.00
1.20	1	Millennium MLC, 120 Leaf	272,105.00
1.21	1	Large Field IMRT	17,730.00
1.22	1	20" LCD Monitor (4:3)	653.00

Item	Qty	Product Description	Offer Price
1.23	1	PortalVision: aS1000	187,720.00
1.24	1	Portal Vision for 4DITC	Included
1.25	1	Laser Backpointer for PortalVision Arm	978.00
1.26	1	On-Board Imager	348,518.00
1.27	1	INCL ED: CL201 OBI Imagng for Physicists	Included
1.28	1	INCL ED: CL101 OBI Imagng for Therapists	Included
1.29	1	STD TRNG: OBI	Included
1.30	1	Cone Beam CT for On-Board Imager	108,910.00
1.31	1	Remote Couch Motion	11,010.00
1.32	1	IGRT Online Marketing Program	10,000.00
1.33	1	NLS: English	Included
1.34	1	RapidArc Delivery Capability	179,550.00
1.35	1	Enhanced Dynamic Wedge	9,300.00
1.36	1	Auto Field Sequencing	15,495.00
1.37	1	Advanced Dynamic MLC	46,493.00
1.38	1	EXCI Interface to R&V System	11,627.00
1.39	1	4D Integrated Treatment Console	36,701.00
1.40	1	4DITC gX for Varian Image Mgmt Network	Included
1.41	1	In-Room 20" Monitor with Mounting Kit	2,271.00
1.42	1	Electron Arc Therapy: TBI, TBE and HDTSE	6,973.00
1.43	1	Beam Isocenter Accuracy: Fine	16,883.00
1.44	1	Additional Advanced RPM Gating System	43,912.00
1.45	1	3D for Advanced RPM Gating System	7,984.00

Item	Qty	Product Description	Offer Price
1.46	1	Configured for Trilogy	Included
1.47	1	Console Package, Deluxe Roll In Console	Included
1.48	1	Remote Access Smart Connect Ready	3,098.00
1.49	1	Factory Data Set	3,671.00
<b>Section Total \$</b>			<b>2,083,471.00</b>

<b>Section 2</b>			
2.01	1	Exact IGRT Bar	1,300.00
2.02	1	Patient Intercom	920.00
2.03	1	CCTV Camera Qty 2; 15" Monitor Qty 2	7,128.00
2.04	1	4 LAP Apollo Green Lasers	18,600.00
<b>Section Total \$</b>			<b>27,948.00</b>

<b>Section 3 Expansion of Eclipse</b>			
3.01	1	Eclipse RapidArc Planning Lic-Addl	55,911.00
3.02	1	Acuros External Beam	39,468.00
3.03	1	SmartSeg Knowledge Based Contouring Pkg	55,255.00
<b>Section Total \$</b>			<b>150,634.00</b>

<b>Quotation Total \$</b>			<b>2,262,053.00</b>
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Item	Qty	Product Description	Offer Price
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***There may be radiological regulatory requirements applicable to possessing and/or operating radiation generating machines. Varian takes no responsibility regarding local radiation safety requirements. These requirements are the customer's responsibility.***

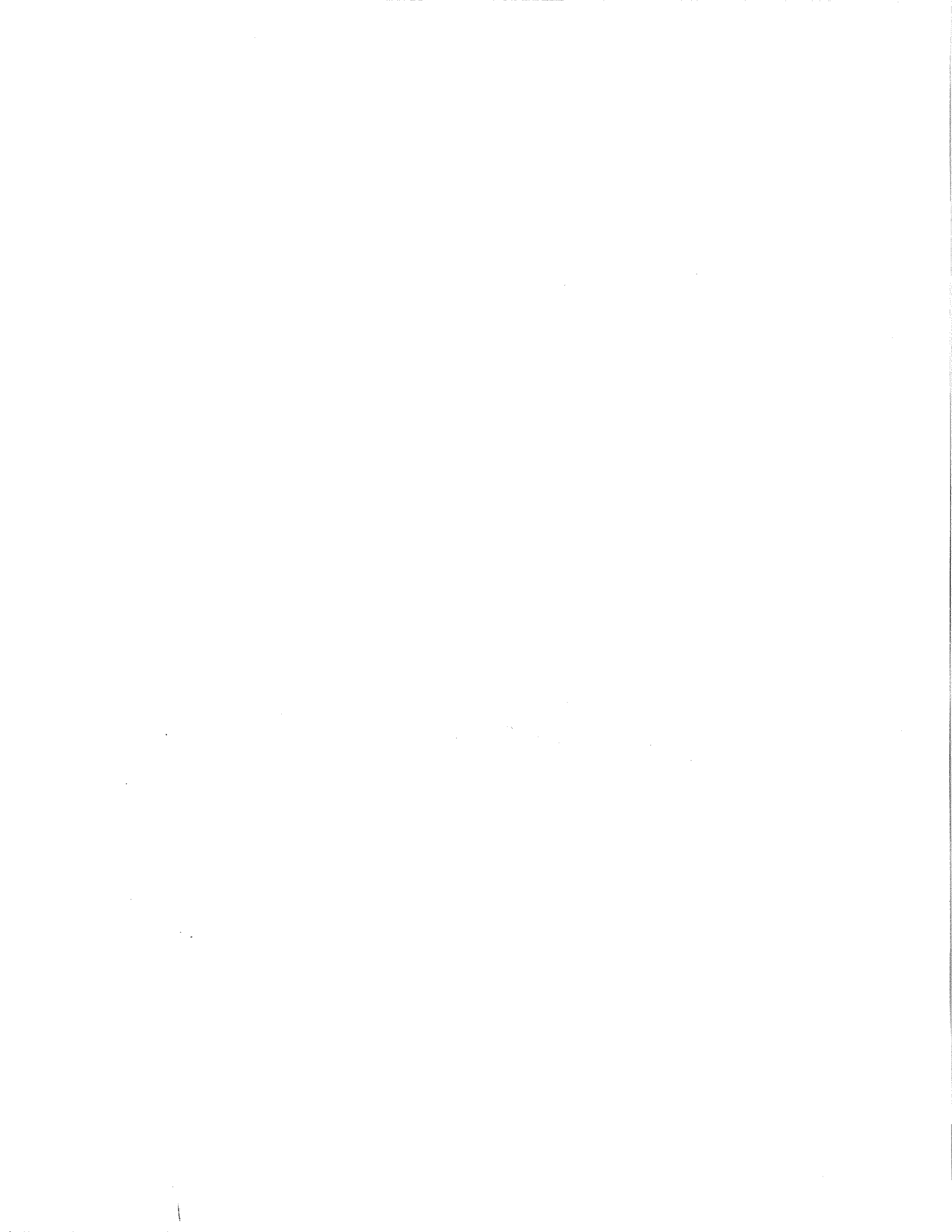
**End of Support:** Varian may terminate the Agreement at the end of support of the Product that is the object of the Support Services by giving **twenty-four (24) months** written notice to the Customer. However, Varian may shorten this notice period in its sole discretion if termination is required due to key component obsolescence issues or material product quality concerns.

**Terms & Conditions of Sale**

**This offer is subject to credit approval and is exclusive of any applicable sales taxes or duties.**

**If Customer chooses to pay by credit card, a four percent (4%) service fee will be added.**

**FINANCING AVAILABLE:** For lease and finance plans, call Tony Susen, Director - Varian Customer Finance, at (508) 668-4609.





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

Beverly Eaves Perdue, Governor  
Lanier M. Cansler, Secretary

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

November 4, 2011

**CERTIFIED MAIL & FACSIMILE**

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

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

Dear Mr. Stewart:

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

Sincerely,

Drexdal Pratt

DP:JH:peb

Enclosure

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



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

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

I, Drexdal Pratt, as Director of the Division of Health Service Regulation, North Carolina Department of Health and Human Services ("Department" or "Agency"), do hereby issue this Declaratory Ruling pursuant to North Carolina General Statute § 150B-4 and 10A NCAC 14A .0103 under the authority granted me by the Secretary of the Department of Health and Human Services.

The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Healthcare System ("CMHA") has requested a declaratory ruling to confirm that its acquisition of the membership interests of University Radiation Oncology Center, LLC ("UROC") and its continued operation of that facility may proceed without first obtaining a Certificate of Need ("CON"). This ruling will be binding upon the Department and the entities requesting it, as long as the material facts stated herein are accurate. This ruling pertains only to the matters referenced herein. Except as provided by N.C.G.S. § 150B-4, the Department expressly reserves the right to make a prospective change in the interpretation of the statutes and regulations at issue in this Declaratory Ruling. William W. Stewart of K&L Gates LLP has requested this ruling on CMHA's behalf and has provided the material facts upon which this ruling is based.

**STATEMENT OF THE FACTS**

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

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

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

#### ANALYSIS

The CON law provides that no person shall offer or develop a "new institutional health service" without first obtaining a CON. N.C. Gen. Stat. § 131E-178. The list of new institutional health services includes "the acquisition by purchase, donation, lease, transfer or comparable arrangement" of a linear accelerator or simulator "by or on behalf of any person," N.C. Gen. Stat. § 131E-176(16)(f)5a, 9, and "the obligation by any person of a capital expenditure exceeding two million dollars (\$2,000,000) to develop or expand a health service or a health service facility, or which relates to the provision of a health service," N.C. Gen. Stat. § 131E-176(16)(b).

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

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


CMHA's acquisition of the membership interests in UROC does not constitute the acquisition of a linear accelerator or a simulator because the ownership of the equipment will not change, and the same equipment will be used to provide the same radiation oncology services, in the same location. UROC will continue to own the two pieces of equipment and UROC's legal status as a corporate entity will not change.

The purchase of ROCC's membership interests in UROC does not involve the offering or expansion of any new facility, service or equipment, and the state's inventory of linear accelerators and simulators will not change. No new or additional equipment will be acquired or placed in operation in the State.

#### CONCLUSION

For the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that CMHA does not require a certificate of need in order to proceed with the purchase of ROCC's membership interests in UROC.

This the 4<sup>th</sup> day of November, 2011.

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

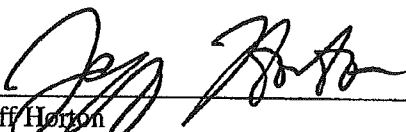
**CERTIFICATE OF SERVICE**

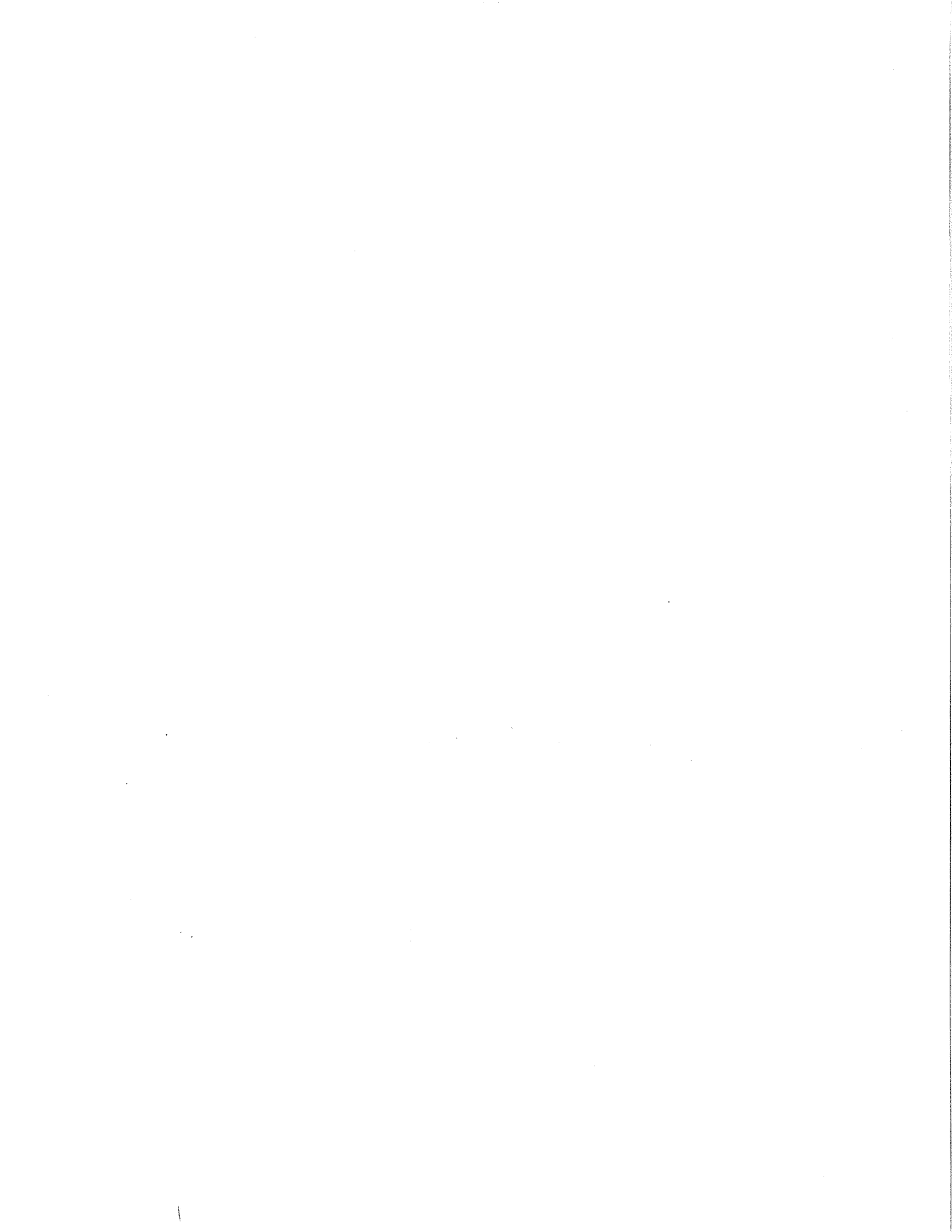
I certify that a copy of the foregoing Declaratory Ruling has been served upon the nonagency party by facsimile and certified mail, return receipt requested, by depositing the copy in an official depository of the United States Postal Service in a first-class, postage pre-paid envelope addressed as follows:

**CERTIFIED MAIL**

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

This the 4<sup>th</sup> day of November, 2011.

  
\_\_\_\_\_  
Jeff Horton  
Chief Operating Officer



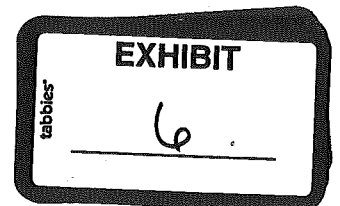


**NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES  
DIVISION OF HEALTH SERVICE REGULATION  
RALEIGH, NORTH CAROLINA**

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

I, Drexdal Pratt, as Director of the Division of Health Service Regulation, North Carolina Department of Health and Human Services ("Department" or "Agency"), do hereby issue this Declaratory Ruling pursuant to North Carolina General Statute § 150B-4 and 10A NCAC 14A .0103 under the authority granted me by the Secretary of the Department of Health and Human Services.

Wake Radiology Oncology Services, PLLC (hereinafter "WROS"); Cancer Centers of North Carolina, P.C. ("CCNC"); US Oncology, Inc. ("USON") and its subsidiary AOR Management Company of Virginia, LLC ("AOR"); and WakeMed have requested a declaratory ruling to confirm that the acquisition of the membership interests in WROS and the continued operation of the oncology treatment center may proceed without first obtaining a certificate of need. This ruling will be binding upon the Department and the entities requesting it, as long as the material facts stated herein are accurate. This ruling pertains only to the matters referenced herein. Except as provided by N.C.G.S. § 150B-4, the Department expressly reserves the right to make a prospective change in the interpretation of the statutes and regulations at issue in this Declaratory Ruling. Attorneys for the Petitioners have requested this ruling on their behalf and have provided the material facts upon which this ruling is based.



## STATEMENT OF THE FACTS

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

CCNC is a professional corporation organized under the laws of the State of North Carolina. CCNC employs physicians licensed to practice medicine in the State of North Carolina, who provide oncology treatment services, including radiation oncology services through the use of a linear accelerator.

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

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

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

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

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

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

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

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

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

#### **ANALYSIS**

The CON law provides that no person shall offer or develop a "new institutional health service" without first obtaining a CON. N.C. Gen. Stat. § 131E-178. The list of new

institutional health services includes “the acquisition by purchase, donation, lease, transfer or comparable arrangement” of a linear accelerator or simulator “by or on behalf of any person,” N.C. Gen. Stat. § 131E-176(16)(f1)5a, 9, and “the obligation by any person of a capital expenditure exceeding two million dollars (\$2,000,000) to develop or expand a health service or a health service facility, or which relates to the provision of a health service,” N.C. Gen. Stat. § 131E-176(16)(b).

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

The entity that owns the linear accelerator and simulator will not change, and the same equipment will be used to provide the same radiation oncology services, in the same location. The LLC will continue to own the linear accelerator, the simulator, and all the oncology treatment center assets that were authorized under the 1997 CON and have been used to furnish oncology treatments to patients. Its membership composition initially will change from the present physician members to a single member, CCNC, with the subsequent purchase of a minority interest by WakeMed.

The Proposed Transaction will involve expenditures by CCNC, and later by WakeMed, but these will be purchases of ownership interests in an existing limited liability company that owns the oncology treatment center. There will be no capital expenditure to develop or expand a

health service or health service facility because the same equipment will continue to be operated at the same location, and no expansion of services is proposed.

The Proposed Transaction does not involve the offering or expansion of any new facility, service or equipment, and the state's inventory of linear accelerators and simulators will not change. No new, or additional equipment will be acquired or placed in operation in the State.

### CONCLUSION

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

This the \_\_\_\_\_ day of September, 2010.

---

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

**CERTIFICATE OF SERVICE**

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

**CERTIFIED MAIL**

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

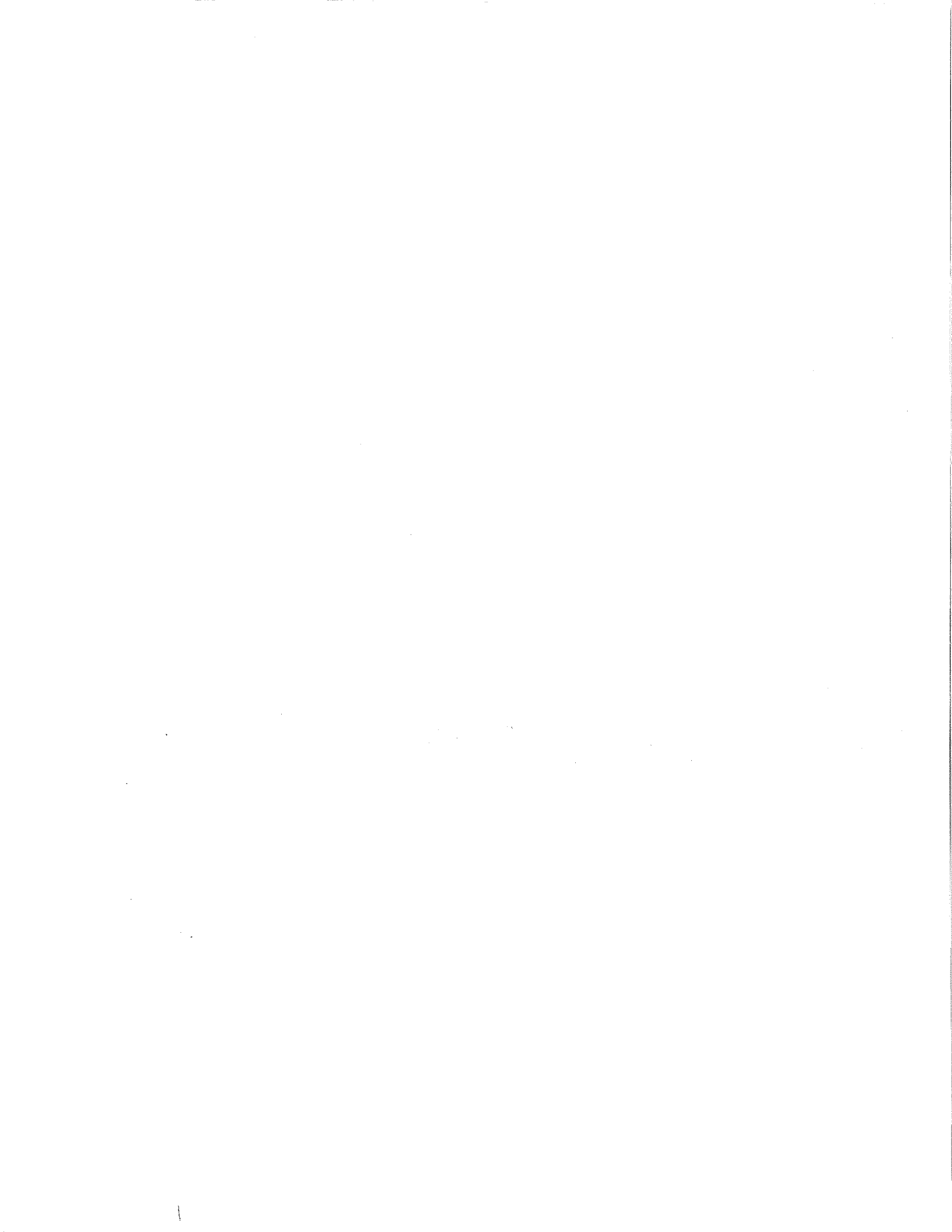
William R. Shenton  
POYNER SPRUILL LLP  
301 Fayetteville Street, Suite 1900  
Raleigh, North Carolina 27601  
Attorneys for U.S. Oncology, Inc. and AOR Management  
Company of Virginia, LLC

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

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

This the \_\_\_\_\_ day of September, 2010.

\_\_\_\_\_  
Jeff Horton  
Chief Operating Officer

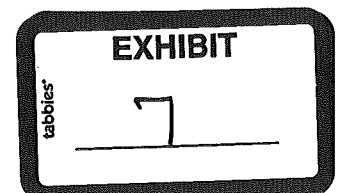


**NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES  
DIVISION OF HEALTH SERVICE REGULATION  
RALEIGH, NORTH CAROLINA**

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

I, Robert J. Fitzgerald, Director of the Division of Health Service Regulation (the "Department"), hereby issue this declaratory ruling to Radiation Therapy Services, Inc. d/b/a/ 21<sup>st</sup> 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. ("CRTCC") 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.C.G.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.C.G.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 health service or a health service facility, or which relates to the provision of a health service,” N.C.G.S. § 131E-176(16)b.

The transaction described by Petitioners does not constitute the acquisition of a linear accelerator or a simulator by any person because ownership of the one reported linear accelerator and one reported simulator here will not change. CRTC will continue to be the owner of these two pieces of equipment, and CRTC’s legal status as a corporate entity will not change.

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

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

Finally, on the specific facts of this case, the transaction proposed by Petitioners is not “a capital expenditure . . . which relates to the provision of a health service” within the meaning of N.C.G.S. § 131E-176(16)b. The definition of “health service” specifically “does not include administrative and other activities that are not integral to clinical management.” Petitioners’ representations indicate that stock ownership of CRTTC is not integral to the clinical management of CRTTC, because in all material respects the operations of CRTTC 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 CRTTC. The Department has no notice of the existence or ownership of the second linear accelerator, and I make no finding that CRTTC 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 CRTTC, 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, CRTTC 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.

---

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:

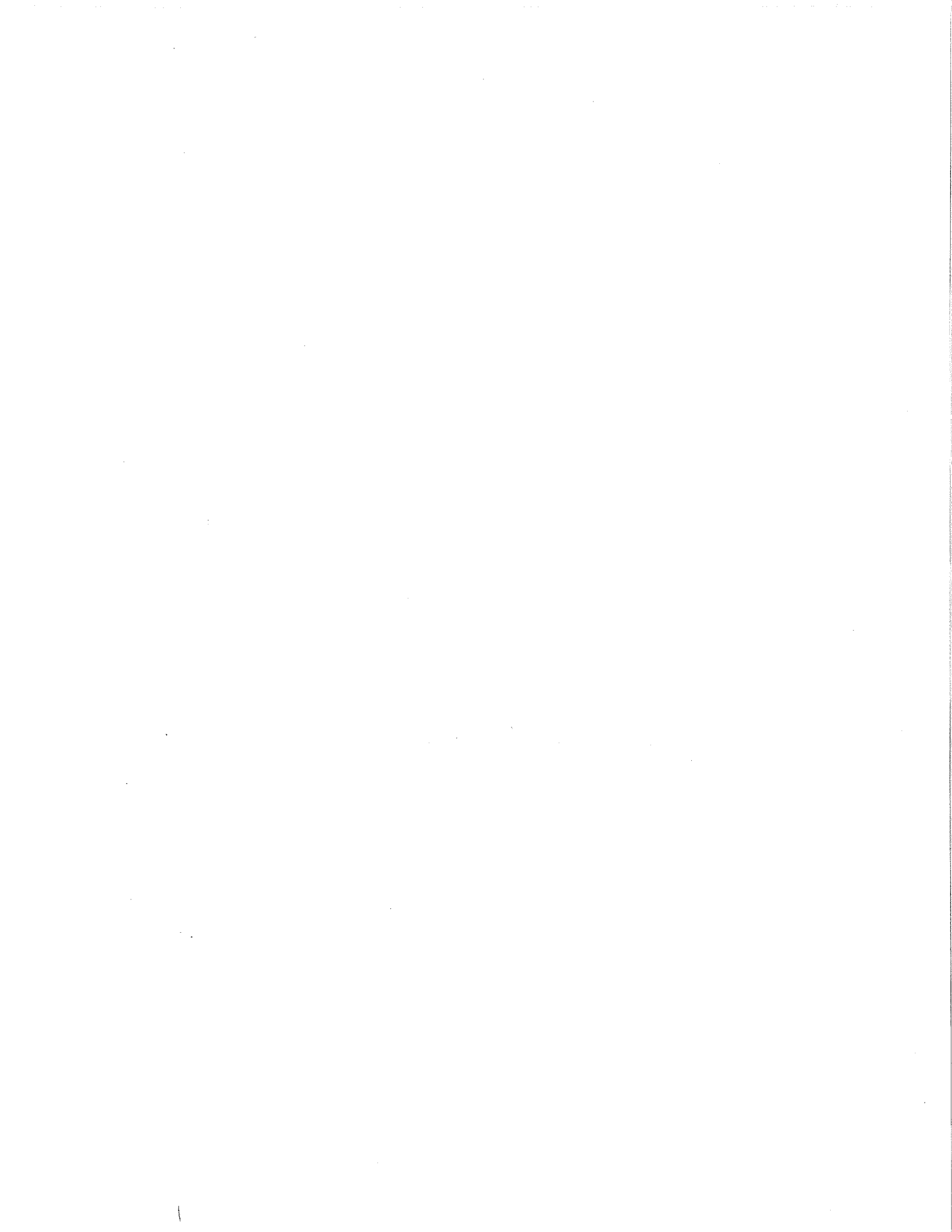
**CERTIFIED MAIL**

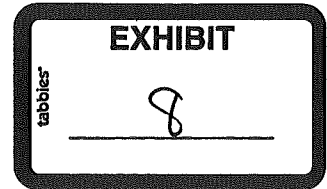
Susan H. Hargrove  
Smith, Anderson, Blount, Dorsett,  
Mitchell & Jernigan, L.L. P  
P.O. Box 2611  
Raleigh, NC 27602-2611

This \_\_\_\_\_ day of \_\_\_\_\_, 2007.

---

Jeff Horton  
Chief Operating Officer





North Carolina Department of Health and Human Services  
 Division of Health Service Regulation  
 Certificate of Need Section  
 2704 Mail Service Center • Raleigh, North Carolina 27699-2704  
<http://www.ncdhhs.gov/dhsr/>

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

Drexdal Pratt, Director

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

February 27, 2012

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

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

Dear Ms. Murray:

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

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

Please contact the CON Section if you have any questions.

Sincerely,

*Michael J. McKillip*  
 Michael J. McKillip  
 Project Analyst

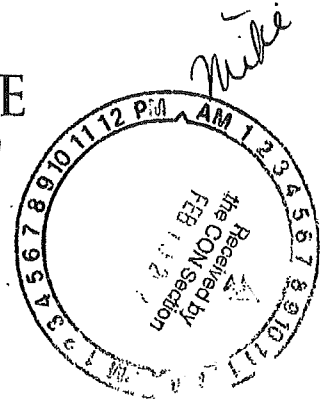
*Craig R. Smith*  
 Craig R. Smith, Chief  
 Certificate of Need Section





# SMITH MOORE LEATHERWOOD

February 8, 2012



*Via E-Mail and U.S. Mail*

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

Re: WakeMed Acquisition of Ownership Interests in CSA-1

Dear Mr. Smith and Ms. Frisone:

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

The Agency has issued numerous declaratory rulings and no review letters that acknowledge that acquisition of ownership interests in a legal entity does not constitute a reviewable acquisition of the medical equipment owned by that legal entity. For example, in a declaratory ruling issued to New Hanover Perfusionists, Inc., the Agency determined that the purchase of stock did not constitute the acquisition of a heart-lung bypass machine because ownership of the regulated heart-lung bypass equipment would not change. The Agency also determined that the transaction was not an obligation to develop or expand a health service or health service facility because the equipment company was not a health service facility. The stock purchase transaction proposed also was not "a capital expenditure . . . which relates to the provision of a health service" within the meaning of N.C. Gen. Stat. § 131E-176(16)(b). The definition of "health service" specifically "does not include administrative and other activities that are not integral to clinical management." Stock or membership interest ownership is not integral to clinical management. *In re: Request for Declaratory Ruling by New Hanover Perfusionists, Inc., January 24, 2008.*



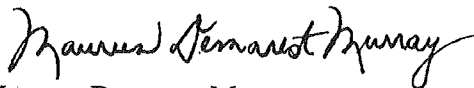
Mr. Craig R. Smith, Chief  
Ms. Martha Frisone, Assistant Chief  
February 8, 2012  
Page 2

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

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

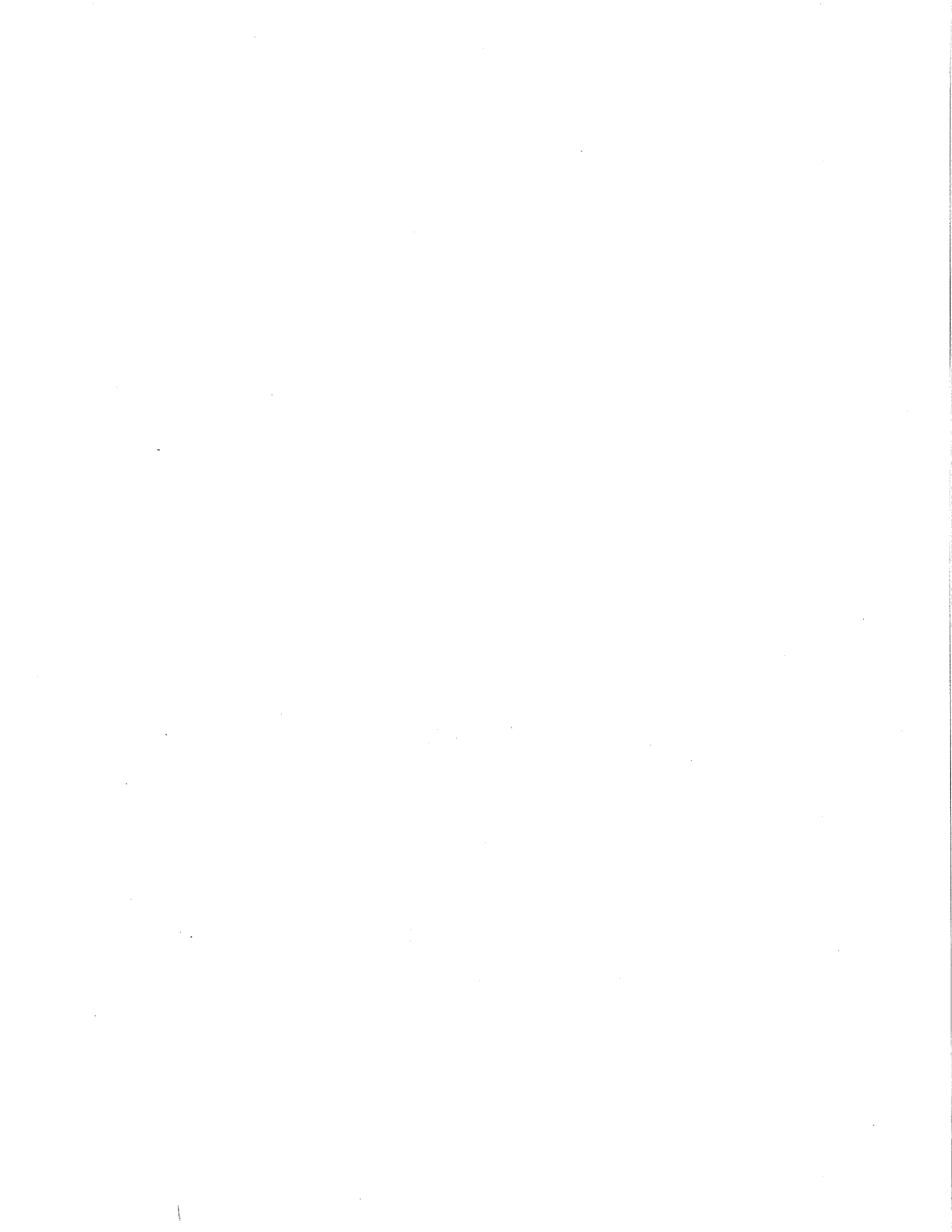
Sincerely yours,

SMITH MOORE LEATHERWOOD LLP



Maureen Demarest Murray

cc: Stan Taylor, WakeMed





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

2704 Mail Service Center • Raleigh, North Carolina 27699-2704  
<http://www.ncdhhs.gov/dhsr/>

Drexdal Pratt, Director

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

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

February 27, 2012

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

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

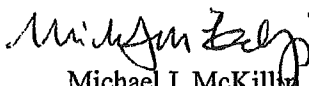
Dear Mr. Qualls:

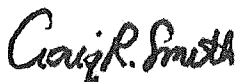
The Certificate of Need (CON) Section received your letter of February 9, 2012 regarding the above referenced proposal. Based on the CON law **in effect on the date of this response to your request**, the proposal described in your correspondence is not governed by, and therefore, does not currently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

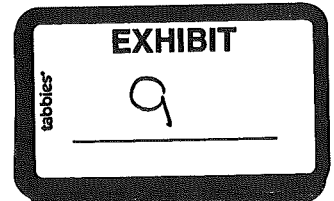
It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by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

Please contact the CON Section if you have any questions.

Sincerely,

  
 Michael J. McKillop  
 Project Analyst

  
 Craig R. Smith, Chief  
 Certificate of Need Section



K&L|GATES



K&L Gates LLP  
Post Office Box 14210  
Research Triangle Park, NC 27709-4210

430 Davis Drive, Suite 400  
Morrisville, NC 27560

T 919.466.1190 www.klgates.com

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

February 9, 2012

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

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

Dear Mr. Smith and Ms. Frisone:

We represent Rex Hospital, Inc. ("Rex"). The purpose of this letter is to provide notice to the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Certificate of Need Section (the "Agency") and confirm that Rex's acquisition of the ownership interests of CSAMS Lake Boone Trail, LLC ("CSA Lake Boone") is not reviewable as a new institutional health service under the North Carolina Certificate of Need ("CON") law. CSA Lake Boone is a wholly owned sub of CSA Medical, LLC ("CSA") and owns three (3) heart-lung bypass ("HLB") machines that have been and are operated at Rex. Rex would acquire the membership interests in CSA Lake Boone, which would continue to exist as a legal entity and to own the three (3) HLB machines that would remain located and operated at Rex.

The Agency has issued numerous declaratory rulings and no review letters that acknowledge that acquisition of ownership interest in a legal entity does not constitute a reviewable acquisition of the medical equipment owned by that legal entity. For example, in a declaratory ruling issued to New Hanover Perfusionists, Inc., the Agency determined that the purchase of stock did not constitute the acquisition of a heart-lung bypass machine because ownership of the regulated heart-lung bypass equipment would not change. The Agency also determined that the transaction was not an obligation to develop or expand a health service or health service facility because the equipment company was not a health service facility. The stock purchase transaction proposed also was not "a capital expenditure . . . which relates to the provision of a health service" within the meaning of N.C. Gen. Stat. § 131E-176(16)(b). The

# K&L|GATES

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

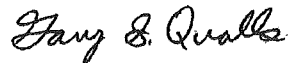
definition of "health service" specifically "does not include administrative and other activities that are not integral to clinical management." Stock or membership interest ownership is not integral to clinical management. *In re: Request for Declaratory Ruling by New Hanover Perfusionists, Inc., January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

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

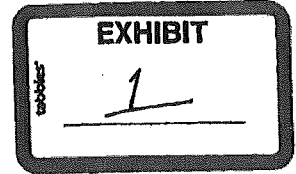
We would appreciate written confirmation from you that the anticipated transaction does not require CON review. If you require additional information to consider this request, please contact us. We appreciate your consideration.

Sincerely yours,

K&L GATES LLP



Gary S. Qualls



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

Beverly Eaves Perdue, Governor  
Lanier M. Canaler, Secretary

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

November 4, 2011

**CERTIFIED MAIL & FACSIMILE**

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

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

Dear Mr. Stewart:

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

Sincerely,

Drexdal Pratt

DP:JH:peb

Enclosure

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



Location: 809 Ruggles Drive ■ Dorothea Dix Hospital Campus ■ Raleigh, 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**

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

I, Drexdal Pratt, as Director of the Division of Health Service Regulation, North Carolina Department of Health and Human Services ("Department" or "Agency"), do hereby issue this Declaratory Ruling pursuant to North Carolina General Statute § 150B-4 and 10A NCAC 14A .0103 under the authority granted me by the Secretary of the Department of Health and Human Services.

The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Healthcare System ("CMHA") has requested a declaratory ruling to confirm that its acquisition of the membership interests of University Radiation Oncology Center, LLC ("UROC") and its continued operation of that facility may proceed without first obtaining a Certificate of Need ("CON"). This ruling will be binding upon the Department and the entities requesting it, as long as the material facts stated herein are accurate. This ruling pertains only to the matters referenced herein. Except as provided by N.C.G.S. § 150B-4, the Department expressly reserves the right to make a prospective change in the interpretation of the statutes and regulations at issue in this Declaratory Ruling. William W. Stewart of K&L Gates LLP has requested this ruling on CMHA's behalf and has provided the material facts upon which this ruling is based.

**STATEMENT OF THE FACTS**

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

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

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

#### ANALYSIS

The CON law provides that no person shall offer or develop a "new institutional health service" without first obtaining a CON. N.C. Gen. Stat. § 131E-178. The list of new institutional health services includes "the acquisition by purchase, donation, lease, transfer or comparable arrangement" of a linear accelerator or simulator "by or on behalf of any person," N.C. Gen. Stat. § 131E-176(16)(f1)5a, 9, and "the obligation by any person of a capital expenditure exceeding two million dollars (\$2,000,000) to develop or expand a health service or a health service facility, or which relates to the provision of a health service," N.C. Gen. Stat. § 131E-176(16)(b).

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



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

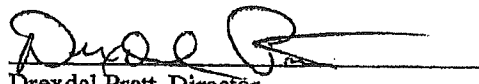
CMHA's acquisition of the membership interests in UROC does not constitute the acquisition of a linear accelerator or a simulator because the ownership of the equipment will not change, and the same equipment will be used to provide the same radiation oncology services, in the same location. UROC will continue to own the two pieces of equipment and UROC's legal status as a corporate entity will not change.

The purchase of ROCC's membership interests in UROC does not involve the offering or expansion of any new facility, service or equipment, and the state's inventory of linear accelerators and simulators will not change. No new or additional equipment will be acquired or placed in operation in the State.

#### CONCLUSION

For the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that CMHA does not require a certificate of need in order to proceed with the purchase of ROCC's membership interests in UROC.

This the 4<sup>th</sup> day of November, 2011.

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

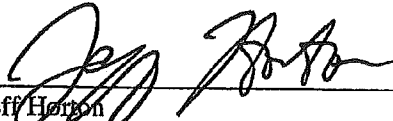
**CERTIFICATE OF SERVICE**

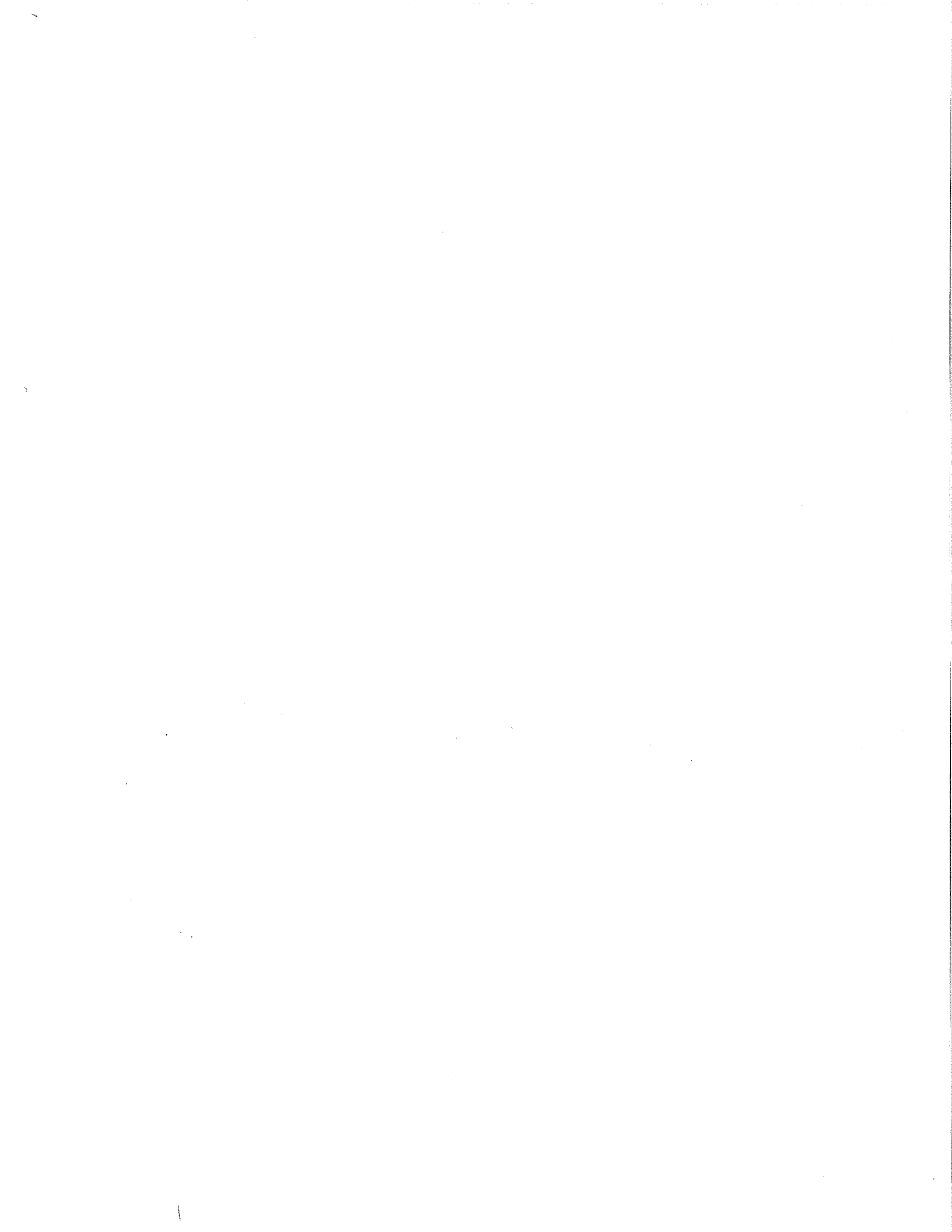
I certify that a copy of the foregoing Declaratory Ruling has been served upon the nonagency party by facsimile and certified mail, return receipt requested, by depositing the copy in an official depository of the United States Postal Service in a first-class, postage pre-paid envelope addressed as follows:

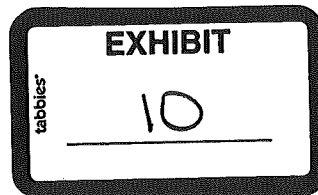
**CERTIFIED MAIL**

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

This the 4<sup>th</sup> day of November, 2011.

  
\_\_\_\_\_  
Jeff Horton  
Chief Operating Officer





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 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

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

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

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

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Mr. Qualls  
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,



Michael J. McKillip, Project Analyst



Martha J. Frisone, Interim Chief  
Certificate of Need Section

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

*Mike*

K&L Gates LLP  
Post Office Box 14210  
Research Triangle Park, NC 27709-4210

430 Davis Drive, Suite 400  
Morrisville, NC 27560

T 919.466.1190 www.klgates.com

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

Received by  
the CON Section  
MAR 24 2014

March 24, 2014

**VIA HAND DELIVERY**

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

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).

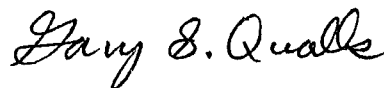
This proposal is similar to other proposals that the Agency has found to be non-reviewable. For example, the Agency recently determined that no CON review was necessary for Hugh Chatham Memorial Hospital, Inc. to independently license a nursing home that historically operated under its hospital license.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



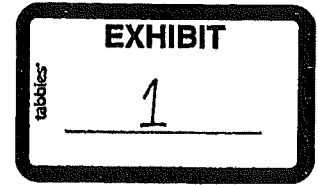
Gary S. Qualls

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

**Exhibits**

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





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

March 11, 2014

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

**No Review**

Facility: Hugh Chatham Memorial Nursing Center  
Project Description: 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.



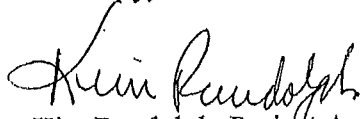
Certificate of Need Section  
www.ncdhhs.gov  
Telephone: 919-855-3873 • Fax: 919-733-8139  
Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603  
Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704  
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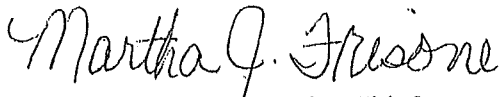
S. Todd Hemphill  
March 11, 2014  
Page 2

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,



Kim Randolph, Project Analyst



Martha J. Frisone, Interim Chief  
Certificate of Need Section

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

JOHN T. BODE  
S. TODD HEMPHILL  
MATTHEW A. FISHER  
DAVID R. BROYLES

*John  
Kim*

**BODE HEMPHILL, L.L.P.**  
ATTORNEYS AT LAW  
3105 GLENWOOD AVENUE, SUITE 300  
RALEIGH, NORTH CAROLINA 27612

TELEPHONE (919) 881-0338  
FACSIMILE (919) 881-9548

WWW.BCS-LAW.COM

MAILING ADDRESS

POST OFFICE BOX 6338  
RALEIGH, NORTH CAROLINA  
27628-6338

Writer's E-mail: [HEMPHILL@BCS-LAW.COM](mailto:HEMPHILL@BCS-LAW.COM)

February 18, 2014



**VIA HAND DELIVERY**

Martha J. Frisone, Interim Chief  
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-subsiary

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, Exhibit 1 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.

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 Exhibit 2 (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.

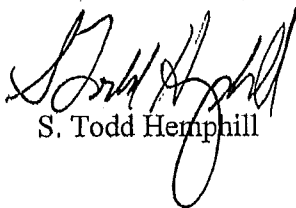
Ms. Frisone and Ms. Randolph  
February 18, 2014  
Page 3

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Please let us know if you need further information or if 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)

C2014 043 00481

State of North Carolina  
Department of the Secretary of State

Limited Liability Company  
ARTICLES OF ORGANIZATION

Pursuant to §57D-2-20 of the General Statutes of North Carolina, the undersigned does hereby submit these Articles of Organization for the purpose of forming a limited liability company.

1. The name of the limited liability company is: Hugh Chatham Nursing Center, LLC  
(See Item 1 of the Instructions for appropriate entity designation)
2. The name and address of each person executing these articles of organization is as follows: (State whether each person is executing these articles of organization in the capacity of a member, organizer or both. Note: This document must be signed by all persons listed.)  
S. Todd Hemphill (Organizer)  
Post Office Box 6338, Raleigh, NC 27628
3. The name of the initial registered agent is: Raymond A. Parker
4. The street address and county of the initial registered agent office of the limited liability company is:  
Number and Street 131 Colony Lane  
City Elkin State: NC Zip Code: 28621 County: Surry
5. The mailing address, if different from the street address, of the initial registered agent office is:  
Number and Street \_\_\_\_\_  
City \_\_\_\_\_ State: NC Zip Code: \_\_\_\_\_ County: \_\_\_\_\_
6. Principal office information: (Select either a or b.)  
a.  The limited liability company has a principal office.  
The principal office telephone number: (336) 527-7000  
The street address and county of the principal office of the limited liability company is:  
Number and Street 180 Parkwood Drive  
City Elkin State: NC Zip Code: 28621 County: Surry



The mailing address, if different from the street address, of the principal office of the company is:

Number and Street Post Office Box 680

City Elkin State: NC Zip Code: 28621 County: Surry

b.  The limited liability company does not have a principal office.

7. Any other provisions which the limited liability company elects to include (e.g., the purpose of the entity) are attached.

8. (Optional): Please provide a business e-mail address Privacy Reduction  
The Secretary of State's Office will e-mail the business automatically at the address provided above at no cost when a document is filed. The e-mail provided will not be viewable on the website. For more information on why this service is offered, please see the instructions for this document.



9. These articles will be effective upon filing, unless a future date is specified:

This is the 12th day of February, 2014

S. Todd Hemphill  
Signature

S. Todd Hemphill, Organizer  
Type or Print Name and Title

The below space to be used if more than one organizer or member is listed in Item #2 above.

_____ Signature	_____ Signature
_____ Type and Print Name and Title	_____ Type and Print Name and Title
_____ Signature	_____ Signature
_____ Type and Print Name and Title	_____ Type and Print Name and Title

NOTES:

1. Filing fee is \$125. This document must be filed with the Secretary of State.

---

**ATTACHMENT TO ARTICLES OF ORGANIZATION  
HUGH CHATHAM NURSING CENTER, LLC**

---

**NAME AND ADDRESS OF INITIAL MEMBER**

The sole member of Hugh Chatham Nursing Center, LLC is Hugh Chatham Memorial Hospital, Inc.

Hugh Chatham Memorial Hospital, Inc.'s address is 180 Parkwood Drive, Elkin, NC 28621





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

Beverly Eaves Perdue, Governor  
 Lanier M. Cansler, Secretary

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

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

December 9, 2011

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

- RE: No Review:
- o Transfer by CSA Medical Services, LLC (CSA) of 100% of its ownership interests in five (5) existing heart lung bypass machines in use at WakeMed to CSAMS New Bern Avenue, LLC, a wholly-owned subsidiary of CSA
  - o Transfer by CSA Medical Services, LLC (CSA) of 100% of its ownership interests in three (3) existing heart lung bypass machines in use at Rex Hospital to CSAMS Lake Boone Trail, LLC, a wholly-owned subsidiary of CSA
- Wake County

Dear Mr. Shenton:

The Certificate of Need (CON) Section received your letter of November 21, 2011 regarding the above referenced proposals. Based on the CON law in effect on the date of this response to your request, the proposals described in your correspondence are not governed by, and therefore, do not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposals would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposals when the new law becomes effective.

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

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

Sincerely,

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

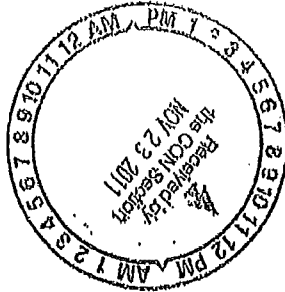
*Craig R. Smith*  
 Craig R. Smith, Chief  
 Certificate of Need Section

cc: Medical Facilities Planning Section, DHSR



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

**EXHIBIT**  
**2**



Poyner Spruill<sup>LLP</sup>

November 21, 2011

Wilson Hayman  
Partner  
D: 919.783.1140  
whayman@poynerspruill.com  
William R. Shenton  
Partner  
D: 919.783.2947  
F: 919.783.1075  
wshenton@poynerspruill.com

VIA U.S. MAIL AND E-MAIL/  
[Craig.smith@dhhs.nc.gov](mailto:Craig.smith@dhhs.nc.gov)  
[Martha.frisonc@dhhs.nc.gov](mailto:Martha.frisonc@dhhs.nc.gov)

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

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

Dear Mr. Smith and Ms. Frisonc:

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

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

#### I. BACKGROUND AND FACTS

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

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301 Fayetteville Street, Suite 1800, Raleigh, NC 27601    P.O. Box 1801, Raleigh, NC 27602-1801    F: 919.783.0400

Mr. Craig R. Smith, Chief  
Ms. Martha Frisone, Assistant Chief  
November 21, 2011  
Page 2

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

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

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

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

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

Mr. Craig R. Smith, Chief  
Ms. Martha Frisone, Assistant Chief  
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Page 3

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

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

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

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

## II. ANALYSIS

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

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

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

Poyner Spruill<sup>LLP</sup>

Mr. Craig R. Smith, Chief  
Ms. Martha Frisone, Assistant Chief  
November 21, 2011  
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Specifically, the provisions of N.C. Gen. Stat. § 131E-189(c) state by analogy that the Department of Health and Human Services may immediately withdraw any CON if the holder of the certificate, before completion of the project or operation of the facility, transfers ownership or control of the facility, the project, or the certificate of need." Further, the Agency's rules at 10A N.C.A.C. 14C.0502(b) state as follows:

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

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

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

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

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

### III. CONCLUSION

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

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

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

Poyner Spruill<sup>™</sup>

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

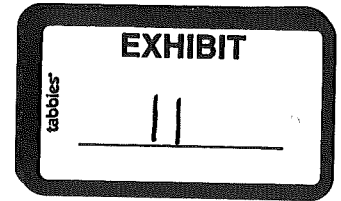
Very truly yours,

A handwritten signature in cursive script, appearing to read "William R. Shenton", with a long horizontal line extending to the right.

Wilson Hayman  
Partner  
William R. Shenton  
Partner

Attachments





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

Pat McCrory  
Governor

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

Drexdal Pratt  
Division Director

March 11, 2014

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

**No Review**

Facility: Hugh Chatham Memorial Nursing Center  
Project Description: 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.ncdhhs.gov

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

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

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

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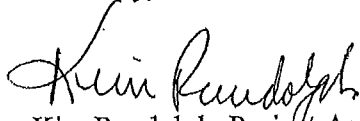




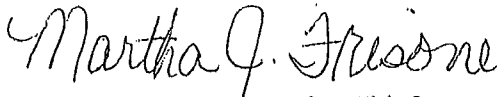
S. Todd Hemphill  
March 11, 2014  
Page 2

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,



Kim Randolph, Project Analyst



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

JOHN T. BODE  
S. TODD HEMPHILL  
MATTHEW A. FISHER  
DAVID R. BROYLES

*John Kim*

**BODE HEMPHILL, L.L.P.**  
ATTORNEYS AT LAW  
3105 GLENWOOD AVENUE, SUITE 300  
RALEIGH, NORTH CAROLINA 27612

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27628-6338

Writer's E-mail: [HEMPHILL@BCS-LAW.COM](mailto:HEMPHILL@BCS-LAW.COM)

February 18, 2014



**VIA HAND DELIVERY**

Martha J. Frisone, Interim Chief  
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-subsiary

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, Exhibit 1 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.

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 Exhibit 2 (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.

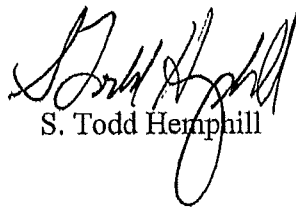
Ms. Frisone and Ms. Randolph  
February 18, 2014  
Page 3

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Please let us know if you need further information or if 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)

C2014 043 00481

State of North Carolina  
Department of the Secretary of State

Limited Liability Company  
ARTICLES OF ORGANIZATION

Pursuant to §57D-2-20 of the General Statutes of North Carolina, the undersigned does hereby submit these Articles of Organization for the purpose of forming a limited liability company.

1. The name of the limited liability company is: Hugh Chatham Nursing Center, LLC  
(See Item 1 of the Instructions for appropriate entity designation)
2. The name and address of each person executing these articles of organization is as follows: (State whether each person is executing these articles of organization in the capacity of a member, organizer or both. Note: This document must be signed by all persons listed.)  
S. Todd Hemphill (Organizer)  
Post Office Box 6338, Raleigh, NC 27628
3. The name of the initial registered agent is: Raymond A. Parker
4. The street address and county of the initial registered agent office of the limited liability company is:  
Number and Street 131 Colony Lane  
City Elkin State: NC Zip Code: 28621 County: Surry
5. The mailing address, if different from the street address, of the initial registered agent office is:  
Number and Street \_\_\_\_\_  
City \_\_\_\_\_ State: NC Zip Code: \_\_\_\_\_ County: \_\_\_\_\_
6. Principal office information: (Select either a or b.)  
a.  The limited liability company has a principal office.  
The principal office telephone number: (336) 527-7000  
The street address and county of the principal office of the limited liability company is:  
Number and Street 180 Parkwood Drive  
City Elkin State: NC Zip Code: 28621 County: Surry



The mailing address, if different from the street address, of the principal office of the company is:

Number and Street Post Office Box 680

City Elkin State: NC Zip Code: 28621 County: Surry

b.  The limited liability company does not have a principal office.

7. Any other provisions which the limited liability company elects to include (e.g., the purpose of the entity) are attached.

8. (Optional): Please provide a business e-mail address: Privacy Redaction  
The Secretary of State's Office will e-mail the business automatically at the address provided above at no cost when a document is filed. The e-mail provided will not be viewable on the website. For more information on why this service is offered, please see the instructions for this document.



9. These articles will be effective upon filing, unless a future date is specified:

This is the 12th day of February, 2014

S. Todd Hemphill  
Signature

S. Todd Hemphill, Organizer  
Type or Print Name and Title

The below space to be used if more than one organizer or member is listed in Item #2 above.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Type and Print Name and Title

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Type and Print Name and Title

\_\_\_\_\_  
Signature

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Type and Print Name and Title

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Type and Print Name and Title

NOTES:

1. Filing fee is \$125. This document must be filed with the Secretary of State.

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**ATTACHMENT TO ARTICLES OF ORGANIZATION  
HUGH CHATHAM NURSING CENTER, LLC**

---

**NAME AND ADDRESS OF INITIAL MEMBER**

The sole member of Hugh Chatham Nursing Center, LLC is Hugh Chatham Memorial Hospital, Inc.

Hugh Chatham Memorial Hospital, Inc.'s address is 180 Parkwood Drive, Blkin, NC 28621



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

Beverly Hayes Perdue, Governor  
Lanier M. Cansler, Secretary

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

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

December 9, 2011

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

RE: No Review:

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

Wake County

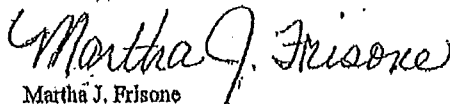
Dear Mr. Shenton:


The Certificate of Need (CON) Section received your letter of November 21, 2011 regarding the above referenced proposals. Based on the CON law in effect on the date of this response to your request, the proposals described in your correspondence are not governed by, and therefore, do not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposals would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposals when the new law becomes effective.

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

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

Sincerely,

  
Martha J. Frisone  
Assistant Chief

  
Craig R. Smith, Chief  
Certificate of Need Section

cc: Medical Facilities Planning Section, DHSR

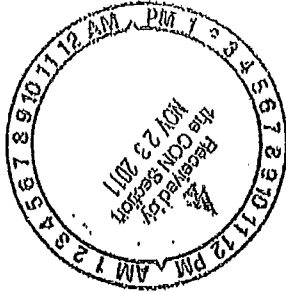


Location: 809 Ruggles Drive ■ Dorothea Dix Hospital Campus ■ Raleigh, N.C. 27603  
An Equal Opportunity / Affirmative Action Employer



EXHIBIT  
2





Poyner Spruill<sup>LLP</sup>

November 21, 2011

Wilson Hayman  
Partner  
D: 919.783.1140  
whayman@poynerspruill.com  
William R. Shenton  
Partner  
D: 919.783.2947  
F: 919.783.1075  
wshenton@poynerspruill.com

VIA U.S. MAIL AND E-MAIL/  
[Craig.smith@dhhs.nc.gov](mailto:Craig.smith@dhhs.nc.gov)  
[Martha.frisono@dhhs.nc.gov](mailto:Martha.frisono@dhhs.nc.gov)

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

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

Dear Mr. Smith and Ms. Frisono:

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

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

#### I. BACKGROUND AND FACTS

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

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

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

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

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

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

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

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

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

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

## II. ANALYSIS

The CON law provides that the "acquisition by purchase, donation, lease, transfer or comparable arrangement" of an HLB machine constitutes a "new institutional health service" that is subject to CON review. N.C. Gen. Stat. § 131E-176(16)f1; § 131E-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 those which the CON rules recognize as non-reviewable.

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

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

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Specifically, the provisions of N.C. Gen. Stat. § 131E-189(c) state by analogy that the Department of Health and Human Services may immediately withdraw any CON if the holder of the certificate, before completion of the project or operation of the facility, transfers ownership or control of the facility, the project, or the certificate of need." Further, the Agency's rules at 10A N.C.A.C. 14C.0502(b) state as follows:

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

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

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

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

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

### III. CONCLUSION

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

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

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

Poyner Spruill<sup>LLP</sup>

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Very truly yours,

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

Wilson Hayman  
*Partner*  
William R. Shenton  
*Partner*

Attachments