DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

April 19, 2018

Elizabeth V. Kirkman
2709 Water Ridge Parkway, Suite 200
Charlotte, NC 28217

Exempt from Review – Replacement Equipment

Record #:	**2565**
Facility Name:	Pineville Radiation Therapy Center
FID #:	060371
Business Name:	Mercy Hospital, Inc.
Business #:	2571
Project Description:	Replace existing linear accelerator and relocate it to the first floor of Medical Plaza II
County:	Mecklenburg

Dear Ms. Kirkman:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of March 29, 2018, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(f). Therefore, you may proceed to acquire without a certificate of need the Varian Trubeam to replace the Varian CL 21iX (Serial #4135). This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

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

It should be noted that the 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 office and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Julie M. Faenza

Julie M. Faenza
Project Analyst

Martha J. Frisone

Martha J. Frisone
Chief, Healthcare Planning and
Certificate of Need Section

cc: Construction Section, DHSR
Radiation Protection Section, DHSR
Amy Craddock, Assistant Chief, Healthcare Planning, DHSR
Acute and Home Care Licensure and Certification Section, DHSR

Carolinas HealthCare System

March 29, 2018

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

RE: Mercy Hospital, Inc. d/b/a Carolinas HealthCare System Pineville – Exemption Notice for Acquisition of Replacement Linear Accelerator ("Linac")

Dear Ms. Frisone:

Mercy Hospital, Inc. d/b/a Carolinas HealthCare System Pineville ("CHS Pineville"), seeks to acquire a Varian Trubeam Linear Accelerator ("Replacement Equipment"). Please see Attachment A for a copy of CHS Pineville's current hospital license. The Replacement Equipment will replace CHS Pineville's current Varian CL 21iX linear accelerator ("Existing Equipment"). The Existing Equipment is currently housed on the first floor of CHS Pineville's Medical Plaza I building connected to the main hospital on the main campus of CHS Pineville (see Attachment B). The replacement equipment will be located on the first floor of the newly constructed CHS Pineville Medical Plaza II located on the main campus of CHS Pineville and connected to the main hospital.

The purpose of this letter is to provide the Agency with notice and to request a determination that CHS Pineville's purchase of the Replacement Equipment is exempt from Certificate of Need ("CON") review under the replacement equipment exemption provisions contained in Session Law 2013-360, Section 12G.3(b) and Session Law 2013-363, Section 4.6 (which are codified at N.C. Gen. Stat. 131E-184(f)(1)-(3)).

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

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

See N.C. Gen. Stat. 131E-176(22a). Under the new provisions found at N.C. Gen. Stat. 131E-184(f)(1)-(3), the CON law provides:

(f) The Department shall exempt from certificate of need review the purchase of any replacement equipment that exceeds the two million dollar ($2,000,000) threshold set forth in G.S. 131E-176(22) if all of the following conditions are met:

(1) The equipment being replaced is located on the main campus.
(2) The Department has previously issued a certificate of need for the equipment being replaced. This subdivision does not apply if a certificate of need was not required at the time the equipment being replaced was initially purchased by the licensed health service facility.
(3) The licensed health service facility proposing to purchase the replacement equipment shall provide prior written notice to the Department, along with supporting documentation to demonstrate that it meets the exemption criteria of this subsection.

See Session Law 2013-360, Section 12G.3(b) and Session Law 2013-363, Section 4.6. The term "main campus" was defined in Session Law 2013-360, Section 13G.3(a) (codified N.C. Gen. Stat. 131E-176(14n)) as follows:

(14n) "Main campus" means all of the following for the purposes of G.S. 131E-184(f) and (g) only:

a. The site of the main building from which a licensed health service facility provides clinical patient services and exercises financial and administrative control over the entire facility, including the buildings and grounds adjacent to that main building.
b. Other areas and structures that are not strictly contiguous to the main building but are located within 250 yards of the main building.

The Existing Equipment is currently located on the first floor of CHS Pineville's Medical Plaza I building which is connected to the main hospital building on CHS Pineville's main campus (see Attachment B). The main hospital building from which Carolinas HealthCare System exercises financial and administrative control over Carolinas HealthCare System Pineville is located at 10628 Park Road, Charlotte, NC 28210 (see Attachment B). CHS Pineville President's office is located on the ground floor of the main hospital building.

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

A. Cost of the Replacement Equipment

The purchase price of the Replacement Linac Equipment is $3,477,505 ($3,234,889 Linac + $242,616 tax). The quote for the Linac Replacement Equipment from Varian is provided in Attachment C. The projected total capital cost of the project is $11,200,000(including taxes and freight) and includes the removal of the existing equipment and installation of the Replacement Equipment. The total capital cost

schedule and the certified cost estimate of the replacement/relocation renovation required to install the new equipment are provided in Attachment D. This capital cost also includes the equipment for and the construction of the radiation therapy medical office space in CHS Pineville Medical Plaza II.

B. Equipment Being Replaced is Located on the Main Campus

The Existing Equipment is currently located on the first floor of CHS Pineville's Medical Plaza I connected to the main hospital building (see Attachment B). The Replacement Equipment will be re-located (along with the radiation therapy medical office space) to the first floor of the newly constructed CHS Pineville Medical Plaza II which is also connected to the main hospital (see Attachment B).

C. Certificate of Need Issued for Equipment Being Replaced

This proposal also fits within the new exemption criterion in Section 131E-184(f)(2) because the Department issued a Certificate of Need for the Existing Equipment (see Attachment E). The Existing Equipment was purchased in 2008.

D. Comparable Equipment

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

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

CHS Pineville intends to use the Replacement Equipment for substantially the same linear accelerator procedures for which it currently uses the Existing Equipment. The Existing Equipment is a Varian CL 21iX that was installed new in 2008. This Existing Equipment has been used for linear accelerator procedures since installation.

The Replacement Equipment will perform all procedures currently performed on the Existing Equipment. Although it possesses some expanded capabilities due to technological improvements, the Replacement Equipment will perform the same linear accelerator procedures (see Attachment F for the Equipment Brochure). The Replacement Equipment is therefore "comparable medical equipment" as defined in Subsection (c).

Furthermore, CHS Pineville does not intend to increase patient charges or per procedure operating expenses within the first 12 months after equipment acquisition. For further equipment comparison, please refer to Attachment G, the Equipment Comparison Chart.

Subsection (d) of the regulation further provides:

(1) it has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements; and
(2) it is functionally similar and is used for the same diagnostic or treatment purposes as the equipment currently in use and is not used to provide a new health service; and
(3) the acquisition of the equipment does not result in more than a 10.0 percent increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.

The Replacement Equipment will meet all three of tests set out in Subsection (d). The Replacement Equipment satisfies the technology and functionality tests in Subsection (1) and (2) as discussed above and identified in the Comparison Chart (Attachment G). Moreover, CHS Pineville represents the use of the Replacement Equipment will not result in the types of expense or charge increases described in Subsection (d)(3).

Documentation provided in Attachment H indicates that 10,255 procedures were performed from February 2017 to January 2018 on the fixed existing equipment.

E. Disposition of Equipment

Please see Attachment I for a letter documenting the Existing Equipment will be taken out of service and will not be re-sold or re-installed in North Carolina without appropriate certificate of need approval.

CONCLUSION:

Based on the foregoing information, CHS Pineville hereby requests that the Agency provide a written response confirming that the acquisition of the Replacement Equipment described herein is exempt from CON review. If the Agency needs additional information to assist in its consideration of this request, please let us know.

Thank you for your consideration of this notice.

Sincerely,

Elizabeth V. Kirkman

Elizabeth V. Kirkman
Assistant Vice President
CHS Strategic Services Group

Attachments

cc: Christopher Hummer, President, Carolinas HealthCare System Pineville

Attachment A

State of North Carolina

Department of Health and Human Services
Division of Health Service Regulation

Effective January 01, 2018, this license is issued to

Mercy Hospital, Inc.

to operate a hospital known as

Carolinas HealthCare System Pineville

located in Charlotte, North Carolina, Mecklenburg County.

This license is issued subject to the statutes of the State of North Carolina, is not transferable and shall remain in effect until amended by the issuing agency.

Facility ID: 110878

License Number: H0042

Bed Capacity: *235*

General Acute 206, Rehabilitation 29 ,

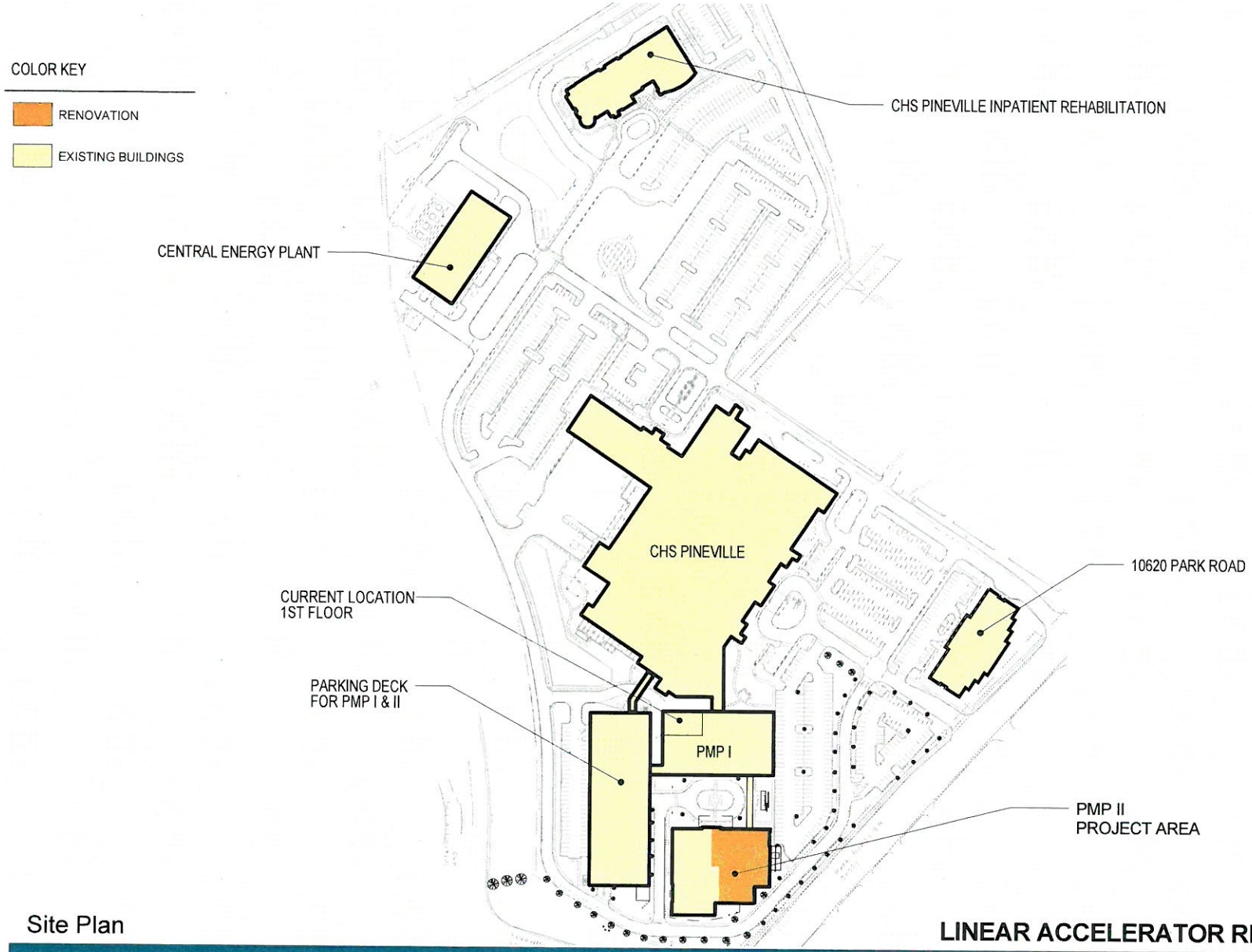
Dedicated Inpatient Surgical Operating Rooms: 3
Dedicated Ambulatory Surgical Operating Rooms: 0
Shared Surgical Operating Rooms: 9
Dedicated Endoscopy Rooms: 2

Authorized by:

Secretary, N.C. Department of Health and Human Services

Director, Division of Health Service Regulation

Attachment B



Site Plan

LINEAR ACCELERATOR REPLACEMENT

Carolinas HealthCare System

03/28/2018

CHS Pineville

COLOR KEY

- RENOVATION
- EXISTING BUILDINGS
- TENANT UPFIT

Pineville Medical Plaza II - Level 01 - Proposed

LINEAR ACCELERATOR REPLACEMENT

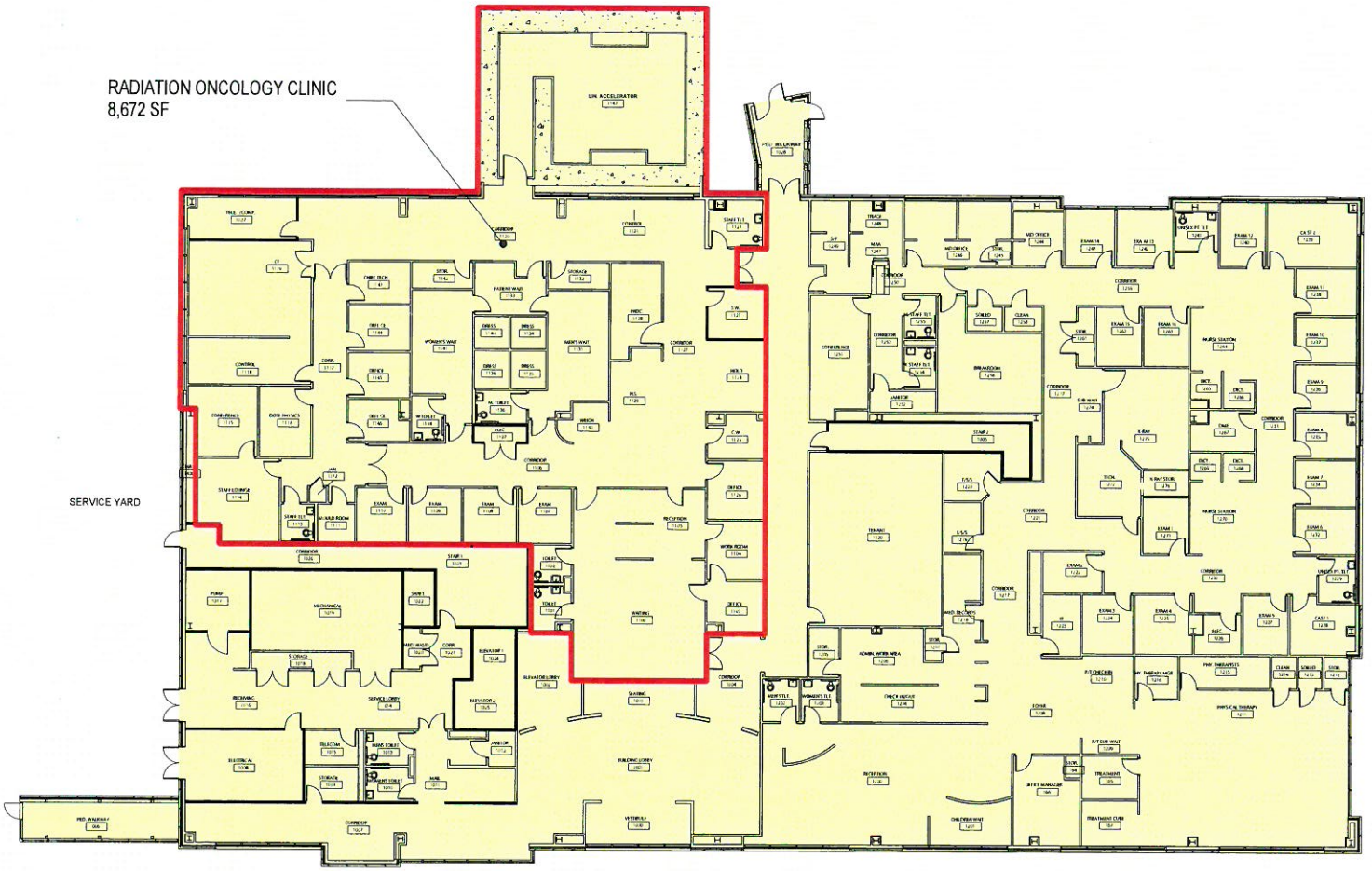
Carolinas HealthCare System

03/28/2018

CHS Pineville

COLOR KEY

EXISTING BUILDING



Existing Pineville Medical Plaza I - Level 01

LINEAR ACCELERATOR REPLACEMENT

Carolinas HealthCare System

03/28/2018

CHS Pineville

Attachment C

varian

Custom System Proposal

Quotation Number - 2018-136046-3

Looking further

varian

CHS Pineville ("Customer")

Tina Holden
10650 PARK RD, STE # 100
CHARLOTTE, North Carolina 28210 United States
Tel : (704) 667 - 0337
Fax : (704) 667 - 0338
Email : katina.holden@carolinashealthcare.org

Varian Medical Systems, Inc.

Shawn McCoy
US District Sales Manager
3290 Northside Parkway, Ste. 500
Atlanta,GA 30327 US
Tel : +1 877 404 0749
Fax : 678-255-3850
Email : shawn.mccoy@varian.com

Quote Information

Quotation Number :	2018-136046-3
Quotation Valid Until :	June 24, 2018
Customer Requested Delivery Date :	October 31, 2018
Quotation Date :	March 08, 2018

Sales

Incoterms :	US1: FOB: Origin
Payment Terms :	30 days net
Shipment :	95.00%
Acceptance :	5.00%

For orders equal or less than $75K, 100% upon shipment, net 30.

Quotation Total

Quotation Total : US $3,234,889.00

Terms and Conditions

This Quotation and Customer's access to and use of the Products and Services as indicated in this Quotation are subject to and governed by: (a) the Varian Terms and Conditions of Sale (Form RAD 1652) that can be viewed and are directly accessible at : https://www.varian.com/1652V_Apr_2017 ; and (b) any Schedules, Exhibits and/or additional terms (including third party terms) contained, attached, referenced or otherwise indicated in this Quotation that apply to the specific products or services indicated in this Quotation. Form RAD 1652 will not apply: (a) to Customer's access and use of Software-as-a-Service or Subscription Products and Services as indicated in the Quotation, which are subject to and governed by the Software-as-a-Service Terms and Conditions (Form RAD 10487 US) that can be viewed and are directly accessible at: https://www.varian.com/ SAAS_Oct_2017 ; or (b) to the extent a separate written agreement (e.g. master agreement) is in effect between the Customer and Varian that expressly and specifically provides for and governs the purchase and sale of the specific products, software, support, and/or services set forth in this Quotation. Hard copies of Form RAD 1652 and Form RAD 10486 will be provided to Customer upon written request.

For and on behalf of Customer

Name : Tina Holden
Title : Director
Date : March 08, 2018

Varian Medical Systems, Inc.

Name : Shawn McCoy
Title : US District Sales Manager
Date : March 08, 2018

Quotation Summary

varian

Offered Products (Sales)	
Scalable TrueBeam	Included
Advantage Credits	Included
Adhoc	Included
Adhoc	Included

varian

Item	Description	Qty
Section 1	Scalable TrueBeam	
1.1	**TrueBeam Base System 120 MLC** Treatment delivery system supporting X-Ray treatment delivery. Includes 120 leaf MLC with dual independent jaws, enhanced dynamic wedge, 6 MV X-ray treatment energy, 43 cm x 43 cm MV imager for radiographic, cine, and integrated imaging, Motion View CCTV camera system, treatment console with integrated audio and video systems, back pointer lasers, front pointer set and upper port film graticule to support basic quality assurance. Features: • Basic X-Ray treatment delivery technique package, including Static Photon, Photon Arc, and Dynamic Conformal Arc treatment delivery techniques • Intensity Modulated RadioTherapy (IMRT) treatment technique, including large field IMRT • Total Body Treatment technique package • 2D MV Radiographic and Cine Image Acquisition, 2D/2D Radiographic Image Review and match, Cine image review • Relative Portal Dosimetry Image and Integrated Image Acquisition • Matching of 2D radiographs to 3D reference images • Online addition of kV and MV imaging protocols to treatment fields, with automated generation of reference images • Online Physician Approval of Images at Treatment Console (compatible with ARIA® only) • Automated Machine Performance Check Testing, Online Machine Performance Check Review • Machine Performance Check Offline Review Prerequisites: • ARIA® Practice Management v10 MR5 or higher • ARIA® Radiation Oncology/Eclipse v10 MR4 or higher Customer Responsibilities: • Customer must verify compatibility with 3rd party systems & devices Notes: • TrueBeam supports IEC 60601 or IEC 61217 scales only • Includes installation and one year warranty • Electron Total Body Irradiation (TBE) and High Dose Total Body Electron (HDTSE) treatment techniques are only activated if optional electron and HDTSE energies are purchased.	1
1.2	**TrueBeam Version 2.7**	1
1.3	**New Universal Baseframe 52" Fixed Floor**	1
1.4	**15/16 MV (BJR 11/17)** 40 cm x 40 cm maximum field size, dose rate range 0-600 MU/Min.	1
1.5	**10/10 MV (BJR 11/17)** 40 cm x 40 cm maximum field size, dose rate range 0-600 MU/Min.	1
1.6	**6/6 MV (BJR 11/17)** 40 cm x 40 cm maximum field size, dose rate range 0-600 MU/Min.	1
1.7	**18 MeV, 0-1000 MU/Min** 25 cm x 25 cm maximum field size, dose rate range 0-1000 MU/Min.	1

Item	Description	Qty
1.8	**16 MeV, 0-1000 MU/Min** 25 cm x 25 cm maximum field size, dose rate range 0-1000 MU/Min.	1
1.9	**15 MeV, 0-1000 MU/Min** 25 cm x 25 cm maximum field size, dose rate range 0-1000 MU/Min.	1
1.10	**12 MeV, 0-1000 MU/Min** 25 cm x 25 cm maximum field size, dose rate range 0-1000 MU/Min.	1
1.11	**9 MeV, 0-1000 MU/Min** 25 cm x 25 cm maximum field size, dose rate range 0-1000 MU/Min.	1
1.12	**6 MeV, 0-1000 MU/Min** 25 cm x 25 cm maximum field size, dose rate range 0-1000 MU/Min.	1
1.13	**PerfectPitch 6DoF Couch** Fully integrated 6-Degrees of Freedom (6DoF) couch system. Features: • Manual and automated positioning of the patient • Image-based 6DoF patient positioning with remote couch motion Prerequisites: • ARIA® Oncology Information System for Radiation Oncology v.11 or later	1
1.14	**10X High Intensity Mode** 40 cm x 40 cm maximum field size, dose rate range 400-2400 MU/min in 400 MU/min steps.	1
1.15	**6X High Intensity Mode** 40 cm x 40 cm maximum field size, dose rate range 400-1400 MU/Min in 200 MU/min steps.	1
1.16	**Low-X Imaging Energy** Low-X imaging energy configuration, providing high soft tissue contrast when imaging in-line with the treatment beam.	1
1.17	**RapidArc Treatment Delivery** A volumetric modulated arc treatment delivery technique which, when used with Eclipse RapidArc Planning and a RapidArc-compatible information system, provides the capability to generate IMRT-quality dose distributions in a single, optimized arc around the patient. When coupled with Respiratory Motion Management System, provides the capability for Gated RapidArc. Features:	1

Item	Description	Qty
	• Simultaneous modulation of MLC aperture shape, beam dose rate, and gantry angle and rotation speed during beam delivery • Supports dynamic jaw tracking and collimator rotation with supporting treatment planning system Prerequisites: • 120 Leaf MLC Notes: • Respiratory Motion Management System is required for Gated RapidArc capability	
1.18	**kV Imaging System** kV Imaging system, providing 2D radiographic and fluoroscopic and 3D CBCT imaging capability. Features: • kV CBCT image acquisition, review, and match to 3D reference image • Radiographic image acquisition, with 2D/2D and 2D/3D image matching to reference image • Fluoroscopic image acquisition, with structure overlay on fluoroscopic images. • kV CBCT image acquisition with a long field of view, provided by merging multiple indexed CBCT images. Online data acquisition and viewing only. Prerequisites: %%	1
1.19	**Triggered Imaging** Automated intrafraction 2D kV radiographic imaging, with images triggered by respiration phase or amplitude, gantry angle, time period, or MU. Automated image-based beam hold on fiducial markers, based on user-defined marker motion thresholds. Features: • Respiration Triggered Imaging • MU Triggered Imaging • Gantry Triggered Imaging • Time Triggered Imaging • Autobeam Hold Prerequisites: • Respiratory Motion Management System	1
1.20	**Advanced Resp Motion Management System** Stereoscopic optical system for managing patient respiration motion during treatment delivery and imaging. Features: • Stereoscopic optical imager, including marker block for tracking patient respiration motion • Respiratory gated treatment delivery • Respiratory gated MV image acquisition and online review, respiration synchronized cine image acquisition and online review • Respiratory gated kV image acquisition and online review, respiration synchronized fluoroscopic image acquisition and online review	1
1.21	**LAP Apollo Blue Room Laser Kit** Features: • One Apollo Blue Remote Controlled Ceiling Crosshair Laser • Two Apollo Blue Remote controlled Lateral Crosshair Lasers • One Apollo Blue Remote Vertical or Horizontal Controlled Sagittal Line Laser (selected prior to system production)	1
1.22	**Enhanced Beam Conformance Specification**	1

Item	Description	Qty
	The Enhanced Beam Conformance Specifications provide tight tolerances for key X-ray and electron beam energy performance specifications.	
1.23	**Filtrine Water Chiller** A closed loop water cooling system, providing clean water at a constant flow, pressure, and temperature for cooling a high energy medical linear accelerator. Ideal for sites where a dependable source of clean water for cooling is not available.	1
1.24	**Additional MotionView CCTV Camera System** Additional set of two Motion View CCTV cameras and displays. Camera placement is at customer discretion. Features: • Two pan, tilt, zoom CCTV cameras • Two desktopLCD displays with built in camera controls • Adjustable viewing angle for patient privacy • Push button pan, tilt, zoom, and home position control Prerequisites: • Motion View camera system, provided with linac system.	1
1.25	**Main Circuit Breaker Panel** Main circuit breaker panel, interfacing to a single power input feed from the facility Mains. Circuit breakers provide independent over-current protection for equipment at the console and in the treatment room. UL and IEC/CE certified.	1
1.26	**VVS v1.1 In-Room Patient Verif** Varian Verification System (for ARIA v15 and higher) is a system which provides the capability to verify accessory and patient identification through the use of a barcode scanning system. Features: • One bar code scanner • One barcode label printer • One package of labels for bar code printer • Accessory and patient verification license Prerequisites: • ARIA® Oncology Information System for Radiation Oncology v15 or later Notes: • TrueBeam Queue does not support patient check in with barcode scanning.	1
1.27	**Motion Management Interface** Motion management interface is an integrated interface for validated external devices that provide patient positioning, patient and target motion monitoring, and/or respiratory gating. The Motion management interface supports connection of up to four external devices, two of which may be used for respiratory motion management or high speed beam hold. Features: • 4-DoF or 6-DoF patient positioning capability for compatible validated devices and couch configurations • Integrated external device beam hold and image-based patient repositioning workflow • Patient-specific external device activation and patient plan verification	1
1.28	**STD TRNG: TB Platform On-Site** The on-site review of the TrueBeam/Edge/VitalBeam components includes imaging and use cases for support of patient treatment for therapists. This support is to ensure that personnel who attended the classroom training are able to operate the TrueBeam Platform machine in a safe and effective manner in the clinical environment.	1

Item	Description	Qty
	Features: • Includes support for TrueBeam/Edge/VitalBeam • Offer is valid for 18 months after installation of product Prerequisites: • TrueBeam Platform classroom trainings Notes: • Training is non-refundable and non-transferable	
1.29	**INCL ED: TB201 TB Platform Physicists** TrueBeam Physics and Administration: TrueBeam Physics and Administration course is designed for personnel (primarily Medical Physicists) responsible for the acceptance, commissioning, and QA program development of the TrueBeam in the clinical environment. It is recommended that the student attend the TrueBeam Physics and Administration course shortly before the installation of the TrueBeam. The course provides instruction of the basic delivery components, basic imaging components, and a general overview of the motion management system components. Machine commissioning, calibration, and QA of the machine are included. The course subject matter is presented from a clinical use perspective. Primary emphasis is on the overall commissioning, calibration, and QA of the TrueBeam and its components. Extensive hands-on laboratory exercises are included. Features: • Includes support for TrueBeam/Edge/VitalBeam • Includes Tuition and Materials for ONE person • Length: 4.5 days • Offer is valid for 18 months after installation of product Customer Responsibilities: • Customer is responsible for all travel expenses (airfare, hotel, rental car, meals and travel incidentals) Notes: • Training is non-refundable and non-transferable	1
1.30	**INCL ED: TB101 TB Platform Operations** TrueBeam Operations is a course designed for personnel (primarily Radiation Therapists) responsible for the routine operation and clinical use of the TrueBeam. It is recommended that students attend the TrueBeam Operations course shortly before clinical use and the commencement of patient treatments. The course provides instruction of the basic delivery components, basic imaging components, and a general overview of the motion management system components. The course subject matter is presented from a clinical use perspective. Primary emphasis is on the overall understanding of the TrueBeam function and operation to include imaging and respiratory gating. Extensive hands-on laboratory exercises are included. The attendees of this class will be provided tools to allow them to instruct other clinical staff upon their return. Features: • Includes support for TrueBeam/Edge/VitalBeam • Includes Tuition and Materials for ONE person • Length: 4 days • Offer is valid for 18 months after installation of product Customer Responsibilities: • Customer is responsible for all travel expenses (airfare, hotel, rental car, meals and travel incidentals) Notes: • Training is non-refundable and non-transferable	2
1.31	**INCL ED: CL222 Respiratory Gating** The Respiratory Gating course provides training for physicists and therapists, to obtain knowledge of principles and practices of respiratory gating in radiation oncology for clinical implementation. Features: • Includes support for TrueBeam Platform • Includes Tuition and Materials for ONE person • Length: 2 days • Offer is valid for 18 months after installation of product Customer Responsibilities: • Customer is responsible for all travel expenses (airfare, hotel, rental car, meals and travel incidentals)	1

Item	Description	Qty
	Notes: • Training is non-refundable and non-transferable	
1.32	**NLS: English**	1
1.33	**Power Cond., 3phase 50KVA** Transtector 50KVA, 3-phase power conditioning unit, providing transient protection, line power regulation, and Input and Output circuit breakers for over-current protection. UL and IEC/CE certified. Notes: • Supports voltage configurations from 208 to 600 VAC and in 50 or 60 Hz for US and ROW applications.	1
1.34	**Qfix™ kVue™ couch top** Indexed Immobilization treatment table kVue™ couch top, by Qfix™ , treatment table with carbon fiber couch top, two locating bars, two removable accessory rails, patient straps. Includes the following inserts: • Standard indexing insert panel • Dose-max insert panel • Universal tip insert • service panel. Note: Compatibility of specific 3rd party accessories, which are intended for use with kVue couch top, should be confirmed by the user directly with the 3rd party supplier before ordering this top.	1
1.35	**Pivotal™ Prone Breast Solution** The Pivotal™ treatment solution supports prone breast technique with the Qfix™ kVue™ Access 360™ prone breast insert. A Pivotal treatment solution online marketing program is included to help build awareness of your facility and promote the Pivotal treatment solution to patients, physicians, and your community. Includes a broad range of marketing materials including public relations, advertising, and educational content. Features: • Right and left prone breast couch top inserts with foam cushions • Prone head cushion & contour pillow cushion • Dual hand grip and ipsilateral hand grip • Adjustable CT Risers (superior & inferior) for CT simulation • Storage Cart Prerequisites: • Qfix™ kVue™ Couch top Notes: • Available for small and large bore CT scanners	1
1.36	**SRS IMB Qfix Couchtop Portrait** The SRS Portrait Immobilization package from Qfix™ is specifically tailored for use with the Qfix kVue™ and Calypso® kVue couch tops. Features: • kVue Portrait™ Head and Neck Insert (quantity: 1) • Silverman Head support (quantity: 5) • Moldcare™ Head Cushion (quantity: 10) • Fibreplast™ Open Face Mask (quantity: 10) • Portrait™ Head and Neck Overlay Device for CT (quantity: 1) • Locating bar (quantity: 1) • Water Bottle for use with Moldcare Head Cushion (quantity: 1) Prerequisites: • Qfix kVue or Calypso kVue couch top • TrueBeam® v2.0 and higher	1

Item	Description	Qty
	• VitalBeam® v2.5 (China only) and higher Notes: • Training will be provided by Qfix	
1.37	**SBRT IMB for existing Qfix couchtops**	1

Section 2 Advantage Credits

2.1 **Advantage Contract Credits**

Advantage Credits can be utilized for Varian's Professional Services, such as consulting, on-site applications training, education, and third-party services including physics services and clinical schools that are purchased through Varian. For further details, please reference the attached Terms and Conditions.

2.2 **ED: TB201 TrueBeam Platform Physicists** 32.0

(Qty: 2, Credit per Qty: 16.0)
Includes Tuition and Materials for ONE Person

This course provides training for Medical Physicists responsible for commissioning and administration of the TrueBeam machine. The course consists of combination of lectures, demonstrations, and hands-on exercises carried out in a lab equipped with fully functioning TrueBeam system. The course provides an overview of TrueBeam hardware, software and control system, to a depth sufficient for the user to prepare the system for clinical use. The course also includes demonstration of common IGRT, Motion Management and treatment plan delivery techniques. PLEASE NOTE: For more in-depth calibration and maintenance training, see TrueBeam Technical Maintenance I & II.

Designed for Medical Physicists
Pre-Requisites: Masters degree in Medical Physics, or equivalent

Duration and Location:
4.0 days
Varian Education Center
Las Vegas, Nevada, USA

Application has been made to CAMPEP credits
Advantage Credits Eligible

Customer is responsible for all travel expenses (airfare, hotel, rental car, meals and travel incidentals), unless otherwise stated.

2.3 **ED: TB101 TrueBeam Platform Operations** 32.0

(Qty: 2, Credit per Qty: 16.0)
Includes Tuition and Materials for ONE Person

This course provides training for Radiation Therapists responsible for the operation of the TrueBeam, providing an overview of the TrueBeam system, hands-on training to include: system components, shutdown procedure, startup with basic morning QA procedures, startup after an emergency shutdown and power failure, basic administrative information and treatment and imaging scenarios to include: basic 2D and 2D-2D imaging, treatment with automation, LaserGuard II and Machine Protection, imaging and treatment with custom blocks, Cone-Beam CT , gated imaging and treatment with intra-fraction motion review, auto-beam hold and emergency treatment.

Designed for Radiation Therapists who will treat patients on a daily basis and will be able to teach TrueBeam others users in the department
Pre-Requisites: Clinical training in Radiation Therapy. Clinical experience if treating patients on Varian machines. Clinical experience of IGRT, OBI and Cone-Beam CT.

Application has been made for MPCEC credits

Item	Description	Qty
	Duration and Location: 4.0 days Varian Education Center Las Vegas, Nevada, USA Advantage Credits Eligible Customer is responsible for all travel expenses (airfare, hotel, rental car, meals and travel incidentals), unless otherwise stated.	
Section 3	Adhoc	
3.1	**Remove/Dispose Existing Equipment**	1
Section 4	Adhoc	
4.1	**Reserve**	1

varian

Summary of Advantage Contract Credits Quoted Above

Section 2

Year 1 Total	64.0
Total Credits	64.0

varian

Quotation Total

Quotation Total	US $3,234,889.00

VARIAN
medical systems

ADVANTAGE CREDITS SUPPLEMENTAL TERMS AND CONDITIONS

(FORM RAD 10442)

These Advantage Credits Supplemental Terms and Conditions ("Supplemental Terms") modify and supplement the Varian Terms and Conditions of Sale (Form RAD 1652, current version issued with the Quotation) (the "Terms and Conditions of Sale"). The terms of the applicable Varian Quotation ("Quotation"), its attachments, including the Terms and Conditions of Sale, are incorporated herein by this reference, and together with these Supplemental Terms and any applicable Third Party Terms (as defined in the Quotation) (collectively referred to as the "Agreement") will apply and govern the use by Customer of Advantage Credits.

1.0 General

The Varian Advantage Credit Program (the "Program") offers customers the ability to purchase Advantage Credits in advance that can be applied toward designated Varian Professional Services including certain consulting (e.g. specified and limited implementation and optimization services), on-site training, educational courses and a limited number of services provided by designated third party service providers, including clinical schools and physics commissioning services. Advantage Credits provide flexibility for the Customer to apply them interchangeably for those designated services available under the Program without having to modify the underlying Quotation and related purchase order. However, Varian must be notified in advance and in writing of any requested changes to selected services.

2. Expiration Schedule

Advantage Credits expire according to the following schedule:

Type of Order	Expiration Date
Advantage Credits only (no Varian products)	24 months from date of order
Advantage Credits with one or more Varian products	24 months from first date of product/service acceptance
Multiyear agreement	End of the term of agreement

3.0 Scopes of Work

Varian or its third party service providers may, at their discretion, set forth in a written Scope of Work (SOW) a description of the services to be provided by Varian or the third party service provider. If the services that will be purchased with Advantage Credits are defined within the Quotation, Varian will offer the specific services listed for the amount of Advantage Credits indicated. If Advantage Credits in the Quotation are "Undefined", Varian will indicate the number of Advantage Credits required for a particular service at the time the Customer wants to use them.

4.0 Third Party Service Providers

4.1 Certain services are provided by and through third party service providers that are not affiliated with Varian, namely clinical schools and physics services (e.g. commissioning). Varian disclaims any warranty or performance obligations related to any third party service provider and will act solely as a pay agent, to collect fees for services from Customer and to pay fees for such services to the third party service provider. Customer has the final decision to purchase services through Varian third party service providers or to select another service provider outside of the Quotation and Varian does not make any recommendations to use third party service providers.

4.2 **Changes to Third Party Service Providers by Customer.** Customer shall have a one-time right to request in writing that a third party service provider be replaced with an alternate provider that is participating in the Program. If Varian, at its sole discretion, approves the request, Customer shall be subject to any related termination fees and additional costs incurred by Varian or the third party service provider and other terms and conditions indicated in the SOW and/or

Quotation. Customer, the third party service provider, and if applicable, its subcontractors, shall have full responsibility for services as defined in the Quotation or SOW, as applicable, and Varian shall have no responsibility, obligation and/or liability whatsoever for those services. The third party service provider shall not be construed to be a subcontractor, employee, or agent of Varian. Varian will forward any requests for warranty work that it receives from Customer to the third party service provider. Except as otherwise provided in this section of the Quotation, the Terms and Conditions of Sale shall apply to this section just as it applies to all other parts of the Quotation.

4.3 **Changes to Third Party Service Providers by Varian.** Varian reserves the right, at its sole discretion, to change, from time to time, its list of third party providers that participate in the Program.

5.0 Performance of Services

All services shall be performed by Varian or the third-party service provider under permits, licenses, authority, supervision, and control of Customer and its staff, including licensed physicists, physicians, and other qualified healthcare professionals. Customer and its staff shall have the requisite permits (including applicable certificates of need), licenses, and authority to oversee and have such services performed on Customer's behalf.

6.0 Service Offerings

Varian reserves the right, at its sole discretion, to change the designated services which are offered under the Program at any time without prior notice. Varian will work with Customer to offer a mutually acceptable alternative or apply affected credits toward other offerings within the Program.

Attachment D

PROPOSED TOTAL CAPITAL COST OF PROJECT

Project name: LCI Pineville – Linear Accelerator Replacement

Provider/Company: LCI Pineville – Carolinas Healthcare System

(1)	Purchase price of land	
(2)	Closing costs	
(3)	Site Preparation	
(4)	Construction/Renovation Contract	$4,800,000
(5)	Landscaping	
(6)	Architect/Engineering Fees	$150,000
(7)	Medical Equipment	$4,200,000
(8)	Non Medical Equipment	$300,000
(9)	Furniture	$350,000
(10)	Consultant Fees (CON Fees, Legal Fees, Design Fees)	$100,000
(11)	Financing Costs	
(12)	Interest During Construction	
(13)	Other (IS, Security, Internal Allocation)	$1,300,000
(14)	**Total Capital Cost**	$11,200,000

I certify that, to the best of my knowledge, the above construction related costs of the proposed project named above are complete and correct.

GEC

March 28, 2018

(Signature of Licensed Architect or Engineer) *DATE*

Sales taxes have been included in these equipment costs. However, because CHS is entitled to a sales tax refund under N.C. Gen. Stat. § 105-164.14(b) and 105-467, the sales tax that CHS initially incurs for this medical equipment purchase will be refunded to CHS, and thus will reduce the capital costs that CHS actually incurs for the equipment by $ 315,000 .

Attachment E

STATE OF NORTH CAROLINA
Department of Health and Human Services
Division of Facility Services

CERTIFICATE OF NEED

for

Project Identification Number #F-7524-06
FID# 060371

ISSUED TO: **Pineville Radiation Therapy Center, LLC and**
The Charlotte-Mecklenburg Hospital Authority
10628 Park Road
Pineville, NC 28210

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: **Acquire a linear accelerator and simulator and establish a new radiation oncology center/Mecklenburg County**

CONDITIONS: **See Reverse Side**

PHYSICAL LOCATION: **Pineville Radiation Therapy Center**
10628 Park Road
Pineville, NC 28210

MAXIMUM CAPITAL EXPENDITURE: **$7,516,996**

TIMETABLE: **See Reverse Side**

FIRST PROGRESS REPORT DUE: **October 1, 2007**

This certificate is effective as of the 27th day of June, 2007.

Lee B. Hoffman

Chief, Certificate of Need Section
Division of Facility Services

CONDITIONS:

1. Pineville Radiation Therapy Center, LLC ("Pineville") and the Charlotte Mecklenburg Hospital Authority ("CMHA") shall materially comply with all representations made in their CON application and the supplemental information they submitted to the Agency on May 29, June 13, and June 15, 2007. In those instances in which the representations made in these documents conflict, Pineville and CHMA shall materially comply with the later-made representation.

2. Pineville and CHMA shall not acquire, as part of this project, any equipment that is not included in the proposed capital expenditure in Section VIII.1 of the application or that would otherwise require a CON.

3. The approved capital expenditure for the project shall be $7,516,996.

TIMETABLE:

Obtain Funds for project ---------- August 1, 2007
Contract Award ---------- February 1, 2008
25% completion of construction---------- March 1, 2008
50% Completion of construction - ---------- May 1, 2008
75% Completion of construction ---------- July 1, 2008
Completion of Construction ---------- August 1, 2008
Offering of Service ----------September 1, 2008

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

December 5, 2017

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

Material Compliance Approval

Project ID #:	F-7524-06
Facility:	Pineville Radiation Therapy Center
Project Description:	Redesignate the Pineville Radiation Therapy Center space and equipment as an unlicensed, provider-based location of CHS Pineville
County:	Mecklenburg
FID #:	60371

Dear Mr. Qualls:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) has determined that the change proposed in your letter of November 28, 2017 is in material compliance with representations made in the application. This change includes redesignating the Pineville Radiation Therapy Center space and equipment from an unlicensed, provider-based location of Carolinas Medical Center to an unlicensed, provider-based location of CHS Pineville. The location of the Pineville Radiation Therapy Center will remain on the CHS Pineville campus. However, you should contact the Agency's Acute and Home Care Licensure and Certification Section, DHSR to determine if they have any requirements pertinent to the proposed change.

It should be noted that the 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 office and a separate determination.

If you have any questions concerning this matter, please feel free to contact this office. Please refer to the Project ID # and Facility ID # (FID) in all correspondence.

Sincerely,

Gloria C. Hale

Gloria C. Hale
Project Analyst

Martha J. Frisone

Martha J. Frisone
Chief, Healthcare Planning and
Certificate of Need Section

cc: Acute and Home Care Licensure and Certification Section, DHSR
Sharetta Blackwell, Program Assistant, Healthcare Planning, DHSR

K&L GATES

November 28, 2017

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

Via Hand Delivery
Martha Frisone, Chief
N.C. Department of Health and Human Services
Division of Health Service Regulation
Healthcare Planning and CON Section
809 Ruggles Drive
Raleigh, NC 27603

Re: No Review / Material Compliance Letter Regarding Redesignation of Radiation Oncology Provider-Based Outpatient Department of CMC to a Provider-Based Outpatient Department of CHS Pineville (No Physical Relocation Involved)

Dear Ms. Frisone:

The Charlotte-Mecklenburg Hospital Authority ("CMHA") and its wholly-owned subsidiary, Mercy Hospital, Inc. ("Mercy"), are requesting a no review or material compliance determination that the North Carolina Certificate of Need ("CON") law does not require CON review of already developed and operational provider-based radiation oncology space and equipment being redesignated in status as follows:

1. The space and equipment being redesignated is currently being operated as an unlicensed, provider-based location of Carolinas Medical Center ("CMC") on the campus of CHS Pineville (the "Pineville Campus Radiation Oncology Space and Equipment").

2. The Pineville Campus Radiation Oncology Space and Equipment will be redesignated as an unlicensed, provider-based location of CHS Pineville (the "Redesignation"), yet physically remaining on the CHS Pineville Campus and not relocating as part of this Redesignation.

CMHA is a North Carolina hospital authority. CMHA owns and operates several hospitals. Among those hospitals, CMHA operates CMC, a hospital in Charlotte, Mecklenburg County. CMHA's wholly-owned subsidiary, Mercy, owns and operates CHS Pineville, also in Charlotte, Mecklenburg County. Both CMC and CHS Pineville are under the organizational umbrella of CMHA – CMC as an operating division of CMHA and CHS Pineville as a subsidiary of CMHA.

In 2013, CMHA received this Agency's permission to redesignate the Pineville Campus Radiation Oncology Space and Equipment from freestanding to provider-based to CMC. See Exhibit A (December 13, 2013 Request) and Exhibit B (Agency's December 19, 2013 Approval of December 13 Request).

The space being redesignated is 8,672 square feet of space on the first floor of the current Pineville Campus Medical Office Building ("Pineville Campus MOB"), which houses the Radiation Oncology Space and Equipment, located on the CHS Pineville Hospital Campus, 10650 Park Road, Charlotte, North Carolina 28210. See Floor Plan attached Exhibit C. As Exhibit C shows, the CON-regulated equipment in the Radiation Oncology Space is comprised of a linear accelerator ("linac") and a CT simulator (collectively "the Radiation Oncology Equipment"). That Radiation Oncology Equipment was approved pursuant to the 2007 CON and 2006 CON Application in Exhibit A1 and A2, respectively. Exhibit D shows where the Pineville Campus MOB is situated on the CHS Pineville Hospital Campus.

CMHA is shifting the designation of that Radiation Oncology Space and Equipment from an unlicensed, provider-based location of CMC to an unlicensed, provider-based location of CHS Pineville. The Radiation Oncology Space and Equipment will be provider-based to CHS Pineville, and will operate as an unlicensed outpatient location under the Business Occupancy Exception to the Hospital Licensure Act, in accordance with N.C. Gen. Stat. § 131E-76(3).[1]

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[1] That statute defines "hospital" as follows for licensure purposes:

> "'Hospital' means any facility which has an organized medical staff and which is designed, used, and operated to provide health care, diagnostic and therapeutic services, and continuous nursing care primarily to inpatients where such care and services are rendered under the supervision and direction of physicians licensed under Chapter 90 of the General Statutes, Article 1, to two or more persons over a period in excess of 24 hours. The term includes facilities for the diagnosis and treatment of disorders within the scope of specific health specialties. **The term does not include** private mental facilities licensed under Article 2 of Chapter 122C of the General Statutes, nursing homes licensed under G.S. 131E-102, adult care homes licensed under Part 1 of Article 1 of Chapter 131D of the General Statutes, and **any outpatient department including a portion of a hospital operated as an outpatient department, on or off of the hospital's main campus, that is operated under the hospital's control or ownership and is classified as Business Occupancy by the Life Safety Code of the National Fire Protection Association as referenced under 42 C.F.R. § 482.41** . . . ."

See N.C. Gen. Stat. § 131E-76(3) (emphasis added).

No assets are physically moving as a result of the Redesignation. The Redesignation does not trigger any of the definitions of a "new institutional health service," which would implicate CON review. N.C. Gen. Stat. § 131E-178 provides that no person shall offer or develop a "new institutional health service" without first obtaining a CON. The term "new institutional health service" is defined in numerous ways in N.C. Gen. Stat. § 131E-176(16).

Among these definitions is N.C. Gen. Stat. § 131E-176(16)(b), which defines a "new institutional health service" to include:

> . . . [T]he 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 . . . .

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

However, the Redesignation does not constitute a "new institutional health service" under N.C. Gen. Stat. § 131E-176(16)(b) because no capital expenditures are being incurred as part of this Redesignation. Those expenditures were incurred years ago when the Radiation Oncology Space and Equipment was developed pursuant to a CON. See Exhibits A1 and A2. Moreover, this is purely an intra-organizational Redesignation within CMHA and its wholly-owned subsidiary, Mercy.[2]

Finally, the Redesignation does not constitute the establishment of a new health service facility under N.C. Gen. Stat. § 131E-176(16)(a) because the existing space is simply transitioning from outpatient space at one existing CMHA-related hospital to outpatient space at another existing CMHA-related hospital. Because no beds are involved, the Redesignation does not constitute a "change in bed capacity" under N.C. Gen. Stat. § 131E-176(16)(c). Because no operating rooms are involved, the Redesignation does not implicate N.C. Gen. Stat. § 131E-176(16)(u). Nor does the Redesignation constitute a new institutional health service under any other CON trigger in N.C. Gen. Stat. § 131E-176(16).

---

[2] The Agency has recently approved intra-organizational moves of CON-regulated equipment between Novant's related entities (even ones which entailed physical relocation of regulated equipment from one service area campus to another). See Exhibits E and F. Our proposed Redesignation does not involve any such physical relocation.

Accordingly, the Redesignation does not require CMHA or Mercy to obtain a CON pursuant to any provision of the CON statutes. Thus, based upon the foregoing information and the attached documents, CMHA and Mercy hereby request that the Agency provide a written response confirming that the Redesignation described herein does not require a CON.

Please let us know if you need additional information. We thank you for your consideration of this submission.

Sincerely,

Gary S. Qualls

Gary S. Qualls

Enclosures

Exhibits

A. December 13, 2013 Request by CMHA to redesignate the Pineville Campus Radiation Oncology Space and Equipment from freestanding to provider-based to CMC.

B. Agency's December 19, 2013 Approval of December 13, 2013 Request.

C. Floor Plan within MOB Showing Space and Equipment to be Redesignated

D. Site Plan Showing MOB Where Redesignated Space and Equipment is Housed

E. August 5, 2015 Material Compliance Letter approving Novant Health to relocate and replace a Cardiac Cath Unit from Novant Health Presbyterian Medical Center to Novant Health Matthews Medical Center.

F. July 16, 2015 Request by Novant Health to relocate and replace a Cardiac Cath Unit from Novant Health Presbyterian Medical Center to Novant Health Matthews Medical Center.

EXHIBIT
exhibitor
A

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

December 13, 2013

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

Via Hand Delivery

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

RE: Material Compliance for Radiation Oncology Center CON Jointly Issued to The Charlotte-Mecklenburg Hospital Authority and Pineville Radiation Therapy Center (Project I.D. No. F-7524-06)

Dear Ms. Frisone:

We represent The Charlotte-Mecklenburg Hospital Authority ("CMHA") and its subsidiary Pineville Radiation Therapy Center, LLC ("PRTC") (collectively the "Applicants"). By a Certificate of Need ("CON") dated June 27, 2007, the Applicants were jointly awarded the CON rights to own and operate a linear accelerator, a simulator, and related equipment and space for a radiation oncology center (the "Center") in Mecklenburg County. See Exhibit 1 (CON for Project I.D. No. F-7524-06).

By this request, the Applicants are asking the North Carolina Department of Health & Human Services, Division of Health Service Regulation, Certificate of Need ("CON") Section (the "Agency") to confirm that, as a matter of material compliance, the Applicants may continue to operate the Center in a slightly different structure, namely as a provider-based and licensed location of Carolinas Medical Center ("CMC"), which is simply an operating division within CMHA (the "Redesignation").

The Redesignation is materially compliant with the Center's CON and CON Application for the following reasons:

1. The primary purpose of the Center has been to provide radiation therapy services to the citizens of Mecklenburg County and the surrounding vicinity. This will not change after the Redesignation.

2. No equipment or services will be relocated as a result of this Redesignation. After redesignating the Center to CMC, the Center's services will continue to operate at the same address as it has always operated.

3. CMHA will operate the Center as part of CMC. This Redesignation will be relatively seamless in terms of day-to-day operations, since CMHA d/b/a CMC was already the manager for the Center through CMC's Radiation Oncology Department. See Exhibit 2, p. 3 and 9 (CON Application for Project I.D. No. F-7524-06). Obviously, after redesignating the Center to CMC, the Center's services will continue to be managed by CMC's Radiation Oncology Department.

4. In representations to the Agency, the Applicants' CON Application touted CMHA's (and more specifically CMC's) radiation therapy experience since CMHA was a co-applicant and CMC's Radiation Oncology Department was proposed to manage (and has managed) the Center. See Exhibit 2, p. 11-14. It will thus be entirely consistent with those CON Application representations for CMC to continue to manage the Center, through licensee and provider-based status.

Accordingly, the Applicants request the Agency's confirmation that redesignating the Center to CMC licensed and provider-based status would not constitute a material change for purposes of N.C. Gen. Stat. § 131E-181(a) and would otherwise materially comply with the representations in the CON Application. Nothing in this proposed Redesignation will change the scope, physical location, or persons named in the CON or Application.

N.C. Gen. Stat. § 131E-181(a) provides that a "certificate of need shall be valid only for the defined scope, physical location and person named in the application." The Agency has generally allowed parties latitude to make changes in CON projects, where convenience dictates and the objectives of the CON law are otherwise advanced. Here, the Redesignation does not change any of these § 131E-181(a) categories, and thus is materially compliant with the representations in the Center's CON Application and the conditions in the CON.

The Applicants will continue to operate the project in a manner materially consistent with the representations made in the Application, as well as with the conditions that were placed on the CON. For example, access to the medically underserved will not change because the proposed Redesignation does not alter the proposed patient population in any manner. Applicants CMHA and PRTC will both continue to be involved in the Center, with PRTC now leasing the Center space and equipment to CMHA, and CMHA d/b/a CMC operating the Center. No new entities are entering the mix.

CONCLUSION

In Conclusion, the Applicants request that the Agency verify that the proposed Redesignation would not constitute a material change for purposes of N.C. Gen. Stat. § 131E-181(a) and would otherwise materially comply with the representations in the CON Application and the conditions in the CON. **The Redesignation is scheduled to occur on January 1, 2014. Therefore, we respectfully request that a determination of material compliance be made as soon as possible.**

Thank you for your consideration. Please let me know if you have any questions.

Sincerely,

Gary S. Qualls

Gary S. Qualls

Enclosures

Exhibits

1. CON for Project I.D. No. F-7524-06

2. CON Application for Project I.D. No. F-7524-06 (Sections I and II)

EXHIBIT 1

STATE OF NORTH CAROLINA
Department of Health and Human Services
Division of Facility Services

CERTIFICATE OF NEED
for
Project Identification Number #F-7524-06
FID# 060371

ISSUED TO: **Pineville Radiation Therapy Center, LLC and**
The Charlotte-Mecklenburg Hospital Authority
10628 Park Road
Pineville, NC 28210

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: **Acquire a linear accelerator and simulator and establish a new radiation oncology center/Mecklenburg County**

CONDITIONS: **See Reverse Side**

PHYSICAL LOCATION: **Pineville Radiation Therapy Center**
10628 Park Road
Pineville, NC 28210

MAXIMUM CAPITAL EXPENDITURE: **$7,516,996**

TIMETABLE: **See Reverse Side**

FIRST PROGRESS REPORT DUE: **October 1, 2007**

This certificate is effective as of the 27th day of June, 2007.

Lee B Hoffman
Chief, Certificate of Need Section
Division of Facility Services

CONDITIONS:

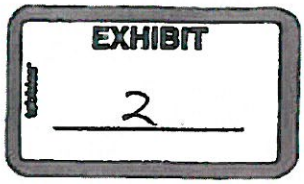
1. Pineville Radiation Therapy Center, LLC ("Pineville") and the Charlotte Mecklenburg Hospital Authority ("CMHA") shall materially comply with all representations made in their CON application and the supplemental information they submitted to the Agency on May 29, June 13, and June 15, 2007. In those instances in which the representations made in these documents conflict, Pineville and CHMA shall materially comply with the later-made representation.

2. Pineville and CHMA shall not acquire, as part of this project, any equipment that is not included in the proposed capital expenditure in Section VIII.1 of the application or that would otherwise require a CON.

3. The approved capital expenditure for the project shall be $7,516,996.

TIMETABLE:

Obtain Funds for project ---------- August 1, 2007
Contract Award ---------- February 1, 2008
25% completion of construction ---------- March 1, 2008
50% Completion of construction - ---------- May 1, 2008
75% Completion of construction ---------- July 1, 2008
Completion of Construction ---------- August 1, 2008
Offering of Service ---------- September 1, 2008



APPLICATION

Pineville Radiation Therapy Center, LLC

Project I.D.#F-7524-06

Original
#-1524-06

Pineville Radiation Therapy Center, LLC

Radiation Oncology Services

Certificate of Need

Applications & Exhibits

March 15, 2006

CERTIFICATION

The undersigned hereby assures and certifies that:

(a) the work on the proposed project will be initiated in accordance with the timetable set forth on the certificate of need:

(b) completion of the proposed project will be pursued with reasonable diligence;

(c) the proposed project will be constructed, operated and maintained in full compliance with all applicable local, State and Federal laws, rules, regulations and ordinances;

(d) the applicant will materially comply with the representations made in its application in the development of the project and the offering of the services pursuant to N.C.G.S. 131E-181(b); and,

(e) that the information included in this application and all attachments is correct to the best of my knowledge and belief and that it is my intent to carry out the proposed project as described.

LEGAL NAME OF APPLICANT: The Charlotte-Mecklenburg Hospital Authority

NAME OF RESPONSIBLE OFFICER: Joseph G. Piemont

TITLE OF OFFICER: Executive Vice President, Strategic Services

ADDRESS: 1000 Blythe Boulevard

Charlotte, North Carolina 28203

SIGNATURE OF OFFICER: _____

DATE: 3-14-06

Sworn to and Subscribed before me Patricia Costner
(Notary Signature)

this the 14th Day of March (Month) 2006

My Commission Expires May 3, 2008

CERTIFICATION

The undersigned hereby assures and certifies that:

(a) the work on the proposed project will be initiated in accordance with the timetable set forth on the certificate of need:

(b) completion of the proposed project will be pursued with reasonable diligence;

(c) the proposed project will be constructed, operated and maintained in full compliance with all applicable local, State and Federal laws, rules, regulations and ordinances;

(d) the applicant will materially comply with the representations made in its application in the development of the project and the offering of the services pursuant to N.C.G.S. 131E-181(b); and,

(e) that the information included in this application and all attachments is correct to the best of my knowledge and belief and that it is my intent to carry out the proposed project as described.

LEGAL NAME OF APPLICANT: Pineville Radiation Therapy Center, L.L.C.

NAME OF RESPONSIBLE OFFICER: Joseph G. Piemont

TITLE OF OFFICER: Executive Vice President, Strategic Services
The Charlotte-Mecklenburg Hospital Authority,
the sole member and manager of the applicant

ADDRESS: 1000 Blythe Boulevard

Charlotte, North Carolina 28203

RECEIVED
MAR 2006
CERTIFICATE OF NEED SECTION

SIGNATURE OF OFFICER: _____

DATE: 3-14-06

Sworn to and Subscribed before me Pat M. Costner
(Notary Signature)

this the 14th Day of March (Month) 2006

My Commission Expires: May 3, 2008

All data in this document was produced by computer and may not add exactly due to computer rounding.

Table of Contents

Certificate of Need Application
ACUTE CARE FACILITY/
MEDICAL EQUIPMENT PROJECT
State of North Carolina
Department of Human Resources

OFFICE USE ONLY

Project I. D. Number: J-7524-06 Batch Category: _____

Proposal Type: _____ Beginning of Review: _____

I. IDENTIFICATION

1. **Legal Name of the Applicant: The applicant is the existing legal entity (i. e., person or organization) that will own the facility. If the facility will be leased, complete two copies of Section VIII for the project; one with the lessor as the applicant and the other with the lessee as the applicant.**

Pineville Radiation Therapy Center, LLC
(Name of Applicant)

10628 Park Road
(Street & Number)

Pineville	NC	28210	Mecklenburg
(City)	(State)	(Zip)	(County)

AND

The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System[1]
(Name of Applicant)

[1] Per instruction from the CON Section, The Charlotte-Mecklenburg Hospital Authority is listed as a co-applicant because it is the developer of the medical office building. The proposed radiation therapy service will be owned by Pineville Radiation Therapy Center, LLC. Please see Section I.8.

1000 Blythe Boulevard
(Street & Number)

Charlotte NC 28203 Mecklenburg
(City) (State) (Zip) (County)

2. **Name of Parent Company (if applicable):**

The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System

1000 Blythe Boulevard
(Street & Number)
Charlotte NC 28203
(City) (State) (Zip)

3. **Person to whom all correspondence and questions regarding this application should be directed:**

Greg Bass Director, CHS Management Company
(Name) (Title)

P.O. Box 32861
(Street & Number)

Charlotte NC 28232-2861 (704) 355-0350
(City) (State) (Zip) (Area Code & Phone Number)

4. **Name of Lessor (If applicable):**

The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System

1000 Blythe Boulevard
(Street & Number)

Charlotte NC 28203
(City) (State) (Zip)

5. **Name of Lessee: (If applicable) (Attach copy of lease agreement)**

Pineville Radiation Therapy Center, LLC

10628 Park Road
(Street & Number)

Pineville NC 28210
(City) (State) (Zip)

Please see Exhibit 1 for a letter of intent for the lease agreement.

6. **Name of Management Company: (If applicable) (Attach copy of management contract)**

The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center

1000 Blythe Boulevard
(Street & Number)

Charlotte NC 28203
(City) (State) (Zip)

Please see Exhibit 2 for a copy of the management agreement.

7. **Name of existing/proposed facility as it will appear on a certificate of need. (i.e. Jones Health Care d/b/a Jones of Smithburg):**

Pineville Radiation Therapy Center Mecklenburg
(Name of Facility) (County)

10628 Park Road	Pineville	NC	28210
(Street & Number)	(City)	(State)	(Zip)

8. **Provide a brief project description to identify the basic components of the project including the bed complement and proposed levels of care. This should be a one sentence description for identification purposes only.**

Pineville Radiation Therapy Center, LLC proposes to acquire one linear accelerator and simulator for treatment simulation for the new radiation oncology service to be located in new and upfitted space in a medical office building in Pineville Medical Plaza on the campus of CMC-Pineville.

9. **Indicate the type of Construction or Change in Service: (Check the appropriate boxes)**

(a)		New Facility or Service
(b)		Total Replacement of Existing Facility
(c)		Renovation or Modernization
(d)		Expansion or Reduction of Services
(e)	X	Medical Equipment
(f)		Change in Bed Capacity
1.		Number of Beds to be Added
2.		Number of Beds to be Deleted
3.		Total Number of Beds Currently Licensed (by licensure category)
4.		Total Numbers of Beds to Be Licensed After Project Completion
5.		Total Beds Currently Operational

10. Type of Ownership: Check one of the following line items to describe the "ownership" of the applicant that is identified in Section I.1 of this application. Attach any documentation that will clearly identify the owner or lessee of the facility even if specific documents are not indicated below.

PROPRIETARY	
	Individual
	Partnership-Attach copy of Partnership Agreement and receipt showing the agreement is recorded with the Secretary of State
	In-State Corp.-Attach a copy of the Articles of Incorporation and Certificate of Incorporation
	Out-of-State Corp-Attach evidence of registration with the Secretary of State
	Other.(Specify)
NON-PROFIT	
	Corporation-Attach a copy of Articles of Incorporation and Certificate of Incorporation.
	Church
X	Other- Limited Liability Company
GOVERNMENTAL	
	State
	County-Attach documentation that the county commissioners have endorsed this project if prior approval is required.
	City
	City/Council

	District
	Hospital Authority or Commission
	Other- (Specify)

11. **Attach a list of the names of all owners, partners or persons having a financial interest of five percent (5%) or more in the facility. If the facility is leased, provide the same information for persons having an interest of five percent (5%) or more in the company leasing the facility.**

Pineville Radiation Therapy Center, LLC is wholly-owned by The Charlotte-Mecklenburg Hospital Authority (CMHA). The Charlotte-Mecklenburg Hospital Authority is a North Carolina hospital authority body corporate and politic, which governs the overall affairs of its subsidiary organizations. As such, there are no individuals who have any financial interest in CMHA or Pineville Radiation Therapy Center, LLC.

(a) **In the case of a proprietary or non-profit corporation, also attach:**

(1) **A list of the officers of the corporation, and**

Pineville Radiation Therapy Center, LLC has no officers, but is wholly-owned by The Charlotte-Mecklenburg Hospital Authority.

The officers of The Charlotte-Mecklenburg Hospital Authority are:

Michael C. Tarwater, M.H.A
President and Chief Executive Officer

Paul S. Franz, M.H.A.
Executive Vice President, Operations

Greg A. Gombar, B.A., C.P.A.
Executive Vice President, Administrative Services and Chief Financial Officer

Joseph G. Piemont, J.D.
Executive Vice President, Strategic Services

Suzanne H. Freeman, B.S.N., M.B.A.
President, Carolinas Medical Center

Russell C. Guerin, M.S.
President, Managed Health Resources

Harrison F. Trammell, B.S., C.P.A.
President, CHS Regional Facilities Group

Keith A. Smith, J.D.
Senior Vice President, Corporate Counsel

Robert H. Wiggins
Senior Vice President, Financial Services

John J. Knox, III, M.H.A.
Senior Vice President and Chief Information Officer

F. Traylor Renfro, M.S.
Senior Vice President, Human Resources

James T. McDeavitt, M.D.
Senior Vice President, Education and Research

Zachary I. Zapack, M.Arch.
Senior Vice President, Corporate Services

(2) The name and address of the registered agent for the corporation.

Keith A. Smith
P.O. Box 32861
Charlotte, NC 28232-2861

(b) In the case of a partnership, also attach the name and address of the general or managing partner.

Not applicable. Pineville Radiation Therapy Center, LLC is not a partnership.

For Facility and Service Related Projects

12. Describe the experience and expertise of the applicant and/or facility's management in the planning, development, financing, construction, and management of health care facilities. At a minimum, provide responses to the following:

(a) If this project is for the construction of a new facility, please list by name and location all health care facilities that you have constructed in North Carolina. When were each of these facilities constructed? How many health care facilities have you constructed in other states?

Pineville Radiation Therapy Center, LLC has not constructed other facilities in North Carolina or in other states; however, the lessor, The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System (CHS), has constructed numerous facilities in North Carolina. Please see response to (c) below.

(b) List by name and location all health care facilities in North Carolina that are currently owned by the applicant identified in

Section I.1. or I.3. How many health care facilities does the applicant own in other states?

Pineville Radiation Therapy Center, the lessee, does not own any other health care facilities in North Carolina or in other states. However, the lessor, Carolinas HealthCare System, does own other health care facilities in North Carolina and South Carolina. Please see response to (c) below.

(c) **List by name and location all health care facilities in North Carolina currently managed/operated by the company or person(s) that will be managing this facility.**

The proposed project will be managed by Carolinas Medical Center (CMC), through its radiation oncology department. Please see the response to Section I.13.(b).

(d) **Describe specific experience of the applicant in providing the proposed service(s).**

Please see the response to Section I.13.(c).

For Medical Equipment Related Projects

13. **Describe the experience and expertise of the applicant and/or facility's management in the planning, development, financing, construction, and management of medical equipment. At a minimum, provide responses to the following:**

(a) **List by name, location, vendor, and serial number all similar medical equipment in North Carolina that are currently owned by the applicant identified in Section I.1. or I.3. What medical equipment of a similar nature does the applicant own in other states?**

Pineville Radiation Therapy Center, LLC does not own any medical equipment in North Carolina or in other states.

CHS owns 50 percent of Rock Hill Radiation Therapy Center in Rock Hill, South Carolina, which includes two linear accelerators. CHS also owns linear accelerators in North Carolina, as discussed in response to (b) below.

(b) **List by name and location all similar medical equipment in North Carolina currently managed/operated by the company or person(s) that will be managing this facility.**

The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center (CMC), the facility that will manage the radiation therapy service, has three linear accelerators in operation as shown in the table below. CHS also manages Grace Hospital in Morganton, Valdese Hospital in Valdese, Cleveland Regional Medical Center in Shelby, and CMC-Union in Monroe, each of which operates one linear accelerator.

Carolinas HealthCare System-Owned Linear Accelerators

Facility	*Location*	*Equipment*	*Vendor*	*Serial Number*
Carolinas Medical Center	Charlotte	Linear Accelerator	Varian 21iX	1099
Carolinas Medical Center	Charlotte	Linear Accelerator	Varian 600C	427
Carolinas Medical Center	Charlotte	Linear Accelerator	Novalis	677

CHS also owns 50 percent of Rock Hill Radiation Therapy Center in Rock Hill, South Carolina, which includes two linear accelerators.

(c) **Describe specific experience of the applicant in providing the proposed service(s).**

Pineville Radiation Therapy Center, as a new entity, does not have any experience in providing radiation therapy services. However, Carolinas HealthCare System and CMC, the proposed manager of the service, have extensive experience in providing radiation therapy services.

The radiation oncology department at CMC functions as part of the Blumenthal Cancer Center. The department works with the referring medical oncologists in coordinating patient treatment protocols, which involve chemotherapy and/or surgical options for cancer treatment in conjunction with the radiation oncology service. CMC has been providing radiation oncology services to residents of Mecklenburg County and the surrounding service area for over twenty-five years. During that time, the department has developed a full-range of radiation oncology services including:

- Dual photon energy radiation treatment (6 and 15 MeV)
- Electron energies ranging from 6 to 16 MeV
- Brachytherapy prostate seed implants
- Low dose rate temporary radioactive implants
- High dose rate temporary implants
- Stereotactic radiosurgery

CMC's radiation oncology department currently houses two Varian linear accelerators. These linear accelerators provide photon energies of 6 and 15 MeV. The two Varian machines perform just over 90 percent of CMC's total linear accelerator treatments. The Novalis equipment, which is specifically configured for stereotactic radiosurgery, is usually reserved for patients in need of that specific type of treatment. Patient treatment plans are prepared following the CT simulation treatment plan, and coordinated by experienced

and highly trained radiation oncologists and prepared by the experienced radiation oncology department staff.

CMC began providing radiation therapy services in the mid 1960s with a Cobalt 60 and 250KV Orthovoltage machine. In September 1979, CMC opened its new radiation therapy department on the third floor with a Varian Clinac 20 and 6/100 linear accelerator and a Picker simulator. In 1989, the Picker simulator was replaced with a Varian Ximatron simulator. In 1993, CMC purchased a GammaMed HDR machine and installed it in the 6/100 shielded vault to provide treatments. CMC expanded and renovated the department in 1995 with the replacement of the Clinac 20 with a Varian 2100C linear accelerator. The HDR machine and simulator were moved into the vacated Clinac 20 vault. In February 1997, CMC replaced the 6/100 treatment machine with the existing Varian 600C linear accelerator. A Leibinger Micromultileaf system was purchased to provide stereotactic radiosurgery in February 1998. In 2003, the simulator was removed and special approval was granted to replace the Leibinger system with the Novalis linear accelerator with stereotactic radiosurgery capabilities. The Novalis was installed as the first of a three phase construction project to include the addition of a CT/simulator and department expansion/renovation which was completed in July 2005. Portal Vision and 120 MLC collimator were installed on the Varian 600C machine in August 2004 in order to provide IMRT treatment options. The GammaMed HDR treatment machine was replaced with the Varian VariSource unit in September 2004.

CMC's staff, due largely to the extensive history of the medical center's provision of radiation oncology services, is highly qualified and experienced. The multi-discipline team consists of the following:

- The Radiation Oncologist consults with the patient, reviews pertinent medical historical information and recommends the treatment required. The patient's medical history and all

radiographic information in studied and utilized for treatment planning. The Oncologist participates in the CT simulation and computerized treatment planning, providing beam placement, contouring treatment volumes and designing blocks to avoid treatment to normal tissues. The patient is seen weekly during treatment and in appropriate follow-up and the completion of treatment to monitor side effects and tumor response.

- The Physicist/Dosimetrist provides assistance during the CT simulation procedure and imports images into the treatment-planning computer (Eclipse). They manipulate the beams and create a dose plan with the physicians. Information is input into the Record and Verify system (Varis) to "drive" the treatment machines and provide a safety backup for the machine parameters and avoid human input errors. The Physicist is responsible for weekly chart quality assurance, maintaining machine calibrations, annual equipment scanning and appropriate reporting to external regulatory agencies.

- Radiation Therapists position patients on the simulator and treatment tables, explain the procedures, ensure appropriate immobilization, take positioning films, position the couch and gantry rotation angles and with a partner, treat and monitor the patient utilizing a strict double check quality assurance system.

- Nurses provide patient education, assist with obtaining consents, administer medications, provide patient assessments, make referrals for dietary, chaplain, or other cancer support services and give patients discharge instructions.

This level of experience, expertise, and quality of services is unmatched in the region and will be available to the radiation therapy service provided by Pineville Radiation Therapy Center under the management direction of CMC. The proposed location in southern Mecklenburg County will allow patients from this area to

receive the same high quality service available in the Center City closer to home.

II. SCOPE OF SERVICES/QUALITY OF CARE

1. Describe all components of the proposed project. Include a discussion of the proposed beds, equipment to be purchased, and services.

Pineville Radiation Therapy Center, LLC (PRTC) is a limited liability company, wholly-owned by The Charlotte-Mecklenburg Hospital Authority. PRTC proposes to acquire linear accelerator equipment to meet the need for one additional linear accelerator in Radiation Oncology Service Area 7 as indicated in the *2006 State Medical Facilities Plan*. PRTC plans to locate the equipment in a medical office building, Pineville Medical Plaza, on the campus of CMC-Pineville.

The following discussion provides a description of radiation therapy technology and all components of the proposed project.

RADIATION THERAPY TECHNOLOGY

Radiation therapy, or radiotherapy, uses high-energy radiation, primarily electronically generated x-rays, as a treatment for cancer and other diseases. This application of high-energy radiation has had a profound positive effect on cancer survival.[2] Normally cells divide and replace themselves in an orderly process, keeping the body healthy. Cancer occurs when cells lose the ability to control their own growth. The abnormal cells multiply quickly, forming clumps of tissue, or tumors, and spreading to nearby tissues and organs or other parts of the body. When the cancer site receives radiation therapy, the DNA of the cancer cells is damaged. DNA contains the genetic information that is vital for reproduction. When the DNA is damaged sufficiently, the cancer cells are not able to divide and grow and the tumor shrinks. The dead cells are broken down, carried away by the blood and excreted by the body. Radiation therapy treatments are designed with detailed accuracy to destroy the cancer cells while limiting the amount of normal tissue exposed to the rays. Despite these protective measures,

[2] http://www.oncolink.com "Radiation Therapy: A Basic Introduction," Heather Jones, M.D., University of Pennsylvania Cancer Center.

some normal cells will be affected by the radiation. However, most of the healthy cells are able to recover from the radiation, as they are typically much better at using the body's natural repair mechanisms to correct the DNA damage. The damage to the healthy cells causes the side effects most often experienced with radiation therapy, which may include hair loss, fatigue, nausea, vomiting, or diarrhea.

The effectiveness of radiation therapy as a treatment for cancer was actually discovered in the late 1800's. Because of continued strides in technology, today's treatment capabilities are highly advanced, delivering maximum therapeutic benefits while minimizing toxicity and damage to healthy tissue.

A team effort, involving a radiation oncologist, a radiation physicist, and a dosimetrist, determines the dosage of radiation to be delivered to the patient. Dosage is determined by the size, extent, type, and grade of tumor along with its response to radiation therapy. Complex calculations determine the dosage and timing of radiation in treatment planning. Typically, the treatments are performed from several different angles to deliver the maximum amount of radiation to the tumor and the minimum amount to normal tissues.

Radiation therapy is used as the primary treatment modality for some cancers, while combined with surgery and/or chemotherapy for effective treatment of others. In some cases, radiation therapy may have an advantage over surgery, offering superior functional and cosmetic outcomes and avoiding higher surgical risks because of pre-existing conditions.[3] Radiation therapy is also used as a palliative treatment for patients with widespread cancer, which means the primary intent is not to cure the cancer but to relieve symptoms. Certain cancer-related symptoms, such as pain, bleeding, compression, and skin lesions, can be managed effectively with palliative radiation, improving the patient's quality of life.

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3 www.oncolink.upenn.edu/ E. Loren Buhle, Ph.D., *Introduction to Radiation Oncology*, University of Pennsylvania Cancer Center, 9/15/97, pg. 3.

External beam radiation is delivered by machines, including linear accelerators that administer high-energy radiation. Because of the toxicity associated with the lethal dose of radiation required to treat a tumor, the doses are divided into smaller portions over a period of time. Treatments are usually given on a daily basis, five days per week, with each patient receiving a number of treatments, depending on the site and the patient's ability to tolerate the treatment.

Prior to the actual treatment, the treatment is planned and "simulated" to determine the most effective way to treat the area and minimize damage to healthy tissue. This allows treatment planners to define the exact treatment area prior to the actual treatment.

COMPONENTS OF THE PROPOSED PROJECT

Proposed Location

PRTC proposes to locate the service in a new medical office building to be located in the Pineville Medical Plaza on the campus of CMC-Pineville. The building will be owned by CHS and leased to Pineville Radiation Therapy Center as per the letter of intent provided in Exhibit 1. Prior to the submission of this application, CHS filed an exemption letter that included details related to the medical office building project.

As shown on the site plan drawings provided in Exhibit 25, the medical office building will be located at the intersection of Park Road, Pineville Matthews Road and Interstate 485 Bypass in southern Mecklenburg County. The linear accelerator and associated support areas will be located on the north side of the medical office building adjacent to the existing central energy plant for the hospital. The medical office building will include a connector corridor to CMC-Pineville, providing access to and from the hospital for patients, physicians and staff.

Proposed Radiation Therapy Services

Prior to having a radiation therapy treatment, certain steps must be completed in order to maximize patient care and comfort. To be most effective, radiation therapy must be directed at the precise location of the cancer site each time a treatment occurs. In order to provide the appropriate dose of radiation targeted to the specific cancer site, detailed planning goes into each patient treatment plan to pinpoint the exact area to be treated and the most effective dose for the treatment. Each patient will be scanned using the CT simulator to provide detailed information to the radiation oncologist. The CT scans of the tumor volume are then used to more accurately locate the tumor and to facilitate planning for the radiation treatment. When the physician pinpoints the tumor location and the treatment port, ink lines or tattoos are placed on the skin to identify the area to be treated so that the radiation will target the same area for every treatment. The radiation physicist and dosimetrist configure the computer program in the simulator that will "speak" to the linear accelerator and, combined with the computerized dosage, provide the exact amount of radiation in the exact spot as directed.

In order to provide the most effective treatment possible, the simulation process allows the staff to further isolate the treatment site by creating molds of the patient's body, which allow the patient to be positioned in the same place for each treatment, assuring maximum accuracy of the treatment. Blocks of alloy material or multileaf collimators are designed to cover parts of the body near the targeted site, which will protect non-cancer tissue from the radiation. Each patient has his or her own set of blocks created specifically for the treatment sessions. The information from the simulator, other tests and the patient's medical history will be used by the radiation oncologist, radiation physicist, and dosimetrist to create a customized treatment plan. The radiation oncologist decides how much radiation is needed, how it will be delivered, and how many treatments the patient will need. After all treatment planning is completed, the patient returns for verification on the linear accelerator and radiation therapy is ready to begin.

After registering, or checking in (for returning patients), patients will be directed through the hallway of the center to the linear accelerator control area. At this point, radiation therapists will take the patient to the linear accelerator room and prepare them for their treatment.

Two of the major side effects associated with radiation therapy are extreme fatigue and bowel problems. For these reasons, it is important to keep patients receiving these treatments as near home as possible. Too, many of the treatments are completed in a short time and some patients, particularly in the early stages of treatment, are able to get a treatment on their lunch hour and return to work. Most treatment plans continue for six or seven weeks, and consist of daily visits except for Saturday and Sunday.

The Pineville Radiation Therapy Center program will be under the direction of Robert Fraser, M.D., medical director of the radiation therapy department at CMC and the proposed medical director for the Pineville Radiation Therapy Center program. PRTC will also be staffed by 4.0 FTE radiation therapy technologists, (including 1.0 FTE lead radiation therapist and 1.0 FTE simulation therapist), 1.0 FTE RN, a 2.0 FTE clerical position, and 1.0 department manager. The medical physicist and dosimetrist will be contracted through Physics and Computer Planning, Inc. as documented in the letter provided in Exhibit 9.

Therapy services will be scheduled during the hours of 7:00 AM and 4:00 PM, Monday through Friday; however, depending on need and volumes, the hours may be extended. The proposed hours exceed the required minimum of seven hours per day, five days per week.

Proposed Equipment

Pineville Radiation Therapy Center proposes to purchase one Varian High Energy Clinac iX linear accelerator, equipment that represents the most advanced linear accelerator technology currently manufactured. The machine has the following features:

- High performance foundation for image-guided radiotherapy
- Fine beam performance per RAD 9510
- Dual independent collimators
- Dynamic arc photon treatment
- Accessory system
- In-room monitor
- Ergonomic command center
- Digital gantry display
- Port film graticule

In addition to the advanced features of the Varian iX, the package includes the Millennium Multileaf Collimator with Intensity Modulated Radiation Therapy (IMRT) software. While this technology is considered "cutting edge" and the planning process is complex, IMRT has been shown to provide greater benefits to patients because it is a more precise form of radiation therapy that delivers a higher radiation dose to a more specific area, minimizing the impact to surrounding tissue. Because of this precise delivery of radiation, IMRT treatments improve recovery time and reduce side effects and complications associated with conventional radiation therapy treatments. This decrease in side effects can result in an improvement in patients' quality of life and may result in lower costs of radiotherapy patient management. The clinical advantages of IMRT are becoming more apparent as advances in research have increased the number of anatomical sites where IMRT is routinely delivered.

Furthermore, the proposed Varian Clinac iX is equipped with a PortalVision system, which allows for basic Image Guided Radiation Therapy (IGRT). IGRT, combined with IMRT, utilizes PortalVision imaging to obtain real-time images and precisely locate a tumor position. The image is compared with the reference images and if necessary, the patient is moved to align the tumor with the treatment beam.

As discussed previously, most patients must complete a treatment plan prior to the actual radiation therapy treatment in order to pinpoint the exact area to be treated and determine the most effective dose to be administered.

Such a treatment plan is accomplished through the use of equipment called a simulator. Pineville Radiation Therapy Center proposes to acquire a General Electric Goldseal LightSpeed QXi computed tomography (CT) simulator to perform this task. As specified in the Varian Clinac quote in Exhibit 4, the linear accelerator will be configured to interface with the GE Goldseal LightSpeed QXi. Through this interface, the treatment plan created by the simulator will be sent to the Eclipse System, then to the linear accelerator, directing it to perform the treatment plan. The entire process takes place under the direction of the radiation oncologist, the physicist and the dosimetrist.

2. **Describe any changes or innovations in existing services, either outpatient and/or inpatient, that will be associated with this project. Explain how this project will differ from any existing services currently being provided in the service area.**

The proposed project will be a change in existing services in that no radiation oncology services are located in southern Mecklenburg County. Because of the increase in population growth in Mecklenburg County as well as the aging of the population, the proposed radiation oncology service will allow residents of this area to access radiation oncology services without having to travel to downtown Charlotte.

As described in Section II.1, Pineville Radiation Therapy Center proposes to locate its service in a medical office building, providing significantly improved access to patients traveling to hospitals in downtown Charlotte.

As described in Section II.1, the proposed Varian Clinic iX linear accelerator is well equipped to provide cutting-edge radiation therapy services to patients in southern Mecklenburg County and surrounding areas. Management of the service by the well-established radiation therapy service of CMC will provide experience and expert direction for the new service. CMC's cancer program was one of only a few programs in the country to be awarded a national quality award from the American College of Surgeons Commission on Cancer (ACS-CoC) in 2005. The American College of Surgeons Commission on Cancer is the national organization that is

charged with setting the standards for organized delivery of cancer care in hospital settings. The receipt of this award indicates that patients cared for through the CMC cancer program have access to some of the best doctors and most modern technology available. Pineville Radiation Therapy Center's patients will have access to this same quality of care.

3. **Explain how the administrative and clinical departments will be organized to accommodate the provision of the additional services or equipment proposed in this application.**

Pineville Radiation Therapy Center will be under the administrative direction of Scott Moroney, Vice President, Administration at CMC, and Craig Comish, Executive Director of Cancer Services at CHS. Robert Fraser, M.D., the medical director of the radiation therapy department, will provide clinical direction for the new service. Gail Satterfield is the Director of CMC Radiation Therapy. Staff will be employees of CMC and leased to Pineville Radiation Therapy Center, per the management agreement provided in Exhibit 2.

4. (a) **Describe any additional services to be offered or other potential components of this project that are being planned for <u>future development</u>. Provide the time frame in which these components/services would be made available.**

The proposed project is in response to the need identified in Radiation Oncology Service Area 7 in the *2006 State Medical Facilities Plan*. No additional services are to be offered as a result of the proposed project.

(b) **Submit a copy of the planning document for the project if one exists.**

There is no single planning document for this project. The essence of any internal documents related to planning for this project has been included in this application.

(c) **Submit an itemized copy of the applicant's three-year capital expenditure budget. How does the proposed project impact this budget?**

Not applicable. As a new entity, Pineville Radiation Therapy Center does not have a three-year capital expenditure budget. The proposed project is the only service currently planned for Pineville Radiation Therapy Center. Pineville Radiation Therapy Center has demonstrated the availability of funds for the project. Please see Section VIII for more detail.

5. **Discuss alternative solutions, including the implications of maintaining the status quo and/or modifying existing resources.**

PRTC considered several alternatives before deciding to pursue the proposed project. Each is discussed below.

MAINTAIN STATUS QUO

PRTC considered maintaining the status quo and not applying for the proposed linear accelerator. However, as explained in Section III.1, after studying the need for an additional linear accelerator in the service area, it determined that there is a specific need in the Pineville area of Mecklenburg County for radiation therapy services. Many patients from this area have radiation therapy at CMC in Charlotte. CMC's existing two linear accelerators configured for standard use are well-utilized; a significant number of these existing patients are from the south Mecklenburg/Pineville area and could be served closer to home through the development of the proposed project. Thus, PRTC determined that maintaining the status quo was not the most effective alternative.

LOCATE LINEAR ACCELERATOR ELSEWHERE IN SERVICE AREA 7

PRTC also considered locating the linear accelerator elsewhere. Anson County, for example, has no linear accelerators, so its residents must travel out of the county for radiation therapy. However, because the population is

so small (approximately 26,000 people), it cannot support a linear accelerator on its own, and patients from other counties are unlikely to travel into Anson County for radiation therapy. Within Mecklenburg County, the existing linear accelerators are located in the northeast in the University area, in the east in Matthews, and in the Center City at CMC and Presbyterian Hospital. It should be noted that Presbyterian Hospital acquired two linear accelerators in June 2005 that have not yet been placed into operation (per its 2006 Hospital License Renewal Application). In addition, physicians at Southeast Radiation Oncology (SERO), the group providing professional services for PRTC, recently began offering radiation therapy in Mooresville, just over the northern Mecklenburg County line. As explained in detail in Section III.1.(a), PRTC performed an extensive study to determine the area of Mecklenburg County most in need of a linear accelerator and determined that the Pineville area had the greatest need. Although the existing linear accelerator in Union County has the second highest utilization per-unit in Service Area 7, patients in Pineville have no linear accelerator in the immediate area. Moreover, locating a linear accelerator in Pineville will help to alleviate some of the capacity issues in Union County, as opposed to a location in Central or North Mecklenburg County. For these reasons, PRTC chose to locate the proposed linear accelerator in Pineville.

DEVELOP A LOW-LEVEL SERVICE

PRTC considered developing radiation therapy services with older generation equipment, which would provide a lower level of services than the proposed project. However, after evaluating the range of services that could be provided with older equipment, PRTC determined that the older equipment alternative would result in a radiation therapy program that is not as effective as the chosen alternative. For example, PRTC could have proposed a lower quality linear accelerator, with fewer capabilities. As the only linear accelerator in the south Mecklenburg area, PRTC believes that patients need access to state-of-the-art equipment. Proposing a linear accelerator with fewer capabilities, such as without IMRT or IGRT, would not provide patients in the south Mecklenburg area with services

commensurate with the level of care available in the downtown area. Specifically, without IMRT capabilities, a certain number of cancer diagnoses would be inadequately treated. PRTC believes its patients should not be forced to choose between traveling to the downtown area for state-of-the-art care or staying closer to home and receiving less than optimal care.

Instead of proposing a simulator on site, PRTC could have proposed simulating patients offsite with an existing CT scanner. However, patients need to have access to a CT simulator dedicated to the radiation therapy program. Having patients be scheduled on an existing CT scanner would result in delays of days or weeks before a patient's treatments could begin. For cancer patients, this delay is simply unacceptable. Further, by having the simulator on site, the simulations will be easily coordinated with the treatment software, simplifying the entire treatment process.

For these reasons, PRTC determined that an older linear accelerator without IMRT or IGRT or a radiation therapy service without onsite simulation was not the most effective alternative.

DEVELOP STATE-OF-THE-ART RADIATION THERAPY PROGRAM IN PINEVILLE

As explained throughout this section, PRTC determined that an additional linear accelerator was needed in Mecklenburg County and that the most effective location was in Pineville. As a facility owned by CHS and managed by Carolinas Medical Center, PRTC concluded that it needed to offer radiation therapy services consistent with the high quality manner with which CHS and CMC currently provide care to their patients. As such, PRTC is proposing to acquire a new linear accelerator with IMRT and IGRT capabilities, as well as a dedicated, onsite simulator. The proposed location in a medical office building on the CMC-Pineville campus will provide integration with the existing health care services in Pineville. The proposed project represents the most effective alternative for the residents of Pineville, Mecklenburg County, and Service Area 7.

6. **Identify all relevant facility, programmatic, and service specific licensure, certification, and accreditation standards associated with the proposed project. How will the project be consistent with these standards?**

The proposed radiation oncology service will be a separately licensed and certified facility in accordance with all standards and licensure regulations required for such a service.

Pineville Radiation Therapy Center will meet all applicable federal, state, and county laws, including employment regulations, building codes and safety regulations.

All construction will be approved by the North Carolina Department of Health and Human Services, Division of Facility Services, Construction Section. The proposed project will be in compliance with the rules established by the North Carolina Department of Environment, Health, and Natural Resources, Division of Radiation Protection. The proposed project will be operated under the quality standards of CMC's existing radiation therapy services and will thus maintain consistency with the certification and accreditation standards established by that department.

7. **Describe the methods used or to be used by the applicant to insure and maintain quality care. Include a copy of facility's quality management program including a description of the facility's utilization review process and risk management program. List any penalties and licensure limitations imposed within the 18 months prior to the submission of this application.**

As a facility operating under the management of the radiation therapy department at CMC, Pineville Radiation Therapy Center will adhere to the quality plans used by CMC. This quality care is assured through a variety of mechanisms, including an organizational performance improvement plan, a utilization management plan and risk management policies. Copies of these plans and policies are included in Exhibit 5. These plans will guide the performance and services provided by the applicant through this project.

8. If there are special CON rules and criteria which pertain to the service(s) included in this application (see list on page 30), please review the rules and provide responses to each criterion by proposed service in this section. Responses must be listed in detail in this section of the application. Insure a response to each criterion is included in your response.

SECTION .1900 – CRITERIA AND STANDARDS FOR RADIATION THERAPY EQUIPMENT

10A NCAC 14C .1901 DEFINITIONS

These definitions shall apply to all rules in this Section:

(1) *"Approved linear accelerator" means a linear accelerator which was not operational prior to the beginning of the review period.*

(2) *"Complex Radiation treatment" is equal to 1.0 ESTV and means: treatment on three or more sites on the body; use of special techniques such as tangential fields with wedges, rotational or arc techniques; or use of custom blocking.*

(3) *"Equivalent Simple Treatment Visit [ESTV]" means one basic unit of radiation therapy which normally requires up to fifteen (15) minutes for the uncomplicated set-up and treatment of a patient on a megavoltage teletherapy unit including the time necessary for portal filming.*

(4) *"Existing linear accelerator" means a linear accelerator in operation prior to the beginning of the review period.*

(5) *"Intermediate Radiation treatment" means treatment on two separate sites on the body, three or more fields to a single treatment site or use of multiple blocking and is equal to 1.0 ESTV.*

(6) *"Linear accelerator" shall have the same meaning as defined in G.S. 131E-176 (14b1).*

(7) *"Linear accelerator service area" means a single or multi-county area as used in the development of the need determination in the applicable State Medical Facilities Plan.*

(8) *"Megavoltage unit" means MRT equipment which provides a form of teletherapy that involves the delivery of energy greater than, or*

equivalent to, one million volts by the emission of x-rays, gamma rays, electrons, or other radiation.

(9) *"Megavoltage radiation therapy (MRT)" means the use of ionizing radiation in excess of one million electron volts in the treatment of cancer.*

(10) *"MRT equipment" means a machine or energy source used to provide megavoltage radiation therapy including linear accelerators and other particle accelerators.*

(11) *"Radiation therapy equipment" means medical equipment which is used to provide radiation therapy services.*

(12) *"Radiation therapy services" means those services which involve the delivery of controlled and monitored doses of radiation to a defined volume of tumor bearing tissue within a patient. Radiation may be delivered to the tumor region by the use of radioactive implants or by beams of ionizing radiation or it may be delivered to the tumor region systemically.*

(13) *"Radiation therapy service area" means a single or multi-county area as used in the development of the need determination in the applicable State Medical Facilities Plan.*

(14) *"Simple Radiation treatment" means treatment on a single site on the body, single treatment field or parallel opposed fields with no more than simple blocks and is equal to 1 ESTV.*

(15) *"Simulator" shall have the same meaning as defined in G.S. 131E-176(24a1).*

(16) *"Special technique" means radiation therapy treatments that may require increased time for each patient visit including:*

- *(a) total body irradiation (photons or electrons) which equals 2.5 ESTVs;*
- *(b) hemi-body irradiation which equals 2.0 ESTVs;*
- *(c) intraoperative radiation therapy which equals 10.0 ESTVs;*
- *(d) neutron and proton radiation therapy which equals 2.0 ESTVs;*
- *(e) intensity modulated radiation treatment (IMRT) which equals 1.0 ESTVs;*
- *(f) limb salvage irradiation at lengthened SSD which equals 1.0 ESTV;*

(g) additional field check radiographs which equals .50 ESTV;
(h) stereotactic radiosurgery treatment management with linear accelerator or gamma knife which equals 3.0. ESTVs; and
(i) pediatric patient under anesthesia which equals 1.5 ESTVs.

PRTC is submitting a Certificate of Need application to acquire a linear accelerator. This application is in compliance with the definitions stated in 10A NCAC 14C. 1901.

10A NCAC 14C .1902 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to acquire radiation therapy equipment shall use the Acute Care Facility/Medical Equipment application form.

PRTC is submitting an acute care facility/medical equipment CON application and is in compliance with this criterion.

(b) An applicant proposing to acquire radiation therapy equipment shall also provide the following additional information:

(1) a list of all the radiation therapy equipment to be acquired and documentation of the capabilities and capacities of each item of equipment;

Please see Exhibit 4 for the equipment quote and specifications of the proposed equipment and Section IV.3 for the projected capacity of the proposed equipment.

(2) documentation of the purchase price and fair market value of each piece of radiation therapy equipment, each simulator, and any other related equipment proposed to be acquired;

Please see Exhibit 4 for the equipment quote for the proposed linear accelerator and simulator and Section VIII.2 for the capital cost line item for the proposed equipment.

(3) *the projected number of patient treatments by county and by simple, intermediate and complex treatments to be performed on each piece of radiation therapy equipment for each of the first three years of operation following the completion of the proposed project and documentation of all assumptions by which utilization is projected;*

Please see Exhibit 6.

(4) . *documentation that the proposed radiation therapy equipment shall be operational at least seven hours per day, five days a week;*

The proposed radiation therapy equipment will observe the same hours of operation as CMC's radiation therapy department - 7:00 AM to 4:00 PM, Monday through Friday - for a total of nine hours per day, 45 hours per week.

(5) *documentation that no more than one simulator is available for every two linear accelerators in the applicant's facility, except that an applicant that has only one linear accelerator may have one simulator;*

As shown on the drawings provided in Exhibit 24 and the equipment quote provided in Exhibit 4, the project proposes to acquire one General Electric simulator for use at PRTC.

(6) *documentation that the services shall be offered in a physical environment that conforms to the requirements of federal, state, and local regulatory bodies; and*

PRTC will employ architects who are familiar with radiation oncology services and will maintain the appropriate physical environment in the vault that will conform to the requirements of federal, state, and local regulatory bodies. In addition, the radiation therapy department at CMC will manage the service at PRTC. As such, the administrators and managers are familiar with

federal, state and local regulations and will assure the Pineville service is in compliance.

(7) *the projected number of patients that will be treated by county in each of the first three years of operation following completion of the proposed project.*

Please see Exhibit 6.

10A NCAC 14C .1903 PERFORMANCE STANDARDS

(a) An applicant proposing to acquire a linear accelerator shall demonstrate that each of the following standards shall be met:

(1) *an applicant's existing linear accelerators located in the proposed service area performed at least 6,750 ESTV treatments per machine in the twelve months prior to the date the application was submitted;*

Not applicable. PRTC is not an existing service.

(2) *each proposed new linear accelerator shall be utilized at an annual rate of 250 patients or 6,750 ESTV treatments during the third year of operation of the new equipment; and*

Please see Section III.1(b). PRTC projects utilization for the proposed linear accelerator to equal 8,962 procedures, or 8,466 ESTVs in the third year of operation.

(3) *an applicant's existing linear accelerators located in the proposed service area shall be projected to be utilized at an annual rate of 6,750 ESTV treatments per machine during the third year of operation of the new equipment.*

Not applicable. PRTC has no existing linear accelerators.

(b) A linear accelerator shall not be held to the standards in Paragraph (a) of this Rule if the applicant provides documentation that the linear accelerator has been or shall be used exclusively for clinical research and teaching.

Not applicable. The proposed linear accelerator equipment will not be used exclusively for clinical research and teaching.

(c) An applicant proposing to acquire radiation therapy equipment other than a linear accelerator shall provide the following information:

(1) the number of patients that are projected to receive treatment from the proposed radiation therapy equipment, classified by type of equipment, diagnosis, treatment procedure, and county of residence; and

Not applicable. PRTC does not propose to acquire radiation therapy equipment other than a linear accelerator based on the definition of radiation therapy equipment as stated in 10A NCAC 14C .1901.

(2) the maximum number and type of procedures that the proposed equipment is capable of performing.

Not applicable. PRTC does not propose to acquire radiation therapy equipment other than a linear accelerator based on the definition of radiation therapy equipment as stated in 10A NCAC 14C .1901.

(d) The applicant shall document all assumptions and provide data supporting the methodology used to determine projected utilization as required in this Rule.

Please see Sections III.1 and IV.3 for assumptions, data, and methodology used to project utilization.

10A NCAC 14C .1904 SUPPORT SERVICES

An applicant proposing to acquire radiation therapy equipment shall document that the following items shall be available; and if any item shall not be available, the applicant shall provide substantive information obviating the need for that item:

(1) an organized program of radiation therapy continuing education for radiation therapists, technologists and medical staff;

CMC's radiation therapy department will manage PRTC. As such, CMC has an established program of continuing education for all staff that will be used by the Pineville program. Please see Exhibit 7 for the education provided for staff.

(2) a program for the collection of utilization data relative to the applicant's provision of radiation therapy services;

PRTC will collect data as is collected at CMC. Monthly data collected from the radiation therapy program include, but is not limited to: patient referrals; physician consults, re-evaluations and follow-ups; number of billable procedures, blocks, calculations, treatment devices, isodose plans, treatments, simulations, special dosimetry; total patient visits; average number of patients treated per day and average number of simulations per day.

(3) medical laboratory services;

PRTC plans to utilize the laboratory services of CMC-Pineville, located adjacent to the medical office building housing the new radiation therapy program. CMC-Pineville operates a full service clinical laboratory 24 hours per day, seven days per week and will be fully available for radiation oncology. Please see Exhibit 8 for a letter from CMC-Pineville verifying the availability of these services.

CMC-Pineville's laboratory is accredited by the Joint Commission on Accreditation of Healthcare Organization (JCAHO).

(4) *pathology services; and*

PRTC will use the pathology services of CMC-Pineville, located adjacent to the new radiation therapy program. CMC-Pineville operates a full range of pathology services 24 hours per day, seven days a week and will be fully available to radiation oncology following the completion of the proposed radiation therapy program. Serving inpatient and outpatient needs, the clinical pathology lab conducts blood, tissue, and microbiology testing, utilizing advanced, computer-controlled analysis and monitoring equipment. A full-time pathologist provides quick diagnosis for surgical specimens, abnormal test results, and consultative services for physicians.

The pathologist examines tissue and blood specimens for the presence of cancer and other disease states, and performs autopsies. The CMC-PIneville laboratory also has a full service blood bank that is staff 24 hours per day, 365 days per year.

The CMC-Pineville pathology lab is fully accredited by the Joint Commission on Accreditation of Healthcare Organization (JCAHO).

Please see Exhibit 8 for a letter from CMC-Pineville verifying the availability of these services.

(5) *pharmaceutical support services.*

PRTC will use the pharmacy services of CMC-Pineville, located adjacent to the proposed radiation therapy program. CMC-Pineville operates a comprehensive pharmaceutical service 24 hours per day, seven days a week and will continue to be fully available to the radiation therapy staff and patients. The CMC-Pineville pharmacy supplies all drugs and medications for hospitalized patients. This includes medications that require special handling and stringent sterile conditions. All patient

medication therapies are profiled on a pharmacy computer system, which allows the pharmacists to check for adverse drug interactions and drug allergies. These same quality pharmaceutical services will be available to the radiation therapy program.

Please see Exhibit 8 for a letter from CMC-Pineville verifying the availability of these services.

10A NCAC 14C .1905 STAFFING AND STAFF TRAINING

An applicant proposing to acquire radiation therapy equipment shall document the number and availability of staff or provide evidence that obviates the need for staff in the following areas:

(1) Radiation Oncologist;

The proposed medical director of PRTC is Robert W. Fraser, M.D.; a radiation oncologist with the Southeast Radiation Oncology (SERO) practice. The group includes approximately 26 physicians. Please see Exhibit 3 for Dr. Fraser's curriculum vitae and his letter indicating his willingness to provide clinical direction for the new radiation therapy program at Pineville.

(2) Radiation Physicist;

PRTC will contract the services of a radiation physicist with a group called Physics and Computer Planning, Inc. Please see Exhibit 9 for a letter from Physics and Computer Planning, Inc. indicating the willingness of this group to provide such services.

(3) Dosimetrist or Physics Assistant;

PRTC will contract the services of a dosimetrist with a group called Physics and Computer Planning, Inc. Please see Exhibit 9 for a letter from Physics and Computer Planning, Inc. indicating the willingness of this group to provide the services of a dosimetrist for the Pineville program.

(4) *Radiation Therapist;*

As indicated in the table in Section VII.2, PRTC proposes to staff the program with 3.0 FTE radiation therapy technologists (1.0 simulation radiation therapy technologist and 2.0 treatment radiation therapy technologists) and 1.0 FTE lead therapist, for a total of 4.0 FTE radiation therapy technologists for PRTC.

(5) *Radiation-Oncology Administrator;*

As shown in the table in Section VII.2, PRTC proposes one department manager to oversee the operations of the Center on a daily basis.

(6) *Registered Nurse or LPN;*

PRTC proposes 1.0 FTE registered nurse to provide clinical support for the proposed radiation therapy program.

(7) *Physical Therapist;*

Physical Therapy services will be provided by CMC-Pineville and will be available upon request for consultation. Please see Exhibit 8 for a letter from CMC-Pineville verifying the availability of this service.

(8) *Dietician;*

Dietician services will be provided by CMC-Pineville and will be available upon request for consultation. Please see Exhibit 8 for a letter from CMC-Pineville verifying the availability of this service.

(9) *Pharmacist;*

Pharmacists employed by CMC-Pineville are available 24 hours per day, seven days per week and will be available to the radiation

therapy program, as needed. Please see Exhibit 8 for a letter from CMC-Pineville verifying the availability of this service.

(10) Social Worker; and

Social workers, employed by CMC-Pineville, will be available upon request for consultation. Please see Exhibit 8 for a letter from CMC-Pineville verifying the availability of this service.

(11) Maintenance Engineer.

As with all CHS equipment, most maintenance will be handled through the CHS engineering department; however, a maintenance contract with the vendor will also be in place for the linear accelerator and simulator. Please see Exhibit 4 for copies of the proposed maintenance contracts.

9. **If the project involves the replacement of existing beds, treatment space, or other support space describe how the vacated space will be used. If renovation of the vacated space is proposed, identify all renovation costs in Application Section VIII.**

Not applicable. The proposed project does not involve the replacement of existing beds, treatment space or other support space.

EXHIBIT
B

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

December 19, 2013

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

RE: Material Compliance / Pineville Radiation Therapy Center / Redesignation of Pineville Radiation Therapy Center in Project I.D. #F-7524-06 / Mecklenburg County

Dear Mr. Qualls:

In response to your letter of December 13, 2013 the above referenced proposal is in material compliance with representations made in the application in accordance with 10 NCAC 14C .0502(c), which states, *"Control of a certificate of need is transferred when any person acquires a majority interest in the facility, project or holder or any parent entity of the facility, project or holder."* The Certificate of Need Section has determined that the proposed change is in material compliance with representations made in the application. These changes include redesignating Pineville Radiation Therapy Center to Carolinas Medical Center's (CMC) licensed and provider-based status. The requestor states that no equipment or services will be relocated as a result of this redesignation and that the Center's services will continue to be managed by CMC's Radiation Oncology Department as indicated in the application. The requestor also states that nothing in this proposed redesgination will change the scope, physical location, or persons named in the CON or Application. However, you should contact the Acute and Home Care Licensure and Certification Section of Health Service Regulation to determine if they have any requirements for the proposed change.

It should be noted that this Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this Agency and a separate determination.

If you have any questions concerning this matter, please feel free to contact this office. Please refer to the Project I.D.# and Facility I.D.# (FID) in all correspondence.

Sincerely,

Fatimah Wilson
Project Analyst

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

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

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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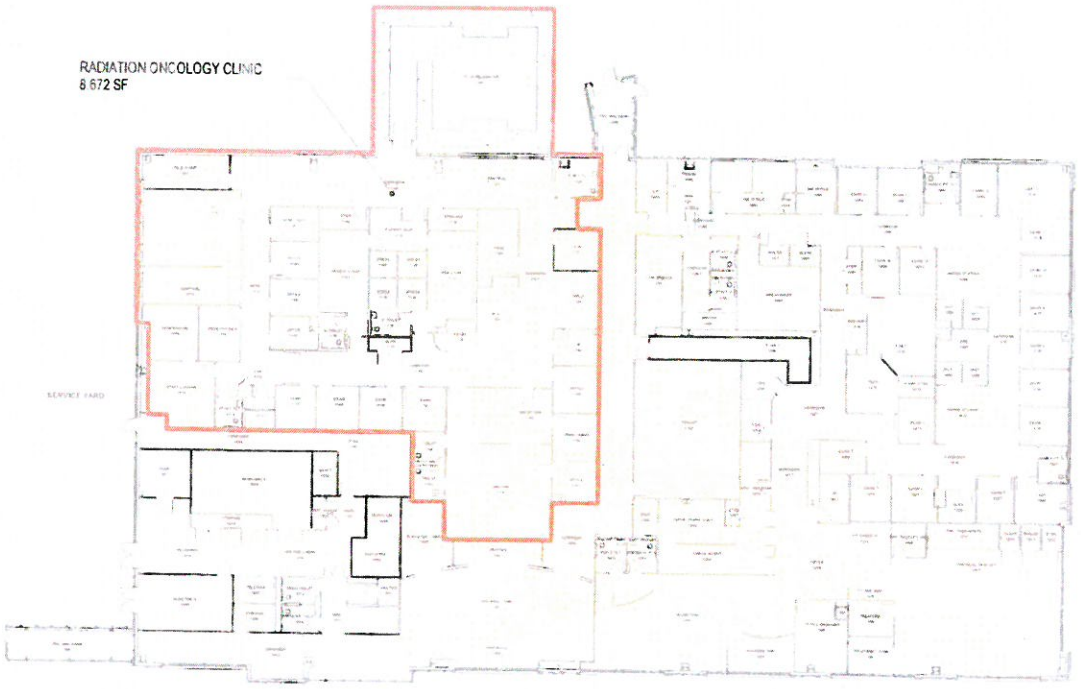
EXHIBIT

C

COLOR KEY

EXISTING BUILDING



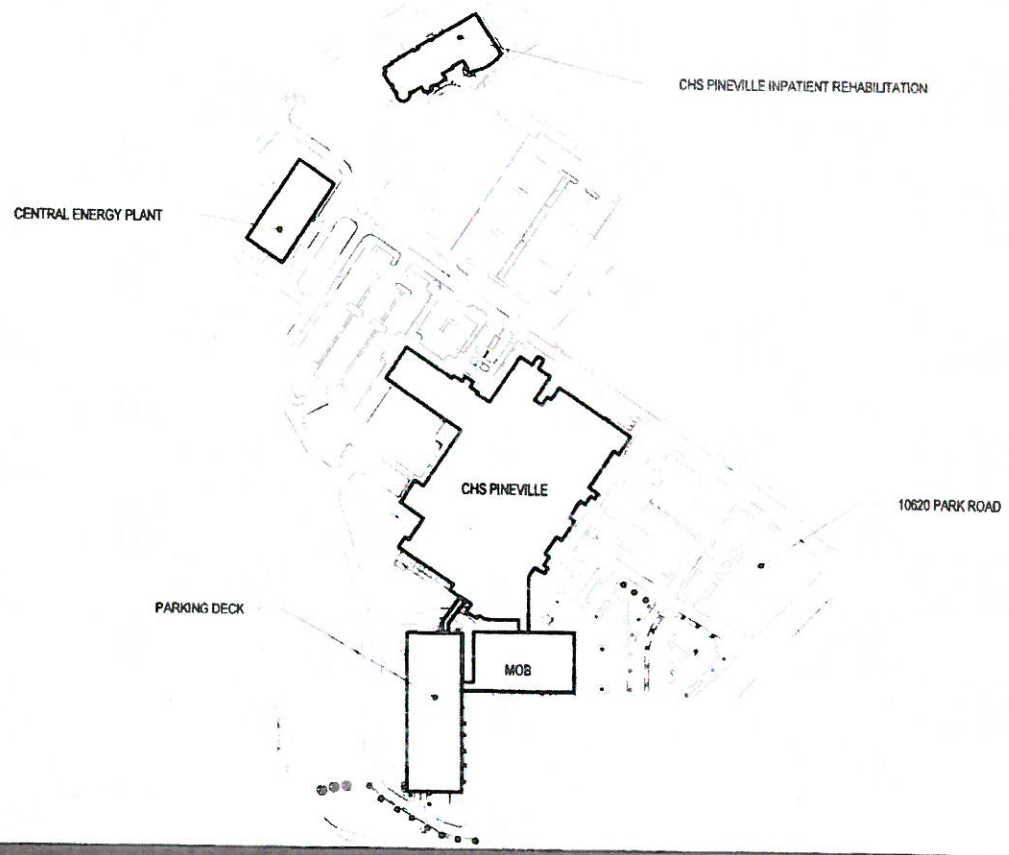
EXISTING PINEVILLE MEDICAL PLAZA - LEVEL 01

Carolinas HealthCare System

10/16/2017

LCI - Pineville

EXHIBIT



Site Plan

Carolinas HealthCare System

10/16/2017

LCI - Pineville

EXHIBIT
tabbies
E

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

Pat McCrory
Governor

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

Drexdal Pratt
Division Director

August 5, 2015

Barbara L. Freedy
Certificate of Need
Novant Health, Inc.
2085 Frontis Plaza Drive
Winston-Salem, North Carolina 27103

Material Compliance Approval

Project ID #:	F-001810-83
Facility:	Novant Health Presbyterian Medical Center (NHPMC)
Project Description:	Locate replacement cardiac catheterization equipment at Novant Health Matthews Medical Center (NHMMC)
County:	Mecklenburg
FID #:	943501

Dear Ms. Freedy:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) has determined that the change proposed in your letter of July 9, 2015 is in material compliance with representations made in the application. This change includes relocating a cardiac catheterization lab from NHPMC's cardiac catheterization lab #1 to NHMMC. Both facilities are in the Mecklenburg County service area. However, you should contact the Agency's Construction Section to determine if they have any requirements pertinent to the proposed change.

It should be noted that the Agency's position is based solely on the facts represented by you, including supplemental information provided to the Agency in an additional letter, dated July 9, 2015, regarding NHMMC's ability to safely perform interventional cardiac catheterization procedures, and that any change in facts as represented would require further consideration by this office and a separate determination.

If you have any questions concerning this matter, please feel free to contact this office. Please refer to the Project ID # and Facility ID # (FID) in all correspondence.

Healthcare Planning and Certificate of Need Section
www.ncdhhs.gov
Telephone: 919-855-3873 • Fax: 919-715-4413
Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603
Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704
An Equal Opportunity/ Affirmative Action Employer

Sincerely,

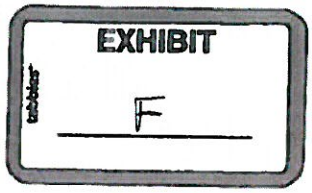
Gloria C. Hale

Gloria C. Hale
Project Analyst

Martha J. Frisone

Martha J. Frisone,
Assistant Chief, Certificate of Need

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



Nelson
Mullins

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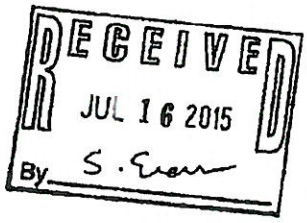
July 16, 2015



Hand Delivered

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

Re: No Review Request for Novant Health, Inc., The Presbyterian Hospital d/b/a Novant Health Presbyterian Medical Center and Presbyterian Medical Care Corp. d/b/a Novant Health Matthews Medical Center
Mecklenburg County
Health Service Area III

Dear Ms. Frisone:

On behalf Novant Health, Inc. ("Novant"), The Presbyterian Hospital d/b/a Novant Health Presbyterian Medical Center ("NHPMC") and Presbyterian Medical Care Corp. d/b/a Novant Health Matthews Medical Center ("NHMMC"), I am writing to request written confirmation that the CON Law does not apply to the following transaction (the "Transaction").

Factual Background

Novant is a nonprofit health care system that owns fourteen hospitals. Two of these hospitals are NHPMC and NHMMC. NHPMC and NHMMC are acute care hospitals located in Mecklenburg County, North Carolina. NHPMC and NHMMC are wholly-owned subsidiaries of Novant Health Southern Piedmont Region, LLC, a member-managed limited liability company whose sole member is Novant. *See* Exhibit A. Novant is therefore the ultimate parent entity of both NHPMC and NHMMC. NHPMC and NHMMC are affiliates within the Novant corporate family. *See* Exhibit B, 2014 audited financials for Novant, p. 6, note 1.

Ex were disposed of

NHPMC owns four units of fixed cardiac catheterization equipment. NHMMC presently provides both diagnostic and interventional cardiac catheterization services using equipment owned by a third party. *See* Tables 9S, 9V and 9W of the 2015 SMFP, attached hereto as Exhibit C.

The Transaction

The contract with the third party ends in December 2015. Rather than continue to incur the cost of the contract, NHPMC proposes to move one of its four existing and operational cardiac catheterization units ("Cath Lab #1") to NHMMC. In separate correspondence to the CON Section, NHPMC and NHMMC request that the CON Section determine that the replacement of Cath Lab #1 qualifies for the replacement equipment exemption under N.C. Gen. Stat. § 131E-184(a)(7)(the "Replacement Cath Lab"). NHMMC has also submitted separate correspondence to the CON Section demonstrating that NHMMC can safely perform interventional cardiac catheterization procedures without open heart surgery services on site.[1] If the Transaction is approved, the Replacement Cath Lab would then be reported on NHMMC's annual Hospital License Renewal Application.

Analysis

The CON Law applies to "new institutional health services." N.C. Gen. Stat. § 131E-178(a). N.C. Gen. Stat. § 131-176(16)f1. defines "new institutional health service" to include "the acquisition by purchase, donation, lease, transfer, or comparable arrangement" of certain types of medical equipment, including cardiac catheterization equipment. *See* N.C. Gen. Stat. § 131E-176(16)f1.3. For the reasons set forth below, this provision of the CON Law should not apply to the Transaction.

The Transaction involves a move between and among entities that are entirely within the Novant corporate family. Novant ultimately controls both NHPMC and NHMMC. No one outside of Novant is acquiring anything in this Transaction. Ultimately, all assets at NHPMC (including Cath Lab #1) and NHMMC are owned by Novant. As has been demonstrated through dozens of CONs applications filed throughout the years, the financials for these hospitals and all other Novant-controlled facilities are consolidated, and only one set of audited financials is produced for the entire Novant family, including NHPMC and NHMMC. *See, e.g.*, Exhibit B, which are Novant's 2014 audited financials. As stated on page 6, note 2 of the 2014 audited financials: "[t]he consolidated financial statements include the accounts of all affiliates controlled by Novant Health." These affiliates include NHPMC and NHMMC. *See id.*, note 1. Further, when Novant issues bonds through the North Carolina Medical Care Commission, the proceeds are used to pay for projects at various

[1] These additional letters are incorporated by reference in this letter.

Novant-owned facilities, including NHPMC and NHMMC. Regarding bonds issued in 2013, page 32 of the 2014 audited financials reports:

> [t]he remaining proceeds [of the 2013 issue] were used to finance and reimburse Novant Health for expenditures primarily related to the construction of the following. . . . the vertical expansion of Novant Health Matthews Medical Center; . . . and the G-wing renovation at Novant Health Presbyterian Medical Center.

Exhibit B, p. 32

There will be no increase in the inventory of cardiac catheterization equipment in Mecklenburg County beyond those units which have already been approved. No new health service facilities or services are being added beyond those already approved. Rather, the Transaction should be regarded merely as a reorganization similar to those which the CON Section and the Department have previously determined are not subject to CON review.

For example, in 2011, CSA Medical Services, LLC ("CSA") proposed to transfer its interest in eight existing heart lung bypass machines to two wholly-owned subsidiary limited liability companies, CSAMS New Bern Avenue, LLC and CSAMS Lake Boone Trail, LLC. *See* Exhibit D. Five of the machines were located at WakeMed, and three of the machines were located at Rex.

In its no review request, CSA pointed out that 10A NCAC 14C.0502(b) allows for the transfer of *undeveloped* CONs in cases of corporate reorganizations. *See* Exhibit D, page 4. CSA further stated that ". . . [i]f 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." *Id.* CSA also relied upon N.C. Gen. Stat. § 131E-189(c):

> [m]oreover, 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).

Id., p. 4. The CON Section determined that the CON Law did not govern CSA's proposal. *See* Exhibit E.[2]

The CSA decision applies here. Cath Lab #1 is an existing and operational cath lab. While NHMMC is not a subsidiary of NHPMC, these two hospitals are corporate affiliates within the Novant corporate family, and are subsidiaries of the same entity (Novant Health Southern Piedmont Region) which is in turn wholly owed by Novant. Ultimately, Novant owns and controls Cath Lab #1, and that will not change as a result of this Transaction. It would not serve the purposes of the CON Law to require regulatory review of an existing cath lab that is being moved from one corporate affiliate to another in Mecklenburg County. Further, both diagnostic and interventional cardiac catheterization services have been provided for years at NHMMC; thus, the need for the service has already been established. It would not make sense for NHMMC to have to reprove the need for a service it already offers.

The CSA no review also included the 2011 Radiation Oncology Centers of the Carolinas, Inc. ("ROCC") declaratory ruling (included in Exhibit D), which permitted ROCC to transfer its interests in two radiation oncology facilities owning linear accelerators to two wholly-owned subsidiaries of ROCC. In a more recent, analogous declaratory ruling, the Department permitted Caldwell Memorial Hospital, a subsidiary of UNC Health Care, to "redesignate" its cancer center space, including a linear accelerator, to unlicensed space of its sister hospital, UNC Hospitals. *See* Exhibit G, a March 12, 2015 declaratory ruling issued to UNC Healthcare System, UNC Hospitals and Caldwell Memorial. In the UNC/Caldwell declaratory ruling, the Department stated:

> Nor does the Redesignation of the Cancer Center Space trigger any of the 'acquisition-related' new institutional health service definitions in N.C. Gen. Stat. § 131E-176(16). The Cancer Center Space, the Radiation Oncology Equipment, and the Medical Oncology Equipment are not being acquired, because no legal entity outside of the UNC Health Care controlled affiliates is acquiring anything. Rather, this Redesignation is purely an intra-organizational Redesignation within UNC Health Care controlled affiliates. See 10A NCAC 14C.0502.

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[2] Subsequently, Rex was permitted to acquire the membership interests in CSAMS Lake Boone Trail, and WakeMed was permitted to acquire the membership interests in CSAMS New Bern Avenue. *See* Exhibit F. No third party outside the Novant corporate family is involved in the Transaction.

***

> This Redesignation does not involve the offering or expansion of any new facility, service or equipment, and the inventory of linear accelerators and CT scanners in Caldwell County and the State overall will not change. No new radiation oncology equipment or services will be placed in operation in Caldwell County or the State as a result of this Project.

Exhibit G, p. 7.

The UNC/Caldwell ruling applies here. No legal entity outside of Novant will be acquiring anything in the Transaction. The Transaction is purely intra-organizational. The Transaction does not involve the offering or expansion of any new facility, service or equipment, and neither the inventory of cardiac catheterization labs in Mecklenburg County nor the State overall will change as a result of the Transaction. No new cardiac catheterization equipment or services will be placed in operation in Mecklenburg County or the State as a result of this Transaction.[3]

As the UNC/Caldwell ruling aptly recognized,

> [i]t is a well-established principle of statutory construction that the intent of the Legislature controls the interpretation of the statute. *See State v. Fulcher*, 294 N.C. 503, 520, 2432 S.E.2d 338, 350 (1978). Prohibiting this simple intra-organizational Redesignation of existing services would not advance the goal of avoiding costly duplication because the Radiation Oncology Equipment and the Cancer Center Space already exist and are used to provide the same services they will provide after the Redesignation. Construing the statute otherwise would lead to absurd results that the General Assembly could not have intended. *King v. Baldwin*, 276 N.C. 316, 325, 172 S.E.2d 12, 18 (1970)('It is presumed that the legislature acted in accordance with reason and common sense and that it did not intend an unjust or absurd result.').

Exhibit G, p. 7.

[3] As discussed in separate correspondence filed with the CON Section, NHMMC intends to replace the nineteen-year old Cath Lab #1 with the Replacement Cath Lab. The proposed replacement, which is exempt under N.C. Gen. Stat. § 131E-184(a)(7), does not increase the inventory of cath labs in Mecklenburg County or the State overall.

The same is true here. The Transaction is not the sort of acquisition the CON Law seeks to regulate. Cath Lab #1 is existing equipment owned by a common parent. It will be used to provide the same services at NHMMC that it provides at NHPMC. Under these circumstances, the Transaction should not be deemed subject to CON review under N.C. Gen. Stat. § 131E-176(16)f1.3. *See also Cape Fear Memorial Hospital v. N.C. Dep't of Human Resources*, 121 N.C. App. 492, 494, 466 S.E.2d 299, 301 (1996) (holding that the legislature clearly did not intend to impose unreasonable limitations on maintaining, or expanding, presently offered health services).

Similarly, the Transaction does not implicate N.C. Gen. Stat. § 131E-176(16)b., requiring CON review for a capital expenditure greater than $2 million "to develop or expand a health service or a health service facility, or which relates to the provision of a health service." As discussed in the companion Replacement Equipment Exemption Request, the total cost to replace Cath Lab #1, including disposal of Cath Lab #1, is $922,524.

Finally, the relocation of Cath Lab #1 from Charlotte to Matthews is not reviewable under the CON Law. Both hospitals are in Mecklenburg County. They are approximately 11 miles and 16 minutes apart from each other. *See* Exhibit H, a Mapquest map. The Department has previously approved relocations of equipment within Mecklenburg County that involved similar or greater distances. *See, e.g.*, Exhibit I (November 13, 2006 ruling allowing Presbyterian to transfer an MRI scanner from Charlotte to Huntersville, a distance of approximately 15.44 miles); Exhibit J (March 3, 2008 ruling allowing Carolinas Imaging Services, LLC to relocate an MRI scanner from Huntersville to the Ballantyne area of Charlotte, a distance of approximately 31 miles); and Exhibit K (February 7, 2014 ruling allowing Presbyterian to change the location of an undeveloped linear accelerator from Matthews to Huntersville, a distance of approximately 25 miles).

Accordingly, Novant, NHPMC and NHMMC respectfully request that the CON Section determine that the Transaction described in this letter does not require CON review.

Thank you for your time and consideration.

Sincerely,

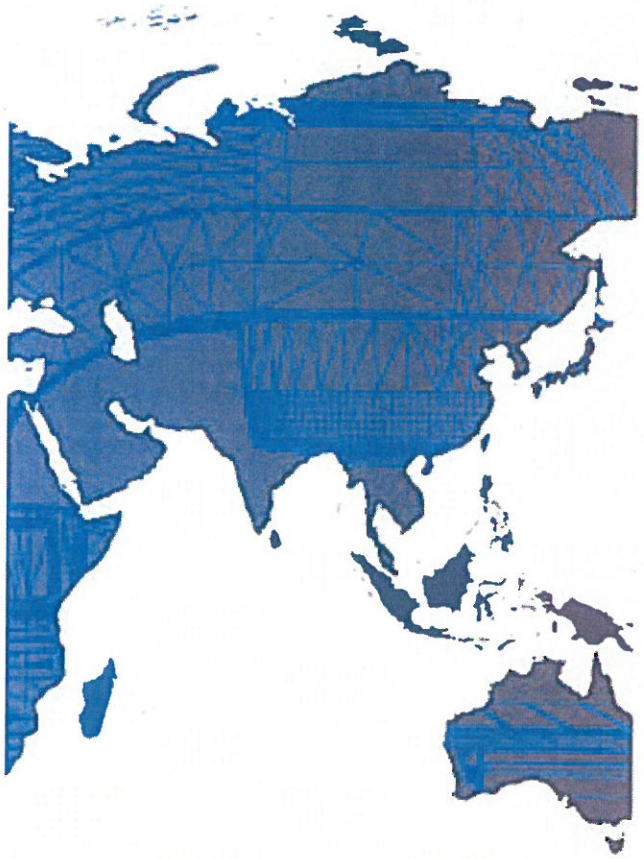
Denise M. Gunter

Enclosures

Attachment F


trueBEAM
VARIAN
medical systems
THE TRUEBEAM SYSTEM


BEAM



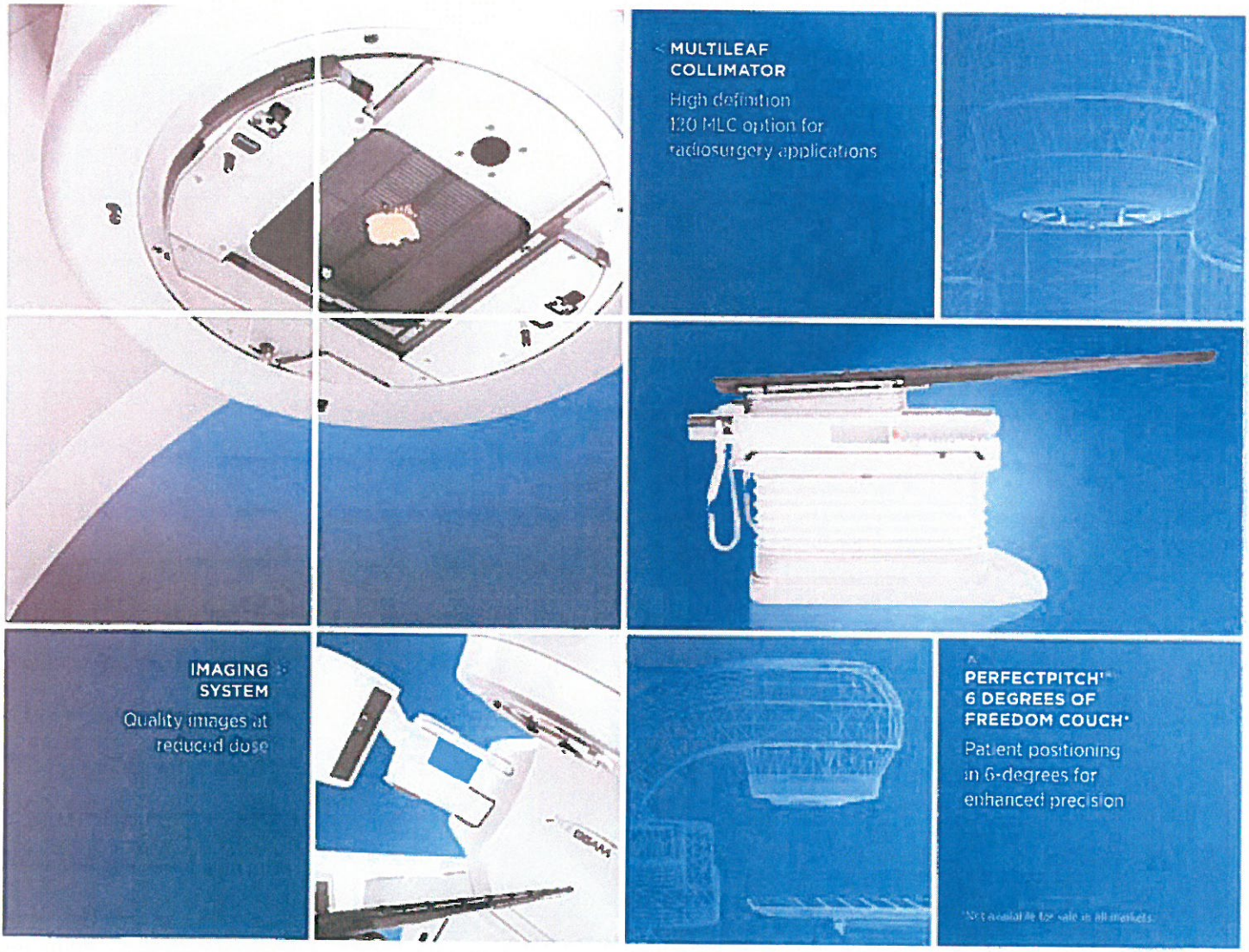
THE TRUEBEAM SYSTEM.

BUILT BY VARIAN, INSPIRED BY OUR CUSTOMERS.

The TrueBeam™ system brings some of the most innovative thinking in cancer care into your clinic. This advanced technology offers a range of capabilities that turn leading research into integrated care. With these advances, you have more options for patients and more opportunities for your clinic.

Such versatility is why the TrueBeam system has been adopted by top clinics around the world. With this rapid growth, TrueBeam and Varian Medical Systems can help position your clinic at the forefront of the global fight against cancer. We know where we're headed. Join us on the journey.

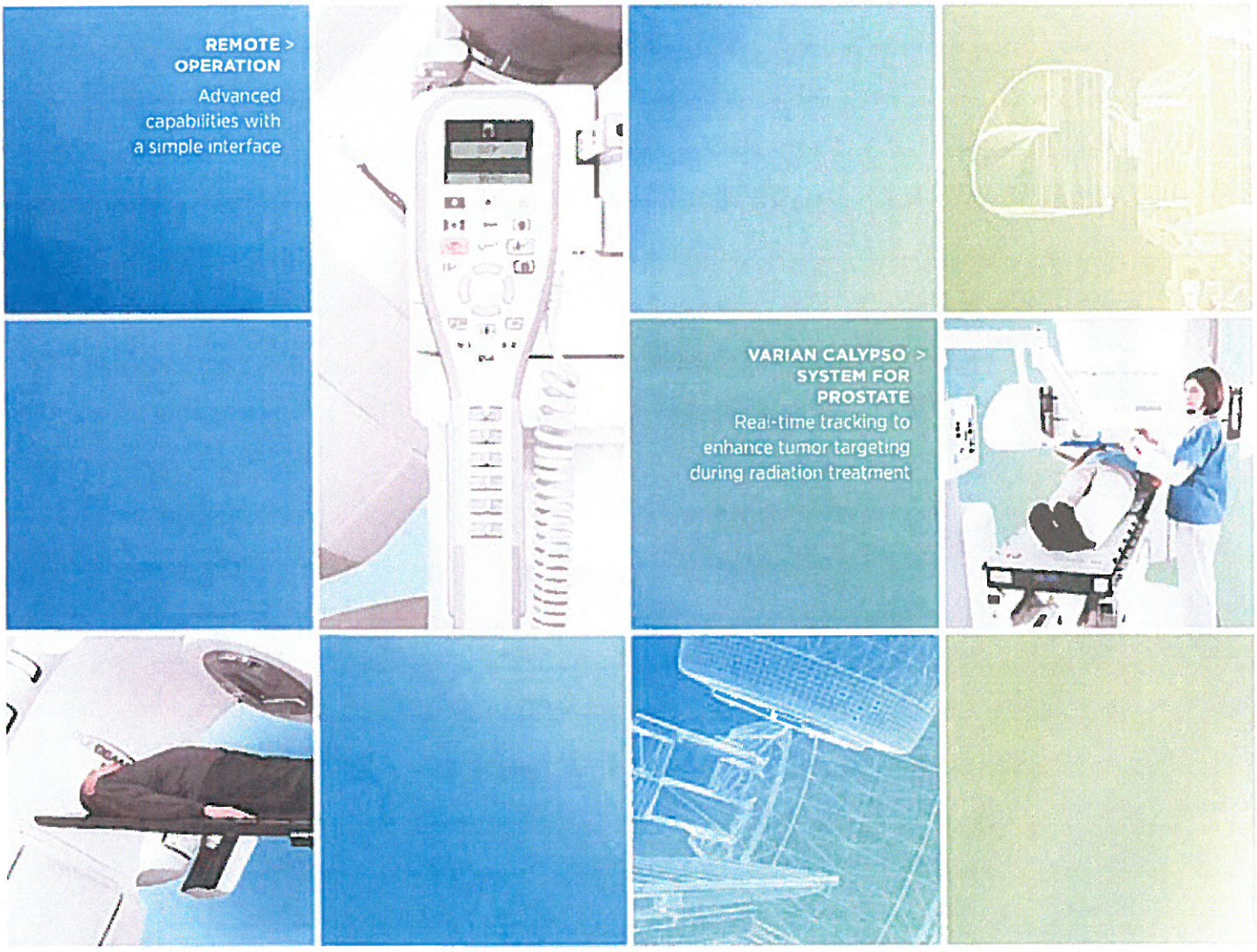
PROVEN AS A TECHNOLOGY.
POSSIBILITIES AS A RESULT.



Expand your offerings with the system built to help you grow.

The TrueBeam system is designed to address a diverse range of clinical cases such as those in the lung, liver, head and neck, and more. TrueBeam integrates respiratory gating, real-time tracking, imaging and treatment delivery to create a streamlined system. With this integration, you can take advantage of the latest treatment techniques, including SBRT, SRS, RapidArc® and Gated RapidArc®.

Interface with multiple technologies for imaging and disease-specific solutions on the TrueBeam system's flexible open architecture. Integrate with the ARIA® oncology information system and the Eclipse™ treatment planning system to simplify planning and manage treatment workflows. Save time and condense tasks with automated, customizable sequences. With this full spectrum of innovative tools, the TrueBeam system puts current advances in your hands.

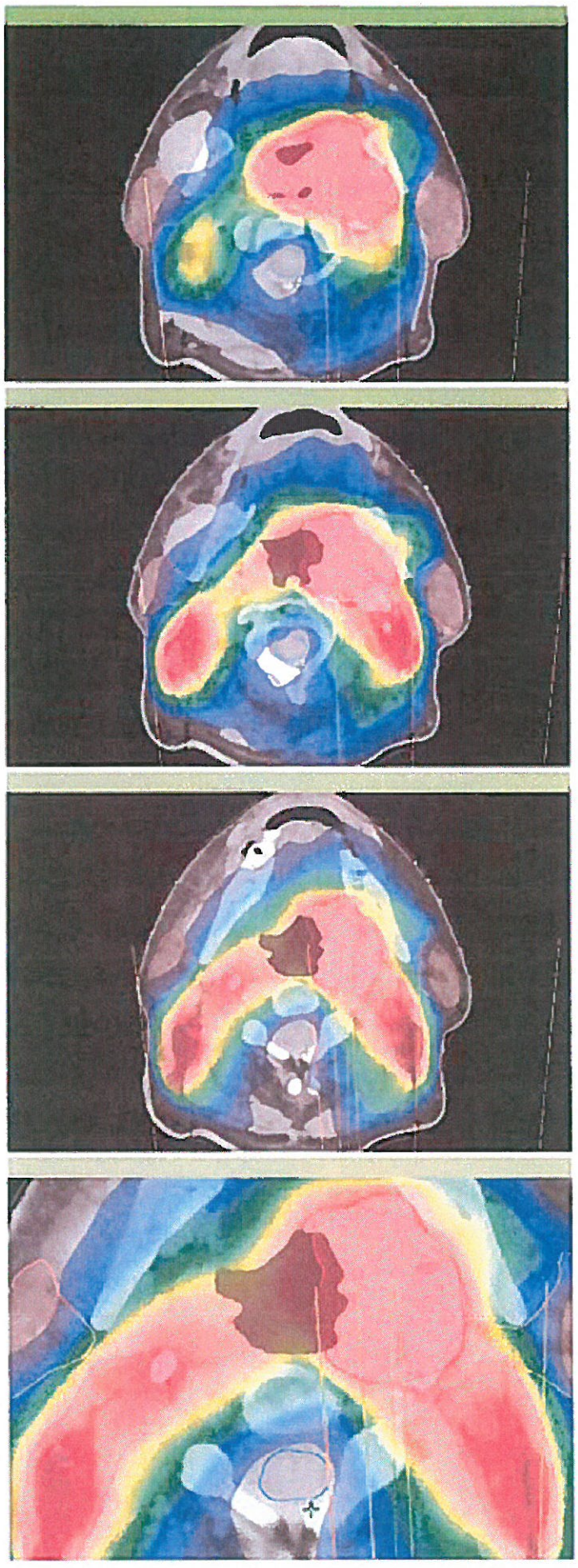


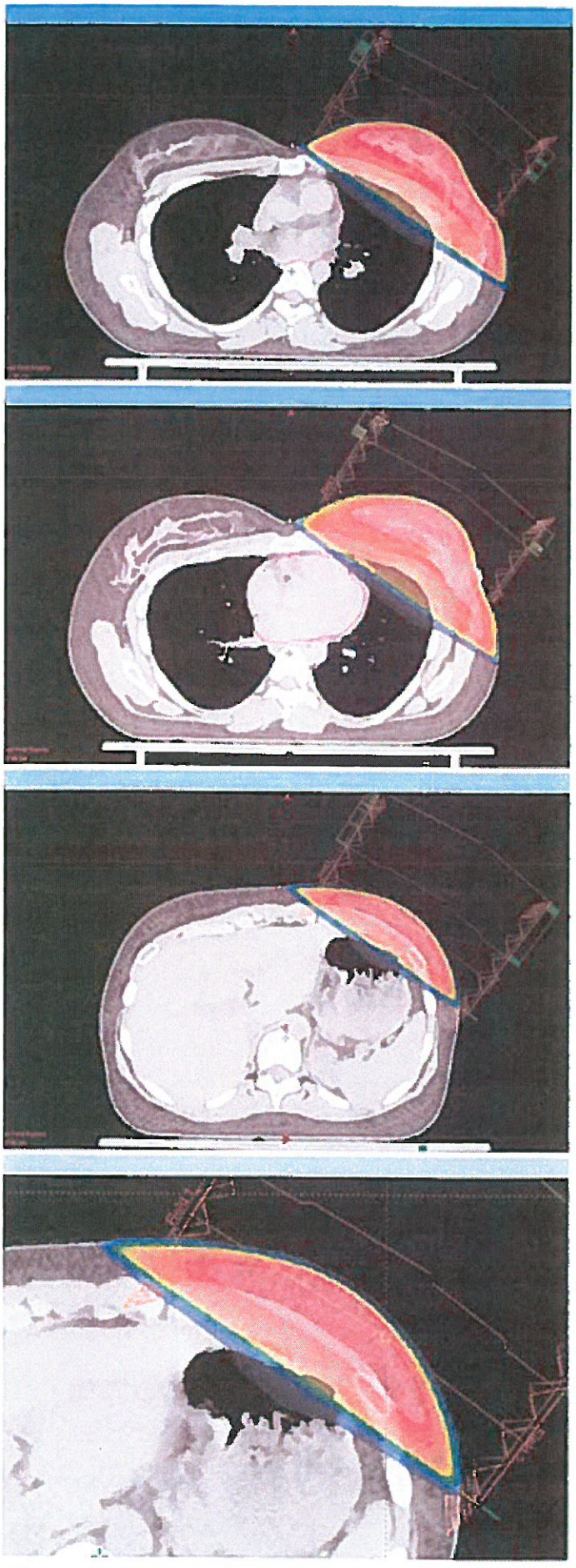
MORE OPTIONS FOR A WIDE VARIETY OF CANCER CASES.

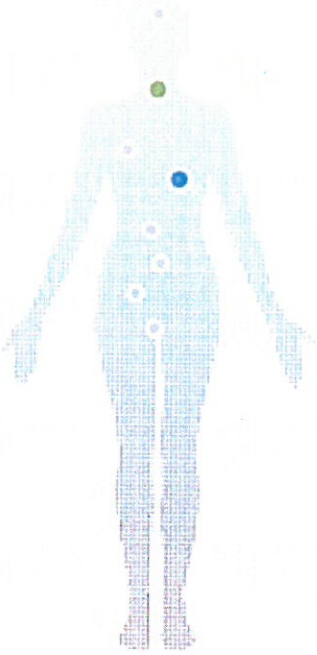
Address a diverse range of cancer cases with the TrueBeam system. Areas located in close proximity to critical structures or significant changes in anatomy during the course of treatment can make difficult targets for clinicians. See how the TrueBeam system addresses the technical challenges of these four common cancer types.

HEAD AND NECK

- Multiple arcs, partial arcs or a combination can be planned and seamlessly delivered using RapidArc radiotherapy technology
- A range of diagnostic imaging studies can be introduced in treatment planning to assist in accurate contouring of the target
- The real-time control system synchronizes and choreographs all elements of delivery 10 times per second
- Imaging hardware and software allow capture of high-quality cone-beam CT images with lower concomitant dose
- Integration of SmartAdapt™ deformable registration algorithms provide a convenient means for clinicians to account for anatomical changes during the course of treatment





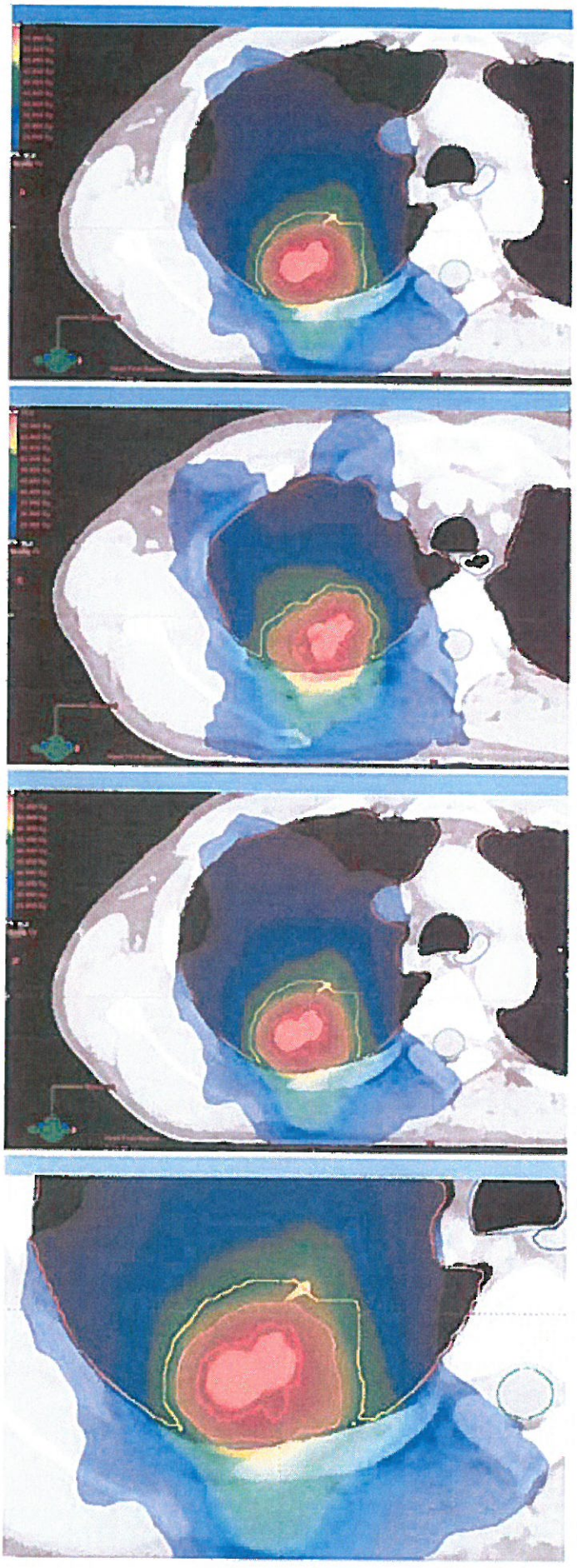


BREAST

- IMRT tools such as field-in-field help create treatment plans designed to minimize radiation exposure of the heart and healthy lung tissue
- Treat patients in the prone position using the Pivotal™ treatment solution for prone breast care to help minimize dose to critical structures such as the heart and lung
- Use Varian Calypso® technology and the Surface Beacon® Transponder for real-time deep inspiration breath hold to help ensure accuracy
- Integration of technologies such as real-time beam gating on a respiratory trigger can allow the reduction of treatment margins when compared to a full ITV-based treatment

VERSATILE TECHNOLOGIES FOR VERSATILE TREATMENTS.

A breadth of technology provides versatility for treatments throughout the body.

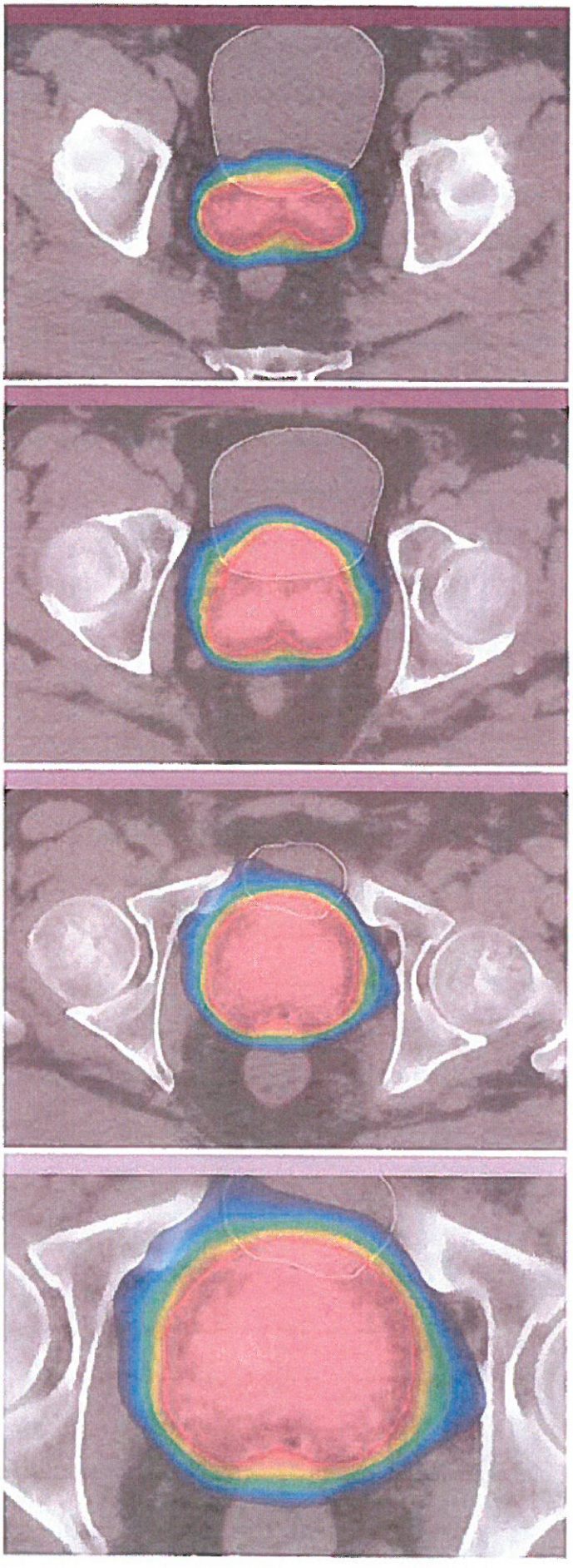


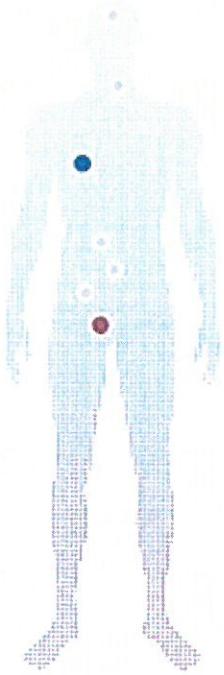
LUNG

- To reduce discrepancies between planned dose and delivered dose, Varian's Acuros™ XB algorithm provides Monte Carlo equivalent dose calculations
- Contour propagation, intermediate dose calculation and a fine calculation grid all contribute to create an efficient and desired treatment plan
- Respiratory gating allows the reduction of irradiated volumes when compared with large ITV-based approaches[1]
- Fluoroscopic, KV, MV and CBCT, along with the capability to mix and match from the menu of imaging possibilities, allow clinicians to tailor treatment delivery
- 2400 MU/minute, the highest dose rate in the industry, allows rapid delivery of large fractions[2]

[1] Data on file

[2] March, 2013

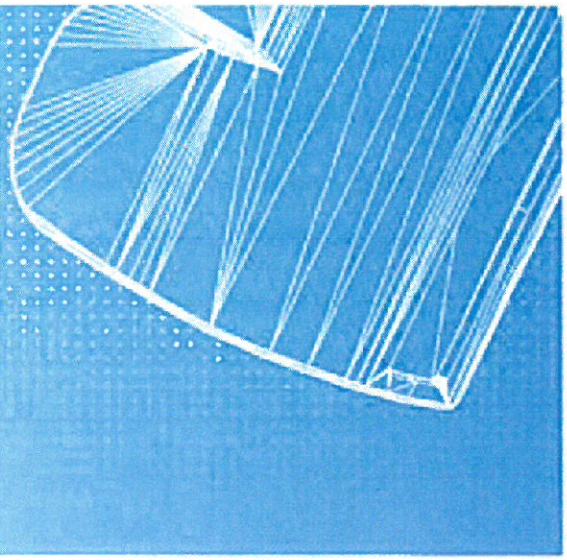




PROSTATE

- Using SmartSegmentation™ knowledge-based contouring, physicians can take advantage of built-in expert cases or create their own cases to standardize treatment across the institution.
- Deliver treatment with speed and accuracy using RapidArc® radiotherapy technology and Eclipse™ treatment planning system
- Deliver fast hypofractionated prostate SBRT treatments using High Intensity Mode at 1400 MU/minute or 2400 MU/minute
- Track and correct, in real time, prostate drift and sporadic motion with Varian Calypso® system for prostate

FIND MORE PATHS TO TREATMENT AND MORE PATHS TO GROWTH.



INNOVATIVE. INTELLIGENT. INTUITIVE.

Medicine does not advance on its own. We pursued innovative technology and the insights of our customers to arrive at this impressively intelligent solution. With the TrueBeam system, your clinic now has the tools to initiate a wide spectrum of advanced treatment options for specific disease sites.

ARCHITECTURE & MAESTRO

Dynamic performance for speed and efficiency

Behind the scenes of the TrueBeam system's advanced performance lies Maestro™ — an innovative control system. Maestro conducts the TrueBeam system by directing, synchronizing and monitoring all of the system's fully integrated, functional components or "nodes." Maestro's sophisticated orchestration of dose, motion and imaging reflects each of the system's moving parts, making treatment fast and efficient. Open up new possibilities for image-guided and motion-managed treatment techniques with this innovative architecture. The TrueBeam system's design also supports SmartConnect® technology, an on-demand remote support feature that allows your Varian service or helpdesk representative to provide immediate, real-time desktop sharing.

BEAM GENERATION

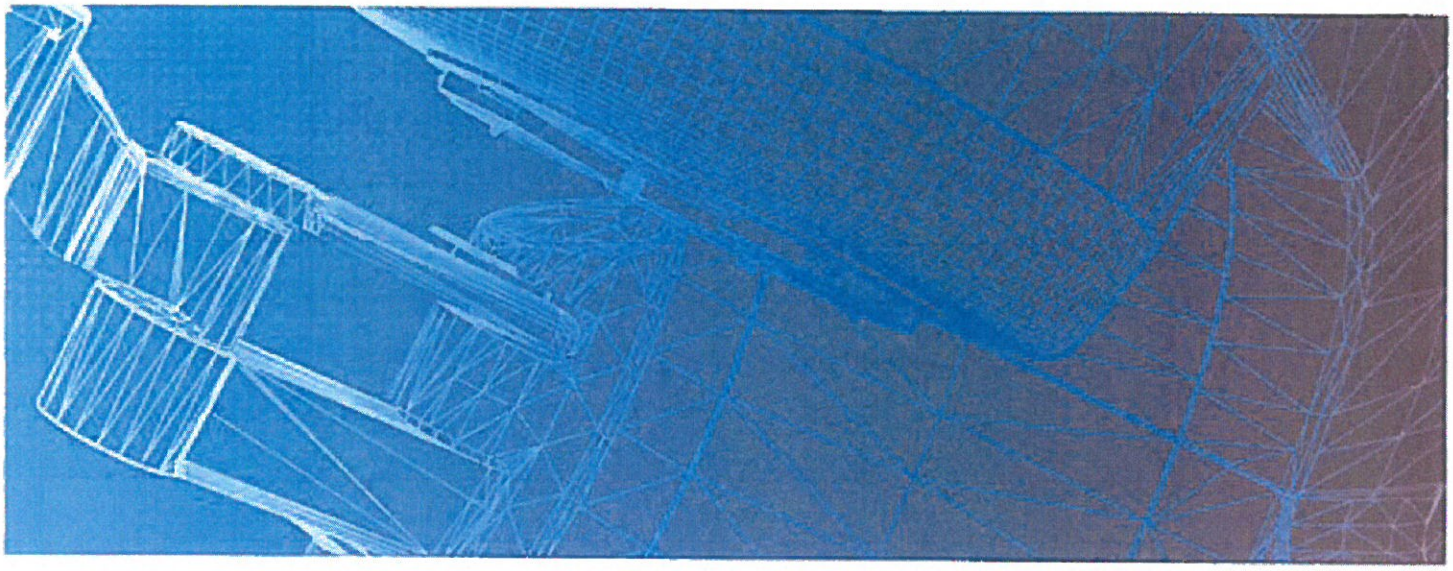
Exceptional performance and technology without compromise

At the heart of the TrueBeam system is a beam generation technology that's patented and unique. This beam generation system can be configured with zero to eight electron energies and up to seven photon energies, including two High-Intensity Modes for stereotactic radiosurgery and hypofractionated stereotactic body radiotherapy treatments. You can now better tailor radiation treatment programs with the advanced versatility found in the TrueBeam system.

IMAGING

A treatment range so generous, it includes space to breathe

The TrueBeam system opens the door to leading edge treatment with advanced positioning and real-time tracking solutions—including a full range of innovative and powerful imaging tools. Generate quality images without compromise through lower dose imaging. Create customized imaging protocols to enable faster, easier imaging with intelligent automation. Gated RapidArc® technology allows you to monitor patient breathing and compensate for tumor motion while quickly delivering dosage. The powerful imaging technologies in the TrueBeam system are an ideal complement to its integrated gating and motion-management system. With such a supportive system, you can image and treat with confidence.



DEVELOPER MODE

Turn possibilities into action

The Developer Mode option allows a broad range of experimentation in a non-clinical environment. This expanded access is designed to give clinicians and physicists an efficient and effective means to innovate with new treatment and imaging techniques in a research mode. Advanced manipulation of mechanical and dose axes puts the dynamic beam, imaging and gating features of the TrueBeam system at your fingertips.*

* Developer Mode is not for use on humans. Treatment decisions should not be made based on data derived from Developer Mode.

SAFETY AND SPEED

Simple automated operation

Visual cues built into the TrueBeam system provide an intuitive operating environment and can help to enhance safety and reduce operation times. For instance, buttons on the controls light up in the correct order to guide the operator through each step. Built-in layers of safety have been added throughout the system, including a Collision Avoidance function to help avoid problems. As an added safeguard, the system automatically performs accuracy checks every ten milliseconds, throughout the entire treatment. And at the control console, you can visually monitor your patient using Safewatch, the CCTV camera system. With these design improvements, the therapist can focus even more on the patient.

PROSTATE AND LUNG SOLUTION

Real-time motion tracking for real-life results

The Varian Calypso® system for prostate provides accurate and precise real-time tracking to keep the radiation focused on the tumor, minimizing exposure to healthy tissue. It utilizes internal transponders that can detect even a slight movement of the target, so you can keep the tumor in the path of the radiation beam. With the Calypso system, you can confidently treat with tighter margins. This can help reduce some potential side effects, escalate dose to improve disease control or accelerate treatments with SABR.

For lung cancer treatment, the Varian Calypso™ system for lung* is designed to help address the ongoing challenge of precisely targeting the tumor as it moves due to respiration. The Calypso system may enable continuous internal target monitoring during radiation treatment by utilizing internal Beacon® Transponders which communicate with an electromagnetic array positioned over the patient. If the tumor target moves out of range, the clinician can stop the beam to adjust the tumor position, thereby minimizing exposure to surrounding healthy tissue.

* 510(k) pending - not available for sale in all markets.
Caution – Investigational Device. Limited by Federal Law to Investigational Use in the U.S.

6 DEGREES OF FREEDOM COUCH

Experience more freedom in patient setups

The new PerfectPitch™ 6 Degrees of Freedom Couch* is designed to advance patient positioning during radiotherapy and radiosurgery procedures by providing two additional rotational motion axes: pitch and roll. This patient positioning option may enable enhanced accurate target positioning and precise beam delivery and can reduce treatment margins in select clinical cases.

* Not available for sale in all markets.

BROADEN YOUR FUTURE IN CANCER CARE.

You can have improved workflow and clinical processes, plus the technology to enable precise treatments that take only minutes. Take a step forward to prepare for the future in cancer care.

With TrueBeam, your clinic is ready tomorrow and beyond.

IMAGINE A WORLD WITHOUT THE FEAR OF CANCER.

Varian Medical Systems has been a pioneer in the field of oncology for over 60 years. During this time, we introduced innovative treatment techniques, equipment and software that have been used to treat tens of thousands of cancer patients worldwide. Today we offer products and services to advance the entire treatment process. Our work creates a community for those affected by cancer, so we can unite around our common goal to fight this disease.

SELECTED SPECIFICATIONS

OUTPUT ENERGIES

X-ray (MV)	4, 6, 8, 10 ,15 ,18 ,20
High intensity mode	6X, 10X
Maximum output dose rates	4 MV at 250 MU/min; all others at 600 MU/min 6X HI at 1400 MU/min; 10X HI at 2400 MU/min
Electron (MeV)	6, 9, 12, 15, 16, 18, 20, 22
HDTSE	6 HDTSE, 9 HDTSE
Maximum output dose rates	1000 MU/min HDTSE Energies at 2500 MU/min

MECHANICAL PERFORMANCE

Gantry and collimator isocenter accuracy	≤ 0.5 mm radius
Gantry, collimator and couch isocenter accuracy	≤ 0.75 mm radius
Gantry rotational accuracy	≤ 0.3 degrees

IMAGING OPTIONS

kV range	40 – 140 kV
mAs range	0.1 – 1000 mAs
Modes	kV planar, kV CBCT, fluoroscopic imaging
Pixel matrix	2048 x 1536 1024 x 768

CBCT

Field of view	0 – 25 cm (head scans); 0 – 46 cm (body scans)
Slice thickness	1 mm – 5 mm in 0.5 mm increments; 10 mm

MULTILEAF COLLIMATOR

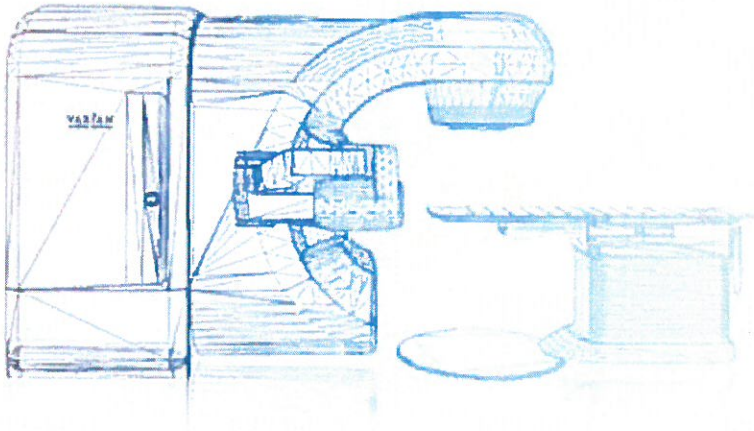
Millennium™ 120 Leaf MLC

Center	5 mm width x 40 pairs
Peripheral	10 mm width x 20 pairs
Maximum static field size	40 cm x 40 cm

High Definition 120 Leaf MLC

Center	2.5 mm width x 32 pairs
Peripheral	5 mm width x 28 pairs
Maximum static field size	40 cm x 22 cm

Varian Medical Systems as a medical device manufacturer cannot and does not recommend specific treatment approaches.


VARIAN

VARIAN medical systems | A partner for life

TRUEBEAM Treatment System

USA, Corporate Headquarters and Manufacturer

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Varian Medical Systems
Palo Alto, CA

Tel: 650.424.5700
800.544.4636
Fax: 650.493.5637

varian.com/truebeam

USA Regional Offices

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EMEA, CIS and India Headquarters

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Finland Oy
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(RUS) LLC
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Scandinavia
Varian Medical Systems
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Spain /Portugal
Varian Medical Systems
Ibérica, S.L.
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Australasia Pty Ltd.
Sydney, Australia
Tel: 61.2.9485.0111

Latin American Headquarters

Brasil
Varian Medical Systems
Brasil Ltda
São Paulo, Brasil
Tel: 55.11.3457.2655

Intended Use Summary

Varian Medical Systems' linear accelerators are intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body where radiation treatment is indicated.

Safety

Radiation treatments may cause side effects that can vary depending on the part of the body being treated. The most frequent ones are typically temporary and may include, but are not limited to, irritation to the respiratory, digestive, urinary or reproductive systems, fatigue, nausea, skin irritation, and hair loss. In some patients, they can be severe. Treatment sessions may vary in complexity and time. Radiation treatment is not appropriate for all cancers.

FAD 10119C

6/2013 (2.5M)

Attachment G

2018 CHS Pineville Linear Accelerator Replacement/Relocation

	Existing Equipment	Replacement Equipment
Type of Equipment (List each component)	Linear Accelerator	Linear Accelerator
Manufacturer of Equipment	Varian	Varian
Tesla Rating for MRIs	N/A	N/A
Model Number	CL 21iX	Trubeam
Serial Number	4135	TBD
Provider's Method of Identifying Equipment	Serial Number	Serial Number
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #	N/A	N/A
Mobile Tractor Serial Number/VIN #	N/A	N/A
Date of Acquisition of Each Component	2008	2018
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	Title
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>	$6,023,175	$11,200,000
Total Cost of Equipment	$2,601,671	$3,477,505
Fair Market Value of Equipment	265,037	$3,477,505
Net Purchase Price of Equipment	$2,601,671	$3,477,505
Locations Where Operated	CHS Pineville Pineville Medical Plaza I	CHS Pineville Pineville Medical Plaza II
Number Days in Use/To Be Used in N.C. per Year	260	260
Percent of Change in Patient Charges (by procedure)	N/A	0%
Percent of Change in Per Procedure Operating Expenses (by procedure)	N/A	0%
Type of Procedures Currently Performed on Existing Equipment	External beam radiotherapy	
Type of Procedures New Equipment is Capable of Performing		External beam radiotherapy

Attachment H

CHS Pineville Linear Accelerator Volumes

Month	Procedures
Feb-17	758
Mar-17	847
Apr-17	818
May-17	872
Jun-17	832
Jul-17	764
Aug-17	879
Sep-17	871
Oct-17	907
Nov-17	881
Dec-17	908
Jan-18	918
Total	10,255

Attachment I

Varian Medical Systems, Inc.
Corporate Headquarters
3100 Hansen Way
Palo Alto, CA 94304-1038

Telephone: 1.650.493.4000
Toll Free: 800.544.4636

www.varian.com

March 21, 2018

Mr. Chris Hollar:

This letter confirms Varian's obligation to deinstall and remove Clinac IX H294135 at the time that CHS Pineville issues the order for Varian Quote Number 2018-136046-3. Also, this letter also confirms that Varian will not reinstall Clinac IX H294135 within the state of North Carolina without CON approval.

Best Regards,

Shawn McCoy
District Sales Manager
Varian Medical Systems
Cell: 256-504-0177
shawn.mccoy@varian.com