

ROY COOPER • Governor

MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

February 14, 2020

Joseph M. Kahn Perimeter Three 3015 Carrington Mill Blvd., Suite 450 Morrisville, NC 27560

No Review

Record #:

3173

Facility Name:

See Attachment A

Business Name:

21st Century Oncology Holdings, Inc

Business #:

See Attachment A

Project Description:

Change in Indirect Ownership Interest

County:

See Attachment A

Dear Mr. Kahn:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the above referenced proposal. Based on the CON law **in effect on the date of this response to your request,** the proposal described in that correspondence is not governed by, and therefore, does not currently require a certificate of need. If the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

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

This determination is binding only for the facts represented in your correspondence. If changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office.

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

Sinceret

cc:

Gregory F Yakaboski

Project Analyst

Martha J. Frisone

Chief

Acute and Home Care Licensure and Certification Section, DHSR

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

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

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

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

### Change in Indirect Ownership of 21st Century Oncology Holdings, Inc.

#### **ATTACHMENT A**

Facility	Business #	County
North Carolina Radiation Therapy Management Services, LLC	2124	Haywood
Vidant Radiation Oncology, LLC	2324	Pitt
Goldsboro Radiation Therapy Services, LLC	3187	Wayne

From:

Hamill, Robert A. <RHamill@hallrender.com>

Sent:

Monday, February 10, 2020 1:44 PM

To: Cc: Yakaboski, Greg

Subject:

Kahn, Joseph M. RE: [External] RE: 21st Century Oncology Holdings- No Review Letter dated 12/20/19

Attachments:

Wayne Radiation Oncology No Review.pdf

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#### Greg-

Attached please find a previous no-review for 21C's Goldsboro facility, located at 2802 McLamb Place, that operates under the name Wayne Radiation Oncology.

Please feel free to contact me with any additional questions.

Best, Bobby

Robert A. Hamill | Attorney

rhamill@hallrender.com | vCard | @hallrender on Twitter

Hall, Render, Killian, Heath & Lyman, LLP RALEIGH D: (919) 447-4970 | F: (844) 801-5883

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From: Yakaboski, Greg <greg.yakaboski@dhhs.nc.gov>

Sent: Monday, January 27, 2020 10:20 AM

To: Hamill, Robert A. < RHamill@hallrender.com >

Subject: RE: [External] RE: 21st Century Oncology Holdings- No Review Letter dated 12/20/19

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Bobby,

Thanks.. will take a look at these and get back to you.

Greg

From: Hamill, Robert A. < RHamill@hallrender.com >

Sent: Friday, January 24, 2020 5:04 PM

To: Yakaboski, Greg <greg.yakaboski@dhhs.nc.gov>

Cc: Kahn, Joseph M. <JKahn@hallrender.com>

Subject: [External] RE: 21st Century Oncology Holdings- No Review Letter dated 12/20/19

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#### Greg-

Attached please find three no reviews and exemptions we pulled from the CON Section's website related to North Carolina Radiation Therapy Management Services and Vidant Radiation Oncology. Note we omitted the attachments to the VRO no review in the interest of keeping file size down.

Goldsboro Radiation Therapy Services operates the radiation oncology center located at 2802 McLamb Place, Goldsboro under the name Wayne Radiation Oncology.

Please let me know if you have any additional questions. Have a great weekend.

Best, Bobby

Robert A. Hamill | Attorney rhamill@hallrender.com | vCard | @hallrender on Twitter

Hall, Render, Killian, Heath & Lyman, LLP RALEIGH D: (919) 447-4970 | F: (844) 801-5883

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From: Yakaboski, Greg <greg.yakaboski@dhhs.nc.gov>

Sent: Tuesday, January 7, 2020 2:18 PM

To: Kahn, Joseph M. < <a href="Mailtender.com">> Mailtender.com</a>

Subject: 21st Century Oncology Holdings- No Review Letter dated 12/20/19

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Mr. Kahn,

When you have a chance please either give me a call or let me know when it would be convenient for me to call you re: your letter dated 12/20/19 about 21st Century Oncology Holdings "No Review" request.

My office number is 919-855-4664.

Thanks, Greg Yakaboski

**Project Analyst** 

Healthcare Planning and Certificate of Need Section.

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

2704 Mail Service Center ■ Raleigh, North Carolina 27699-2704

Beverly Eaves Perdue, Governor Lanier M. Cansler, Secretary

www.ncdhhs.gov/dhsr

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

Fax: 919-733-8139

December 7, 2011

William R. Shenton
Pamela A. Scott
PoynerSpruill
Post Office Box 1801
Raleigh, North Carolina 27602-1801

RE:

No Review / Goldsboro Radiation Therapy Services d/b/a Wayne Radiology Oncology / North Carolina Radiation Therapy Management Services, LLC acquire ownership interests in Goldsboro Radiation Therapy Services d/b/a Wayne Radiology Oncology / Wayne County

Dear Mr. Shenton and Ms. Scott:

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

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

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

Craig R smith, Chief

Certificate of Need Section

Sincerely,

Jane Rhoe-Jones

Project Analyst

Medical Facilities Planning Section, DHSR

Radiation Protection Section, DHSR

cc:



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

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

Pamela A. Scott D: 919.783.2954 F: 919.783.1075 pscott@poynerspruill.com

November 21, 2011

#### Via Hand Delivery

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

RE: Request for No Review Determination – Acquisition of Ownership Interests in Goldsboro Radiation Therapy Services

Dear Mr. Smith:

WWW.POYNERSPRUILL.COM

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

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

#### FACTUAL BACKGROUND

Since 1995, Goldsboro Radiation Therapy Services, P.A. d/b/a Wayne Radiation Oncology ("GRTS") has owned and operated an oncology treatment center located at 2802 McLamb Place in Goldsboro, North Carolina ("Wayne Radiation Oncology Center" or "Wayne Radiation Oncology"). GRTS is a professional corporation organized under the laws of the State of North Carolina, with its principal place of business located at 2802 McLamb Place, Goldsboro, North Carolina. Its sole shareholder is Dr. Kevin J. Kerlin ("Dr. Kerlin"), a North Carolina licensed physician who provides oncology treatment services, including radiation oncology services through the use of a Varian 2100 Linac, treatment planning system, CT Scanner, and other equipment associated with Wayne Radiation Oncology. Dr. Kerlin has provided radiation oncology services to cancer patients in the Wayne County area since June 1992, initially as an employee of the physician practice which originally established the Wayne Radiation Oncology Center. GRTS has served cancer patients in the Wayne County area since 1995 when Dr. Kerlin first formed the practice.

GRTS purchased the oncology treatment center located at 2802 McLamb Place from Wayne Radiation Oncology Center, Inc. in early 1995. Prior to that time, the Wayne Radiation Oncology Center had operated at the same location since approximately 1989, before North Carolina's Certificate of Need Law was amended to include oncology treatment centers and their equipment among the activities that are deemed to be among the "New Institutional Health Services" subject to certificate of need ("CON") review. Currently, a Varian Clinac 2100C/D linear accelerator (the "Varian 2100 Linac") along with an associated Varian Eclipse integrated treatment planning system (the "Treatment Planning System") are used to provide radiation therapy services to patients at Wayne Radiation Oncology. A GE QX/i LightSpeed CT Scanner (the "CT Scanner") also is currently used at the center for purposes of locating cancerous tumors and monitoring the change in size of the cancerous tumors during radiation treatment.

RTS, NCRTMS, and GRTS (collectively, the "Parties") have discussed and reached agreement on a transaction (the "Proposed Transaction") that would involve the transfer of the ownership interests in Wayne Radiation Oncology and its associated equipment including the Varian 2100 Linac, Treatment Planning System and CT Scanner (collectively, the "Equipment"). Wayne Radiation Oncology and its Equipment will continue to serve patients at the same location, and there will be no change in the scope of services provided by the radiation oncology center as part of the Proposed Transaction. The Proposed Transaction does not involve the offering or expansion of any new facility, service or equipment, and the State's inventory of linear accelerators will not change as a result of the transaction. Based upon prior declaratory rulings and "no review" determinations that have been issued by the Office of the Director of the Division of Health Service Regulation and by the CON Section, it is clear that the Proposed Transaction is not a "New Institutional Health Service," and should be permitted to proceed without first obtaining a certificate of need.

This letter describes the details of the Proposed Transaction and identifies the grounds for a determination that it is not subject to CON review.

#### Background on the Oncology Center and Equipment

As discussed above, GRTS acquired and began operating Wayne Radiation Oncology in 1995, without a CON because none was required. See 1995 Correspondence Between GRTS and CON Section confirming that the acquisition of oncology center was exempt from CON review (Exhibit 1). At the time GRTS acquired Wayne Radiation Oncology, it included a Varian Clinac 6/100 linear accelerator (the "Original Linac") and a Kermath Simulator (the "Original Simulator"). Each of these assets had been acquired and put into use at Wayne Radiation Oncology well before the CON Law was amended in March of 1993 to mandate review for any acquisition of major medical equipment.

In 1998, GRTS acquired the Varian 2100 Linac to replace the Original Linac, and a Varian Ximatron CD-X simulator (the "Varian Simulator") to replace the Original Simulator, in order to provide improved radiation therapy services to its patients. The Varian 2100 Linac and Varian Simulator were acquired and made operational pursuant to N.C. Gen. Stat. § 131E-184(a)(7), which exempts the acquisition of replacement equipment from certificate of need review. See 1998 Exemption Approval Letter from CON Section to GRTS Regarding Replacement Linac and Simulator (Exhibit 2), and Varian 2100 Linac Quote Accepted by GRTS (Exhibit 3). When the Varian 2100 Linac and Varian Simulator came online, the Original Linac and Original Simulator that they replaced were taken out of service and disposed of.

The Varian 2100 Linac presently in use was installed and began operating at Wayne Radiation Oncology late in 1998, before the CON Law was amended to mandate review for any acquisition of a linear accelerator. In 1998, oncology treatment centers were included in the list of facilities which were

"new institutional health services," the development of which required a CON. See Former N.C. Gen. Stat. § 131E-176(18a) (repealed effective August 25, 2005). However, since Wayne Radiation Oncology already was an existing oncology treatment center, it was not limited by the \$250,000 statutory threshold for oncology treatment centers, and could acquire the Varian Linac and Varian Simulator under the replacement equipment exemption in N.C. Gen. Stat. § 131E-184(a)(7).

The Varian Linac has been operated at Wayne Radiation Oncology since 1999 and recognized in the inventory in the State Medical Facilities Plan. See State Medical Facilities Plan Excerpts for 2001-2011 (Exhibit 4).

In February 2011, GRTS purchased and placed into operation the CT Scanner at Wayne Radiation Oncology for a total capital expenditure of approximately \$112,000, including acquisition, transportation, installation and commissioning. See CT Scanner Proposal Accepted by GRTS (Exhibit 5) While the CT Scanner acquires high quality radiographs, in the form of 3-D patient data, it is not used to "reproduce the geometric relationships of megavoltage radiation therapy equipment [the Linac] to the patient." Therefore, the CT Scanner is not a simulator within the meaning of the CON Law. See N.C. Gen. Stat. § 131E-176(24b). The data acquired through the CT Scanner is input into the Treatment Planning System, which reproduces the geometric relationships of the Linac to the patient.

The CT Scanner is the only medical diagnostic equipment currently utilized at Wayne Radiation Oncology. Because the total costs for the acquisition and installation of the CT Scanner were well below the \$500,000 threshold for a diagnostic center, as well as the \$750,000 threshold for major medical equipment, this acquisition did not constitute a "new institutional health service" as defined in N.C. Gen. Stat. § 131E-176(16).

#### The Proposed Transaction

The parties have reached agreement on the Proposed Transaction to transfer the ownership interests in Wayne Radiation Oncology and they plan to proceed as follows after receiving confirmation that no certificate of need is required. GRTS will be converted from a professional corporation to a business corporation, which will be named Goldsboro Radiation Therapy Services Inc. ("GRTS Inc."). North Carolina law recognizes that a conversion to a different form of business entity, such as this conversation of GRTS to a business corporation, is simply a change in form; and there is no interruption in the existence of the legal entity. The legal entity remains in existence throughout the process with title to all its property and continuing responsibility for all its liabilities and obligations. See N.C. Gen. Stat. § 55-11A-13. Therefore, the conversion of GRTS to a business corporation will not break the continuity of ownership of Wayne Radiation Oncology.

Immediately following the conversion of GRTS to a business corporation, NCRTMS will acquire all of the shares of GRTS Inc. After the Proposed Transaction is complete, GRTS Inc. will continue to exist as a legal business entity, and will continue to own Wayne Radiation Oncology and its associated Equipment, including the Varian 2100 Linac and CT Scanner. Wayne Radiation Oncology and its Equipment will continue to serve patients at the same location at 2802 McLamb Place in Goldsboro. No additional equipment will be purchased, nor will any new services be offered, in connection with the Proposed Transaction. The only change will be in the ownership interests of the corporate entity that owns Wayne Radiation Oncology and its associated Equipment, with NCRTMS acquiring all of the stock in GRTS Inc.

All medical services associated with oncology treatment at Wayne Radiation Oncology will be furnished by licensed physicians, and GRTS Inc. will not offer any medical services. The Parties

anticipate that Dr. Kerlin who has been practicing with GRTS and has supervised the care of the patients receiving treatment at Wayne Radiation Oncology will continue to supervise and direct the treatment of patients under his care. Dr. Kerlin will provide his medical services through an existing professional corporation which he will join. Under an agreement that preserves the physician's authority over all clinical and medical decisions, GRTS Inc. will make the Linac and CT Scanner available for treatment of patients by Dr. Kerlin and other licensed physicians authorized to care for patients at Wayne Radiation Oncology.

Based upon the longstanding approach that the Division of Health Service Regulation and the CON Section have taken to the purchase of equity interests in existing North Carolina organizations that already are operating health services when there is no change in the services offered or the equipment, NCRTMS respectfully submits that none of these steps relating to the Proposed Transaction constitutes a New Institutional Health Service that requires a certificate of need.

#### **ANALYSIS**

The CON Law was enacted to prevent the development and operation of unneeded health services, equipment and facilities. This is made explicit in the first section of the law, where the General Assembly finds: "That the proliferation of unnecessary health service facilities results in costly duplication and underuse of facilities, with the availability of excess capacity leading to unnecessary use of expensive resources and overutilization of health care services." N.C. Gen. Stat. § 131E-175(4). Accordingly, the CON Law essentially focuses on the development and offering of those "new institutional health services" that would create additional capacity, and which are catalogued in N.C. Gen. Stat. § 131E-176(16). Each of these new institutional health services entails in some way the acquisition or establishment of a new health service, new equipment, new facilities, or expansions and relocations of existing facilities or services (which also would have an impact on how health services are deployed and utilized). In keeping with its fundamental goals, the CON Law expressly recognizes that certain activities are not subject to review, such as purchases of existing facilities, or the repair or replacement of existing facilities or equipment, since these actions do not change the overall capacity of the health care system. Based upon the clear terms of the CON Law and prior declaratory rulings by the Department that have recognized this fundamental principle, the Proposed Transaction does not require a certificate of need.

#### The Proposed Transaction Will Not Result in a New Institutional Health Service

The CON Law provides that no person shall offer or develop a "new institutional health service" without first obtaining a CON. N.C. Gen. Stat. § 131E-178. However, none of the components of the "new institutional health service" definition address, directly or indirectly, the acquisition of ownership interests in an organization that already is operating a health service. This type of transaction is among the activities that are "administrative and other activities that are not integral to clinical management," and which are specifically excluded from the definition of "health service" in the CON Law. N.C. Gen. Stat. § 131E-176(9a). Therefore, an acquisition of corporate ownership interests, such as the Proposed Transaction at issue in this request, does not involve a new institutional health service at all and should not be subject to CON Review.

The list of new institutional health services does include "the acquisition by purchase, donation, lease, transfer or comparable arrangement" of a linear accelerator or simulator "by or on behalf of any person," N.C. Gen. Stat. § 131E-176(16)(f1)5a, 9, as well as "the obligation by any person of a capital expenditure exceeding two million dollars (\$2,000,000) to develop or expand a health service or a health service facility, or which relates to the provision of a health service," N.C. Gen. Stat. § 131E-176(16)(b). However, neither of these definitions applies to the Proposed Transaction. In prior declaratory rulings

and no review determinations, the Department and CON Section have consistently recognized that other transactions like the Proposed Transaction, which involve only an acquisition of underlying corporate ownership interests in an existing legal entity that already owns and operates an existing oncology center and its associated equipment, fall within the above-referenced exclusion recognized in the definition of "health service" in N.C. Gen. Stat. § 131E-176(9a). Accordingly, the Department and CON Section have consistently determined that events such as the Proposed Transaction do not trigger certificate of need review under either the linear accelerator acquisition or the \$2,000,000 capital expenditure provision.

#### The Department's Prior Declaratory Rulings Confirm the Transaction Does Not Require a CON

This No-Review Request is consistent with the Department's prior declaratory rulings which have interpreted the applicability of the CON Law to the purchase of ownership interests in corporate entities that already are operating a health service. In at least four rulings that were issued after the enactment of the August 2005 amendment to the CON Law, the Department has determined specifically that the transfer of ownership interests in organizations that own linear accelerators does not require a certificate of need.

- On August 18, 2011, the Department issued a declaratory ruling finding that Radiation Oncology Centers of the Carolinas, Inc.'s transfer of two CON-approved radiation oncology centers to two wholly-owned subsidiaries did not constitute a new institutional health service or require a certificate of need. See In re: Request for Declaratory Ruling by Radiation Oncology Centers of the Carolinas, Inc. (Exhibit 6).
- On September 27, 2010, the Department issued a declaratory ruling confirming that the
  acquisition by Cancer Centers of North Carolina, P.C. of the majority of the membership
  interests in Wake Radiology Oncology Services and the continued operation of WROS's
  oncology treatment center did not require a certificate of need. See In re: Request for
  Declaratory Ruling by Wake Radiology Oncology Services, PLLC, Cancer Centers of North
  Carolina, P.C., US Oncology, Inc. et al. (Exhibit 7).
- On December 21, 2007, the Department issued a declaratory ruling finding that Rex Healthcare, Inc.'s acquisition of 100% of the membership interest of Smithfield Radiation Oncology, LLC, which owned and operated a linear accelerator, was not subject to CON review. See In re: Request for Declaratory Ruling by Rex Healthcare, Inc. and Smithfield Radiation Oncology, LLC (Exhibit 8).
- On September 14, 2007, the Department issued a declaratory ruling confirming that
  certificate of need review was not required for the sale to another entity of 100% of the issued
  and outstanding stock of a company that owned a linear accelerator. See In re: Request for
  Declaratory Ruling by Radiation Therapy Services, Inc. and North Carolina Radiation
  Therapy Management Services, Inc. (Exhibit 9).

In the September 2010 declaratory ruling involving Wake Radiology Oncology Services, the Department reviewed a proposed transaction under which WROS would be converted from a professional limited liability company to a limited liability company, followed immediately by the sale of the ownership interests in WROS. Subsequently, in a separate transaction, WakeMed proposed purchasing a minority membership interest in the renamed WROS entity. After the two transactions, the resulting LLC would continue to exist as a legal and business entity and would continue to own the oncology treatment center and equipment that was authorized by a previously issued CON. The Department concluded that these proposed transactions did not require a certificate of need. In its Declaratory Ruling, the Department

noted that the entity which owned the linear accelerator and simulator would not change and the same equipment would continue to be used to provide the same radiation oncology services at the same location. The Declaratory Ruling explained that although the proposed transaction involved expenditures by CCNC and WakeMed, "these will be purchases of ownership interests in an existing limited liability company that owns the oncology treatment center. There will be no capital expenditure to develop or expand a health service or health service facility because the same equipment will continue to be operated at the same location, and no expansion of services is proposed."

In its September 2007 declaratory ruling involving NCRTMS, the Department reviewed a request that involved the purchase of all of the stock of Carolina Radiation and Cancer Treatment Center, Inc. ("CRTC"). In its declaratory ruling request, CRTC stated that it was operating one linear accelerator and simulator that were in the Department's equipment inventory reports, as well as an additional linear accelerator that was not listed in the inventory. After reviewing the proposed transaction, the Department concluded, as to the one linear accelerator and simulator that were in the equipment inventory reports, that the proposed stock purchase could proceed without a CON. The Declaratory Ruling stated: "The transaction described by Petitioners does not constitute the acquisition of a linear accelerator or a simulator by any person because ownership of the one reported linear accelerator and one reported simulator here will not change. CRTC will continue to be the owner of these two pieces of equipment, and CRTC's legal status as a corporate entity will not change." The Department's ruling permitted all of the stock of CRTC, which owned the linear accelerator and simulator, to be purchased without a certificate of need.

In the December 2007 declaratory ruling involving Smithfield Radiation Oncology, the Department reached a similar conclusion. In that situation, Rex Healthcare already had a 25% ownership interest in Smithfield Radiation Oncology, LLC ("SRO"), and proposed to acquire the remaining 75% of the ownership interests from the physician owners. The Department concluded that "[t]he transaction described by Petitioners does not constitute the acquisition of a linear accelerator by any person because ownership of the linear accelerator here will not change." Thus, the Department concluded that these purchases of the ownership interests of companies which own an operating linear accelerator did not require a CON.

The transactions involved in the above-described declaratory rulings are exactly analogous to the Proposed Transaction at issue in this request. Under the Proposed Transaction, NCRTMS will acquire all of the ownership interests in GRTS Inc. which will continue to own Wayne Radiation Oncology and its associated Equipment, including the Varian 2100 Linac and CT Scanner. Wayne Radiation Oncology will continue to use the same equipment to provide the same radiation therapy services to patients at the same location following the Proposed Transaction.

#### The Proposed Transaction Is Not an Acquisition of a Linear Accelerator

The proposed acquisition of 100% of the shares of GRTS Inc. by NCRTMS does not constitute the acquisition of a linear accelerator. As explained above, the transaction is limited to the acquisition of the underlying ownership interests in the corporate entity that owns the existing Wayne Radiation Oncology Center and its associated Equipment. The Varian 2100 Linac will continue to be used to provide the same radiation therapy services, in the same location, and the entity that owns the Varian 2100 Linac will not change as a result of the Proposed Transaction. The ownership of the GRTS entity will change to a single shareholder, NCRTMS, but its legal status as an existing business entity will not change.

Since GRTS will remain the same legal entity, the same "person" will own and operate Wayne Radiation Oncology and its Equipment following the Proposed Transaction. See N.C. Gen. Stat. § §131E-176(19) and 178. Accordingly, and consistent with the rulings issued since the August 2005 amendment, there is no basis to require CON review of the Proposed Transaction as an acquisition of a linear accelerator under the provisions of N.C. Gen. Stat. § 131E-176(16)(f1)5a.

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

The Proposed Transaction will not entail a capital expenditure to develop or expand a health service or health service facility because the same equipment will continue to be operated at the same location, and no expansion of services is proposed. Likewise, the Proposed Transaction will not entail "a capital expenditure . . . which relates to the provision of a health service" under N.C. Gen. Stat. § 131E-176(16)(b). The only change that will result from the Proposed Transaction will be in the ownership of the GRTS business entity, and that change in ownership is not a health service.

As the Department must have determined in the prior declaratory rulings discussed above, the purchase of ownership interests in an existing enterprise, which already is lawfully operating medical equipment and offering services, is not a capital expenditure that "relates to the provision of a health service" under N.C. Gen. Stat. § 131E-176(16)(b). The definition of "health service" in the CON Law specifically excludes "administrative and other activities that are not integral to clinical management." N.C. Gen. Stat. § 131E-176(9a). The ownership of the GRTS business entity is not integral to the clinical management of Wayne Radiation Oncology, and the center's operations will not change as a result of the Proposed Transaction. Therefore, the purchase of ownership interests in GRTS is not an activity that is "integral to clinical management," and accordingly is not "a capital expenditure . . . which relates to the provision of a health service" within the meaning of N.C. Gen. Stat. § 131E-176(16)(b).

#### CONCLUSION

For all of the foregoing reasons, the regulation of events like the Proposed Transaction, involving existing and previously reviewed and approved oncology centers and their associated equipment which do not otherwise implicate the fundamental purposes of the CON Law stated in N.C. Gen. Stat. § 131E-175, is beyond the scope of the CON Law, and should not require a CON. As explained above, since 1995, Wayne Radiation Oncology and its associated Equipment have been operated as part of an ongoing radiation oncology center and that will continue after completion of the Proposed Transaction.

North Carolina courts have recognized that because the CON Law interferes with the normal right to do business, it must be narrowly construed. See HCA Crossroads Residential Centers, Inc. v. N.C. Dep't of Human Resources, 327 N.C. 573, 579, 398 S.E.2d 466, 470 (1990) ("When viewed in its entirety, Article 9 of Chapter 131E of the General Statutes, the Certificate of Need Law, reveals the legislature's intent that an applicant's fundamental right to engage in its otherwise lawful business be regulated but not be encumbered with unnecessary bureaucratic delay.") Failure to issue the requested no-review determination would delay and impede the Parties that are requesting this determination in proceeding with a lawful business transaction.

We have enclosed a copy of the Exhibits referenced in this letter (see attached Index). We request your earliest possible attention to this request and look forward to your confirmation that the Proposed Transaction is not a new institutional health service and may proceed without a certificate of need. The Parties wish to close on the Proposed Transaction on or about December 16, 2011, and accordingly, we request a response from you before December 14, 2011, if possible.

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

With best wishes, we are

Very truly yours,

William R. Shenton

Pamela A. Scott

#### Enclosures

CC:

Martha Frisone, Assistant Chief, CON Section Norton L. Travis, General Counsel for RTS Lee Spinks, Counsel for GRTS

From:

Hamill, Robert A. <RHamill@hallrender.com>

Sent:

Friday, January 24, 2020 5:04 PM

To: Cc:

Yakaboski, Greg

Kahn, Joseph M.

Subject:

[External] RE: 21st Century Oncology Holdings- No Review Letter dated 12/20/19

**Attachments:** 

NCRTMS Exemption (January 2018).pdf; NCRTMS No Review (February 2013).pdf; Vidant

Radiation Oncology - No Review (Oct 2019).pdf

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#### Greg-

Attached please find three no reviews and exemptions we pulled from the CON Section's website related to North Carolina Radiation Therapy Management Services and Vidant Radiation Oncology. Note we omitted the attachments to the VRO no review in the interest of keeping file size down.

Goldsboro Radiation Therapy Services operates the radiation oncology center located at 2802 McLamb Place, Goldsboro under the name Wayne Radiation Oncology.

Please let me know if you have any additional questions. Have a great weekend.

Best,

Bobby

Robert A. Hamill | Attorney rhamill@hallrender.com | vCard | @hallrender on Twitter

Hall, Render, Killian, Heath & Lyman, LLP RALEIGH D: (919) 447-4970 | F: (844) 801-5883

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From: Yakaboski, Greg <greg.yakaboski@dhhs.nc.gov>

Sent: Tuesday, January 7, 2020 2:18 PM

To: Kahn, Joseph M. < JKahn@hallrender.com>

Subject: 21st Century Oncology Holdings- No Review Letter dated 12/20/19

#### This message was sent securely using Zix®

Mr. Kahn,

When you have a chance please either give me a call or let me know when it would be convenient for me to call you re: your letter dated 12/20/19 about  $21^{st}$  Century Oncology Holdings "No Review" request.

My office number is 919-855-4664.

Thanks,
Greg Yakaboski
Project Analyst
Healthcare Planning and Certificate of Need Section.

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From:

Yakaboski, Greg

Sent:

Tuesday, January 7, 2020 2:18 PM

To:

jkahn@hallrender.com

Subject:

21st Century Oncology Holdings- No Review Letter dated 12/20/19

Mr. Kahn,

When you have a chance please either give me a call or let me know when it would be convenient for me to call you re: your letter dated 12/20/19 about 21st Century Oncology Holdings "No Review" request.

My office number is 919-855-4664.

Thanks, Greg Yakaboski Project Analyst Healthcare Planning and Certificate of Need Section.



Hall, Render, Killian, Heath & Lyman, LLP Perimeter Three, 3015 Carrington Mill Blvd., Suite 450 Morrisville, NC 27560 https://www.hallrender.com

> Joseph M. Kahn (919) 447-4966 jkahn@hallrender.com

December 20, 2019

#### SENT VIA UPS OVERNIGHT

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



Re: Request for No Review – Change in Indirect Ownership Interest

Dear Ms. Frisone:

This letter is being sent on behalf of our client, 21st Century Oncology Holdings, Inc. ("21C Holdings"). The purpose of this letter is to notify the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (the "Department") of the change in indirect ownership of the entities and facilities identified on Exhibit A of this letter (each, a "Provider") and to request a "no review" determination. Each of the Providers is engaged in the provision of radiation oncology services through the use of certain equipment for which the Provider holds a certificate of need ("CON"), including, as applicable, CT imaging technology, linear accelerators, and simulators.

21C Holdings, through multiple subsidiaries, is the indirect owner of the Providers in North Carolina. This notification is provided in connection with a transaction in which the ownership of 21C Holdings will change and Orion US Holdings, Inc. will become the new owner of 21C Holdings. The transaction is currently expected to be completed in the first quarter of 2020.

We do not expect that the transaction will have any effect on any Provider's business or operations, and each Provider will continue to conduct business at the same location, under the same legal entity name and federal tax identification number. The Provider's personnel, equipment and operations will also remain the same. 21C Holdings will retain its existing subsidiary structure and indirect interest in the Providers, none of which will change as a result of the transaction. The subsidiaries will also retain their current federal tax identification numbers. The organizational chart attached as **Exhibit B** shows the pre- and post-transaction structures.

We believe that the above transaction is not a "new institutional health service" within the meaning of N.C. Gen. Stat. § 131E-176(16), which would a require certificate of need ("CON") review and approval, because the direct owner of each Provider will not change. Based on that

statutory definition and multiple previous CON Section determinations, a change in ownership or control of an indirect owner of a health service facility is a not new institutional health service, requiring a CON.

Our understanding is that corporate reorganizations and changes in the indirect ownership of entities which hold a CON is not subject to CON review. In the alternative, even if the Department were to conclude that the transaction is a reviewable acquisition of an existing health service facility, then please accept this letter as a notice of exemption pursuant to N.C. Gen. Stat. § 131E-184(a)(8). N.C. Gen. Stat. § 131E-184(a)(8) provides that upon receiving prior written notice from an entity that it will "acquire an existing health service facility, including equipment owned by the health service facility at the time of the acquisition," the CON Section "shall" exempt such project from CON review. Each of the Provider's centers is an existing health service facility within the meaning of the CON law. See N.C. Gen. Stat. § 131E-176(9b).

Therefore, we respectfully request the Department's confirmation that this transaction is not subject to CON review, or, in the alternative, that this transaction is exempt from CON review. We trust that this letter provides all of the necessary information for the change in indirect ownership related to these Providers, and no further action is required. If you have any questions or require any additional information, please do not hesitate to contact me at 919.447.4966. Thank you for your attention to this matter.

Best regards,

Hall, Render, Killian, Heath & Lyman, LLP

Joseph M. Kahn

Attachments

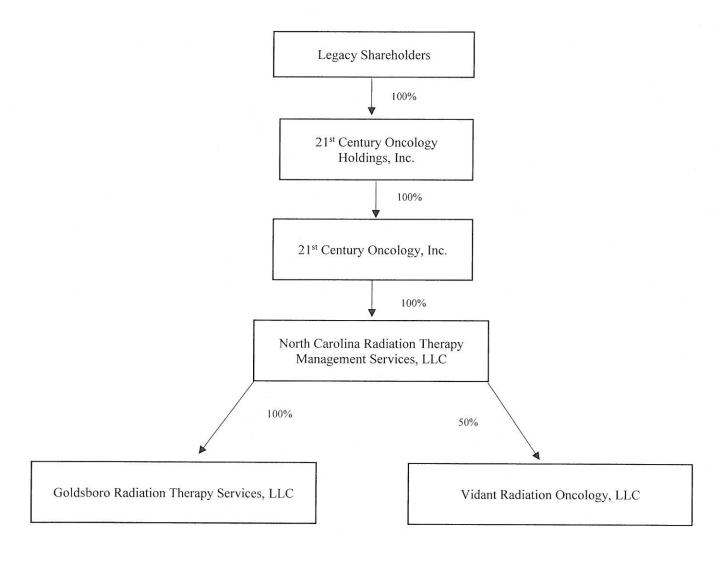
#### Exhibit A

#### **Providers**

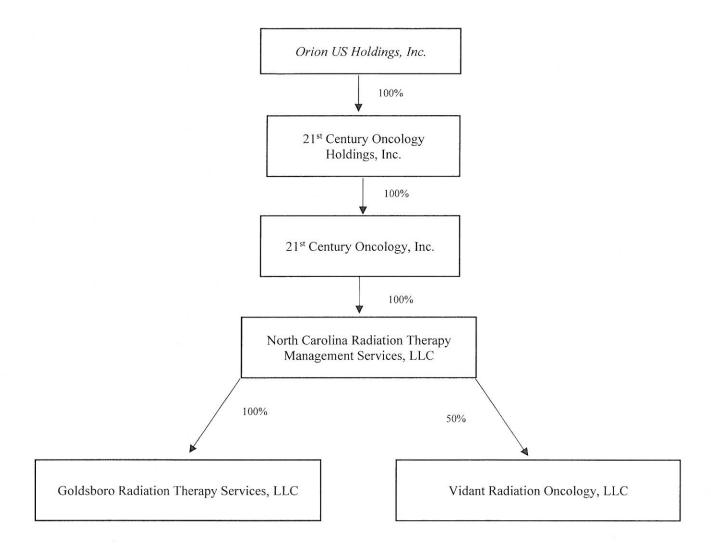
- 1. North Carolina Radiation Therapy Management Services, LLC
- 2. Goldsboro Radiation Therapy Services, LLC
- 3. Vidant Radiation Oncology, LLC

# Exhibit B Pre & Post Close Organization Charts

#### 1. <u>Pre-Closing Organizational Chart:</u>



#### 2. Post-Closing Organizational Chart:





MANDY COHEN, MD, MPH • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

October 9, 2019

Gary Qualls 430 Davis Drive Suite 400 Morrisville, NC 27560

No Review

Record #:

3078

Business Name:

Vidant Radiation Oncology, LLC

Business #:

2324

Project Description:

Vidant Radiation Oncology, LLC (VRO) acquisition of two Linacs and one

CT scanner from VRO's current members, Vidant Medical Center and North

ROY COOPER . Governor

Carolina Radiation Therapy Management Services, LLC

County:

Pitt

Dear Mr. Qualls:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the above referenced proposal. Based on the CON law in effect on the date of this response to your request, the proposal described in that correspondence is not governed by, and therefore, does not currently require a certificate of need. If the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

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

This determination is binding only for the facts represented in your correspondence. If changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office.

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

16

Sincerely

cc:

Gregory F. Yakaboski

Project Malyst

Martha J. Frisone

Chief

Acute and Home Care Licensure and Certification Section, DHSR

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

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

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

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

From:

Qualls, Gary <Gary.Qualls@klgates.com> Wednesday, October 02, 2019 3:20 PM

Sent: To:

Yakaboski, Greg

Subject:

[External] RE: additional guestion

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#### Greg:

In response to your question by phone earlier today, this e-mail clarifies that, once the transaction described in my August 22, 2019 VRO No Review Request occurs:

- 1. VRO will have 100% ownership of the two linacs and one CT scanner described in the August 22 letter (in Ahoskie and Roanoke Rapids); and
- 2. As represented on page 1 of my August 22 letter, VRO is -- and will continue to be -- a joint venture between Pitt County Memorial Hospital, Incorporated, d/b/a Vidant Medical Center ("Vidant") and North Carolina Radiation Therapy Management Services, LLC ("NCRT").

Let me know if I can assist with any other questions.

**Thanks** 

Gary

From: Yakaboski, Greg <greg.yakaboski@dhhs.nc.gov>

**Sent:** Wednesday, October 2, 2019 8:56 AM **To:** Qualls, Gary <Gary.Qualls@klgates.com>

Subject: additional question

Morning Gary,

An additional question has come up re: VRO No Review request. Is there a good time for a phone call either today or tomorrow?

Thanks,

Greg

Sincerely,

Gregory F. Yakaboski

Gregory F. Yakaboski

Project Analyst

Division of Health Service Regulation, Certificate of Need

NC Department of Health and Human Services

Office: 919-855-3873

Greg.Yakaboski@dhhs.nc.gov

809 Ruggles Drive, Edgerton Building 2704 Mail Service Center Raleigh, NC 27699-2704

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From:

Qualls, Gary < Gary.Qualls@klgates.com>

Sent:

Tuesday, October 01, 2019 10:48 AM

To:

Yakaboski, Greg

Subject:

RE: [External] RE: Question re: VRO Acquisition of additional LINAC and CT Scanner

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Correct

Thanks

Gary

From: Yakaboski, Greg <greg.yakaboski@dhhs.nc.gov>

**Sent:** Tuesday, October 1, 2019 10:47 AM **To:** Qualls, Gary <Gary.Qualls@klgates.com>

Subject: RE: [External] RE: Question re: VRO Acquisition of additional LINAC and CT Scanner

Hey Gary,

One last question. I have to put down a County on the letter.... I put Pitt County since it is my understanding that VRO is operated out of Vidant in Greenville... is this correct?

Thanks,

Greg

From: Qualls, Gary < Gary.Qualls@klgates.com>
Sent: Monday, September 30, 2019 3:43 PM

To: Yakaboski, Greg <greg.yakaboski@dhhs.nc.gov>

Subject: RE: [External] RE: Question re: VRO Acquisition of additional LINAC and CT Scanner

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919-466-1182

Thanks

From: Yakaboski, Greg <greg.yakaboski@dhhs.nc.gov>

Sent: Monday, September 30, 2019 3:42 PM To: Qualls, Gary <Gary.Qualls@klgates.com>

Subject: RE: [External] RE: Question re: VRO Acquisition of additional LINAC and CT Scanner

#### Raleigh, NC 27699-2704

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From:

Qualls, Gary < Gary.Qualls@klgates.com> Wednesday, September 18, 2019 11:24 AM

Sent: To:

Yakaboski, Greg

Subject:

[External] RE: No Review Request dated 8/22/19 for VRO's acquisition of additional

Linear Accelerators and a CT Scanner from current members

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Greg:

Sorry, I got tied up.

This is a different project, in different locations, than the ones you referenced below. The projects you referenced below involve radiation oncology equipment in Greenville. The two sites at issue in my August 22 letter are in Ahoskie and Roanoke Rapids, and my August 22 request deals exclusively with equipment in those two locations. However, the same entity is involved, Vidant Radiation Oncology ("VRO"), as in the projects you referenced below.

As background in my August 22 request, I referenced the Agency's 2015 approval to merge the radiation oncology assets of Vidant and NCRT into VRO to remind the Agency of how VRO was formed and the assets VRO currently holds. I also referenced the 2015 approval because it is precedent for allowing this new request for the Ahoskie and Roanoke Rapids sites.

Let me know if you have any further questions.

Thanks

Gary

From: Yakaboski, Greg <greg.yakaboski@dhhs.nc.gov>

Sent: Tuesday, August 27, 2019 10:27 AM
To: Qualls, Gary <Gary.Qualls@klgates.com>

Subject: No Review Request dated 8/22/19 for VRO's acquisition of additional Linear Accelerators and a CT Scanner from

current members

Good Morning Gary,

Actually just left you a voice mail, then discovered I had a follow up question, so sent this email.

Questions re: the No Review Request that you sent over...

- #1) Does this involve the facility "Vidant Radiation Oncology Center at VMC FID #170020" or is this something different?
- #2) Does this involve Project ID # Q-11292-17 re: "Vidant Radiation Oncology Center at VMC FID #170020" Project Description "Relocate five existing linear accelerators, two from NC Radiation Therapy Center and three from Leo Jenkins Cancer Center (replacing four) to a new outpatient cancer center at Vidant Medical Center which is currently under construction for a total of five linear accelerators upon project completion"

Overall, as part of your response, please explain the relationship of the No Review request with the facility and project identified above.

Thanks, Greg

Sincerely,

Gregory F. Yakaboski

Gregory F. Yakaboski
Project Analyst
Division of Health Service Regulation, Certificate of Need
NC Department of Health and Human Services

Office: 919-855-3873

Greg.Yakaboski@dhhs.nc.gov

809 Ruggles Drive, Edgerton Building 2704 Mail Service Center Raleigh, NC 27699-2704

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From: Sent: To: Subject:	Qualls, Gary <gary.qualls@klgates.com> Wednesday, September 11, 2019 1:09 PM Yakaboski, Greg RE: [External] RE: No Review Request dated 8/22/19 for VRO's acquisition of additional Linear Accelerators and a CT Scanner from current members</gary.qualls@klgates.com>
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Thanks. Will respond very so	oon.
Gary	
From: Yakaboski, Greg <greg.ya Sent: Wednesday, September 1 To: Qualls, Gary <gary.qualls@l Subject: FW: [External] RE: No R a CT Scanner from current mem</gary.qualls@l </greg.ya 	1, 2019 12:56 PM klgates.com> Review Request dated 8/22/19 for VRO's acquisition of additional Linear Accelerators and
Hey Gary,	
7.50	re: this letter and my questions/additional information request. Realize that younder no time deadline but just wanted to bring this back to your attention in case
Greg	
From: Qualls, Gary < Gary. Qualls Sent: Tuesday, August 27, 2019 To: Yakaboski, Greg < greg. yakab Subject: [External] RE: No Review Scanner from current members	10:32 AM
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Will do	
Thanks	
Gary	

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From:

Qualls, Gary < Gary. Qualls@klgates.com>

Sent:

Tuesday, August 27, 2019 10:32 AM

To:

Yakaboski, Greg

Subject:

[External] RE: No Review Request dated 8/22/19 for VRO's acquisition of additional

Linear Accelerators and a CT Scanner from current members

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Will do

Thanks

Gary

From: Yakaboski, Greg <greg.yakaboski@dhhs.nc.gov>

Sent: Tuesday, August 27, 2019 10:27 AM
To: Qualls, Gary <Gary.Qualls@klgates.com>

Subject: No Review Request dated 8/22/19 for VRO's acquisition of additional Linear Accelerators and a CT Scanner from

current members

Good Morning Gary,

Actually just left you a voice mail, then discovered I had a follow up question, so sent this email.

Questions re: the No Review Request that you sent over...

- #1) Does this involve the facility "Vidant Radiation Oncology Center at VMC FID #170020" or is this something different?
- #2) Does this involve Project ID # Q-11292-17 re: "Vidant Radiation Oncology Center at VMC FID #170020" Project Description "Relocate five existing linear accelerators, two from NC Radiation Therapy Center and three from Leo Jenkins Cancer Center (replacing four) to a new outpatient cancer center at Vidant Medical Center which is currently under construction for a total of five linear accelerators upon project completion"

Overall, as part of your response, please explain the relationship of the No Review request with the facility and project identified above.

Thanks, Greg



Received to Health Conscion

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

August 22, 2019

#### Via Hand Delivery

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

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

Dear Ms. Frisone:

The purpose of this request is to inform the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (the "Agency") of the contribution of existing radiation oncology equipment and services by the two existing members of Vidant Radiation Oncology ("VRO") into VRO.

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

#### I. Prior CON Approval for VRO.

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

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

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

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

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

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

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

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

# III. Continuing to Use VRO as a Conduit for Linac Ownership is Not Regulated Under CON Law.

Vidant and NCRT contributing their respective equipment to VRO does not require a CON. The CON statute provides a lengthy and exclusive list of activities that constitute development of a new institutional health service, requiring a CON. The contribution of equipment by a joint venture member to its own joint venture that already actively provides health services is not included on that list.

Pursuant to a well-established maxim of statutory construction, expressio unius est exclusio alterius, those transactions not included in N.C. Gen. Stat. § 131E-176(16) do not require a CON. See, e.g., In re Miller, 357 N.C. 316, 325, 584 S.E.2d 772, 780 (2003) (stating that "[u]nder the doctrine of expressio unius est exclusio alterius, when a statute lists the situations to which it applies, it implies the exclusion of situations not contained in the list"); see also Jackson v. A Woman's Choice, Inc., 130 N.C. App. 590, 594, 503 S.E.2d 422, 425 (1998) (internal citations omitted) ("Where a statute is explicit on its face, the courts have no authority to impose restrictions that the statute does not expressly contain.").

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

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

#### IV. Prior Analogous Precedent.

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

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

Martha J. Frisone, Chief August 22, 2019 Page 4

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

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

# A. Original VRO Transaction Approval and Other Radiation Therapy Facility Analogues.

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

#### B. Heart Lung Bypass Equipment Analogues

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

#### C. Nursing Facility Analogues

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

<sup>&</sup>lt;sup>2</sup> These examples are contained in Exhibit A because they were cited in support of, and attached to, the Original VRO Transaction No Review Request.

Martha J. Frisone, Chief August 22, 2019 Page 5

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

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

## D. Hospital Splits

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

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

<sup>&</sup>lt;sup>3</sup> <u>See</u> N.C. Gen. Stat. §§ 131E-176(9b) and 176(16)(a).

### E. Applying Prior Analogous Precedent

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

A "new institutional health service" includes "the acquisition by purchase, donation, lease, transfer, or comparable arrangement . . . by or on behalf of any person" a linear accelerator and simulator. See N.C. Gen. Stat. § 131E-176(16)(f1)(5a) and (f1)(9). However, the transaction contemplated here will not constitute the acquisition of a linear accelerator as defined by N.C. Gen. Stat. § 131E-176(16). As with the Original VRO Transaction:

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

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

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

Martha J. Frisone, Chief August 22, 2019 Page 7

## **CONCLUSION**

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

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

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

Sincerely,

Lary S. Qualle Gary S. Qualls



# DEPARTMENT OF HEALTH AND HUMAN SERVICES DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER GOVERNOR

MANDY COHEN, MD, MPH SECRETARY

> MARK PAYNE DIRECTOR

January 10, 2018

Robert A. Hamill 3015 Carrington Mill Boulevard, Suite 450 Morrisville, NC 27560

Exempt from Review - Replacement Equipment

Record #:

2468

Business Name:

2124

Business #:

North Carolina Radiation Therapy Management Services, Inc.

Project Description:

Replace existing CT simulator

County:

Haywood

Dear Mr. Hamill:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of January 3, 2018, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the GE LightSpeed QXI (Serial #233866CN3) to replace the GE ProSpeed (Serial #169725YM9). 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 and Radiation 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. Jaemya

Julie M. Faenza

Project Analyst

Construction Section, DHSR

Radiation Protection Section, DHSR

Sharetta Blackwell, Program Assistant, Healthcare Planning, DHSR

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

Chief, Healthcare Planning and Certificate of Need Section

WWW.NCDHHS.GOV TELEPHONE 919-855-3873

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

cc:



Hall, Render, Killian, Heath & Lyman, LLP Perimeter Three 3015 Carrington Mill Blvd. Suite 450 Morrisville, North Carolina 27560

> Robert A. Hamill (919) 447-4970 rhamill@hallrender.com

January 3, 2018

### VIA OVERNIGHT COURIER

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



RE: Notice of an Exempt Replacement of CT Simulator Pursuant to N.C. Gen. Stat. § 131E-184(a)(7).

Dear Ms. Frisone:

We represent 21<sup>st</sup> Century Oncology, Inc. and its wholly-owned subsidiary, North Carolina Radiation Therapy Management Services, Inc. (collectively, "21C"). We are writing to inform the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Health Planning and Certificate of Need Section ("CON Section") of 21C's intention to replace its existing GE ProSpeed Simulator (Serial No. 169725YM9) ("Existing Equipment") that is currently in operation at the Haywood Cancer Center, located at 600 Hospital Drive, Clayton, NC 28721. For the reasons explained below, 21C's replacement of the Existing Equipment is except from certificate of need ("CON") review pursuant to N.C. Gen. Stat. § 131E-184(a)(7).

# 1. <u>Description of Equipment</u>.

The Existing Equipment is a GE ProSpeed Simulator, that is used to simulate patients' radiation therapy treatment. The Existing Equipment was originally acquired by 21C on October 28, 2002. The Existing Equipment was used at a 21C location in Florida prior to being relocated to Haywood Cancer Center in 2007, pursuant to an exempt replacement that was confirmed by the CON Section in a July 10, 2007 letter, which is attached hereto as Exhibit A. The Existing

January 3, 2018 Page 2

Equipment has been in operation at Haywood Cancer Center since 2007. Upon replacement, the Existing Equipment will be scrapped, so it will no longer be used in North Carolina.

21C intends to replace the Existing Equipment with a GE LightSpeed QXI Simulator (Serial No. 233866CN3) ("Replacement Equipment"). The Replacement Equipment is currently owned by 21C, and has been used by 21C at a facility in New Jersey. The Replacement Equipment has generally the same technology as the Existing Equipment, is functionally similar to the Existing Equipment, and will be used by 21C to provide the same radiation simulation services in support of treatment planning. The acquisition of the Replacement Equipment will not result in any increase in patient charges or per-procedure operating expenses within the first twelve months following acquisition. 21C's total cost to acquire and relocate the Replacement Equipment to Haywood Cancer Center will be significantly less than \$2,000,000.

## 2. Overview of Applicable Law.

"Replacement equipment" is except from CON review. N.C. Gen. Stat. § 131E-184(a)(7). "Replacement equipment" is equipment that costs less than \$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. N.C. Gen. Stat. § 131E-176(22a). The cost of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making the equipment operational shall be included when calculating the total cost of replacement equipment. *Id.* 

Replacement equipment is comparable to the equipment being replaced if: (i) it has the same technology as the existing equipment, although it may possess expanded capabilities due to technological advancements; (ii) it is functionally similar and used for the same diagnostic or treatment purposes and is not used to provide a new health service; and (iii) the acquisition of the equipment does not result in more than a 10% increase in patient charges or per-procedure operating expenses within the first twelve months after replacement. 10A N.C.A.C. 14C. 0303(d).

Replacement equipment will be deemed not to be comparable if the replacement equipment is new or reconditioned, the existing equipment was purchased secondhand, and the replacement equipment is purchased less than three years after the acquisition of the existing equipment. 10A N.C.A.C. 14C.0303(e)(1).

### 3. Analysis.

The Replacement Equipment constitutes "replacement equipment" as defined in N.C. Gen. Stat. § 131E-176(22a), satisfies the regulatory requirements set forth at 10A N.C.A.C. 14C.0303, and is therefore exempt from CON review, for the following reasons:

- a. The total cost of the Replacement Equipment, inclusive of the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation and other activities essential to acquiring and making operational the Replacement Equipment will be significantly less than \$2,000,000. The current fair market value of the Replacement Equipment is estimated to be \$80,000. The costs to transport and install the Replacement Equipment, and to dismantle and scrap the Existing Equipment is \$13,500. A quote for such services, obtained by 21C from BC Technical, is attached as Exhibit B. The Replacement Equipment will be commissioned by a 21C employee, at an approximate cost of \$1,257.76 (8 hours at \$157.22 per hour). Construction will not be required in connection with installing the Replacement Equipment. Electrical work will be required in conjunction with installation of the Replacement Equipment, at a rate of \$1,680.98. No other activities that are essential to acquiring and making operational the Replacement Equipment will be required. The total cost of replacement, therefore, is approximately \$96,438.74.
- b. The Existing Equipment will be scrapped, and will no longer be used in the State of North Carolina.
- c. The Replacement Equipment has the same technology as the Existing Equipment, although it will have certain expanded capabilities due to technological advancements. Despite such technological advancements, the Replacement Equipment is functionally similar to the Existing Equipment, will be used for the same treatment purposes, and will not be used to provide any new health services. The Replacement Equipment is not capable of performing procedures that could result in the provision of a new health service or type of procedure that has not been provided with the Existing Equipment. A chart comparing the Existing Equipment and Replacement Equipment is attached as Exhibit C.
- d. The acquisition of the Replacement Equipment will not result in any increase in patient charges or per-procedure operating expenses within the first twelve months following installation.
- e. The Replacement Equipment is being acquired more than three years after the acquisition of the Existing Equipment.

On behalf of 21C, we respectfully request that the CON Section provide written confirmation that 21C's replacement of the Existing Equipment with the Replacement Equipment, as described herein, is exempt from CON review pursuant to N.C. Gen. Stat. § 131E-

January 3, 2018 Page 4

184(a)(7). 21C desires to complete the replacement as soon as possible, and therefore requests expedited review of this matter.

Please do not hesitate to contact me if you have any questions or require additional information. Thank you for your review and consideration of this matter.

Sincerely,

HALL, RENDER, KILLIAN, HEATH & LYMAN, LLP

Robert A. Hamill

Robert damill

# Exhibit A



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

2704 Mail Service Center Baleigh, North Carolina 27699-2704

Michael F. Easley, Governor Carmen Hooker Odom, Secretary

http://facility-services.state.nc.us

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

Fax: 919-733-8139

July 10, 2007

Sean Timmons Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan, LLP PO Box 2611 Raleigh, NC 27602

Cancer

RE:

Exempt from Review - Replacement Equipment/ Radiation Therapy Services, Inc., Haywood

Cancer Center/ Replace existing simulator/ Haywood County

Dear Mr. Timmons:

In response to your letters of May 17, 2007, the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, the G.E. ProSpeed CT simulator, serial number 169725YM9, to replace the existing Varian Ximatron simulator, serial number 607. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need. Further please be advised that as soon as the replacement equipment is acquired, you must provide the CON Section and the Medical Facilities Planning Section with the serial number of the new equipment to update the inventory, if not already provided.

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.

Sincerel

Ronald Loftin, Project Analyst

Lee B/Hoffman, Chief

Certificate of Need Section

cc: Medical Facilities Planning Section, DFS



# Exhibit B



# EQUIPMENT RELOCATION & INSTALLATION AGREEMENT

This Equipment Relocation & Installation Agreement dated, <u>November</u>, <u>2017</u> is offered by BC Technical, Inc. ("BC TECHNICAL"), a UTAH corporation, having its principal place of business at 7172 South Airport Road – West Jordan, UT <u>84084</u>, to 21<sup>st</sup> Century Oncology, Inc. ("CUSTOMER") having its principal place of business at <u>2270 Colonial Boulevard</u>, Ft. Myers, FL 33907.

Invoice To:

Same as Above

Contact:

Enrique Vaiani

BC TECHNICAL agrees to sell the services described below at the prices and deliveries stated to CUSTOMER, subject to the conditions stated in Scope of Work herein, and the Standard Terms and Conditions attached hereto.

### SCOPE OF WORK:

BC TECHNICAL will transport a certain **GE LightSpeed OXI CT Scanner** (#CT40195) ("Equipment") owned by CUSTOMER from the BC TECHNICAL warehouse to 21st Century Oncology, Inc. at the following location: 600 Hospital Drive. Clyde. NC 28721 ("Install Location") for installation. BC TECHNICAL will de- install their **GE ProSpeed OJ CT Scanner** (#CT40187) at the Install Location, and transport it to the BC TECHNICAL warehouse for scrapping. BC TECHNICAL will unload, rig-in, reconnect, and calibrate the Equipment to OEM specifications at the Install Location.

• BC TECHNICAL shall transport the Equipment to the Install Location above, and rig into the room on November 13, 2017, at which time installation shall proceed.

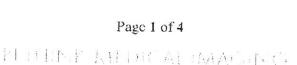
 Upon installation, Equipment shall be added to the 21st Century Master Service Agreement at the rate of <u>\$3.115.00 per month</u>.

#### SERVICES PRICE:

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Price and payments. The relocation & installation price is \$13.500.00 plus any applicable tax, and
is due and payable upon acceptance of this Agreement.

CUSTOMER hereby agrees and acknowledges that, if the initiation and finalization of the relocation extends beyond <u>January 1, 2018</u>, due to circumstances resulting from CUSTOMER (i.e., lack of room preparation), the Services Price may require adjustment.







## TERMS AND CONDITIONS ON FOLLOWING PAGES

BC Technical, Inc.	21st Century Oncology, Inc.
Approved: BY: Told laden	CUSTOMER Acceptance Authorized Signature; BY:
Printed: To bo (ADERER	Printed: Doug Staut
Title: EV C	Title: Interim CFO
Date: 11 / 8 / 2017	Date: (1 /8 / 17
	CUSTOMER PO#:



#### TERMS AND CONDITIONS:

#### Customer Representations/Responsibilities:

- CUSTOMER represents that it owns the Equipment and that no liens are held against the Equipment.
   CUSTOMER holds BC TECHNICAL harmless from any liability concerning ownership, obligations and lien disputes.
- CUSTOMER is responsible for all removal, construction or modification to the current facility to allow the
  Equipment to be removed. Any costs for construction, demolition, permits, modifications and union labor are
  not included in this Agreement.

#### Project Timing/Installation:

Unless otherwise agreed in writing, BC TECHNICAL will require three (3) weeks advance notice to schedule
the deinstallation. While BC TECHNICAL shall endeavor to meet Customer expectations on project timing,
actual project initiation dates shall be subject to the current BC TECHNICAL schedule.

<u>Prices</u>: The Prices quoted do not include local, state, federal, value-added or any other form of taxes, unless otherwise indicated. CUSTOMER will be responsible for any such taxes or obligations. Further, the prices of items quoted herein do not include: the cost of permits or fees relating to any equipment, installation work, construction, building additions or modifications and other activities, unless otherwise indicated. CUSTOMER will be responsible for any such fees or obligations.

<u>Payment</u>: Payment of undisputed invoices shall become due in accordance with the specific terms on the deposits made hereunder shall be nonrefundable. Failure to abide by the payment terms shall be considered a default of this Agreement. Upon default due to failure to abide by payment terms, BC TECHNICAL shall have option to terminate this Agreement.

Warranty/ Disclaimer: BC TECHNICAL REPRESENTS AND WARRANTS THAT SERVICES PERFORMED BY BC TECHNICAL OR BY A PERMITTED SUBCONTRACTOR, EMPLOYEE, OR AGENT OF BC TECHNICAL SHALL BE PERFORMED ON A PROFESSIONAL BASIS, CONSISTENT WITH THE BEST PRACTICES IN THE INDUSTRY AND IN A DILIGENT, WORKMANLIKE, AND EXPEDITIOUS MANNER AND IN COMPLIANCE WITH ALL APPLICABLE FEDERAL AND STATE LAWS, RULES, ORDINANCES AND REGULATIONS. UNLESS SPECIFICALLY STATED IN THIS AGREEMENT, BC TECHNICAL MAKES NO WARRANTIES HEREUNDER, AND EXPRESSLY DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

Indemnification: Each party shall indemnify, defend, and hold harmless the other from and against any loss, damage, cost or expense (including reasonable attorneys' and experts' fees) that the indemnified party may incur by reason of or arising out of: (1) the indemnifying party or its personnel's, subcontractors', or agents' acts or omissions; (2) any personal injury (including death) or property damage caused by or arising from the negligence, acts or omissions of the indemnifying party or any employee or agent of such party to the extent not caused by the gross negligence or willful misconduct of the indemnified party; and (3) the indemnifying party's breach of any federal, state or local law, rule, regulation or ordinance.

Insurance: BC TECHNICAL shall maintain commercial general liability insurance against any claim or claims which might or could arise under the Agreement, including, but not limited to, replacement of the Equipment, which shall include CUSTOMER as an additional insured. The minimum limit of liability shall be \$1 million per occurrence and \$3 million in the annual aggregate for product and general commercial general liability. This may be accomplished through a combination of primary and excess insurance. In addition, BC TECHNICAL shall maintain insurance that will protect it from claims under workers' compensation acts and other employee benefit acts. BC TECHNICAL will provide CUSTOMER with a certificate of insurance, upon request by CUSTOMER, which shall set forth the insurance coverage carried by or on behalf of BC TECHNICAL with respect to the services provided hereunder. Each of the certificates shall provide that the coverage will not be canceled until at least thirty (30) days after written notice has been given to CUSTOMER.



Limitations of Liability: In no event, whether as a result of breach of contract, warranty, tort (including negligence and strict liability) or otherwise, shall either party be liable for any special, consequential, incidental or penal damages including, but not limited to, loss of profit or revenues, loss of use of the products or any associated equipment, damage to associated equipment, cost of capital, cost of substitute products, facilities, services or replacement power, down time costs, or claims of third parties for such damages alleged under this Agreement. In no event, whether as a result of breach of contract, warranty, tort (including negligence and strict liability) or otherwise, shall either party's liability to the other party for any loss or damage arising out of, or resulting from this Agreement, or from its performance or breach, or from the products or services furnished hereunder, exceed the price of the specific product or service which gives rise to the claim.

Termination: CUSTOMER may terminate this Agreement at any time prior to the commencement of services with prior notice to BC TECHNICAL. If BC TECHNICAL, however, has expended any costs associated with this Agreement prior to such notice of termination, CUSTOMER shall be liable for such costs, up to the price of the services offered hereunder, and such costs shall be billed to CUSTOMER.

Assignment. This Agreement may not be assigned by either party without the prior written consent of the other party.

Notices. All notices pursuant to this Agreement shall be in writing, except as provided herein. Notices in writing shall be sufficient if hand delivered or mailed by first class mail, postage prepaid, or sent by telecommunications to the attention of the person listed below and to the party intended as the recipient thereof at the address listed in the Quotation, or at such other address or to the attention of such other person as such party shall have designated for such purpose in a written notice complying as to delivery with the terms of this Section.

No Waiver of Performance. Failure by either party at any time to require performance by the other party or to claim a breach of any provision of this Agreement will not be construed as a waiver of any right accruing under this Agreement, nor affect any subsequent breach, nor affect the effectiveness of this Agreement or any part hereof, nor prejudice either party as regards any subsequent action.

Entire Agreement; Conflicting Provisions. This Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof and no representation or statement not contained in this Agreement shall be binding upon the parties as a warranty or otherwise.

Validity. The invalidity, in whole or part, of any of the foregoing paragraphs will not affect the remainder of such paragraph or any other paragraph in this section of this quotation.

Excluded Provider. BC TECHNICAL represents and warrants that neither it, nor any of its employees or other contracted staff has been or is about to be excluded from participation in any federal health care program.

Compliance with Laws. BC TECHNICAL represents and warrants that BC TECHNICAL and all services comply with the requirements of all applicable federal, state and local laws, ordinances, regulations.

Employee Conduct. BC TECHNICAL acknowledges CUSTOMER's obligations to comply with certain laws and regulations as well as the need for BC TECHNICAL's employees and agents to comply with reasonable requests, standard rules, and regulations of CUSTOMER regarding personal and professional conduct, including the use of an identification badge or personal protective equipment and the adherence to health care facility laws or regulations, including in some instances, criminal background checks, credit checks, health screening, vaccinations and testing, and general safety practices or procedures, generally applicable to such facilities.

Corporate Responsibility. CUSTOMER has in place a corporate responsibility program to ensure compliance with federal, state and local laws and regulations (the "Program"). The Program focuses on the risk management, the promotion of good corporate citizenship, the commitment to uphold a high standard of ethical and legal business practices, and the prevention of misconduct. BC TECHNICAL will conduct all business transactions pursuant to this Agreement in accordance with the Program.

# Exhibit C

# 21st Century Oncology

# Comparison of Existing Simulator and Replacement Simulator

Equipment Comparison	Existing Equipment	Replacement Equipment
Type of Equipment	Simulator	Simulator
Manufacturer of Equipment	General Electric	General Electric
Model Name	ProSpeed	LightSpeed QXI
Serial Number	169725YM9	233866CN3
Provider's Method of Identifying Equipment	Serial number	Serial number
Specify if Mobile or Fixed	Fixed	Fixed
Date of Acquisition of Each Component	October 28, 2002 (relocated to North Carolina facility in 2007)	
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	Title
Specify if Equipment Was/Is New or Used When Acquired	Refurbished	Refurbished
Total Capital Cost of Project (Including Construction, etc.)	\$236,857.16	\$96,438.74
Total Cost of Equipment When Originally Acquired by 21C	\$111,300.00 (Acquired in 2002 for use at a Florida facility)	\$344,500.00 (Acquired in 2005 for use at a New Jersey facility)
Current Fair Market Value of Equipment	Less than \$5,000.00	Approximately \$80,000.00
Locations Where Operated	Haywood Cancer Center 600 Hospital Drive, Clayton, NC 28721	Haywood Cancer Center 600 Hospital Drive, Clayton, NC 28721
Number Days in Use/To be Used in N.C. Per Year	365	365
Percent of Change in Patient Charges (by Procedure)	NA	No expected change in Patient charges by procedure
Percent of Change in Per Procedure Operating Expenses (by Procedure)	NA	No expected change in per procedure operating expenses
Type of Procedures Currently Performed on Existing Equipment	Simulation of Radiation Therapy	Simulation of Radiation Therapy
Type of Procedures New Equipment is Capable of Performing	Simulation of Radiation Therapy	Simulation of Radiation Therapy



# 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

February 27, 2013

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

No Review

Facility or Business:

North Carolina Radiation Therapy Management Services, Inc.

Project Description:

Install refurbished GE Light Speed CT Scanner at 445 Biltmore Avenue

County:

Buncombe

Dear Mr. Shenton:

The Certificate of Need Section (CON Section) received your letter of February 18, 2013 regarding the above referenced proposal. Based on the CON law **in effect on the date of this response to your request**, the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

Moreover, you need to contact the Construction Section of the Division of Health Service Regulation to determine if they have any requirements for development of the proposed project.

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

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

Sincerely,

Julie Halatek Project Analyst

Julie Halatek

Craig R. Smith, Chief

cc:

Medical Facilities Planning Section, DHSR

Construction Section, 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
An Equal Opportunity/ Affirmative Action Employer

P. C.



# Poyner Spruill<sup>up</sup>



February 18, 2013

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

VIA HAND DELIVERY

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

RE: Replacement of Linear Accelerator at 445 Biltmore Avenue in Asheville

Dear Mr. Smith and Ms. Frisone:

We are writing on behalf of our client North Carolina Radiation Therapy Management Services, Inc. ("NCRTMS") to inform the Certificate of Need Section that NCRTMS plans to proceed with the replacement of one of the two linear accelerators that were operated at 445 Biltmore Avenue in Asheville, prior to the fire there which occurred in July of 2011. As we have explained previously, in July of 2011, there was a fire at the 445 Biltmore Avenue location in Asheville, North Carolina where NCRTMS had operated two linear accelerators. As a result of the significant damage to the premises, NCRTMS had to remove both machines and place them in storage; and since that time, NCRTMS has made arrangements for the treatment of patients at other locations in the area.

We have previously written to the CON Section to describe NCRTMS' plans to: 1) Relocate one of the two linear accelerators that had been in operation at the 445 Biltmore Location from that location to Weaverville; and 2) more recently, we wrote in late November to describe plans to proceed with repairs to the 445 Biltmore Location, indicating in that letter that NCRTMS still was reviewing options for replacing the second, older linear accelerator that had been operated there from June of 2005 until the fire. In each instance, the CON Section confirmed that NCRTMS could proceed with its development plans for Weaverville and for repairs at 445 Biltmore. NCRTMS now has finalized its plans to replace the older Varian 600 Linear Accelerator which was in operation at 445 Biltmore. This letter explains the contemplated arrangements and demonstrates that the replacement of this machine should be exempt from certificate of need review under N.C. Gen. Stat. § 131E-184(a)(7), and 10A NCAC 14C .0303.

#### The Replacement Machine

The linear accelerator that NCRTMS plans to install at 445 Biltmore is a 2007 Siemens Oncor linear accelerator which employs the same technology as the Varian 600 machine. Exhibit A is a quote from Oncology Services International for the acquisition and installation of this machine. The total price is \$170,000.00 and as noted in the comments on page two concerning what is "Included in Sale," this price includes shipping and installation of the machine.

WWW.POYNERSPRUILL.COM

Craig R. Smith Martha Frisone February 18, 2013 Page 2

The only other cost that will be associated with the Siemens Oncor linear accelerator is the purchase of computer software, and Exhibit B is a quote from Siemens showing that the total of those costs is \$220,900.00, resulting in a total replacement cost of \$390,900.00. Even if Buncombe County's seven per cent sales tax (See http://www.dornc.com/taxes/sales/taxrates.html) is added to the entire total that, would only add \$27,363, for a grand total of \$418,263 for all replacement costs.

No other costs will be associated with the deployment of the Siemens Oncor linear accelerator at the 445 Biltmore Avenue location, besides the repair costs that were previously described in the November letter, and which already have been determined to be exempt from review as repairs due to disaster damage. As indicated in the prior letter, under the current CON Law and rules, the costs associated with repairing the fire damage at 445 Biltmore Avenue should not be considered in determining whether the replacement of the linear accelerator should be exempt from review. Thus, only the market value of the machine, its transportation costs and installation costs (which are included in the quote), and the software costs are relevant to whether this proposal meets the cost limitations of replacement equipment.

Finally, NCRTMS also has instructed us to confirm that the acquisition of the Siemens Oncor will not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the acquisition. NCRTMS also has instructed us to confirm that the Varian 600 machine that had been operated at 445 Biltmore, which has been in storage since the fire, will be moved out of state.

NCRTMS also plans to deploy a refurbished GE Light Speed CT scanner at 445 Biltmore Avenue. This CT scanner is not replacing other equipment, but it will not function as a simulator because it will be used only to provide diagnostic scans of patients. The quote from CT Enterprises that is found in Exhibit C documents the total cost of this scanner to be \$160,000. Adding in \$ 11,200 for sales tax at seven per cent, brings the total to \$171,200. At present, no other diagnostic equipment with a unit cost of \$10,000 is to be deployed at 445 Biltmore Avenue.

### Analysis of Provisions in CON Law and Rules

Based on the foregoing information, it is clear that the proposed replacement meets all requirements to be exempted from review. The total cost of the replacement linear accelerator, with sales tax falls far below the \$2 Million threshold and so this qualifies as "Replacement Equipment" under the CON Law. The proposal also meets each of the requirements set out in 10A NCAC 14C .0303: The replacement machine has the same technology, is functionally similar, is used for the same treatment purposes, and will not result in an increase in patient charges or per procedure operating costs that would disqualify the replacement under 10A NCAC 14C .0303 (d) (3).

Likewise, the deployment of the CT scanner at a total cost with sales tax of \$171,200 does not require certificate of need review because it does not constitute the establishment of a diagnostic center at 445 Biltmore and is not subject to review under any other provision of the Certificate of Need Law.

Craig R. Smith Martha Frisone February 18, 2013 Page 3

#### Conclusion

Please confirm that the replacement of the Varian 600 Linear Accelerator at the 445 Biltmore Avenue location, as well as the deployment of the GE Light Speed CT scanner as described in this letter are both exempt from CON review pursuant to N.C. Gen. Stat. § 131E-184(a)(7). We look forward to your confirmation and thank you in advance for your prompt consideration of this request.

Very truly yours,

William R. Shenton

Sherter

Partner

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			EXHIBIT  A

IOTE: Any pre-owned equipment sold to a new owner may be subject to re-licensing according to the Original Manufacturers license transfer policy. Only the Original Manufacturer can supply any license transfers, and Oncology Services International shall not be responsible for any license fees subsequently charged by the Original Manufacturer, unless specifically agreed to in the Description above.

Customer— Initials: Customer-Schedule A

Equipment Division: 950 Airport Road, Lakewood, New Jersey 08701 Tel 888-317-1370 Fax 732-730-0664 OSI -

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VHEREAS, the Customer desires to purchase from VHEREAS, the Company is prepared to sell said eq NOW, THEREFORE, the parties hereto agree 1. PRICE. The Customer agrees to purche attached Schedule "A" and to install it in the Customer at the price set forth in Schedule "A." The to IS dollars, not including any sales/state taxes, if ap	the Company said medical equipment; are pulpment to the Customer for the price set to as follows: chase and the Company agrees to sell the estomer's facility detailed in Schedule "A, otal sale price of the equipment reference oplicable. Il prepare the installation site to specificate a customer is responsible for any and all of reparation to manufacturer's specification delayed or improper installation site prepare and rig in Equipment to manufacturer' and basic rigging. The Customer is responsible for any incurred to the second stream of the rigging path of observing labor, delays in preparing facility contains the further responsible for any incurred limited to those caused by incomplete contains the second seco	" and " forth in Schedule "A"; equipment set forth in on the terms set forth in Schedule "A" is in \$ lions outlined by the ration, power, water, and construction involved in s. The Customer is aration incurred by the s original equipment estructions, demolition, for removal, costs rred expenses resulting enstruction, improper

Equipment Division: 950 Airport Road, Lakewood, New Jersey 08701 Tel 888-317-1370 Fax 732-730-0664

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A. DATE MODIFICATION. All dates are estimates based upon conditions at the time of purchase. If the Equipment installation date is delayed by the Company for more than 30 business days, the Customer shall have the option of either (a) receiving a full refund of all moneys paid, or (b) adjourning the installation date in writing to a mutually agreed upon date.

The Customer must give the Company at least thirty(30) days written notice of any changes of installation date that it initiates. If the Equipment installation date is delayed by the Customer more than six (6) months from the contract acceptance date, delivery payment is still due on the originally scheduled date or six months from contract acceptance, whichever is sooner. The Customer shall be liable for payment of equipment storage charges from

original date of delivery until the actual delivery date at current commercial storage rates.

5. EQUIPMENT ACCEPTANCE. Acceptance of the equipment by the Customer shall occur upon completion of the applicable original equipment manufacturer's acceptance tests. Notwithstanding the foregoing, use of the equipment by the Customer, its agents, employees of licensees for any purpose including but not limited to patient treatment, after its receipt without the express written approval of the Company shall constitute acceptance of the equipment by the Customer.

6. TITLE. The Customer will be issued a Bill of Sale from the Company upon receipt of delivery payment. Included in this Bill of Sale will be the statement that the Equipment is free and clear of any encumbrances. Title to the Equipment will then belong wholly and exclusively to the Customer subject only to any UCC or lien rights retained

by the Company pending final payment.

7. PRIOR SALE. All Equipment shall be subject to prior sale and this agreement shall not be binding upon the Company until the required down payment and this signed Agreement is received and accepted by the

Company. Acceptance is defined as being executed by the Company and the Customer.

8. PAYMENT TERMS. The Customer is responsible for payments as defined in Schedule "A." All payments must be made via certified funds or wire transfer and are non-refundable. Due dates are as defined therein. In the event that the Customer fails to meet payment deadlines by more than three (3) business days, the Company may terminate this Agreement and retain all moneys paid along with all claim or title in Equipment as liquidated damages and not as a penalty. Past due accounts are subject to a service charge of the lesser of 1.5% per month or the highest legal rate of interest. In the event that the unpaid balance goes to collection, the Customer will be assessed a collection fee due in addition to original amount owed. This fee will be for court costs, attorney's fees, and other reasonable costs associated with the liquidation of merchandise plus liquidated damages in the amount of twenty (20%) percent of the balance due. All payments are payable in Montebello, New York at the Company's corporate headquarters.

9. STATE & FEDERAL COMPLIANCE. The Customer is solely responsible for compliance with all state and federal requirements for sales/state taxes, shielding, licensing and registration, as applicable. The Customer is

responsible for any software licensure required by the original equipment manufacturer.

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elved by the Compan lage claimed. In no e	y for the equipment furnished or to event shall the Company be liable	damages or otherwise shall not exo o be furnished, as the case may be, for incidental, consequential, indire ost business revenue, lost profits, a	resulting in the loss ct, punitive or specia

this Agreement.

The Company assumes no responsibility whatsoever for any matters relating to equipment calibration and use.

Customer hereby agrees to hold harmless the Company and its respective officers, employees, agents, representatives, and their respective successors and assigns from and against any and all loss, liability, damages, claims, causes of action, costs, and expenses, including, but not limited to, attorney's fees and any other types of liability, whether accrued, absolute, contingent or otherwise, arising out of or related to the ownership or use of the Equipment at any time from and after the date that buyer obtains title to the Equipment.

intentional act or omission of the Customer, its agents or employees. This provision shall survive the termination of

- 11. SCOPE OF AGREEMENT. The signing of and the execution of this agreement shall constitute the entire agreement between the parties and supersedes any and all prior agreements. No amendment or variation of this agreement shall be valid unless mutually agreed upon in writing and signed by authorized officers of both the Company and the Customer.
- 12. ARBITRATION. Any controversy arising out of this Agreement shall be settled by arbitration in accordance with the Commercial Arbitration Rules of the American Arbitration Association (single arbitrator). All actions relating to this Agreement or any party's performance or nonperformance under this Agreement shall be instituted in, and both parties consent to jurisdiction and venue in, Rockland County, New York. Judgment upon the award rendered in any arbitration may be entered in any court of competent jurisdiction in New York. Each party in any such arbitration shall be responsible for its own attorneys' fees and costs incurred in such arbitration, as well as one-half of the arbitrator's fees and AAA charges. This Agreement shall be governed by and interpreted in accordance with the laws of the State of New York.
- 13. CONFIDENTIALITY. The terms and conditions of this agreement and of the aforementioned quotation are confidential and shall not be disclosed except as necessary to the performance of this agreement or as required by law.

Oncology Services International	Customer Acceptance: Dated:
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Initials:

Customer ———

Equipment Division: 950 Airport Road, Lakewood, New Jersey 08701 Tel 888-317-1370 Fax 732-730-0664 OSI ————

# SIEMENS

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

SIEMENS REPRESENTATIVE Emily Hale - (610) 448-1716

#### PRELIMINARY PROPOSAL

Customer Number: 0000053932

Date: 2/7/2013

21st Century Oncology Center 445 Biltmore Avenue Asheville, NC 28801

Quote Nr:

1-5MNNOB Rev. 0

## **Promotional Upgrade Packages**

All items listed below are included for this system:

Qty	Part No.	Item Description
1	10652175	PREF current R4.2
1	08167541	Mvision Upgrade Install Fee, US/CA SMS-OCSG factory personnel will install and calibrate the MVision upgrade, including customer sign-off of the Acceptance Test Protocol (ATP).
1	OCS_PM	OCS Project Management
1	10652223	PREF Elekta Mosaiq
1	10652208	MVision Upgrade for OPTIVUE 500  The OPTIVUE 500 to MVision upgrade preference is a special package that includes the necessary components in

The OPTIVUE 500 to MVision upgrade preference is a special package that includes the necessary components in order to upgrade ONCOR or PRIMUS installed with an OPTIVUE 500 to Siemens unique megavoltage cone beam (MVCB) imaging package: MVision comprises three major components: - M egaVoltage Cone Beam Imaging software and firmware - New High Quality flat panel - Adaptive Targeting software application on COHERENCE Therapist Workspace that facilitates Patient Position correction in 3 dimensions by analysis of treatment and Reference Volumetric datasets. This Upgrade includes Flat Panel auto-deploy, 3D Viewing and Reference Image Auto-load - Flat Panel Auto-Deploy enables PRIMEVIEW(tm) 3i on PRIMUS to automatically deploy/retract OPTIVUE(tm) 500. - 3D Viewing Option enables 3D Viewing capabilities on the PRIMEVIEW(tm) 3i platform. - Reference Image Auto-load enables PRIMEVIEW 3i(tm) on PRIMUS to automatically load reference images. Please be informed that Siemens will maintain a service and support structure to fulfill contractual commitments for installed Siemens linear accelerators. All services will be provided for the term of the service contract and spare parts will be available as per standard Siemens product end of life processes. The purchase of the linac upgrade solution as per this offer does not extend such timelines or any warranties given for the Installed products.

System Total:

\$220,900



# SIEMENS

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

SIEMENS REPRESENTATIVE Emily Hale - (610) 448-1716

### PRELIMINARY PROPOSAL

### **OPTIONS:**

Qty	Part No.	Item Description	Extended Price
1	10652039  OCS_MVI_INIT IAL_16	Apps Training Package  Training content: System introduction for - ARTISTE(tm), ONCOR(tm), PRIMUS(tm) linear accelerators - patient treatment tables and accessories - Imaging options (OPTIVUE(tm), MVision(tm)) - COHERENCE(tm) Dosimetrist and other COHERENCE workspace products, syngo(r) RT Workspaces - LANTIS(tm); IMAGE RT - instruction on how to use the system in modern therapy and in adjuvant therapeutic measures.	+ \$0
1		Initial onsite training 16 hrs - Mvision  Up to (16) hours of on-site clinical education training, scheduled consecutively (Monday - Friday) during standard business hours for a maximum of (4) Imaging professionals. Training will cover agenda items on the ASRT approved checklist. Uptime Clinical Education phone support is provided during the warranty period for specified posted hours. This educational offering must be completed (12) months from install end date. If training is not completed within the applicable time period, Siemens obligation to provide the training will expire without refund.	+ \$4,100

**FINANCING:** The equipment listed above may be financed through Siemens. Ask us about our full range of financial products that can be tailored to meet your business and cash flow requirements. For further information, please contact your local Sales Representative.

Siemens Healthcare is pleased to submit this Preliminary Pricing Proposal. A Preliminary Pricing Proposal is provided for planning purposes only; it is not contractually binding. To receive a contractually binding proposal for the Products listed above, inclusive of Terms, Conditions, and Warranty coverage, please contact your Siemens Healthcare Sales Representative.

Siemens Healthcare

Emily Hale (610) 448-1716 emily.hale@siemens.com

Buyer: 21st Century Oncology

Phone: 1-Fax: 1Gantry S/N To Follow Site Location: Asheville, NC Office

Contact: Daniel Galmarini

Seller: CT Enterprises, LLC

6209 Gheens Mill Rd. Jeffersonville, IN 47130

X

Phone: 812-280-0048

Fax: 812-280-0850

jeneisonvine, na 1715

Email: todd@cgtscan.com Date: January 28, 2013

Quote: LS-Plus\_ID

Contact: Todd Raderer

CTE Technologies, Inc. (CTE) is pleased to submit the following quotation and agrees to sell the products and services described at the prices and deliveries stated, subject to the conditions stated in this quotation, and the

Standard Conditions shown on the last two (2) pages of this quotation.

# **Equipment Description**

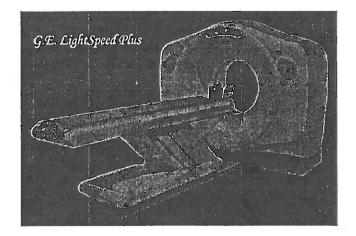
# **GE Light Speed CT Scanner**

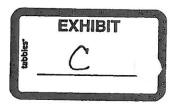
CTE offers the GE Light Speed CT as quoted herein. The GE Light Speed CT is comprised of the following components described in this quotation. This quotation includes all of the terms and conditions of sale attached hereto or incorporated herein by reference.

# **GE Light Speed Plus**

System Components Include:

- BASEPLATELESS GANTRY
- PERFORMIX 6.3MHU TUBE
- QUAD SLICE DETECTOR
- PATIENT TABLE W/METALLESS CRADLE
- LIGHT SPEED PDU
- HIGH PERFORMANCE DAS
- LIGHT SPEED OPERATOR'S CONSOLE
- HIGH SPEED COMPUTER
- 53.2KW GENERATOR, 10 TO 440MA
- 80, 100, 120, & 140KV SELECTIONS
- SUB-SECOND SCANNING (0.5 SEC. SCAN TIME)
- EMC COLLIMATOR
- Two 20" Color Monitors
- 70CM GANTRY APERTURE
- MAGNETIC OPTICAL DISK IMAGE STORAGE
- +/- 30 DEGREE GANTRY TILT
- 120sec. continuous Helical
- 160CM MAX. SCAN VOLUME BASED ON TABLE TRAVEL
- PITCH OF QUAD 0.75:1 (3:1) OR 1.5:1 (6:1)
- SMART OPTIONS FOR ENHANCED EXPOSURE CONTROL, IMAGE QUALITY, AND THROUGHPUT.
- SMART HELICAL
- SMART BEAM





Quote: LS-Plus\_ID page 2

Value added services: The system will be staged in our facility. It will be cleaned and undergo a full functional check to assure all systems are to OEM specifications. We will replace any items that do not meet specifications. We will service the slip-ring and refurbish the CT both cosmetically and mechanically. The unit will be available for inspection before shipping to the site for installation. We will ship to your site with our own air-ride truck and driver to minimize the risk of damage along the way. Specialized factory equipment dollies will be used to move the CT into your facility for further protection to the CT and your premises. We will install the CT and calibrate to produce likenew image quality. Site must be ready prior to installation or additional costs may be incurred.

Package Price: \$160,000.00 refurbished, delivered, and installed with a one year warranty on parts and labor. X-Ray tubes will be warranted for 2 years or 70,000 amp seconds on a pro-rata basis. Price includes the interface for Respiratory gating, a carbon fiber top, and a 10 KW UPS. Service after the warranty is \$3,250/mo. for parts and labor, less tubes, according to our Master Service Agreement currently in force.

Payment Terms: 50% down, and 50% when installed.

Acceptance and Agreement

Signatures (below) of authorized representatives of Seller and Buyer organizations constitutes mutual agreement to accept and comply with the terms and conditions set forth in this quotation, and the Standard Conditions, attached hereto and made part of this agreement. Warranty details are available on request.

### Accepted By:

Buyer: 21st Century Oncology	Seller: CT Enterprises, LLC	
Ву:	By: Todd Raderer	
Signature	Signature	_Date
Its		
Date:		

#### STANDARD TERMS AND CONDITIONS OF SALE

#### Acceptance of Quotation and Agreement:

The authorized signatures of CT Enterprises, LLC (Seller) and Customer (Buyer) constitute acceptance by both parties of the provisions of the attached Quotation ("Quotation") and these Standard Terms and Conditions of Quotation (collectively referred to herein as the "Agreement"). Any changes to the Quotation or it's content shall not be binding unless reduced to writing, and signed by authorized representatives of both Seller and Buyer.

Seller will not accept or be bound by any Terms and/or Conditions stated on Buyer's Purchase Order or any correspondence related thereto, unless specifically stated in writing and signed by Seller's authorized representative.

The Quotation is subject to withdrawal or change at any time prior to Seller's acceptance, and the quoted prices are valid until the Quotation is withdrawn, or expires as specified on the face thereof.

#### Prices

The Price of items quoted (hereinafter referred to as the "Equipment") do not include local, state, federal, value-added or any other form of taxes, unless otherwise indicated. Buyer will be responsible for any such taxes or obligations.

Further, the prices of items quoted herein do not include: the cost of permits or fees relating to any equipment, installation work, site preparation, construction, building additions or modifications and other activities, unless otherwise indicated. Buyer will be responsible for any such fees or obligations.

#### **Payment**

Payment shall become due in accordance with the specific terms on the deposits made hereunder shall be nonrefundable. Failure to abide by the payment terms shall be considered a default of this Agreement. Upon default due to failure to abide by payment terms, Seller shall have option to terminate this Agreement.

Execution of this Agreement by Buyer shall constitute a representation that Buyer is solvent. All financing plans (notes or otherwise) must be accompanied by a suitable security agreement acceptable to the Seller. In addition, upon the Seller's request, Buyer will furnish financial documentation that proves its solvency at time prior to shipment.

If the financial condition of the Buyer, at any time, is such as to give the Seller, in its sole judgment, reasonable grounds for insecurity concerning the Buyer's ability to perform its obligation under this Agreement, the Seller may require full or partial payment in advance and suspend delivery until such payment has been received. Failure to furnish such payment within ten (10) days of demand by the Seller shall constitute a breach of this Agreement, and in such event, in addition to all rights available to it at law or in equity, the Seller shall be entitled to receive reimbursement for any and all costs incurred by Seller in its performance under this Agreement.

#### Inspection

Unless otherwise indicated in writing by Seller, Buyer shall have the right to inspect the Equipment at the Seller's warehouse for a period of twenty (20) days following the date of this Agreement. If the Buyer fails to exercise its right of inspection, the Equipment shall be deemed accepted, and any deposit made hereunder shall become nonrefundable. If the Buyer exercises its right of inspection, and chooses not to accept the Equipment, the Buyer's sole and exclusive remedy shall be the return of any deposit paid to Seller for the Equipment.

#### Delivery:

Except as otherwise agreed upon in writing between the parties, the delivery date of the Equipment sold herein shall be ninety (90) days following the date of this Agreement. Please be advised delivery dates are dependent on the cooperation between all parties involved, the timely flow of information, payments, shipment of equipment, site preparation, inspections and approvals, availability of specialist personnel, etc.

Seller agrees to make all reasonable efforts to meet quoted delivery dates, but will not be responsible for any damages or loss incurred by Buyer or its contractors based on delay caused by: fires, floods, earthquakes or other acts of God, accidents, riots, wars, operation of law, government regulations or requirements, strikes, labor difficulties, shortages of fuel, power, materials or supplies, unavailability of transportation, or other acts or circumstances that are not within reasonable control of Seller.

In the event the Equipment is delivered via a third-party courier service, and suffers damage in delivery, unless the Buyer gives Seller written notice of such damage via Certified Mail-Return Receipt Requested within three (3) days of delivery, Buyer waives any claim against Seller for any determinable deficiency or defect in said delivery or Equipment. Buyer agrees to inspect all material and equipment immediately upon delivery to verify: (a) the quantities described in the accompanying delivery ticket are the quantities delivered and (b) there are no visible defects. Buyer also agrees to examine all delivery tickets upon receipt.

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Extended Shipment Delays:

Buyer may request reasonable delays in shipment and/or installation of equipment quoted, and Seller will reasonable efforts to comply with such requests at no additional cost to Seller.

In the event that such delays could cause unreasonable financial burden to Seller, in Seller's sole discretion, Seller reserves the right to: 1) charge Buyer for all costs associated with storage of equipment on Seller's floor or in Seller's facility; 2) charge Buyer for all costs associated with the crating, shipping and storage of equipment in an outside facility; or 3) demand all payments due for the Equipment in accordance with terms of this Agreement.

Title, Risk of Loss:

Title to the equipment or any part thereof shall pass to the Buyer upon: 1) delivery of such product or part to the Buyer; and 2) when payments to the Seller are made in full. Risk of loss shall pass to the Buyer upon delivery. The Seller hereby reserves and retains, and the Buyer hereby grants to the Seller, a lien under the UCC, or adopted in the state of delivery (or, if the product is located in Louisiana, a vendor's lien) in the Equipment or the parts thereof until such time as full payment is received. Buyer will cooperate fully with the Seller with respect to any documentation of the security interest and the filing thereof.

#### Installation:

If installation is specified in writing, the Seller will install the Equipment, and will connect the same to the safety switches or electrical outlets to be provided and installed by the Buyer. If for any reason such final assembly or electrical connections, herein referred to as the installation of the products, are made by other than the Seller's own employees, any additional charge for the cost of such outside labor must be borne by the Buyer. It is understood that proper electrical current for operation of the products, including any required power conversion units, will be brought to the safety switches and outlets by the Buyer, and the Buyer will supply all of the necessary conduits, connectors, wiring, support in the ceiling, plumbing, carpentry, construction work, and rigging required for making the installation. It is further understood that should anything additional be required for making the installation, it shall be supplied by the Buyer at the Buyer's expense. Additionally, if, upon arrival for installation, Seller determines, in its sole discretion, that the installation site is not prepared per Seller's instructions, causing a delay in the installation of the Equipment, Seller may charge a per-day delay fee in the amount of \$1,500.00 per day.

#### Software:

In the event that computer software is provided to Buyer in connection with the sale of the Equipment, the Buyer must obtain a non-exclusive license and/or sublicense to use such software with the product. By acceptance of this Agreement, or the software, at Buyer's expense, Buyer agrees to obtain the applicable license and/or sublicense. Seller shall not be responsible for the transfer of any software licenses hereunder, and Buyer shall hold Seller harmless from any liabilities arising from or relating to software licensing.

Warranty/ Disclaimer:

Warranty services hereunder, if applicable, shall include on-call remedial service and part replacement, as required due to Equipment malfunction, and as described in this Agreement. For purposes of this Agreement, "Equipment malfunction" shall be defined as the inability to produce diagnostic images. Any warranty service shall be provided during regular business hours (9:00A.M. to 5:00 P.M), Monday through Friday, excluding holidays.

Seller's warranty obligations shall not include the replacement of X-Ray tubes (Unless indicated above in this Agreement), supply items, cosmetics, and other accessories (including, but not limited to, film cassettes, phantoms, magnetic tapes, optical disks, table cushions, patient restraints and holders). Seller's warranty obligations shall also not include coverage of damage caused by misuse or abuse, in the sole determination of C&G, fire, water, building collapse, power failure or fluctuations, vandalism, riot, air conditioning failure, "acts of god" (i.e. tornado, hurricane, earthquake, etc.), or any other cause beyond the reasonable control of C&G. Additionally, operation contrary to the advice of Seller or its designated representative may result in exclusion from warranty coverage.

Alterations, additions, adjustments, adjustments or repairs to the Equipment by other than authorized representatives of Seller shall void any warranty granted hereunder, and Seller shall not be responsible to Buyer for loss of use of the Equipment or for any other liabilities arising from such alterations, additions, adjustments or repairs.

UNLESS SPECIFICALLY STATED IN THIS AGREEMENT, SELLER MAKES NO ADDITIONAL WARRANTIES HEREUNDER, AND EXPRESSLY DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY AND FITNESS

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FOR A PARTICULAR PURPOSE.

#### Limitations of Liability:

In no event, whether as a result of breach of contract, warranty, tort (including negligence and strict liability) or otherwise, shall the Seller be liable for any special, consequential, incidental or penal damages including, but not limited to, loss of profit or revenues, loss of use of the products or any associated equipment, damage to associated equipment, cost of capital, cost of substitute products, facilities, services or replacement power, down time costs, or claims of Buyer's customers for such damages. In no event, whether as a result of breach of contract, warranty, tort (including negligence and strict liability) or otherwise, shall the Seller's liability to Buyer for any loss or damage arising out of, or resulting from this Agreement, or from its performance or breach, or from the products or services furnished hereunder, exceed the price of the specific product or service which gives rise to the claim. Except as to title, any such liability shall terminate upon the expiration of the warranty period.

If the Seller furnishes Buyer with advice or other assistance which concerns any product supplied hereunder or any system or equipment in which any such product may be installed and which is not required pursuant to this agreement, the furnishing of such advice or assistance will not subject the Seller to any liability, whether in contract, warranty, tort (including negligence and strict liability) or otherwise.

#### Arhitration

Any and all disputes arising under, in connection with, or incidental to this Agreement shall be submitted to binding arbitration in Salem, Indiana. Arbitration shall be conducted by a single arbitrator in accordance with the rules of the American Arbitration Association. Buyer shall pay fifty percent (50%) of fees charged by the arbitrator, and the Seller the remaining fifty percent (50%). Judgment upon the award rendered by the Arbitration may be entered into any court having jurisdiction. The Buyer and Seller agree that jurisdiction is proper in the courts of the County of Washington, State of Indiana. This Agreement shall be construed in accordance with Indiana Law.

#### General:

Assignment. This Agreement may not be assigned by either party without the prior written consent of the other party.

Notices. All notices pursuant to this Agreement shall be in writing, except as provided herein. Notices in writing shall be sufficient if hand delivered or mailed by first class mail, postage prepaid, or sent by telecommunications to the attention of the person listed below and to the party intended as the recipient thereof at the address listed in the Quotation, or at such other address or to the attention of such other person as such party shall have designated for such purpose in a written notice complying as to delivery with the terms of this Section.

No Waiver of Performance. Failure by either party at any time to require performance by the other party or to claim a breach of any provision of this Agreement will not be construed as a waiver of any right accruing under this Agreement, nor affect any subsequent breach, nor affect the effectiveness of this Agreement or any part hereof, nor prejudice either party as regards any subsequent action.

Entire Agreement; Conflicting Provisions. This Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof and no representation or statement not contained in this Agreement shall be binding upon the parties as a warranty or otherwise.

<u>Validity</u>. The invalidity, in whole or part, of any of the foregoing paragraphs will not affect the remainder of such paragraph or any other paragraph in this section of this quotation.

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