



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

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Governor

Aldona Z. Wos, M.D.
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August 8, 2014

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

Exempt from Review – Acquisition of Facilities

Facilities: Cancer Centers of North Carolina – Raleigh and Wake Radiation Oncology Services
Acquisition by: Duke University Health System d/b/a Duke Raleigh Hospital
County: Wake and Johnston
FID #s: 050382 (Raleigh facility) and 960894 (Cary facility)

Dear Mr. Burgess and Mr. Shenton:

In response to your letter of August 1, 2014, the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-184(a)(8). Therefore, Duke University Health System d/b/a Duke Raleigh Hospital may proceed to acquire the above referenced health service facilities without first obtaining a certificate of need. Note that pursuant to G.S. 131E-181(b): *“A recipient of a certificate of need, or any person who may subsequently acquire, in any manner whatsoever permitted by law, the service for which that certificate of need was issued, is required to materially comply with the representations made in its application for that certificate of need.”*

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

Sincerely,

Michael J. McKillip
Project Analyst

Martha J. Frisone, Interim Chief
Certificate of Need Section

cc: Medical Facilities Planning Branch, DHSR
Radiation Protection Section, DHSR



Certificate of Need Section

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August 1, 2014

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Acting Chief
Certificate of Need Section
N.C. Division of Health Service Regulation
809 Ruggles Drive
Raleigh, NC 27603

RE: Request for No Review Determination and Notice of Exempt Transaction – Transfer of Ownership Interests in Medical Oncology and Radiation Oncology Centers

Dear Ms. Frisone:

We are writing on behalf of our firm's client, Duke University Health System, Inc. d/b/a Duke Raleigh Hospital ("DUHS"), regarding alternate proposed transactions described below that DUHS plans to undertake which would involve DUHS or an affiliate of DUHS taking steps to continue the operation of existing oncology centers in Wake and Johnston Counties that currently are owned by Cancer Centers of North Carolina, P.C. ("CCNC") and AOR Management Company of Virginia, LLC ("AOR"), a subsidiary of US Oncology, Inc. ("USON"). Before proceeding with one of these proposed transactions, DUHS is requesting that the Certificate of Need Section issue written confirmation that the proposed transactions and related activities described below, and the subsequent provision of radiation therapy and other oncology services at these oncology centers with the existing linear accelerators and treatment simulator equipment described below, will not constitute a new institutional health service or require a certificate of need.

1. Background on Oncology Centers and Equipment

DUHS is a North Carolina nonprofit corporation, with its principal place of business in Durham County, North Carolina. Duke owns and operates Duke Raleigh Hospital, a licensed acute care hospital located in Raleigh, Wake County, North Carolina. Duke provides a comprehensive array of medical and surgical services at Duke Raleigh Hospital.

CCNC is a North Carolina professional corporation that employs physicians licensed to practice medicine in North Carolina, who provide oncology treatment services. CCNC has cared for patients residing in and around Wake and Johnston Counties for over 30 years. CCNC and AOR own and operate the following offices where CCNC provides a variety of services including medical oncology, radiation oncology, ENT oncology, and gynecologic oncology:

Wake County

Cary Offices:

- 216 Ashville Ave., Suite 20, Cary, NC 27518 (medical oncology)
- 300 Ashville Ave., Suite 110, Cary, NC 27518 (radiation oncology)

Raleigh Offices:

- 4101 Macon Pond Road, Raleigh, NC 27607 (ENT oncology, gynecologic oncology, medical oncology, and radiation oncology)
- 10010 Falls of Neuse Road, Suite 203, Raleigh, NC 27614 (medical and ENT oncology)

Johnston County

Clayton Office: 555 Medical Park Place, Suite 201-B, Clayton, NC 27520 (medical oncology)

CCNC's radiation oncology centers include the following equipment:

- (1) Varian Clinac 2100C/D linear accelerator, operating at the Macon Pond center in Raleigh ("Macon Pond Linac");
- (2) GE Lightspeed Qx/I CT Scanner, operating at the Macon Pond center in Raleigh ("Macon Pond CT Scanner")
- (3) Siemens Primus linear accelerator, operating at the Cary radiation oncology center ("Cary Linac");
- (4) Siemens SimView 3000 simulator, operating at the Cary radiation oncology center ("Cary Simulator").

The Macon Pond and Cary Linacs (collectively, the "Linacs") are used to provide radiation therapy treatments to patients, as they have been since they were initially acquired and installed at these locations. The Macon Pond CT Scanner and Cary Simulator each is used as a treatment simulator to help plan radiation therapy treatments delivered on the Linacs.

Macon Pond Oncology Center. In 2001, the CON Section issued a determination confirming that Raleigh Hematology Oncology Associates, P.C. ("RHOA"), now known as CCNC, operated a grandfathered oncology treatment center, within the meaning of the CON Law. See Grandfathered Oncology Treatment Center Determination and Request Correspondence (Appendix 1). RHOA was approved by the CON Section in 2004 to relocate its oncology treatment center and to expand the center with the acquisition of a reconditioned linear accelerator, computed tomography ("CT") simulator, and treatment planning equipment, without a certificate of need. See No Review Determination and Request Correspondence Regarding Macon Pond Linac and CT Scanner (Appendix 2). The Macon Pond Linac and CT Scanner were purchased in March 2005 consistent with the CON Section's no review determination. See CCNC January 2014 Registration and Inventory of Medical Equipment, pp. 2-3 (Appendix 3). At that time, linear accelerators and simulators were not specifically regulated, but instead, the CON Law regulated oncology treatment centers, which were included within the definition of "health service facility" in N.C. Gen. Stat. § 131E-176. See N.C. Gen. Stat. § 131E-176 (1997) (Appendix 4).

Cary Oncology Center. In April 2011, CCNC acquired the limited liability company that owns the radiation oncology center and associated equipment formerly operated by Wake Radiology Oncology Services, PLLC ("WROS"), located at 300 Ashville Avenue in Cary. CCNC acquired membership interests in this LLC pursuant to a Declaratory Ruling issued on September 27, 2010 (Appendix 5), which confirmed that this acquisition did not require a certificate of need. Since that acquisition, CCNC has been providing radiation therapy to patients on the Cary Linac and Simulator at the Cary radiation oncology center.

The original CON for this Cary center was issued to WROS in 1997, and this CON specifically authorized the development of "an oncology treatment center consisting of one medical linear accelerator, one therapeutic simulator and specialized computer systems" See Certificate of Need issued to WROS for Project I.D. No. J-5464-96 (Appendix 6). Thus, the CON for the Cary center now owned and operated by CCNC and AOR, specifically authorized the operation of an oncology treatment center -- a facility providing services for the diagnosis, evaluation or treatment of cancer, including a linear accelerator and simulator to furnish radiation oncology services.

Grandfathered Oncology Centers Developed Prior to 2005 Changes to CON Law. Based upon changes to the Certificate of Need Law which took effect August 26, 2005, the law now regulates the acquisition of linear accelerators and simulators regardless of cost. N.C. Gen. Stat. § 131E-176(16)(f1)5a and 9. Under the 2005 changes to the law, "oncology treatment centers" are no longer a regulated type of new health service facility. See 2005 N.C. Sess. Laws 325, §§ 1 and 7. However, because the Linacs, Macon Pond CT Scanner and Cary Simulator were acquired prior to the current CON Law provisions which specifically regulate acquisitions of these types of new equipment, they are "grandfathered" as part of the oncology treatment centers for which they were acquired, and should not be subject to regulation under the current provisions of the law. Even if they were not grandfathered, however, it is our understanding that their acquisition as set forth below is not subject to certificate of need review.

Trilogy Linac CON. In addition to the two existing Linacs described above, in February of 2011, CCNC and AOR obtained a certificate of need to acquire a Trilogy linear accelerator with stereotactic radiosurgery capabilities ("Trilogy Linac"). Contemporaneously with this letter, DUHS is submitting a transfer for good cause request to the CON Section regarding this Trilogy Linac certificate of need.

DUHS, CCNC and USON (collectively, the "Parties") have discussed and reached agreement in principle on the alternate proposed transactions described below, with the ultimate goal being to ensure that the Oncology Centers currently owned by CCNC and USON continue operating uninterrupted to provide needed diagnostic and therapeutic services to cancer patients residing in and around Wake and Johnston Counties, and to continue improving cancer care and access for patients and their families in this area. See Support Letter from CCNC and USON (Appendix 7). Continuity of patient care is a fundamental objective of the Parties' agreement.

2. Proposed Acquisition of Corporate Ownership Interests.

DUHS is providing this letter to request a no review determination regarding a transaction being considered by the Parties, in which DUHS or an affiliated entity of DUHS ("Duke") would acquire 100 percent of the ownership interests in a corporate entity that will own the CCNC Oncology Centers and associated equipment. This proposed acquisition of corporate ownership interests will proceed in two steps. First, CCNC and/or USON will transfer all of their interests in the Oncology Centers and their associated equipment to a wholly-owned subsidiary (the "LLC"). The transaction will be completed with Duke purchasing 100% of the membership interests in the LLC as a second step.

The Oncology Centers owned by the LLC and their equipment will continue to serve patients at the same locations. There will be no purchase of additional equipment, nor will any new services be offered, as a result of this proposed transaction. The only change will be the membership composition of the corporate entities that own the Oncology Centers and equipment, with CCNC and/or USON initially transferring their ownership interests to the wholly-owned subsidiary LLC, followed by a separate transaction in which Duke will acquire all of the membership interests in the LLC. The entity that owns the Linacs and Simulator will not change as a result of Step 2 of the proposed transaction.

At some point subsequent to the proposed transaction, and probably quite soon thereafter, the LLC would likely be merged into DUHS or otherwise consolidated with DUHS pursuant to an internal corporate reorganization, in the interests of operational efficiencies and streamlining the corporate organization. Where DUHS or an entity affiliated with DUHS would be the sole member of the LLC and essentially will be stepping into the shoes of the operators of these existing oncology centers and their equipment, all of which have been previously reviewed by the CON Section, in order to allow the centers to continue serving patients, such an internal corporate reorganization will be nothing more than an administrative activity which should not be subject to CON review.

Based upon the clear terms of the CON Law and the long-standing approach that the Division of Health Service Regulation ("DHSR") and the CON Section have taken to the purchase of equity interests in existing North Carolina health care facilities when there is no change in the services offered or the equipment employed to offer the services, DUHS respectfully submits that none of these steps relating to the acquisition of corporate ownership interests constitutes a new institutional health service that requires a certificate of need. The CON Law 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.

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 membership 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 and should not be subject to CON review.

In prior declaratory rulings and no review determinations, DHSR and the CON Section have recognized that transactions which are limited to an acquisition of underlying corporate membership interests in an existing legal entity which owns and operates an existing oncology center and its associated equipment, such as this proposed transaction, fall within the above-referenced exclusion recognized in the definition of "health service" in the CON Law. Accordingly, DHSR and the CON Section have consistently determined that events such as this proposed acquisition of the ownership interests in the CCNC oncology centers do not trigger certificate of need review under either the linear accelerator or simulator provisions in N.C. Gen. Stat. § 131E-176(17)(f1)5a and 9, or the \$2,000,000 capital expenditure provision in N.C. Gen. Stat. § 131E-176(16)(b).

More specifically, this no review request is consistent with the following prior declaratory rulings which have interpreted the applicability of the CON Law to the purchase of ownership interests in corporate entities that own linear accelerators:

- *In re: Request for Declaratory Ruling by JRH Ventures, LLC et al.* dated January 2012 (transfer of membership interests and change in membership composition of existing owners of linear accelerators did not require a CON) (Appendix 8)
- *In Re: Request for Declaratory Ruling by Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System et al.* dated January 2012 (acquisition of membership interests in existing radiation oncology center did not require a CON) (Appendix 9)
- *In re: Request for Declaratory Ruling by Radiation Oncology Centers of the Carolinas, Inc.* dated August 18, 2011 (transfer of two CON-approved radiation oncology facilities to two wholly-owned subsidiaries did not constitute a new institutional health service or require a certificate of need) (Appendix 10)
- *In re: Request for Declaratory Ruling by Rex Healthcare, Inc. and Smithfield Radiation Oncology, LLC* dated December 21, 2007 (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) (Appendix 11)

While DHSR has in the past responded to these types of proposed transactions through declaratory rulings, most recently the CON Section has acknowledged it is appropriate to address this type of transaction through a no review determination:

- *In re: Request for No Review Determination by East Carolina Health d/b/a Vidant Roanoke-Chowan Hospital* dated September 20, 2012 (acquisition of 100% of the membership interests in existing owner of linear accelerator did not require a CON) (Appendix 12)
- *In re: Request for No Review Determination by Radiation Therapy Services, Inc. et al.* dated January 6, 2012 (acquisition of membership interests in corporate entities that owned Cancer Centers of North Carolina-Asheville, P.C.'s oncology center including linear accelerator and CT scanner did not require a CON) (Appendix 13)

The CON Law is intended to regulate new institutional health services and is not intended to impede routine business transactions such as an acquisition of a limited liability company's ownership interests. This 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. The Oncology Centers and their equipment have been established and operating for years. As a result, the proposed transaction does not implicate the fundamental objective of the CON Law -- to control the new development or expansion of health service facilities.

3. Proposed Exempt Acquisition of Existing Health Service Facilities.

In the alternative, DUHS is providing this letter pursuant to N.C. Gen. Stat. § 131E-184(a)(8) to inform the CON Section that Duke will acquire ownership and control of the CCNC Oncology Centers, located in Raleigh, Cary, and Clayton, North Carolina. The CON Law provides that, upon receiving prior written notice, the CON Section "**shall exempt** from certificate of need review" the acquisition of "an

Ms. Martha Frisone
Acting Chief, CON Section
August 1, 2014
Page 6

Poyner Spruill^{LLP}

existing health service facility, including equipment owned by the health service facility at the time of acquisition." N.C. Gen. Stat. § 131E-184(a)(8) (emphasis added).

Duke, CCNC and USON will enter into a purchase agreement pursuant to which Duke will acquire the Oncology Centers, including substantially all of the radiation oncology assets associated with the Centers. Thus, in the proposed exempt transaction, Duke will acquire ownership and control of the existing CCNC oncology treatment centers which are existing health service facilities under the CON Law. As discussed in Part 1 above, prior to the 2005 changes to the CON Law, facilities providing diagnostic and therapeutic services to cancer patients were regulated as oncology treatment centers, which were included within the definition of "health service facility" in N.C. Gen. Stat. § 131E-176. Both CCNC's Macon Pond and Cary radiation oncology centers were established and have continued to operate as oncology treatment centers, under applicable CON Law. As set forth above, the Macon Pond radiation oncology center is part of a grandfathered oncology treatment center, and the Cary radiation oncology center was established pursuant to a CON which specifically authorized development of an oncology treatment center with a linear accelerator and simulator. Accordingly, both of these oncology centers and their equipment were developed as health service facilities and should continue to be treated as such under the CON Law. Because the Linacs and treatment simulators at these centers were acquired in conjunction with these oncology treatment centers before the 2005 change in the CON Law, this equipment is clearly grandfathered and should not be subject to regulation under the current provisions of N.C. Gen. Stat. § 131E-176(16)(f1)5a and 9 for purposes of either this proposed exempt acquisition of existing health service facilities or the proposed acquisition of corporate ownership interests described above in Part 2.

The medical oncology, ENT oncology and gynecologic oncology offices and associated equipment owned by CCNC and USON are part of and operated in connection with the existing oncology treatment facilities to be acquired in this transaction. These medical offices do not constitute a separate "new institutional health service" or "new institutional health facility," as defined in N.C.G.S. § 131E-176, and therefore, did not require a certificate of need. Moreover, for purposes of certificate of need, these components of the Oncology Centers essentially are akin to physician offices which are specifically exempted from certificate of need review and approval by the CON Section.

4. Conclusion

For all of the foregoing reasons, the regulation of events like the proposed transactions described above, involving existing and previously reviewed and approved facilities 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. 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 exemption and no review determinations would delay and impede DUHS in proceeding with a lawful business transaction.

We have enclosed a copy of the materials referenced in this letter (see attached Appendices). Based upon the information provided in this letter, DUHS respectfully requests your earliest possible attention to this request and looks forward to your written confirmation that the proposal described herein does not require a certificate of need. In order to ensure continued and uninterrupted care for cancer patients residing in and around Wake and Johnston Counties, DUHS and the other Parties wish to move

Ms. Martha Frisone
Acting Chief, CON Section
August 1, 2014
Page 7

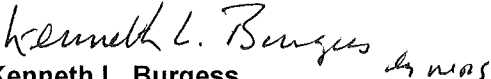
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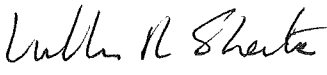
forward with the pending transaction as soon as feasible, and accordingly, request a response from you on or before August 22, 2014, if possible.

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

With best regards, we are

Very truly yours,


Kenneth L. Burgess


William R. Shenton

cc: Christy Gudaitis, Esq., Counsel for DUHS
Catharine Cummer, Esq., Counsel for DUHS
Larry Robbins, Esq., Counsel for CCNC
Scott Aitken, Esq., Counsel for USON

INDEX TO APPENDIX
REQUEST FOR NO REVIEW DETERMINATION AND
NOTICE OF EXEMPT TRANSACTION

| Tab | Description |
|-----|--|
| 1. | RHOA's 2001 Grandfathered Oncology Treatment Center Determination and Request Correspondence |
| 2. | 2004 No Review Determination and Request Correspondence Regarding Macon Pond Linac and CT Scanner |
| 3. | CCNC January 2014 Registration and Inventory of Medical Equipment pp. 2-3 |
| 4. | N.C. Gen. Stat. § 131E-176 (1997) |
| 5. | September 27, 2010 Declaratory Ruling re acquisition of WROS membership interests by CCNC and Petition |
| 6. | CON issued to WROS for Project I.D. No. J-5464-96 |
| 7. | Support Letter from CCNC and USON |
| 8. | <i>In re: Request for Declaratory Ruling by JRH Ventures, LLC (January 2012)</i> |
| 9. | <i>In re: Request for Declaratory Ruling by Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System et al. (January 2012)</i> |
| 10. | <i>In re: Request for Declaratory Ruling by Radiation Oncology Centers of the Carolinas, Inc. (August 18, 2011)</i> |
| 11. | <i>In re: Request for Declaratory Ruling by Rex Healthcare, Inc. and Smithfield Radiation Oncology, LLC (December 21, 2007)</i> |
| 12. | <i>In re: Request for No Review Determination by East Carolina Health d/b/a Vidant Roanoke-Chowan Hospital (September 20, 2012)</i> |
| 13. | <i>In re: Request for No Review Determination by Radiation Therapy Services, Inc. et al. (January 6, 2012)</i> |

Appendix 1



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

Michael F. Easley, Governor
Carmen Hooker Buell, Secretary

Lee Hoffman, Section Chief
Phone: 919-733-6360
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June 29, 2001

S. Todd Hemphill
Bode, Call & Stroupe, L.L.P.
3105 Glenwood Avenue, Suite 300
Raleigh, NC 27612


RE: Inquiry/Status of Raleigh Hematology Oncology Associates, P.C. as an oncology treatment center/Wake County

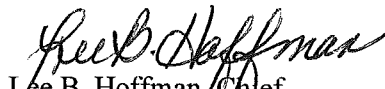
Dear Mr. Hemphill:

In response to your June 15, 2001 and June 28, 2001 letters, the Certificate of Need Section has determined that Raleigh Hematology Oncology Associates, P.C. was an "oncology treatment center" as defined in N.C.G.S. 131-E176(18a) immediately prior to March 18, 1993. This determination does not permit Raleigh Hematology Oncology Associates, P.C. to operate more than one oncology treatment center or to relocate and operate the existing single oncology treatment center on more than one campus.

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

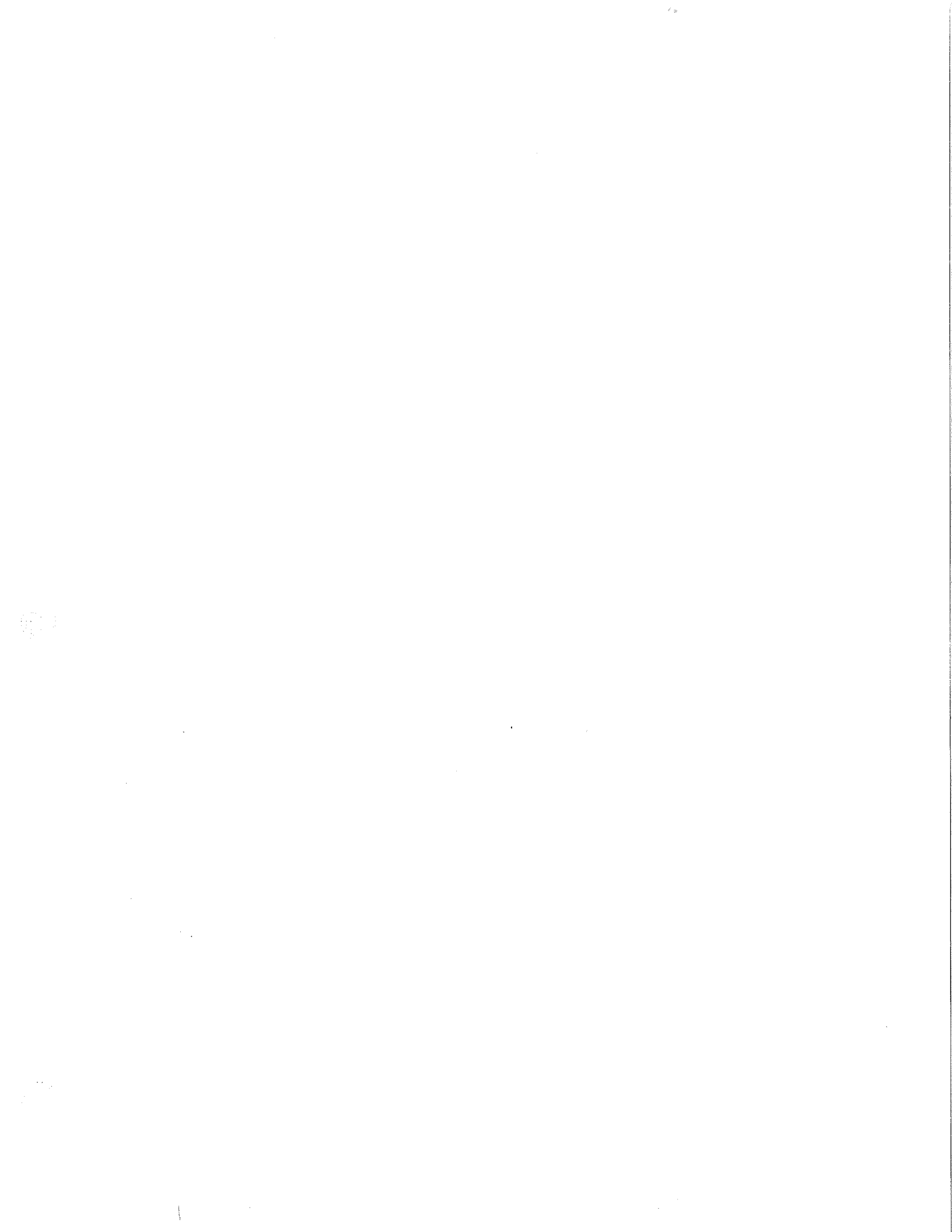
Sincerely,


Mary Edwards
Project Analyst


Lee B. Hoffman, Chief
Certificate of Need Section

cc: Section Chief, Licensure and Certification Section, DFS
Section Chief, Construction Section, DFS
Medical Facilities Planning Section, DFS





BODE, CALL & STROUPE, L.L.P.

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June 28, 2001

Via Hand Delivery

Lee B. Hoffman, Chief
Mary Edwards, Project Analyst
Certificate of Need Section
Division of Facility Services
701 Barbour Drive
Raleigh, North Carolina 27603

Re: Raleigh Hematology Oncology Associates, P.C.

Dear Ms. Hoffman and Ms. Edwards:

Responding to your additional questions regarding Raleigh Hematology Oncology Associates, P.C., please see the following:

1. Raleigh Hematology Oncology Associates was established in 1979, as a medical partnership, by Dr. William R. Berry. The purpose of the practice was to provide medical oncology services, including medical oncology, hematology and pharmacy services. See Raleigh Hematology Oncology Associates web site, Exhibit A hereto and letter from William Berry, M.D., Exhibit C hereto¹. The practice was originally located on Computer Drive in Raleigh, and incurred expense upfitting the space which it leased.
2. In 1981, the practice incorporated as Raleigh Hematology-Oncology Clinic, P.A. See North Carolina Secretary of State web site, Exhibit B hereto and Dr. Berry's letter, Exhibit C hereto.

¹ Please note that there are two copies of the second page of Dr. Berry's letter, because the fax we received of the signed copy had a line through it, obscuring some of the information.

Ms. Hoffman and Ms. Edwards

June 28, 2001

Page 2

3. Between 1981 and 1987, the practice moved two additional times, upfitting space each time. The records regarding the upfit of space are lost, so we can provide no itemized cost estimate. See Dr. Berry's letter, Exhibit C hereto.
4. In 1987, the practice moved to its present site at the Rex Cancer Center, 4420 Lake Boone Trail, Raleigh, North Carolina 27607. At that time, the practice upfit space in the Rex Cancer Center for its medical oncology practice. Again, the records regarding that upfit are lost. However, a second major upfit of Raleigh Hematology's space was begun in early 1993. Specifically, Rex Hospital engaged in a major expansion and renovation of its cancer center. The construction and renovation upfit of the space for chemotherapy treatment was the financial obligation of Raleigh Hematology. See Dr. Berry's letter, Exhibit C hereto. The construction costs related to that space were \$583,210.00. See construction cost estimate from John C. Brown, AIA, dated January 4, 1993, Exhibit D hereto. The costs associated with Raleigh Hematology are highlighted on page 2 of that document. As set forth in Dr. Berry's letter, construction of that project began in February, 1993, and Raleigh Hematology was legally committed to paying its portion of those costs prior to March 18, 1993.
5. In addition to the above documented construction costs, Raleigh Hematology was involved in the upfit of space three times at its Computer Drive space, as well as the initial upfit of the Rex Cancer Center space in 1987. Dr. Berry estimates that the total construction costs from 1979 to 1987 related to that medical oncology space were \$80,000 to \$100,000. See Exhibit C.
6. Since the beginning of the practice in 1979, Raleigh Hematology purchased or leased laboratory equipment similar to the equipment currently leased, as described in my June 13, 2001 letter to you. However, the records regarding the purchase or lease much of that equipment have been lost. The practice has been able to locate records regarding the following equipment.
 - a. A Bone Marrow Biopsy Tray, purchased March 23, 1992 from Roane-Barker, Incorporated, purchase price \$305.28. As this equipment was purchased new, the fair market value of this equipment at the time it was purchased would have been the same. See letter from Jane Kirkeby, MT, Laboratory Manager, Exhibit E hereto, and invoice attached thereto as Exhibit 1.
 - b. Four Accupro pumps, purchased March 31, 1992 from Biomedical Home Care, purchase price \$420.00. This pump is used to accurately measure the administration of chemotherapy medication into a patient's vein. Raleigh

Hematology had at that time and continues to have over 20 of these pumps in stock.

As this equipment was purchased new, the fair market value of this equipment at the time it was purchased would have been the same. See invoice attached as Exhibit 2 to Ms. Kirkeby's letter.

- c. Various Coulter Optichem chemotherapy equipment, purchased April 8, 1992 from Coulter Source, Inc., purchase price \$545.00. As this equipment was purchased new, the fair market value of this equipment at the time it was purchased would have been the same. See invoice attached as Exhibit 3 to Ms. Kirkeby's letter.
 - d. A Coulter Optichem 180 (which measures complete blood counts), leased from Coulter Leasing Corp. beginning June, 1990. The monthly lease payment on this equipment was approximately \$3,900.00. Had Raleigh Hematology elected to purchase, rather than lease the equipment, its purchase price at the time the lease began (and hence its fair market value) would have been \$105,000. See Ms. Kirkeby's letter, and invoices attached thereto as Exhibit 4.
 - d. A Kodak Ektachem 500 Analyzer which (which analyzes serum chemistries, such as sodium, potassium and chloride), leased from Kodak beginning October, 1992. The yearly lease payment on this equipment was \$70,497. Had Raleigh Hematology elected to purchase, rather than lease the equipment, its purchase price at the time the lease began (and hence its fair market value) would have been \$88,000. See Ms. Kirkeby's letter, and memo attached thereto as Exhibit 5. In addition, as can be seen from Exhibit 6 to Ms. Kirkeby's letter, the Kodak Ektachem was replaced with the Dade Dimension AR Chemistry Analyzer currently operated by Raleigh Hematology and referenced on page 5, paragraph 2 of my June 13, 2001 letter to you.
7. Therefore, Raleigh Hematology is able to document that between 1979 and March 18, 1993, it incurred capital costs to upfit space of \$583,210 and acquired medical equipment in the amount of \$254,000, all for the provision of oncology treatment services, for a total capital cost of \$837,210. In addition, Dr. Berry has estimated additional construction costs prior to 1993 of between \$80,000 and \$100,000, and Ms. Kirkeby has estimated that the practice acquired additional medical equipment costing between \$60,000 and \$70,000 prior to 1993. Therefore, Raleigh Hematology provided "services for diagnosis, evaluation, or treatment of cancer and its aftereffects or secondary results and for which the total cost of all the medical equipment utilized by the center, exceed[ed] two hundred fifty thousand dollars (\$250,000)." G.S. 131E-176(18a). The practice has continually provided these services since 1987 at its current site.
 8. In 1995, the practice was reconstituted in a new corporation, Raleigh Hematology

Ms. Hoffman and Ms. Edwards

June 28, 2001

Page 4

Oncology Associates, P.C. The shareholders were the same physician shareholders as Raleigh Hematology-Oncology Clinic, P.A. See North Carolina Secretary of State web site, Exhibit B hereto and Dr. Berry's letter, Exhibit C hereto. All of the assets of Raleigh Hematology-Oncology Clinic, P.A. were transferred to Raleigh Hematology Oncology Associates, P.C.

Based upon the above information, we would request that your office find that Raleigh Hematology is an oncology treatment center as defined in G.S. 131E-176(18a), and was prior to March 18, 1993. As you can see from the attached materials, the statutory prerequisites for meeting the definition of an oncology treatment center were in place prior to the amendment to the CON law in 1993. The practice had upfit space and was utilizing medical equipment have a cost in excess of \$250,000, to provide medical oncology, hematology and laboratory services as of March 18, 1993. Based upon our review of the facts and law related thereto, we believe Raleigh Hematology is an oncology treatment center. We would appreciate you confirming that our analysis is correct and advising us as to what, if any, further steps Raleigh Hematology needs to take to be properly recognized as an oncology treatment center by the State of North Carolina.

Very truly yours,

BODE, CALL & STROUPE, L.L.P.

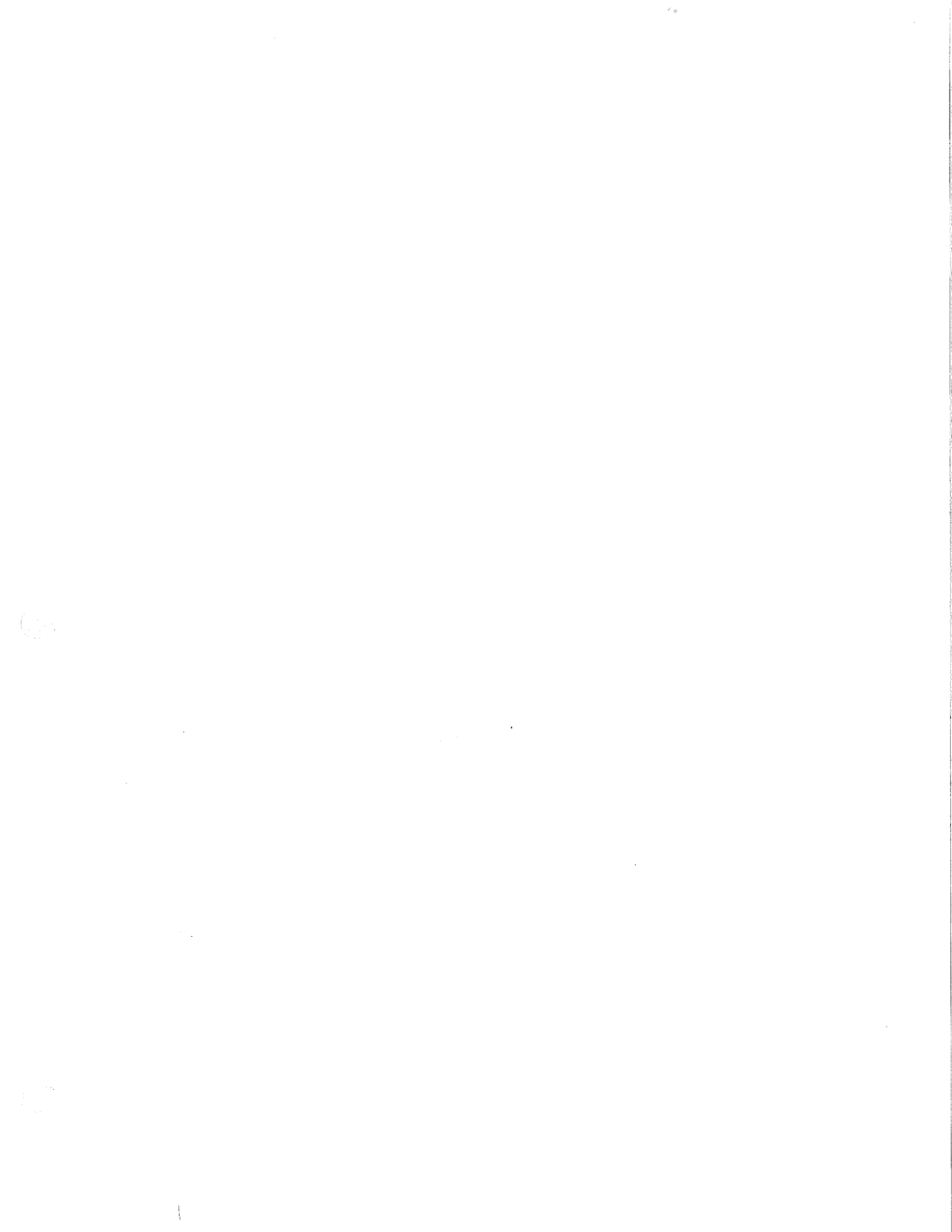


S. Todd Hemphill

STH/sh: 4016.000

INDEX OF EXHIBITS

- A. Pertinent portions of Raleigh Hematology Oncology Associates web site
- B. North Carolina Secretary of State web site
- C. Letter from William R. Berry, M.D.
- D. Letter from John C. Brown, AIA, Peterson Associates, to Bill Barbour, Rex Hospital, dated January 4, 1993, with construction cost estimate for Rex Cancer Center
- E. Letter from Jane Kirkeby, MT, with exhibits



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JAMES N. JORGENSEN
CHRISTIE M. FOPPIANO

June 13, 2001

Via Hand Delivery

Lee B. Hoffman, Chief
Mary Edwards, Project Analyst
Certificate of Need Section
Division of Facility Services
701 Barbour Drive
Raleigh, North Carolina 27603

Re: Raleigh Radiation Oncology, P.C. / Request for "No Review" Letter, Wake County

Dear Ms. Hoffman and Ms. Edwards:

This letter is in response to your letter of June 7, 2001, requesting additional information with regard to the proposal described in my May 7, 2001 letter to Ms. Hoffman, requesting the CON Section to issue, pursuant to 10 NCAC 3R.0304, a letter determining that the proposal of our client, Raleigh Radiation Oncology, P.C., to acquire a linear accelerator and provide radiation therapy services in Raleigh, Wake County, North Carolina, is not a new institutional health service, within the meaning of the certificate of need law. Your specific questions are set forth below in bold, with our client's responses following each question.

1. **A detailed itemization of all taxes to be paid on all equipment, furniture and other furnishings and goods included in the proposal.**

The estimates previously provided were inclusive of all taxes. See letter from Thomas J. Crowder, AIA, NCARB, Architektur, P.A., Exhibit 1 hereto, and letter from Tim Ochran, Vice President of Radiation, Clinical Services, US Oncology, Exhibit 2, hereto.

2. **Documentation of the cost of transporting the linear accelerator to the proposed vault.**

Ms. Hoffman and Ms. Edwards
June 13, 2001
Page 2

Attached as Exhibit 4 to our May 7, 2001 letter was a cost estimate from Mr. Crowder estimating the entire cost of acquiring and installing the linear accelerator, and upfitting space. Included in that estimate was a \$25,000 line item for "Linear Accelerator Installation." That estimate was intended to include both transportation and installation of the linear accelerator. See Mr. Crowder's letter attached hereto as Exhibit 1. In addition, since our May 7th letter, our client has investigated this further, and determined that the likely cost of transportation and installation will be lower. Specifically, the only costs estimated to associated with transportation and installation are projected to be:

- Rental truck for transportation of the linear accelerator, including fuel charges, is expected to be no more than \$2,000.
- The cost to rent a rigger to lift the equipment on and off the truck and install it in the vault is expected to be no more than \$5,000.

Under any circumstance, Mr. Crowder's original rough estimate of \$25,000 to cover transportation and installation costs should be more than enough.

3. A larger and more readable line drawing of the proposed office space, than the copy provided as Attachment 3, that clearly identifies the specific use of all space in the building.

Attached hereto as Exhibit 3 are line drawings for the building, clearly identifying the spaces to be leased, and their square footage. The specific pages of that document are comprised of the following:

- Page 1: List of square footage for all space to be leased or used by Raleigh Radiation, Raleigh Hematology, or US Oncology¹ on Floors 1 and 2 of the building.
- Page 2: A floor plan of the existing space on Floor 1, showing the space as it is currently configured.
- Page 3: A floor plan of the existing space on Floor 1, showing the space as it will be configured after the move (including the vault, which has not yet been constructed). Please note that the space highlighted in yellow will be leased by Raleigh Radiation, the space highlighted in green will be leased by Raleigh Hematology, and the space highlighted in pink will be leased by US Oncology.
- Page 4: A floor plan of the existing space on Floor 1, showing the space as it will be configured after the move, including the specific use of the space. The highlighting is the same as on page 3. This plan also demonstrates how little upfit cost there

¹ As explained in my May 7, 2001 letter, US Oncology is the manager of Raleigh Hematology Oncology Associates, P.C.'s office, and will be the manager of Raleigh Radiation Oncology, P.C.'s office. See discussion under paragraph 5 below.

Ms. Hoffman and Ms. Edwards
June 13, 2001
Page 3

will be for Raleigh Radiation. The lines in bold in the area of the waiting room and check-in space represent the only walls which will be changed. The rest of the space will remain the same.

Page 5: A floor plan of the existing space on Floor 2, showing the space as it is currently configured.

Page 6: A floor plan of the existing space on Floor 2, showing the space as it will be configured after the move. The space highlighted in green will be leased by Raleigh Hematology.

Page 7: A floor plan of the existing space on Floor 2, showing the space as it will be configured after the move, including the specific use of the space. Again, the highlighting is the same as on page 6.

4. The number of square feet for the entire building and the number of square feet designated for each of the components, separately: (a) Raleigh Radiation and (b) Raleigh Hematology.

The building is comprised of three floors, with approximately 21,000-21,500 square feet of usable space on each floor, for a total square footage of approximately 63,000-64,500 square feet. Raleigh Radiation will lease 4,023 square feet of existing space on the bottom floor. In addition, the vault and control room for the linear accelerator which will be constructed by Raleigh Radiation will be approximately 2,261 square feet, and will be leased from the owner once completed. Therefore, Raleigh Radiation will lease approximately 6,284 square feet of space. See Exhibit 3, page 2, yellow highlight.

Raleigh Hematology's offices will be on the second floor of the building, and will lease approximately 19,681 square feet of space. See Exhibit 3, page 6, in green highlight. In addition, Raleigh Hematology will lease approximately 6,766 square feet of space on the first level which will be used as storage, and allow for future expansion of the practice. See Exhibit 3, page 3, green highlight. Therefore, the total space which will be leased by Raleigh Hematology will be only 26,447 square feet, less than the 45,000 square feet estimated in our May 7, 2001 letter.

In addition, as explained in my earlier letter, Raleigh Hematology has a management agreement with US Oncology to provide management services for the medical practice. US Oncology also will provide similar services for Raleigh Radiation. US Oncology will relocate its offices from its current location at 2501 Atrium Drive in Raleigh and lease approximately 9,096 space on the first level of the building. See Exhibit 3, page 3, pink highlight. US Oncology's upfit costs are discussed under paragraph 8.

Finally, there is identified on the first level a tenant "staff lounge" of approximately 1,361 square feet. That lounge is for use by all tenants of the building, and each tenant is required pay some lease

Ms. Hoffman and Ms. Edwards

June 13, 2001

Page 4

amount for use of that space. None of the tenants have any capital costs associated with that space, and no upfit will be required.

5. Information about billing for treatment services, including the information about the provider number that will be used.

Billing for treatment services will be provided through Raleigh Radiation's management agreement with US Oncology, similar to the manner in which Raleigh Hematology currently bills for its services. Specifically, Raleigh Hematology is a partner in North Carolina Oncology Associates, and provides and bills its services through the partnership,² using the partnership's Federal Tax ID No. 56-1944145 and its own identifying Medicare/Medicaid provider numbers. Raleigh Radiation's services will be billed the same way, although its provider numbers have not been obtained as it is not yet operational.

6. Copies of any agreements between Raleigh Radiation Oncology, P.C. and Raleigh Hematology Oncology Associates, P.C.

There are no written agreements between Raleigh Radiation Oncology, P.C. and Raleigh Hematology Oncology Associates, P.C.

7. A detailed description of the services to be provided by Raleigh Hematology Oncology at the new site, for the diagnosis, evaluation or treatment of cancer, including chemotherapy and lab services.

The services to be provided by Raleigh Hematology at the new site will be the same as are currently provided at its existing site. Attached hereto as Exhibit 4 is a copy of the pages from Raleigh Hematology's web site, identifying the services it provides. Please feel free to check the web site for any additional information you may need.

8. Documentation of the cost of all medical equipment to be utilized by Raleigh Hematology Oncology in the diagnosis, evaluation or treatment of cancer at the proposed building. In accordance with N.C. Gen. Stat. §131E-176(18a), in determining the cost of all medical equipment utilized by Raleigh Hematology Oncology at the new site, include *"the cost of any equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to the acquiring and making operational the facility,*

² US Oncology performs the actual billing and collection function on behalf of the provider as part of the management services it has contracted to perform.

program, or provider. . .” Provide a list of each piece of equipment or activity and related expenses for each, including upfit costs of the 45,000 square feet to be leased.

Raleigh Hematology does not own any medical equipment, and does not have current plans to acquire any medical equipment at the new site. It currently leases three items of medical equipment, but those leases are not capital leases. Once the lease term ends, the medical equipment is returned to the lessor, and newer medical equipment is leased on similar terms. The only medical equipment to be utilized by Raleigh Hematology at the new site will be the equipment which it currently leases, which is comprised of:

1. One Beckman Coulter HMX (which measures complete blood counts). Although it is not owned and will not be acquired by Raleigh Hematology, its current estimated fair market value is \$15,000.³
2. One Dade Dimension AR Chemistry Analyzer (which analyzes serum chemistries, such as sodium, potassium and chloride). Its current fair market value is \$10,000.
3. One Abbot HMX (which is used for immuno-assay tests, i.e., tumor markers). It is over four years old, and its fair market value is approximately \$1,000.
4. One T660 Coulter, which is used solely as a back-up in the event that the Beckman Coulter HMX is out of operation. Due to its age, its fair market value is negligible.

Because this medical equipment already is operational, nothing is required to make it operational, and because it is leased, Raleigh Hematology has no capital costs associated with the equipment. Raleigh Hematology already has its own furniture, and the space already is configured as medical office space. The upfit costs associated with the physician offices operated by Raleigh Hematology Oncology will be approximately \$923,645. See letter from Thomas J. Crowder, AIA, NCARB, Architektur, P.A., Exhibit 5 hereto. Essentially, Raleigh Hematology is moving its existing medical practice to a new building two blocks down the street. Since there is no equipment being acquired by Raleigh Hematology, the only costs associated with in the move are the above upfit costs.

Please contact us if you have any questions or if you need any further information regarding this review. As I have advised your earlier, our client believes that unless we can obtain your office's approval of this project quickly, The Lewis Group will pursue other potential lessees for the space, making the project effectively impossible. Therefore, we would appreciate your attention to this request as quickly as

³ As discussed above, because the equipment is leased, and will not be purchased at the conclusion of the lease, we believe that its fair market value is irrelevant for your purposes. Nevertheless, per your request, our client has estimated the current fair market value of the equipment.

Ms. Hoffman and Ms. Edwards
June 13, 2001
Page 6

possible. In addition, I would appreciate it if you would fax a copy of any future correspondence on this issue directly to me, given the time constraints under which our client is operating.

Very truly yours,

BODE, CALL & STROUPE, L.L.P.

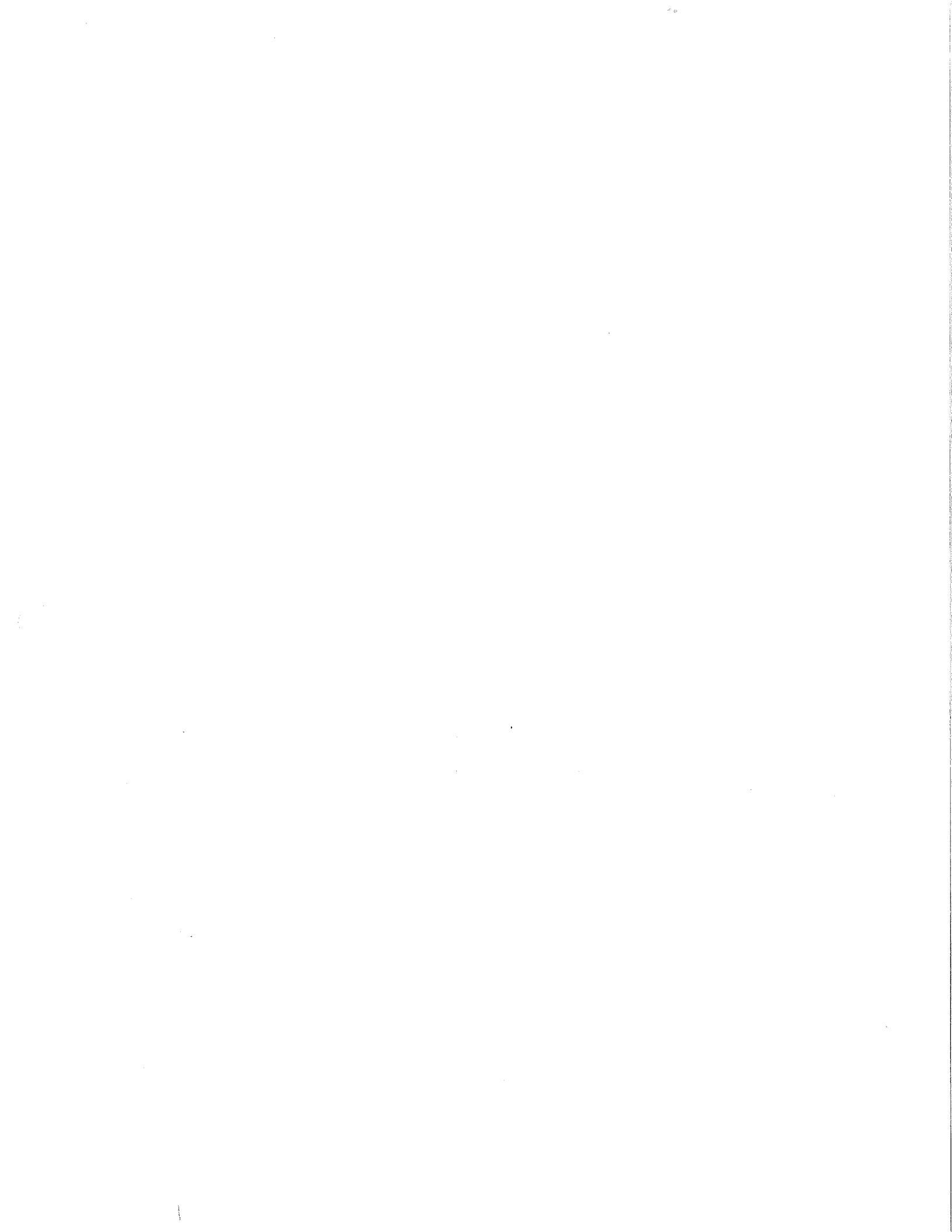
A handwritten signature in cursive script, appearing to read "Todd", written in black ink.

S. Todd Hemphill

STH/sh: 4016.000

INDEX OF EXHIBITS

1. Letter from Thomas J. Crowder, AIA, NCARB, Architektur, P.A., regarding transportation, installation and tax estimates
2. Letter from Tim Ochran, Vice President of Radiation, Clinical Services, US Oncology regarding taxes on equipment purchase
3. Floor plans
4. Raleigh Hematology Associates, PC web site information
5. Letter from Thomas J. Crowder, AIA, NCARB, Architektur, P.A., regarding upfit costs for Raleigh Radiation Oncology, Raleigh Hematology, and US Oncology





RECEIVED JUN 12 2001

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

Michael F. Easley, Governor
Carmen Hooker Buell, Secretary

Lee Hoffman, Section Chief
Phone: 919-733-6360
Fax: 919-733-8139

June 7, 2001

S. Todd Hemphill
Bode, Call & Stroupe, L.L.P.
3105 Glenwood Avenue, Suite 300
Raleigh, NC 27612

RE: Information Required for No Review Determination/Raleigh Radiation Oncology, P.C./Establish a radiation therapy practice/Wake County

Dear Mr. Hemphill:

The Certificate of Need (CON) Section has received your request for a determination as to whether the above mentioned project requires a certificate of need. In order for the CON Section to make such a determination, please submit the following information to this office:

1. A detailed itemization of all taxes to be paid on all equipment, furniture and other furnishings and goods included in the proposal.
2. Documentation of the cost of transporting the linear accelerator to the proposed vault.
3. A larger and more readable line drawing of the proposed office space, than the copy provided as Attachment 3, that clearly identifies the specific use of all space in the building.
4. The number of square feet for the entire building and the number of square feet designated for each of the components, separately: (a) Raleigh Radiation and (b) Raleigh Hematology.
5. Information about billing for treatment services, including the information about the provider number that will be used.
6. Copies of any agreements between Raleigh Radiation Oncology, P.C. and Raleigh Hematology Oncology Associates, P.C.
7. A detailed description of the services to be provided by Raleigh Hematology Oncology at the new site, for the diagnosis, evaluation or treatment of cancer, including chemotherapy and lab services.



Mr. S. Todd Hemphill

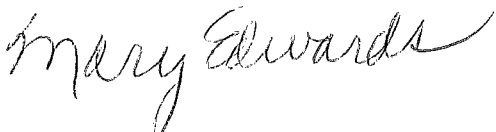
Page 2

June 7, 2001

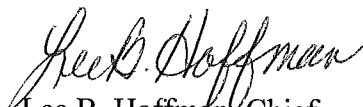
8. Documentation of the cost of all medical equipment to be utilized by Raleigh Hematology Oncology in the diagnosis, evaluation or treatment of cancer at the proposed building. In accordance with NCGS 131E-176(18a), in determining the cost of all medical equipment utilized by Raleigh Hematology Oncology at the new site, include *"the cost of any equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to the acquiring and making operational the facility, program, or provider . . ."* Provide a list of each piece of equipment or activity and related expenses for each, including upfit costs of the 45,000 square feet to be leased.

Your prompt response will assist the CON Section in making a timely review of your request. If you have any questions regarding this matter, please feel free to contact this office.

Sincerely,

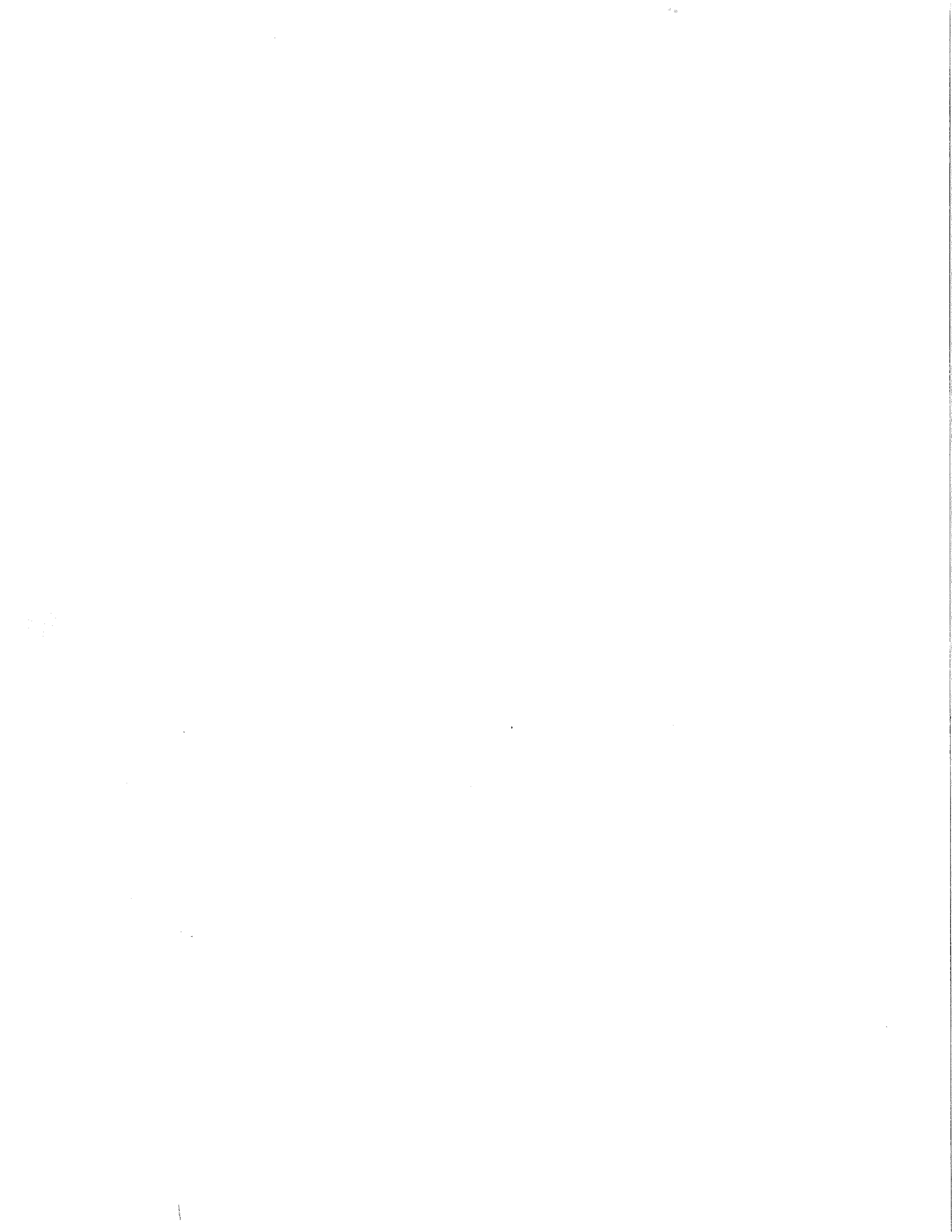


Mary Edwards
Project Analyst



Lee B. Hoffman, Chief
Certificate of Need Section

Enclosure



F

BODE, CALL & STROUPE, L.L.P.

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CHRISTIE M. FOPPIANO

May 7, 2001

Via Hand Delivery

Lee B. Hoffman, Chief
Certificate of Need Section
Division of Facility Services
701 Barbour Drive
Raleigh, North Carolina 27603

Re: Raleigh Radiation Oncology, P.C. / Request for "No Review" Letter, Wake County

Dear Ms. Hoffman:

We are writing you on behalf of our clients, Raleigh Radiation Oncology, P.C. and Raleigh Hematology Oncology Associates, P.C., requesting the CON Section to issue, pursuant to 10 NCAC 3R.0304, a letter determining that the following proposal to acquire a linear accelerator and provide radiation therapy services in Raleigh, Wake County, North Carolina, is not a new institutional health service, within the meaning of the certificate of need law.

The operative statute in this regard is N.C.Gen.Stat. §131E-176(18a), which defines an oncology treatment center as follows:

"Oncology treatment center" means a facility, program, or provider, other than an existing health service facility that provides services for diagnosis, evaluation, or treatment of cancer and its aftereffects or secondary results and for which the total cost of all the medical equipment utilized by the center, exceeds two hundred fifty thousand dollars (\$250,000). In determining whether costs are more than two hundred fifty thousand dollars (\$250,000), the costs of equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the facility, program, or provider shall be included.

Lee B. Hoffman
May 7, 2001
Page 2

The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater.

Where the costs essential to the development of the facility do not exceed \$250,000, the facility is not an oncology treatment center, and therefore is not a new institutional health service. N.C.Gen.Stat. §§131E-176(9b), 131E-176(16)a., and 131E-178(a). For the reasons set forth below, the costs essential to the development of this service will not exceed \$250,000.

Facts

Raleigh Hematology Oncology Associates, P.C. ("Raleigh Hematology") is a North Carolina professional corporation engaged in the practice of medical oncology. The physician owners of Raleigh Hematology intend to set up a new professional corporation known as Raleigh Radiation Oncology, P.C. ("Raleigh Radiation"), for the purpose of providing radiation oncology services in Raleigh, North Carolina. The Articles of Incorporation of Raleigh Hematology are attached hereto as Exhibit 1. The proposed Articles of Incorporation of Raleigh Radiation are attached hereto as Exhibit 2. We anticipate that the Articles of Incorporation of Raleigh Radiation will be filed by the end of this week.¹ Raleigh Radiation will lease space to provide its services in the former Kaiser Permanente building located at the intersection of Duraleigh Road and Edwards Mill Road in Raleigh (hereinafter, the "Building"). The Building is owned by The Lewis Group (hereinafter, "Lessor"), an unrelated North Carolina limited liability company. Raleigh Radiation will acquire all essential radiation oncology equipment, and will be directly responsible to the contractor for all construction costs associated with the development of the radiation oncology service.

In addition, Raleigh Hematology will relocate its current offices from Rex Hospital to the Building. Attached as Exhibit 3 is a floor plan² of the proposed space in the Building to be leased by Raleigh Radiation and Raleigh Hematology. Raleigh Hematology will lease approximately 45,000 square feet of space on the first floor and the second floor of the building.

¹ Because Raleigh Radiation Oncology, P.C. will be a professional corporation, the Board of Medicine must verify that all of the shareholders are licensed physicians, before the Articles of Incorporation can be filed.

² Letter-sized floor plans of the first floor and the second floor are included, as well as a larger floor plan of the first floor showing only the currently existing space which will be upfit for the radiation oncology service. Please note that this is the *existing* floor plan. That is why there is a reference to a mental health suite on the larger plan.

Lee B. Hoffman
May 7, 2001
Page 3

The spaces to be separately leased by Raleigh Radiation are located on the first floor, as shown on Exhibit 3. Raleigh Radiation will upfit approximately 5,000 square feet of existing space, comprised of changing rooms, a dark room, and various offices and storage space.³ In addition, Raleigh Radiation will construct a control room and vault immediately adjacent to the other leased radiation space.⁴ Radiation therapy procedures will be performed by staff operating from the control room. The darkroom will be used for developing x-rays used for treatment field verification and setup.

Services to be provided by the radiation oncology facility will include:

- treatment scheduling
- patient consultation;
- patient examination; and
- radiation treatment with the use of high energy X-rays.

Treatment simulation and treatment planning will be performed off-site, through arrangements with Rex Hospital, or through another existing radiation oncology facility or hospital in Raleigh.

Raleigh Radiation's costs associated with the upfit of the above space and the acquisition of all necessary equipment is estimated to be \$242,768.63, as set forth in the architect's letter and certified construction cost estimate attached hereto as Exhibit 4, the Centre Construction Group, Inc. construction estimate attached as Exhibit 5, and the Varian Medical Systems equipment cost estimate attached hereto as Exhibit 6.⁵ Raleigh Radiation will acquire no other equipment and will incur no other capital cost with regard to this proposal.

Raleigh Hematology will separately provide professional services to cancer patients, including the following:

- patient consultation;
- patient examination;
- medical oncology treatment;

³ Due to the fact that the space was most recently used as medical offices, there is very little cost involved in upfitting the existing office space.

⁴ The space in which the control room and vault are located will then be owned by and leased from The Lewis Group at the same rate as the other space.

⁵ The addressee on those documents is identified as US Oncology. US Oncology is the manager of Raleigh Hematology Oncology Associates, P.C.'s office, and will be the manager of Raleigh Radiation Oncology, P.C.'s office.

- nutritional counseling; and
- patient screening, education, early detection and public awareness programs.

The upfit of the space to be occupied by Raleigh Hematology will be borne solely by Raleigh Hematology, and none of these costs directly relate to the provision of radiation therapy.

Raleigh Radiation will lease its separate space from The Lewis Group pursuant to an operating lease. A Letter of Intent from The Lewis Group evidencing its willingness to enter into the lease is attached hereto as Exhibit 7. The lease will be an operating, not a capital lease, and Raleigh Radiation will have no right to purchase the premises (or any part thereof) at the conclusion of the lease term.

Discussion

New Institutional Health Service

To determine whether a proposed facility is an "oncology treatment center" under the above statute, the only costs to be considered are "the costs of equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational *the facility, program, or provider.*" N.C.Gen. Stat. §131E-176(18a) (emphasis added). The other separate capital costs of the physician office space of Raleigh Hematology which are not attributable to the service to be provided should not be considered. Indeed, a physician office building *per se* is exempt from certificate of need review, irrespective of the cost. N.C.Gen.Stat. §131E-184(9). Only when a particular service offered in that physician office building otherwise may be a new institutional health service, may the costs of such service be considered in making such a determination. Therefore, the cost thresholds in N.C.Gen. Stat. §131E-176(18a) would not apply to the upfit costs associated with the relocation of that physician practice.

The facts presented show that the costs associated with the acquisition of the linear accelerator and other essential equipment, together with the construction and development costs associated with the radiation oncology facility, total \$242,768.63,⁶ which is below the statutory \$250,000 threshold. That being the case, the proposed service is not a new institutional health service, and would not require a

⁶ In addition, Raleigh Radiation and its architect have made every effort to make sure that this projected capital cost is *the most* this project will cost. In that regard, the high end of Varian's projected linear accelerator acquisition (\$30,000) and installation (\$25,000) cost estimates are included in the architect's total cost estimate. See Exhibits 4 and 6. In addition, the architect has included a 5% contingency of \$8,383 on the total construction cost estimate. See Exhibit 4.

Lee B. Hoffman
May 7, 2001
Page 5

certificate of need.

Conclusion

Based upon our research and analysis of the facts, the proposed acquisition and provision of radiation services is exempt from review. It is our opinion that the CON Section should determine that Raleigh Radiation's proposal is not subject to certificate of need review and issue its letter of "no review."

Please contact us if you have any questions or if you need any further information regarding this review. The Lewis Group has advised our client that time is of the essence in signing the lease, as there have been other parties interested in the space. Therefore, we would appreciate your attention to this request at your earliest convenience.

Very truly yours,

BODE, CALL & STROUPE, L.L.P.



S. Todd Hemphill

STH/sh: 4016.000

INDEX OF EXHIBITS

1. Articles of Incorporation of Raleigh Hematology Oncology Associates, P.C.
2. Proposed Articles of Incorporation of Raleigh Radiation Oncology, P.C.
3. Floor plan
4. Letter from Thomas J. Crowder, AIA, NCARB, Architektur, P.A., with certified construction cost estimate
5. Centre Construction Group, Inc. construction bid
6. Letter from Kevin A. Cassidy, Major Accounts Manager, Varian Medical Systems, regarding linear accelerator cost estimate
7. Letter of Intent from The Lewis Group regarding lease of the radiation oncology space

Appendix 2



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

2704 Mail Service Center ■ Raleigh, 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

March 11, 2004

S. Todd Hemphill
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Raleigh NC 27612

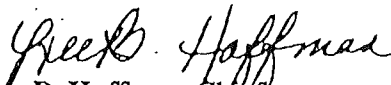
RE: No Review/ Raleigh Hematology Oncology Associates, P.C./ Relocation of an existing oncology treatment center to leased space and acquisition of a Linear Accelerator, CT scanner, and Treatment Planning Equipment/ Wake County

Dear Mr. Hemphill:

In response to your letters of February, 25, 2004, and September 23 and December 23, 2003, the proposal described in your correspondence is not a new institutional health service as defined in N.C.G.S. 131E-176(16) and, therefore, does not require a certificate of need. 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 the 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 original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

Please contact this office if you have any questions.

Sincerely,


Lee B. Hoffman, Chief
Certificate of Need Section

LBH:mhb

cc: Medical Facilities Planning Section, DFS



F

BODE, CALL & STROUPE, L.L.P.

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S. TODD HEMPHILL
DIANA EVANS RICKETTS
CHRISTIE M. FOPPIANO

February 25, 2004

Hand Delivery

Lee B. Hoffman, Chief
Certificate of Need Section
Division of Facility Services
701 Barbour Drive
Raleigh, North Carolina 27603

Re: Raleigh Hematology Oncology Associates, P.C./Relocation and Medical
Equipment Acquisition Request

Dear Ms. Hoffman:

This letter is to address some questions you raised in our February 5, 2003 meeting related to our September 23, 2003 letter, requesting that you confirm that (1) the relocation of our client's existing oncology treatment center, (2) the acquisition of a linear accelerator, (3) the acquisition of a CT scanner and (4) the acquisition of treatment planning equipment, is not a new institutional health service, within the meaning of the CON law. The specific issues raised are addressed below.

Calculation of Space Attributable to Each Service

As we discussed, the entire space on Exhibit 1 to my September 23, 2003 letter is the relocated oncology treatment center. Within that facility, following are the spaces related to the equipment described above:

Linear Accelerator

| | |
|-----------------|---------------------------------|
| Vault | 1,705 sq.ft. |
| Control room | 180 sq.ft. |
| Mold Room | 99 sq.ft. |
| Mechanical room | 180 sq.ft. |
| TOTAL | 2,144 sq.ft.¹ |

¹ Contrary to our earlier assumption, a dark room will not be necessary for the operation of either the linear accelerator or the CT scanner. Therefore, the space identified in Exhibit 1 as "DARKRM" will simply be storage space.

Treatment Planning Equipment

Treatment planning room 204 sq.ft.

CT Scanner

CT room 504 sq.ft.

Control room 135 sq.ft.

TOTAL 639 sq.ft.²

Calculation of Developer Base Cost

You asked us to provide an explanation of how the developer's base cost was calculated in Exhibit 2 to my September 23, 2003 letter, as opposed to costs which have been attributed to the oncology treatment center and the equipment to be acquired. Developer's base cost is the cost which the developer will incur to build a basic medical office building. Only where such cost can be directly attributed to upfit of space that is necessary to make the equipment or health service operational, has that cost been attributed to the service.

For instance, with radiation oncology, the space which is necessary to make the linear accelerator operational is the vault, the control room, the mold room, and the mechanical room. Because the vault is a unique space, which has no other practical purpose, all of the "hard" construction costs related to that space were included in Exhibit 2. In addition, estimated "soft" construction costs, such as architect and engineering fees, bonds, permits, etc., were included in the cost of radiation oncology.

With regard to the control room, mold room and mechanical room, unlike the vault, these are simply general office space, with some additional upfit related to the operation of the linear accelerator. The costs attributed to the linear accelerator are the hard and soft costs related to the upfit of those spaces necessary to operate the linear accelerator. For instance, the mechanical room will require the installation of a chiller, to ensure that the linear accelerator does not overheat. Additional HVAC and electrical upgrades will be necessary, which have been included in the costs attributable to the linear accelerator.

The same is true for space related to the treatment planning room, the CT scanner room and the medical oncology space. To the extent that each of those spaces is general office space, hard and soft costs are attributed to the developer's base costs. Only those additional upfit and related costs directly related to making either the equipment or the medical service operational are attributed to the cost thresholds. Where there are soft costs related to that upfit (as with the CT room, as described in the attachment to my December 23, 2003 letter to you), they have been included in the calculation.

² There also is a 54 sq.ft. rest room attached to the CT scanner room, as a convenience to patients. Per our discussion, you advised that this space need not be included in the cost calculation for the CT scanner, since it is not essential to the operation of that equipment.

Calculation of Radiation Oncology Costs

Attached hereto as Exhibit 2A is a revised certified capital cost form, providing more specificity regarding the spaces described above. We also have included a breakdown of all of the costs for each space related to the operation of the linear accelerator. This cost is a refinement of the cost estimates in our September 23, 2003 letter, and was developed by the developer and our client through a more detailed determination of actual construction costs on similar projects, as well as contacts with subcontractors. As you can see from the bottom line, based on these refinements, we expect that the total cost attributable to the linear accelerator actually will *decrease* from the projection of \$747,134, in Exhibit 2 of my September 23, 2003 letter, to \$738,358.

Following is a discussion of significant revisions to the capital costs, as reflected in Exhibit 2A:

- The developer has revised the cost of bonds, insurance, surveys and testing (Line 1) has been revised. In addition, the costs previously identified in Line 7 (permits and fees for impact studies, etc.) have been incorporated into Line 1. Based on the developer's experience, this total cost should be approximately 2.5% of the construction costs (Line 33). These costs previously had been allocated pro rata to the linear accelerator based on square footage. The developer concluded that such an allocation was not as accurate as projected here.
- The developer has also revised cost estimates on Lines 4 (architect and engineering fees), 5 (construction management fees), 11 (consultants) and 34 (contingency), on a percentage of construction cost basis. Again, this is based on the developer's experience with similar projects, and replaces the less accurate allocation based on square footage.
- Construction costs (line 33) have been further refined. In this regard, attached as Exhibit 2B is a breakdown of all costs related to the linear accelerator, other than equipment costs. This breakdown now includes the specific costs related to the vault, the mechanical room and the mold room. As you can see from that document, the total cost of construction related to the linear accelerator is \$343,030.35. If you add all movable equipment (line 14, \$34,063), fixed equipment (line 15, \$346,680), cost of financing (line 22, \$11,035) and legal fees associated with the project (line 23, \$3,551), the total expenditure related the linear accelerator will be \$738,359, as reflected in Exhibit 2A.

Calculation of Medical Oncology Costs

We have also reconsidered costs related to the relocation of the existing oncology treatment center, and determined that there will be certain upfit costs for the medical oncology space which might not typically be included in a physician office. Those costs relate to the installation of additional HVAC supply, a sink and additional electrical outlets in the pharmacy and lab areas. They are included in the capital cost form in Exhibit 2A, under the "Other Costs" column, and also are broken out in Exhibit 2C, attached. We have also included in Line 11 of

Exhibit 2A estimated consultation fees not previously included. As you will see from that Exhibit 2A, the overall cost related to the oncology treatment center still remains significantly below \$2,000,000.

Calculation of CT Scanners Costs

As per the letter from Mark A. Kury, Vice President of Centex Concord, attached to my December 23, 2003 letter to you, the projected costs of \$38,000 associated with the upfit of the CT room include all costs associated with converting that space for CT use. There were no additional upfit costs related to the control room. A copy of Mr. Kury's letter is attached hereto as Exhibit 2D.

Miscellaneous Questions

Following are responses to specific questions or concerns you raised during our meeting:

- Exhibit 2, line 34, contingency costs - You asked why there were no contingency costs associated with anything other than the linear accelerator. The reason is that the contingency cost for the linear accelerator was related to the cost of the construction of the vault, which is entirely attributed to the linear accelerator, and is based on the square footage of the vault relative to the square footage of the entire building. With regard to the other space related to the acquisition of equipment, the base square footage is the developer's base cost, and any contingency would relate to that base cost. Only incremental upfit costs are included in costs attributable to the equipment. The developer has been able to narrow down those upfit costs to the extent that no contingency cost is likely.
- Sales taxes on equipment - You indicated that some of the invoices attached to our September 23, 2003 letter did not include sales taxes. However, if you will look at the equipment detail sheets in Exhibits 3, 5 and 7 to the letter, you will see that sales tax, where applicable, has been included with each item. Some equipment is already US Oncology equipment located at another facility, which will be transferred to the Raleigh location (e.g., simulation software identified in Exhibit 7). The fair market value of that equipment has been included in the cost calculations. However, no sales tax has been included, as there will be none.
- Cost of installation and training - Our client has been advised by the vendors that the cost of equipment de-installation and installation, as well as employee training, is included in the price of the equipment.
- Exhibit 2, line 18, moving costs - No costs were included there, as they were included as part of line 16. Moving costs have been broken out of line 16 and moved to line 18 in Exhibit 2A, attached. Our clients estimate that this cost will be in the vicinity of \$10,000.

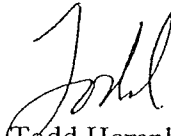
Ms. Hoffman
February 25, 2004
Page 5

- You have advised that net cost should not include any trade-in allowance for replacement equipment. That is not applicable here, and no trade-in allowance is included in any of the estimates.
- Signage costs – The total signage cost is \$10,000. The developer estimated that the outside signage would be \$5,000, and should be attributable to the developer, since they would have to put a similar sign up outside any building they develop. The inside signage cost of \$5,000 has been attributed to the oncology treatment center costs.

I believe that the above addresses all of the questions raised. Please contact me at your earliest convenience if you should need any further information regarding this request. We are prepared to promptly address any further questions you may have.

Very truly yours,

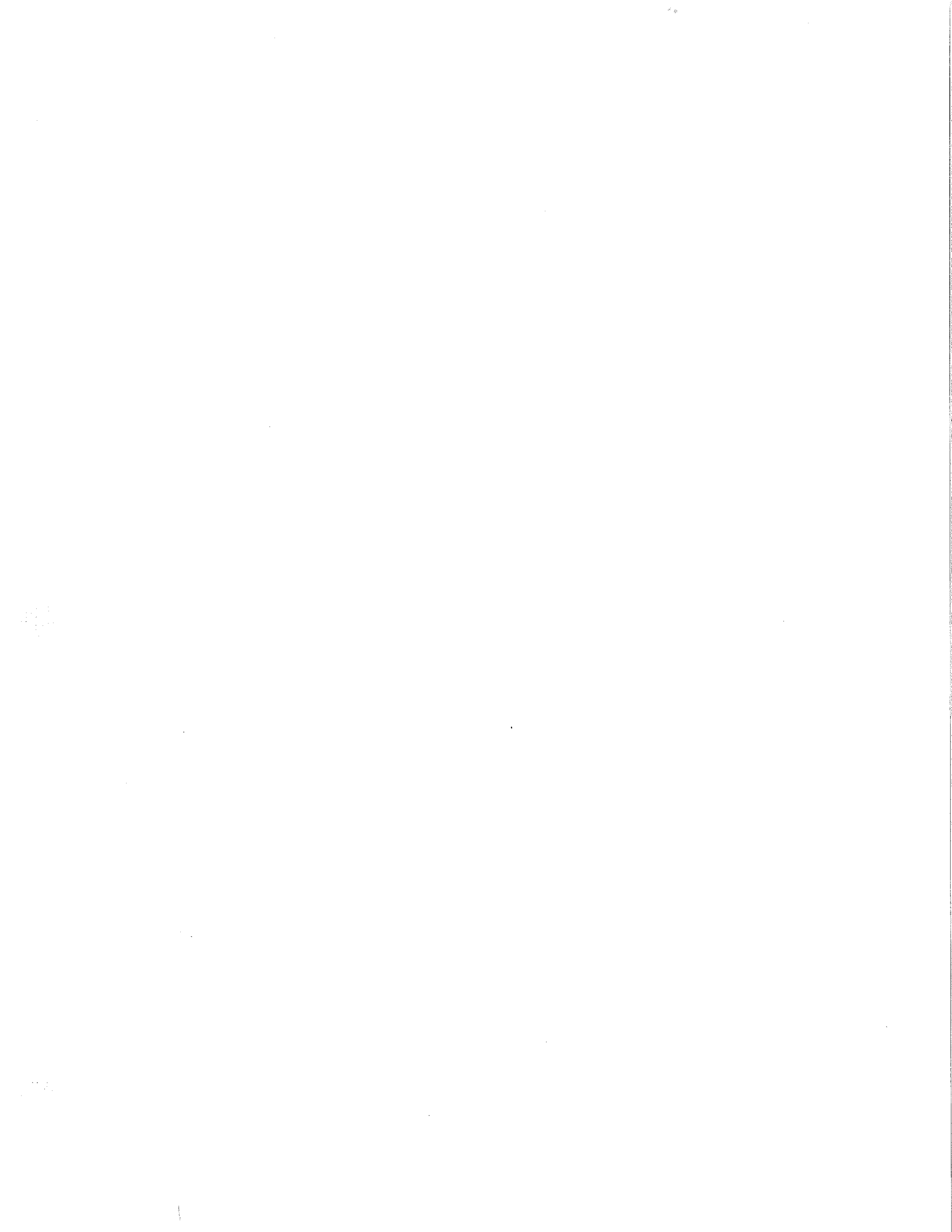
BODE, CALL & STROUPE, L.L.P.



S. Todd Hemphill

STH:sh
Enclosure

cc w/enc.: Melissa L. Trippe
Special Deputy Attorney General



BODE, CALL & STROUPE, L.L.P.

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JAMES N. JORGENSEN
CHRISTIE M. FOPPIANO

December 23, 2003

Hand Delivery

Lee B. Hoffman, Chief
Certificate of Need Section
Division of Facility Services
701 Barbour Drive
Raleigh, North Carolina 27603

Re: Raleigh Hematology Oncology Associates, P.C./Relocation and Replacement Equipment
Exemption Request

Dear Ms. Hoffman:

Per your request, please find enclosed a letter from Mark A. Kury, Vice President of Centex Concord, providing a break-out of the projected costs of \$38,000 associated with the upfit of the CT room for the above project, as set forth in Exhibit 2 to my September 23, 2003 letter to you.

Please contact me at your earliest convenience if you should need any further information regarding this request. Our client is anxious to proceed with this project, and we are prepared to promptly address any further questions you may have.

Very truly yours,

BODE, CALL & STROUPE, L.L.P.

S. Todd Hemphill

STH:sh
Enclosure



COMPREHENSIVE RESOURCES
FOR HEALTHCARE PROVIDERS

SENT VIA OVERNIGHT DELIVERY

December 22, 2003

Lee B. Hoffman
Chief Certificate Need Section
Division of Facilities Services
701 Barbour Dr.
Raleigh, NC 27603

RE: Raleigh Hematology Oncology Associates, P.C./Proposed Cancer Center

Dear Ms. Hoffman:

This letter is in response to your question regarding the cost to up-fit a CT room in the aforementioned proposed Cancer Center in Raleigh, North Carolina.

The \$38,000 cost to up-fit a standard room with shielding, electrical, HVAC and necessary cabinetry required to make the CT scanner operational includes architect and engineering fees, construction management, permits and fees, cost of financing, interest during construction and all other relevant project costs. Attached is a summary of the costs that make up the \$38,000.

Please feel free to contact us should you have any additional questions.

Sincerely,



Mark A. Kury
Vice President

MAK/ss

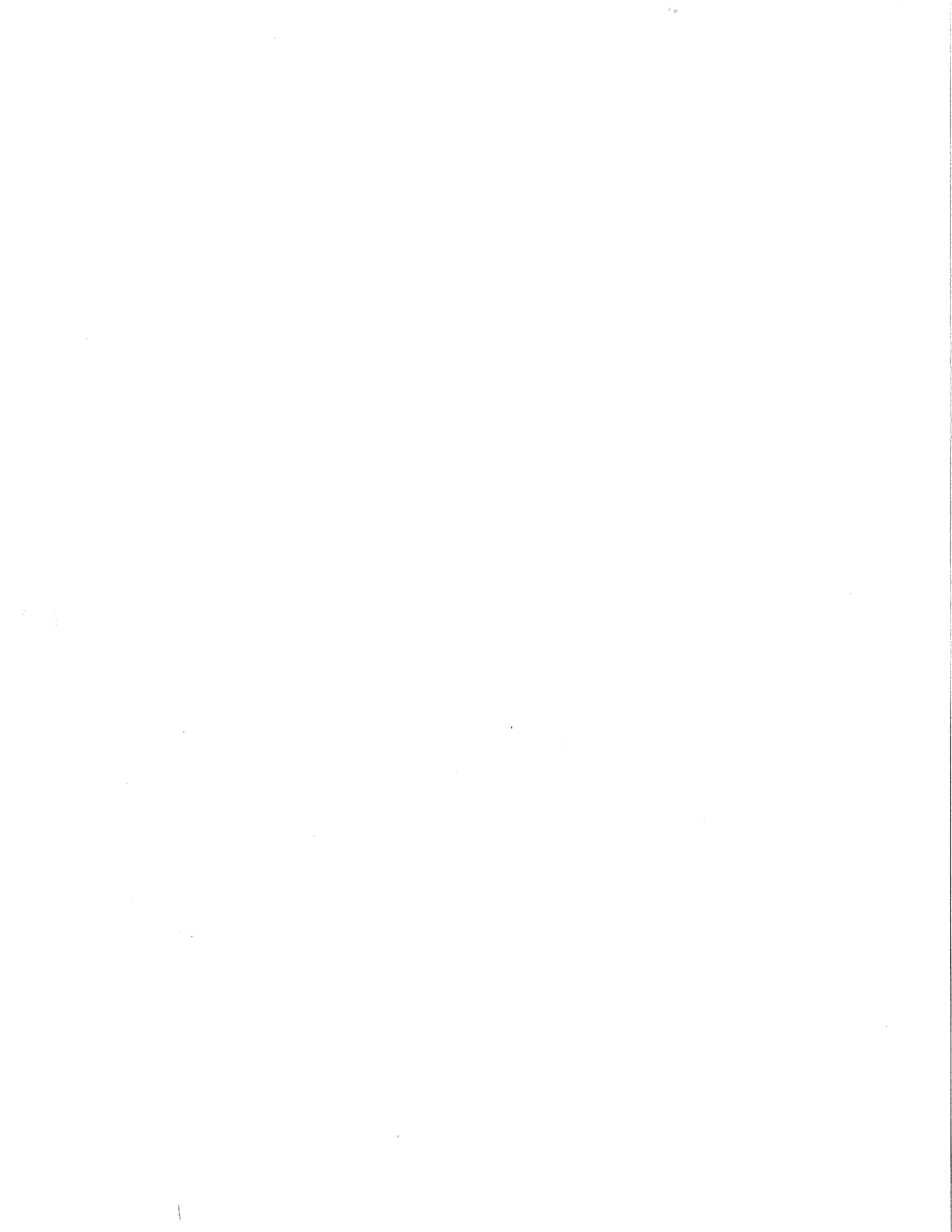
Attachment

cc: S. Todd Hemphill

CONSTRUCTION COST OF UPGRADING STANDARD ROOMS

| Description of Work | Cost |
|---|--------------|
| TO CT ROOM | |
| Total Costruction Cost | \$ 34,475.00 |
| <i>Leaded Glass</i> \$ 3,000.00 | |
| <i>Electrical</i> \$ 9,500.00 | |
| <i>AC (assumes part of base system)</i> \$ 7,500.00 | |
| <i>Control Desk/Storage (25 LF x 175)</i> \$ 4,375.00 | |
| <i>Leaded Wall</i> \$ 5,900.00 | |
| <i>Lead Lined Doors & Frames (2x)</i> \$ 4,200.00 | |
| Permits/Bonds | \$ 775.69 |
| Misc Legal/Financing Fees | \$ 689.50 |
| A&E Fees | \$ 2,068.50 |
| Total | \$ 38,008.69 |

~~CONFIDENTIAL~~



BODE, CALL & STROUPE, L.L.P.

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JAMES N. JORGENSEN
CHRISTIE M. FOPPIANO

September 23, 2003

Hand Delivery

Lee B. Hoffman, Chief
Certificate of Need Section
Division of Facility Services
701 Barbour Drive
Raleigh, North Carolina 27603

Re: Raleigh Hematology Oncology Associates, P.C./Relocation and Replacement Equipment
Exemption Request

Dear Ms. Hoffman:

We represent Raleigh Hematology Oncology Associates, P.C. ("Raleigh Hematology"), which is a North Carolina professional corporation engaged in the practice of medical oncology.

Raleigh Hematology owns and operates a physician practice and an oncology treatment center at 4420 Lake Boone Trail, Raleigh, N.C. By this letter, we are requesting that your office issue a no review letter determining that the relocation and equipment acquisition described herein does not require a certificate of need.

Raleigh Hematology was established in 1979, as a medical partnership, by Dr. William R. Berry. The purpose of the practice was, and continues to be, to provide oncology services, including medical oncology, hematology, pharmacy and other related services. Over the course of its practice, Raleigh Hematology constructed space and acquired medical equipment valued in excess of \$250,000. In 2001, we submitted a request asking you to determine that Raleigh Hematology operated a grandfathered oncology treatment center, within the meaning of the CON law. By letter dated June 29, 2001, you issued that determination.

Raleigh Hematology has now entered into a tentative agreement with Centex Development Company ("Centex")¹ to lease space in a new building to be constructed by Centex in Raleigh, North

¹ Centex is not related by common ownership to Raleigh Hematology or its management company, US Oncology. Centex's sole benefit from this project will be the rental payments associated with leasing space.

Carolina. Centex and our client are looking at several sites, all of which are within approximately three miles of Raleigh Hematology's current offices. Raleigh Hematology will lease its space pursuant to an operating lease. The cost of acquiring the site and constructing the building will be borne by Centex.

Our client also intends to purchase a linear accelerator, a CT scanner, and treatment planning equipment, which will be installed during the upfit of the leased space. The equipment will be placed on line at the same time that the oncology treatment center is moved. As set forth in more detail below, Raleigh Hematology will bear the cost for the upfit of space to the extent that such upfit is essential to the operation of the medical equipment to be acquired. All other construction costs not directly attributable to the installation and operation of this equipment will be part of the developer's base costs.

To assist you in understanding what space has been attributed to each aspect of the project, we have enclosed as Exhibit 1 a line drawing of the entire space. The linear accelerator vault, the CT scanner room, and the treatment planning room are all on the left-hand side of the line drawing, and are clearly marked.

We have been requested by our client to request that you confirm that the relocation of the existing oncology treatment center, and the acquisition of a linear accelerator, CT scanner and treatment planning equipment, is not a new institutional health service, within the meaning of the CON law.

Acquisition and Installation of Linear Accelerator

The question of whether an existing oncology treatment center may acquire a linear accelerator without a certificate of need turns upon whether the linear accelerator is major medical equipment, within the meaning of the CON law. "Major medical equipment" means

a single unit or single system of components with related functions which is used to provide medical and other health services and which costs more than seven hundred fifty thousand dollars (\$750,000). In determining whether the major medical equipment costs more than seven hundred fifty thousand dollars (\$750,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the major medical equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater...

G.S. 131E-176(14f). Here, the linear accelerator is not major medical equipment, because the cost to acquire and make operational that equipment does not exceed \$750,000. As set forth in the certified capital cost form attached as Exhibit 2 the total cost associated with the linear accelerator will be \$747,134. The assumptions associated with the breakdown of capital costs for the project are at the end of Exhibit 2. As set forth at the beginning of Exhibit 2, the capital cost form is certified by John L. Thompson, Jr., a licensed North Carolina architect. The actual cost of the linear accelerator and related equipment is \$380,743, and is broken out in further detail in the chart attached as Exhibit 3 and the vendor

quotes attached as Exhibit 4.²

The construction costs associated with the radiation oncology portion of the project are the actual cost to upfit the vault. The shelved in space for control room, dark room and mold room are not included, because that cost will be borne by the developer,³ and there are no special construction costs (such as shielding or additional electrical requirements) associated with the construction of those spaces. However, all equipment in those rooms essential to the operation of the linear accelerator is included.

Because Raleigh Hematology's cost to acquire and make operational the linear accelerator does not exceed \$750,000, it is our opinion that the acquisition of that equipment is not a new institutional health service and that a no review letter can be issued for that acquisition.

Acquisition of CT Scanner

As with the linear accelerator, the question of whether the acquisition of CT scanner would require a CON turns on the question of whether it is major medical equipment. In addition, because a CT scanner is medical diagnostic equipment, the statute related to diagnostic centers comes into play.

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

G.S. 131E-176(7a).

Raleigh Hematology is not a diagnostic center. Therefore, in order to acquire a CT scanner (which would be the only medical diagnostic equipment owned or operated by Raleigh Hematology) without CON review, the cost of acquiring and making that equipment operational may not exceed \$500,000.

As set forth in the certified capital cost form attached as Exhibit 2 the total cost associated with the CT Scanner will be \$495,048. The actual cost of the CT scanner and related equipment is \$457,048, and is broken out in further detail in the chart attached as Exhibit 5 and the vendor quotes attached as Exhibits

² The quotes included are for pieces of equipment to be purchased that are greater than \$1,000, as well as a few quotes for individual pieces of equipment that add up to over \$1,000. Costs for new equipment valued at less than \$1,000 are based on US Oncology experience. In addition, certain items of used equipment are currently owned by US Oncology, and will be transferred from a facility that has been recently closed. The items are 3 to 4 years old, and US Oncology has estimated their fair market value in the chart attached as Exhibit 3.

³ The developer's base costs related to its construction of the building are included in a separate column in Exhibit 2.

6. The construction cost associated with the CT scanner is the actual cost to upfit the space identified. Again, the shell space for the building is not included, because that will be borne by the developer.

Because Raleigh Hematology's cost to acquire and make operational the CT scanner does not exceed \$500,000, it is our opinion that the acquisition of that equipment is not a new institutional health service and that a no review letter can be issued for that acquisition.

Acquisition of Treatment Planning Equipment

As with the linear accelerator, the question of whether the acquisition of treatment planning equipment would require a CON turns on the question of whether it is major medical equipment. As set forth in the certified capital cost form attached as Exhibit 2, the total cost associated with the treatment planning equipment will be \$153,400. The actual cost of the treatment planning computer and related simulation software is broken out in further detail in the chart attached as Exhibit 7. The vendor quote for the treatment planning hardware is included in the quote for the linear accelerator, Exhibit 4. The simulation software quote is based on a fair market value estimate from GE (see Exhibit 8), because it is currently owned by US Oncology, and will be transferred from a facility which it closing and installed on the treatment planning computer. There is no construction cost associated with the installation of the treatment planning equipment, because no special construction (such as shielding or additional electrical requirements) is required to operate this equipment.

Because Raleigh Hematology's cost to acquire and make operational the treatment planning equipment does not exceed \$750,000, it is our opinion that the acquisition of that equipment is not a new institutional health service and that a no review letter can be issued for that acquisition.

Relocation of Oncology Treatment Center

With regard to the relocation of the oncology treatment center, the only issue involved is whether the capital costs associated with that relocation will cost in excess of \$2,000,000. According to G.S. 131E-176(b), included among new institutional health services is

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. The cost of any studies, surveys, designs, plans, working drawings, specifications, and other activities, including staff effort and consulting and other services, essential to the acquisition, improvement, expansion, or replacement of any plant or equipment with respect to which an expenditure is made shall be included in determining if the expenditure exceeds two million dollars (\$2,000,000).

As set forth in the certified capital cost form attached hereto as Exhibit 2, Raleigh Hematology's total capital costs related to the relocation of the oncology treatment center, unrelated to the acquisition and installation of the above equipment, will be \$364,528. Raleigh Hematology will bear no construction costs related to the relocation of the oncology treatment center, other than the costs discussed above related to the linear accelerator, the CT scanner and the treatment planning equipment; rather, this cost

will be borne by the developer. Vendor quotes related to the cost of medical equipment to be purchased for the relocated oncology treatment center are attached as Exhibit 9.

The combination of the costs related to the acquisition of the linear accelerator (\$747,134), the acquisition of the CT scanner (\$495,048), the acquisition of treatment planning equipment (\$153,400) and the relocation of the oncology treatment center (\$364,528), totals \$1,760,110, well below the \$2,000,000 threshold. Therefore, the relocation of the oncology treatment center is not a new institutional health service within the meaning of the CON law.

We have enclosed with this letter an exhibit notebook which contains the following:

1. Line drawing of new office space;
2. Cancer Center cost breakdown chart, with letter from John L. Thompson, Jr., licensed architect, certifying construction costs;
3. Equipment cost breakdown, linear accelerator and miscellaneous radiation therapy equipment;
4. Vendor quotes, linear accelerator, treatment planning hardware and miscellaneous radiation therapy equipment;
5. Equipment cost breakdown, CT scanner and related equipment;
6. Vendor quotes, CT scanner and related equipment;
7. Equipment cost breakdown, treatment planning equipment;
8. GE fair market value estimate for treatment planning equipment; and
9. Vendor quotes, miscellaneous oncology treatment center medical equipment.

We respectfully request that you review the attached documentation and provide us at your earliest convenience with a no review letter stating that the relocation of the existing oncology treatment center and physician office, and the acquisition of a linear accelerator, CT scanner and treatment planning equipment, do not require certificate of need review and are not new institutional health services, within the meaning of the CON law.

Please let me know if you need further information or if there are questions I can answer. I look forward to hearing from you shortly.

Very truly yours,

BODE, CALL & STROUPE, L.L.P.



S. Todd Hemphill

Appendix 3



Section 2: Equipment and Procedures Information

Time Period for Report: 10/01/2012 – 9/30/2013 Other time period: _____

(Please make additional copies of pages of this form as needed.)

| | Linear Accelerator Number 1 | Linear Accelerator Number 2 | Total Units |
|---|---|--|-----------------------------------|
| Serial or I.D. Number | 1009 | M2896 | 2 |
| Model Number | 2100 CD | Primus | |
| Manufacturer | Varian | Siemens | |
| Certificate of Need Project ID | None | J5464-96 | |
| Date of Purchase | 3/16/2005 | 7/01/1998 | |
| Purchase Price | \$325,460.58 | \$1,460,426.00 | |
| Service Site Information: Please include all of the information requested for each location. | Service Site <u>CCNC-Macon Pond</u> Address <u>4101 Macon Pond Rd</u> City, State, Zip <u>Raleigh, NC 27607</u> County <u>Wake</u> | Service Site <u>CCNC-Cary Rad</u> Address <u>300 Ashville Ave</u> <u>Suite 300</u> City, State, Zip <u>Cary, NC 27518</u> County <u>Wake</u> | |
| Configured for stereotactic radiosurgery? | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Total Configured Units 0 |
| Number of unduplicated patients* who received radiation oncology treatment on the linear accelerator | 385 | 282 | Total Patients 667 ✓ |

* Patients shall be counted once if they receive one course of radiation oncology treatment using the linear accelerator and more if they receive additional courses of treatment. For example, one patient who receives one course of treatment counts as one, and one patient who receives three courses of treatment counts as three. The number of patients reported here should match the number of patients reported in the Linear Accelerator Treatment Patient Origin chart on page 4 of this report.

Name of entity that acquired the equipment (from page 1) Cancer Centers of North Carolina, P.C.



Section 2: Equipment and Procedures Information continued

| | Simulator** Number 1 | Simulator Number 2 | Total Units |
|--|--|--|----------------------------|
| Serial or I.D. Number | 919787USCT | 4125 | 2 |
| Model Number | Lightspeed Qx/I CT Scanner | SimView 3000 | |
| Manufacturer | GE | Siemens | |
| Certificate of Need Project ID | None | J5464-96 | |
| Date of Purchase | 3/08/2005 | 7/01/1998 | |
| Purchase Price | \$402,841.00 | \$464,658.00 | |
| Service Site Information: Please include all of the information requested for each location. | Service Site <u>CCNC-Macon Pond</u> Address <u>4101 Macon Pond Rd</u> City, State, Zip <u>Raleigh, NC, 27607</u> County <u>Wake</u> | Service Site <u>CCNC-Cary Rad</u> Address <u>300 Ashville Ave</u> <u>Suite 300</u> City, State, Zip <u>Cary, NC 27518</u> County <u>Wake</u> | |
| Number of unduplicated patients who receive treatment simulation | 348 | 260 | Total Patients 608 ✓ |

** "... (machine that produces high quality diagnostic radiographs and precisely reproduces the geometric relationships of megavoltage radiation therapy equipment to the patient." (GS 131E-176 (24b))

Name of entity that acquired the equipment (from page 1) Cancer Centers of North Carolina, P.C.



Section 3: Linear Accelerator Treatment Data (including Cyberknife® & Similar Equipment)

In the chart below, write the number of procedures, by CPT Code provided by the entity's linear accelerator(s) during the time period of this report.

| CPT Code | Description | Number of Procedures | |
|---|---|----------------------|--------------|
| | | Linac 1 | Linac 2 |
| Simple Treatment Delivery | | | |
| 77401 | Radiation treatment delivery | | |
| 77402 | Radiation treatment delivery (<=5 MeV) | | |
| 77403 | Radiation treatment delivery (6-10 MeV) | 12 | 10 |
| 77404 | Radiation treatment delivery (11-19 MeV) | 42 | 19 |
| 77406 | Radiation treatment delivery (>=20 MeV) | | |
| Intermediate Treatment Delivery | | | |
| 77407 | Radiation treatment delivery (<=5 MeV) | | |
| 77408 | Radiation treatment delivery (6-10 MeV) | | |
| 77409 | Radiation treatment delivery (11-19 MeV) | 0 | 32 |
| 77411 | Radiation treatment delivery (>=20 MeV) | | |
| Complex Treatment Delivery | | | |
| 77412 | Radiation treatment delivery (<=5 MeV) | | |
| 77413 | Radiation treatment delivery (6-10 MeV) | 1,742 | 2,140 |
| 77414 | Radiation treatment delivery (11-19 MeV) | 4,013 | 2,475 |
| 77416 | Radiation treatment delivery (>= 20 MeV) | 31 | 264 |
| Other Treatment Delivery Not Included Above | | | |
| 77418 | Intensity modulated radiation treatment (IMRT) delivery | 1,939 | 1,391 |
| 77371 | Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; multisource Cobalt 60 based (Gamma Knife) | | |
| 77372 | Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator | | |
| 77373 | Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions | | |
| G0339 | (Image-guided) robotic linear accelerator-based stereotactic radiosurgery in one session or first fraction | | |
| G0340 | (Image-guided) robotic linear accelerator-based stereotactic radiosurgery, fractionated treatment, 2nd-5th fraction | | |
| | Intraoperative radiation therapy (conducted by bringing the anesthetized patient down to the linac) | | |
| | Pediatric Patient under anesthesia | | |
| | Neutron and proton radiation therapy | | |
| | Limb salvage irradiation | | |
| | Hemibody irradiation | | |
| | Total body irradiation | | |
| Imaging Procedures Not Included Above | | | |
| 77417 | Additional field check radiographs | 1,339 | 1,298 |
| Total Procedures | | 9,118 | 7,629 |

Name of entity that acquired the equipment (from page 1) Cancer Centers of North Carolina, P.C.



Section 4: Linear Accelerator Treatment Patient Origin Data

Please provide the county of residence for unduplicated patients (see note on page 2) served by your facility's linear accelerators during the time period of this report. The total number served should be the same as on page 2 of this report. This data is needed to calculate linear accelerator service areas.

County in which service was provided: _____

| Patient County | Number of Patients | | Patient County | Number of Patients | | Patient County | Number of Patients | |
|-------------------|-----------------------|----|-------------------|-----------------------|----|--|-----------------------|------|
| | L1 | L2 | | L1 | L2 | | L2 | L1 |
| 1. Alamance | | | 37. Gates | | | 73. Person | | 1 |
| 2. Alexander | | | 38. Graham | | | 74. Pitt | | |
| 3. Alleghany | | | 39. Granville | | 1 | 75. Polk | | |
| 4. Anson | | | 40. Greene | | | 76. Randolph | | |
| 5. Ashe | | | 41. Guilford | | | 77. Richmond | | |
| 6. Avery | | | 42. Halifax | 1 | 1 | 78. Robeson | | |
| 7. Beaufort | | | 43. Harnett | 14 | 20 | 79. Rockingham | | |
| 8. Bertie | | | 44. Haywood | | | 80. Rowan | | |
| 9. Bladen | | | 45. Henderson | | | 81. Rutherford | | |
| 10. Brunswick | | | 46. Hertford | | | 82. Sampson | 4 | |
| 11. Buncombe | | | 47. Hoke | | | 83. Scotland | | |
| 12. Burke | | | 48. Hyde | | | 84. Stanly | | |
| 13. Cabarrus | | | 49. Iredell | | | 85. Stokes | | |
| 14. Caldwell | 1 | | 50. Jackson | | | 86. Surry | 1 | |
| 15. Camden | | | 51. Johnston | 22 | 7 | 87. Swain | | |
| 16. Carteret | | | 52. Jones | | | 88. Transylvania | | |
| 17. Caswell | | | 53. Lee | | 6 | 89. Tyrrell | | |
| 18. Catawba | | | 54. Lenoir | 1 | | 90. Union | | |
| 19. Chatham | 1 | 4 | 55. Lincoln | | | 91. Vance | 1 | |
| 20. Cherokee | | | 56. Macon | | | 92. Wake | 300 | 236 |
| 21. Chowan | | | 57. Madison | | | 93. Warren | 1 | |
| 22. Clay | | | 58. Martin | | | 94. Washington | | |
| 23. Cleveland | | | 59. McDowell | | | 95. Watauga | | |
| 24. Columbus | 1 | | 60. Mecklenburg | | | 96. Wayne | | |
| 25. Craven | | | 61. Mitchell | | | 97. Wilkes | | |
| 26. Cumberland | 1 | | 62. Montgomery | | | 98. Wilson | | 1 |
| 27. Currituck | | | 63. Moore | | | 99. Yadkin | | |
| 28. Dare | | | 64. Nash | 5 | | 100. Yancey | | |
| 29. Davidson | | | 65. New Hanover | | | | | |
| 30. Davie | | | 66. Northampton | 1 | | 101. Georgia | | |
| 31. Duplin | 1 | | 67. Onslow | | | 102. South Carolina | | 1 |
| 32. Durham | 2 | 2 | 68. Orange | | 1 | 103. Tennessee | | |
| 33. Edgecombe | | | 69. Pamlico | | | 104. Virginia | 1 | |
| 34. Forsyth | | | 70. Pasquotank | | | 105. Other (specify) <small>Linac 1: 1 ea: AZ, FL, KY, PA</small> | 4 | 1 FL |
| 35. Franklin | 22 | | 71. Pender | | | | | |
| 36. Gaston | | | 72. Perquimans | | | Total Number of Patients | 385 | 282 |

29 6

44 36

312 240

Name of entity that acquired the equipment (from page 1) Cancer Centers of North Carolina, P.C.



Section 5: Reimbursement/Payment Source

Please provide the source of reimbursement/payment for linear accelerator treatment procedures. Total procedures should equal the total number of procedures reported on page 2 of this form.

| Primary Payer Source | Number of Procedures | |
|--|----------------------|--------------|
| | Linac 1 | Linac 2 |
| Self Pay | 495 | 63 |
| Medicare & Medicare Managed Care | 4,335 | 3,270 |
| Medicaid | 547 | 158 |
| Commercial Insurance | 73 | 4 |
| Managed Care | 3,332 | 4,012 |
| Unreimbursed Care (Indigent/Charity) | 262 | 13 |
| Other (Specify) Other Government Managed Plans | 74 | 109 |
| Total | 9,118 | 7,629 |

Section 6: Certification and Signature

The undersigned Chief Executive Officer or approved designee certifies the accuracy of the information contained on all pages of this form.

Signature Thomas A. Grates

Print Name Thomas A. Grates

Date signed 1/30/14

Please complete all sections of this form and return to the Medical Facilities Planning Branch by **Friday, January 31, 2014.**

1. Complete and sign the form
2. Return the form by one of two methods:
 - a. Email a scanned copy to DHSR.SMFP.Registration-Inventory@dhhs.nc.gov
 - b. Mail the form to Kelli Fisk in the Medical Facilities Planning Branch, 2714 Mail Service Center, Raleigh, NC 27699-2714.

If you have questions, call Kelli Fisk in the Medical Facilities Planning Branch at (919) 855-3865 or email DHSR.SMFP.Registration-Inventory@dhhs.nc.gov.

Name of entity that acquired the equipment (from page 1) Cancer Centers of North Carolina, P.C.

Appendix 4

GENERAL STATUTES OF NORTH CAROLINA

NORTH CAROLINA
DEPARTMENT OF JUSTICE

DEC. 16 1997

Chapter 131E Health Care Facilities and Services

DECEMBER 1997

STATE OF NORTH CAROLINA

DEPARTMENT OF JUSTICE

Raleigh, North Carolina

December 1, 1997

I, Michael F. Easley, Attorney General of North Carolina, do hereby certify that the attached recompilation of Chapter 131E of the General Statutes of North Carolina was prepared and published by Michie under the supervision of the Department of Justice of the State of North Carolina.

MICHAEL F. EASLEY

Attorney General of North Carolina

52050-12

review process of an application requesting approval of a virtually identical proposal. In re Denial of Request by Humana Hosp. Corp., 78 N.C. App. 637, 338 S.E.2d 139 (1986), decided under former § 131-175.

Hospital Granting Exclusive Privilege to Use Equipment Held Not Immune Under State Action Exemption. — In an antitrust action brought under §§ 1 and 2 of the Sherman Act (15 U.S.C. §§ 1 and 2) brought by plaintiff physicians asserting that defendant hospital had improperly restricted use of its CAT Scan, defendant was held to have failed to show, in support of its motion to dismiss, that the General Assembly had authorized defendant to grant exclusive privileges to certain physicians to use its facilities with the intent to restrict competition, so as to render defendant immune from antitrust liability under the state action exemption. Coastal Neuro-Psychiatric Assocs. v. Onslow County Hosp. Auth., 607 F. Supp. 49 (E.D.N.C. 1985).

Exemptions from Obtaining Certificate of Need. — Agency properly granted summary judgment to petitioners on the grounds that they were exempt from obtaining a certificate of need

because they had entered into binding legal contacts to develop and offer a health service as contemplated by grandfather clause. Koltis v. North Carolina Dep't of Human Resources, 125 N.C. App. 268, 480 S.E.2d 702 (1997).

Grandfather Clause. — To satisfy the requirements of grandfather clause, which would exempt one from obtaining a certificate of need, one need only show a binding legal contract to develop any service that was not a new institutional health service requiring a certificate of need prior to March 18, 1993. Koltis v. North Carolina Dep't of Human Resources, 125 N.C. App. 268, 480 S.E.2d 702 (1997).

Quoted in Total Care, Inc. v. Department of Human Resources, 99 N.C. App. 517, 393 S.E.2d 338 (1990).

Cited in Shelton v. Morehead Mem. Hosp., 318 N.C. 76, 347 S.E.2d 824 (1986); In re Wake Kidney Clinic, 85 N.C. App. 639, 355 S.E.2d 788 (1987); State ex rel. Utils. Comm'n v. Empire Power Co., 112 N.C. App. 265, 435 S.E.2d 553 (1993); Laurel Wood of Henderson, Inc. v. North Carolina Dep't of Human Resources, 117 N.C. App. 601, 452 S.E.2d 334 (1995).

§ 131E-176. Definitions.

As used in this Article, unless the context clearly requires otherwise, the following terms have the meanings specified:

- (1) "Air ambulance" means aircraft used to provide air transport of sick or injured persons between destinations within the State.
- (1a) "Ambulatory surgical facility" means a facility designed for the provision of a specialty ambulatory surgical program or a multispecialty ambulatory surgical program. An ambulatory surgical facility serves patients who require local, regional or general anesthesia and a period of post-operative observation. An ambulatory surgical facility may only admit patients for a period of less than 24 hours and must provide at least two designated operating rooms and at least one designated recovery room, have available the necessary equipment and trained personnel to handle emergencies, provide adequate quality assurance and assessment by an evaluation and review committee, and maintain adequate medical records for each patient. An ambulatory surgical facility may be operated as a part of a physician or dentist's office, provided the facility is licensed under G.S. Chapter 131E, Article 6, Part D, but the performance of incidental, limited ambulatory surgical procedures which do not constitute an ambulatory surgical program as defined in subdivision (1b) and which are performed in a physician's or dentist's office does not make that office an ambulatory surgical facility.

- (1b) "Ambulatory surgical program" means a formal program for providing on a same-day basis those surgical procedures which require local, regional or general anesthesia and a period of post-operative observation to patients whose admission for more than 24 hours is determined, prior to surgery, to be medically unnecessary.
- (2) "Bed capacity" means space used exclusively for inpatient care, including space designed or remodeled for licensed inpatient beds even though temporarily not used for such purposes. The number of beds to be counted in any patient room shall be the maximum number for which adequate square footage is provided as established by rules of the Department except that single beds in single rooms are counted even if the room contains inadequate square footage. The term "bed capacity" also refers to the number of dialysis stations in kidney disease treatment centers, including freestanding dialysis units.
- (2a) "Bone marrow transplantation services" means the process of infusing bone marrow into persons with diseases to stimulate the production of blood cells.
- (2b) "Burn intensive care services" means services provided in a unit designed to care for patients who have been severely burned.
- (2c) "Campus" means the adjacent grounds and buildings, or grounds and buildings not separated by more than a public right-of-way, of a health service facility and related health care entities.
- (2d) "Capital expenditure" means an expenditure for a project, including but not limited to the cost of construction, engineering, and equipment which under generally accepted accounting principles is not properly chargeable as an expense of operation and maintenance. Capital expenditure includes, in addition, the fair market value of an acquisition made by donation, lease, or comparable arrangement by which a person obtains equipment, the expenditure for which would have been considered a capital expenditure under this Article if the person had acquired it by purchase.
- (2e) "Cardiac angioplasty equipment" means the cardiac catheterization equipment used in surgery for the restoration, repair, or reconstruction of coronary blood vessels.
- (2f) "Cardiac catheterization equipment" means the equipment required to perform diagnostic procedures or therapeutic intervention in which a catheter is introduced into a vein or artery and threaded through the circulatory system to the heart.
- (3) "Certificate of need" means a written order which affords the person so designated as the legal proponent of the proposed project the opportunity to proceed with the development of such project.
- (4) Repealed by Session Laws 1993, c. 7, s. 2.
- (5) "Change in bed capacity" means (i) any relocation of health service facility beds, or dialysis stations from one licensed facility or campus to another, or (ii) any redistribution of health service facility bed capacity among the categories of health service facility bed as defined in G.S. 131E-176(9c),

- or (iii) any increase in the number of health service facility beds, or dialysis stations in kidney disease treatment centers, including freestanding dialysis units.
- (5a) "Chemical dependency treatment facility" means a public or private facility, or unit in a facility, which is engaged in providing 24-hour a day treatment for chemical dependency or substance abuse. This treatment may include detoxification, administration of a therapeutic regimen for the treatment of chemically dependent or substance abusing persons and related services. The facility or unit may be:
- a. A unit within a general hospital or an attached or freestanding unit of a general hospital licensed under Article 5, Chapter 131E, of the General Statutes,
 - b. A unit within a psychiatric hospital or an attached or freestanding unit of a psychiatric hospital licensed under Article 1A of General Statutes Chapter 122 or Article 2 of General Statutes Chapter 122C,
 - c. A freestanding facility specializing in treatment of persons who are substance abusers or chemically dependent licensed under Article 1A of General Statutes Chapter 122 or Article 2 of General Statutes Chapter 122C; and may be identified as "chemical dependency, substance abuse, alcoholism, or drug abuse treatment units," "residential chemical dependency, substance abuse, alcoholism or drug abuse facilities," "social setting detoxification facilities" and "medical detoxification facilities," or by other names if the purpose is to provide treatment of chemically dependent or substance abusing persons, but shall not include half-way houses or recovery farms.
- (5b) "Chemical dependency treatment beds" means beds that are licensed for detoxification or for the inpatient treatment of chemical dependency. Residential treatment beds for the treatment of chemical dependency or substance abuse are chemical dependency treatment beds.
- (6) "Department" means the North Carolina Department of Health and Human Services.
- (7) To "develop" when used in connection with health services, means to undertake those activities which will result in the offering of institutional health service or the incurring of a financial obligation in relation to the offering of such a service.
- (7a) "Diagnostic center" means a freestanding facility, program, or provider, including but not limited to, physicians' offices, clinical laboratories, radiology centers, and mobile diagnostic programs, in which the total cost of all the medical diagnostic equipment utilized by the facility which cost ten thousand dollars (\$10,000) or more exceeds five hundred thousand dollars (\$500,000). In determining whether the medical diagnostic equipment in a diagnostic center costs more than five hundred thousand dollars (\$500,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the equipment shall be included.

The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater.

- (7b) "Expedited review" means the status given to an application's review process when the applicant petitions for the review and the Department approves the request based on findings that all of the following are met:
- a. The review is not competitive.
 - b. The proposed capital expenditure is less than five million dollars (\$5,000,000).
 - c. A request for a public hearing is not received within the time frame defined in G.S. 131E-185.
 - d. The agency has not determined that a public hearing is in the public interest.
- (7c) "Gamma knife" means equipment which emits photon beams from a stationary radioactive cobalt source to treat lesions deep within the brain and is one type of stereotactic radiosurgery.
- (8), (9) Repealed by Session Laws 1987, c. 511, s. 1.
- (9a) "Health service" means an organized, interrelated medical, diagnostic, therapeutic, and/or rehabilitative activity that is integral to the prevention of disease or the clinical management of a sick, injured, or disabled person. "Health service" does not include administrative and other activities that are not integral to clinical management.
- (9b) "Health service facility" means a hospital; psychiatric facility; rehabilitation facility; long term care facility; kidney disease treatment center, including freestanding hemodialysis units; intermediate care facility for the mentally retarded; home health agency office; chemical dependency treatment facility; diagnostic center; oncology treatment center; hospice, hospice inpatient facility, hospice residential care facility; and ambulatory surgical facility.
- (9c) "Health service facility bed" means a bed licensed for use in a health service facility in the categories of (i) acute care beds; (ii) psychiatric beds; (iii) rehabilitation beds; (iv) nursing care beds; (v) intermediate care beds for the mentally retarded; (vi) chemical dependency treatment beds; (vii) hospice inpatient facility beds; and (viii) hospice residential care facility beds.
- (10) "Health maintenance organization (HMO)" means a public or private organization which has received its certificate of authority under Article 67 of Chapter 58 of the General Statutes and which either is a qualified health maintenance organization under Section 1310(d) of the Public Health Service Act or:
- a. Provides or otherwise makes available to enrolled participants health care services, including at least the following basic health care services: usual physician services, hospitalization, laboratory, X ray, emergency and preventive services, and out-of-area coverage;
 - b. Is compensated, except for copayments, for the provision of the basic health care services listed above to enrolled participants by a payment which is paid on a periodic basis without regard to the date the health care services are provided and which is fixed without regard to

the frequency, extent, or kind of health service actually provided; and

- c. Provides physicians' services primarily (i) directly through physicians who are either employees or partners of such organizations, or (ii) through arrangements with individual physicians or one or more groups of physicians organized on a group practice or individual practice basis.

(10a) "Heart-lung bypass machine" means the equipment used to perform extra-corporeal circulation and oxygenation during surgical procedures.

(11) Repealed by Session Laws 1991, c. 692, s. 1.

(12) "Home health agency" means a private organization or public agency, whether owned or operated by one or more persons or legal entities, which furnishes or offers to furnish home health services.

"Home health services" means items and services furnished to an individual by a home health agency, or by others under arrangements with such others made by the agency, on a visiting basis, and except for paragraph e. of this subdivision, in a place of temporary or permanent residence used as the individual's home as follows:

- a. Part-time or intermittent nursing care provided by or under the supervision of a registered nurse;
- b. Physical, occupational or speech therapy;
- c. Medical social services, home health aid services, and other therapeutic services;
- d. Medical supplies, other than drugs and biologicals and the use of medical appliances;
- e. Any of the foregoing items and services which are provided on an outpatient basis under arrangements made by the home health agency at a hospital or nursing home facility or rehabilitation center and the furnishing of which involves the use of equipment of such a nature that the items and services cannot readily be made available to the individual in his home, or which are furnished at such facility while he is there to receive any such item or service, but not including transportation of the individual in connection with any such item or service.

(13) "Hospital" means a public or private institution which is primarily engaged in providing to inpatients, by or under supervision of physicians, diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons. The term includes all facilities licensed pursuant to G.S. 131E-77 of the General Statutes.

(13a) "Hospice" means any coordinated program of home care with provision for inpatient care for terminally ill patients and their families. This care is provided by a medically directed interdisciplinary team, directly or through an agreement under the direction of an identifiable hospice administration. A hospice program of care provides palliative and supportive medical and other health services to meet the physical, psychological, social, spiritual and spe-

cial needs of patients and their families, which are experienced during the final stages of terminal illness and during dying and bereavement.

- (13b) "Hospice inpatient facility" means a freestanding licensed hospice facility or a designated inpatient unit in an existing health service facility which provides palliative and supportive medical and other health services to meet the physical, psychological, social, spiritual, and special needs of terminally ill patients and their families in an inpatient setting. For purposes of this Article only, a hospital which has a contractual agreement with a licensed hospice to provide inpatient services to a hospice patient as defined in G.S. 131E-201(4) and provides those services in a licensed acute care bed is not a hospice inpatient facility and is not subject to the requirements in G.S. 131E-176(5)(ii) for hospice inpatient beds.
- (13c) "Hospice residential care facility" means a freestanding licensed hospice facility which provides palliative and supportive medical and other health services to meet the physical, psychological, social, spiritual, and special needs of terminally ill patients and their families in a group residential setting.
- (14) Repealed by Session Laws 1987, c. 511, s. 1.
- (14a) "Intermediate care facility for the mentally retarded" means facilities licensed pursuant to Article 2 of Chapter 122C of the General Statutes for the purpose of providing health and habilitative services based on the developmental model and principles of normalization for persons with mental retardation, autism, cerebral palsy, epilepsy or related conditions.
- (14b) Repealed by Session Laws 1991, c. 692, s. 1.
- (14c) "Lithotripter" means extra-corporeal shock wave technology used to treat persons with kidney stones and gallstones.
- (14d) "Long term care facility" means a health service facility whose bed complement of health service facility beds is composed principally of nursing care facility beds.
- (14e) "Magnetic resonance imaging scanner" means medical imaging equipment that uses nuclear magnetic resonance.
- (14f) "Major medical equipment" means a single unit or single system of components with related functions which is used to provide medical and other health services and which costs more than seven hundred fifty thousand dollars (\$750,000). In determining whether the major medical equipment costs more than seven hundred fifty thousand dollars (\$750,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the major medical equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater. Major medical equipment does not include replacement equipment as defined in this section.
- (15) Repealed by Session Laws 1987, c. 511, s. 1.
- (15a) "Multispecialty ambulatory surgical program" means a formal program for providing on a same-day basis surgical

procedures for at least three of the following specialty areas: gynecology, otolaryngology, plastic surgery, general surgery, ophthalmology, orthopedic, or oral surgery.

- (15b) "Neonatal intensive care services" means those services provided by a health service facility to high-risk newborn infants who require constant nursing care, including but not limited to continuous cardiopulmonary and other supportive care.
- (16) "New institutional health services" means any of the following:
- a. The construction, development, or other establishment of a new health service facility.
 - b. 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. The cost of any studies, surveys, designs, plans, working drawings, specifications, and other activities, including staff effort and consulting and other services, essential to the acquisition, improvement, expansion, or replacement of any plant or equipment with respect to which an expenditure is made shall be included in determining if the expenditure exceeds two million dollars (\$2,000,000).
 - c. Any change in bed capacity as defined in G.S. 131E-176(5).
 - d. The offering of dialysis services or home health services by or on behalf of a health service facility if those services were not offered within the previous 12 months by or on behalf of the facility.
 - e. A change in a project that was subject to certificate of need review and for which a certificate of need was issued, if the change is proposed during the development of the project or within one year after the project was completed. For purposes of this subdivision, a change in a project is a change of more than fifteen percent (15%) of the approved capital expenditure amount or the addition of a health service that is to be located in the facility, or portion thereof, that was constructed or developed in the project.
 - f. The development or offering of a health service as listed in this subdivision by or on behalf of any person:
 1. Bone marrow transplantation services.
 2. Burn intensive care services.
 3. Neonatal intensive care services.
 4. Open-heart surgery services.
 5. Solid organ transplantation services.
 - fi. The acquisition by purchase, donation, lease, transfer, or comparable arrangement of any of the following equipment by or on behalf of any person:
 1. Air ambulance.
 2. Cardiac angioplasty equipment.
 3. Cardiac catheterization equipment.
 4. Gamma knife.
 5. Heart-lung bypass machine.
 6. Lithotripter.

- 7. Magnetic resonance imaging scanner.
 - 8. Positron emission tomography scanner.
 - g. to k. Repealed by Session Laws 1987, c. 511, s. 1.
 - l. The purchase, lease, or acquisition of any health service facility, or portion thereof, or a controlling interest in the health service facility or portion thereof, if the health service facility was developed under a certificate of need issued pursuant to G.S. 131E-180.
 - m. Any conversion of nonhealth service facility beds to health service facility beds.
 - n. The construction, development or other establishment of a hospice, hospice inpatient facility, or hospice residential care facility;
 - o. The opening of an additional office by an existing home health agency within its service area as defined by rules adopted by the Department; or the opening of any office by an existing home health agency outside its service area as defined by rules adopted by the Department.
 - p. The acquisition by purchase, donation, lease, transfer, or comparable arrangement by any person of major medical equipment.
 - q. The relocation of a health service facility from one service area to another.
 - r. The conversion of a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or the addition of a specialty to a specialty ambulatory surgical program.
 - s. The furnishing of mobile medical equipment to any person to provide health services in North Carolina, which was not in use in North Carolina prior to the adoption of this provision, if such equipment would otherwise be subject to review in accordance with G.S. 131E-176(16)(fl.) or G.S. 131E-176(16)(p) if it had been acquired in North Carolina.
- (17) "North Carolina State Health Coordinating Council" means the Council that prepares, with the Department of Health and Human Services, the State Medical Facilities Plan.
- (17a) "Nursing care" means:
- a. Skilled nursing care and related services for residents who require medical or nursing care;
 - b. Rehabilitation services for the rehabilitation of injured, disabled, or sick persons; or
 - c. Health-related care and services provided on a regular basis to individuals who because of their mental or physical condition require care and services above the level of room and board, which can be made available to them only through institutional facilities.
- These are services which are not primarily for the care and treatment of mental diseases.
- (18) To "offer," when used in connection with health services, means that the person holds himself out as capable of providing, or as having the means for the provision of, specified health services.
- (18a) "Oncology treatment center" means a facility, program, or provider, other than an existing health service facility that

provides services for diagnosis, evaluation, or treatment of cancer and its aftereffects or secondary results and for which the total cost of all the medical equipment utilized by the center, exceeds two hundred fifty thousand dollars (\$250,000). In determining whether costs are more than two hundred fifty thousand dollars (\$250,000), the costs of equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the facility, program, or provider shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater.

- (18b) "Open-heart surgery services" means the provision of surgical procedures that utilize a heart-lung bypass machine during surgery to correct cardiac and coronary artery disease or defects.
- (19) "Person" means an individual, a trust or estate, a partnership, a corporation, including associations, joint stock companies, and insurance companies; the State, or a political subdivision or agency or instrumentality of the State.
- (19a) "Positron emission tomography scanner" means equipment that utilizes a computerized radiographic technique that employs radioactive substances to examine the metabolic activity of various body structures.
- (20) "Project" or "capital expenditure project" means a proposal to undertake a capital expenditure that results in the offering of a new institutional health service as defined by this Article. A project, or capital expenditure project, or proposed project may refer to the project from its earliest planning stages up through the point at which the specified new institutional health service may be offered. In the case of facility construction, the point at which the new institutional health service may be offered must take place after the facility is capable of being fully licensed and operated for its intended use, and at that time it shall be considered a health service facility.
- (21) "Psychiatric facility" means a public or private facility licensed pursuant to Article 2 of Chapter 122C of the General Statutes and which is primarily engaged in providing to inpatients, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons.
- (22) "Rehabilitation facility" means a public or private inpatient facility which is operated for the primary purpose of assisting in the rehabilitation of disabled persons through an integrated program of medical and other services which are provided under competent, professional supervision.
- (22a) "Replacement equipment" means equipment that costs less than two million dollars (\$2,000,000) and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced. In determining whether the replacement equipment costs less than two million dollars (\$2,000,000), the costs of equipment, studies, surveys, designs, plans, working drawings, specifications, construc-

tion, installation, and other activities essential to acquiring and making operational the replacement equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater.

- (23) Repealed by Session Laws 1991, c. 692, s. 1.
- (24) Repealed by Session Laws 1993, c. 7, s. 2.
- (24a) "Service area" means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.
- (24b) "Solid organ transplantation services" means the provision of surgical procedures and the interrelated medical services that accompany the surgery to remove an organ from a patient and surgically implant an organ from a donor.
- (24c) "Specialty ambulatory surgical program" means a formal program for providing on a same-day basis surgical procedures for only the specialty areas identified on the ambulatory surgical facility's 1993 Application for Licensure as an Ambulatory Surgical Center and authorized by its certificate of need.
- (25) "State Medical Facilities Plan" means the plan prepared by the Department of Health and Human Services and the North Carolina State Health Coordinating Council, and approved by the Governor.
- (26) Repealed by Session Laws 1983 (Regular Session, 1984), c. 1002, s. 9.
- (27) Repealed by Session Laws 1987, c. 511, s. 1. (1977, 2nd Sess., c. 1182, s. 2; 1981, c. 651, ss. 1, 2; c. 1127, ss. 24-29; 1983, c. 775, s. 1; 1983 (Reg. Sess., 1984), c. 1002, ss. 1-9; c. 1022, ss. 2, 3; c. 1064, s. 1; c. 1110, ss. 1, 2; 1985, c. 589, ss. 42, 43(a); c. 740, ss. 1, 2, 6; 1985 (Reg. Sess., 1986), c. 1001, s. 2; 1987, c. 34; c. 511, s. 1; 1991, c. 692, s. 1; c. 701, s. 1; 1993, c. 7, s. 2; c. 376, ss. 1-4; 1997-443, s. 11A.118(a).)

Editor's Note. — Session Laws 1987, c. 511, s. 3 provided that the act, which amended this section, would become effective July 1, 1987, and would apply to all new institutional health services that are proposed on and after that date, but would not apply to applications for certificates of need which begin review, or to projects for which certificates of need were issued, before that date. Section 3 of Session Laws 1987, c. 511 further provided that the act would supersede all previous acts that were to become effective at any time after the effective date of the act (July 1, 1987). Thus an amendment by Session Laws 1985, c. 589, s. 43(b), which would have deleted "Article 1A of General Statutes Chapter 122" following "licensed under" in paragraph (5a)b and (5a)c, and was scheduled to become effective on January 1, 1988, was superseded and did not go into effect.

Session Laws 1993, c. 7, which rewrote this section, in s. 12 provides: "This act is effective upon ratification, and applies to any person, trust or estate, partnership, corporation, the State, any political subdivision of the State, and any other comparable entity that undertakes or is undertaking to offer or develop new institutional health services as defined in G.S. 131E-176(16), as amended by this act, except that it shall not apply to any person, trust or estate, partnership, corporation, the State, any political subdivision of the State, or any other comparable entity who has lawfully entered into a binding legal contract to develop and offer any service that was not a new institutional health service requiring a certificate of need prior to the ratification of this act. This act shall not affect litigation pending on the date of ratification. The inventories required by Section 3 of this act shall be completed by the

Appendix 5



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

2701 Mail Service Center • Raleigh, North Carolina 27699-2701

<http://www.ncdhhs.gov/dhsr>

Beverly Eaves Perdue, Governor
Lanier M. Cansler, Secretary

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

September 27, 2010

CERTIFIED MAIL

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

RE: Declaratory Ruling for Wake Radiology Oncology Services, PLLC, Cancer Centers of North Carolina, P.C., US Oncology, Inc., AOR Management Company of Virginia, LLC and WakeMed.

Dear Mr. Shenton:

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

Sincerely,

Drexdal Pratt

DP:JH:peb

Enclosure

cc: Ronald I. Kirschbaum, Esq., Kirschbaum, Nanney, Keenan & Griffin, P.A.
Larry E. Robbins, Esq., Wyrick Robbins Yates & Ponton, LLP
Maureen Demarest Murray, Esq., Smith Moore Leatherwood LLP
Jeff Horton, Chief Operating Officer, DHSR
Craig Smith, Chief, Certificate of Need Section
Steven Lewis, Chief, Construction Section
Azzie Conley, Chief, Acute and Home Care Licensure and Certification Section
Medical Facilities Planning Section
Marc Lodge, Special Deputy Attorney General, DOJ



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

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

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

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

STATEMENT OF THE FACTS

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

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

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

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

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

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

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

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

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

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

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

ANALYSIS

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

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

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

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

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


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

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

CONCLUSION

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

This the 27th day of September, 2010.



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

CERTIFICATE OF SERVICE

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

CERTIFIED MAIL


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Raleigh, NC 27601
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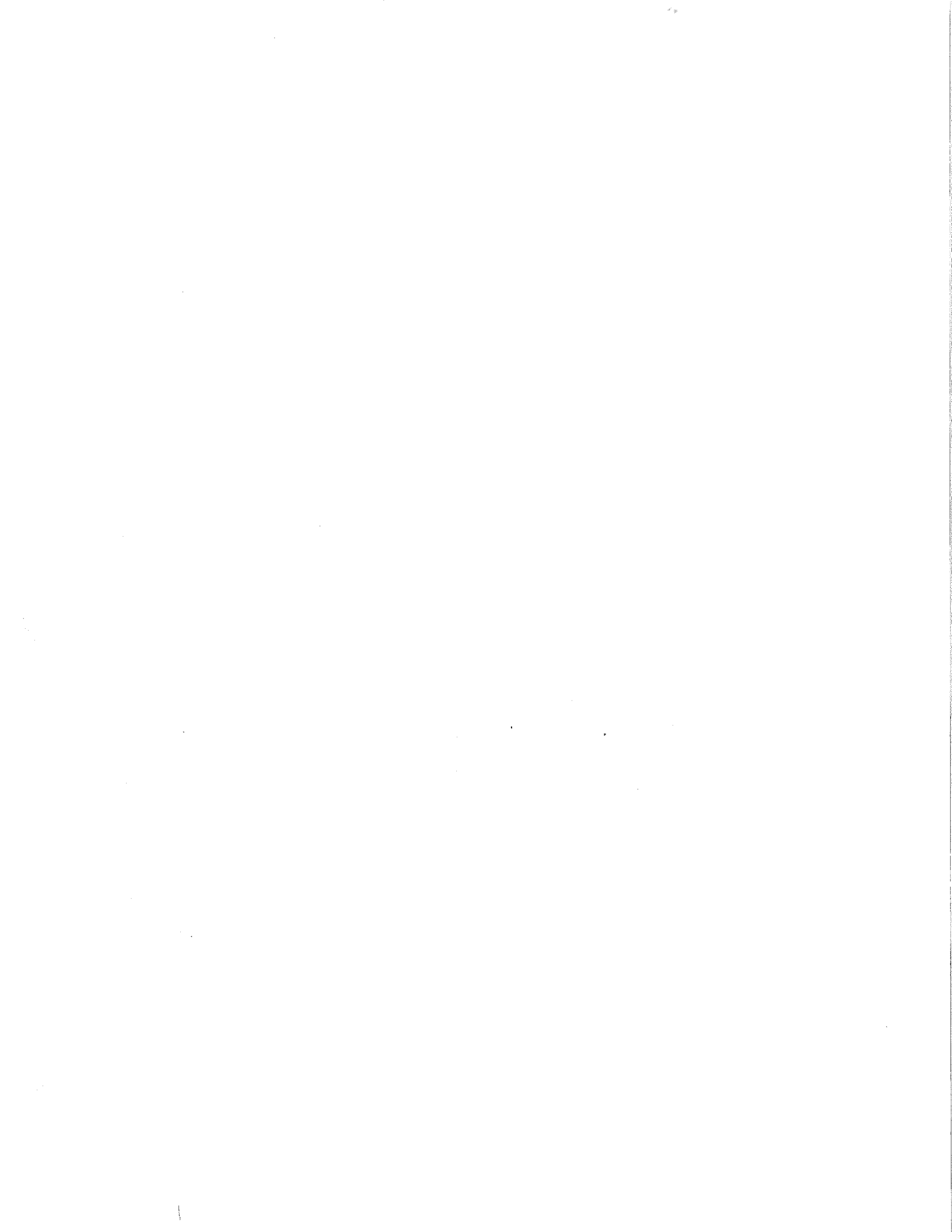
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Attorneys for WakeMed

This the 27th day of September, 2010.



Jeff Horton
Chief Operating Officer



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

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



This Petition for Declaratory Ruling is submitted by the following Petitioners: Wake Radiology Oncology Services, PLLC (“WROS”); Cancer Centers of North Carolina, P.C. (“CCNC”); US Oncology, Inc. (“USON”) and its subsidiary AOR Management Company of Virginia, LLC (“AOR”); and WakeMed. Pursuant to N.C. Gen. Stat. § 150B-4 and 10A N.C.A.C. 14A .0103, Petitioners respectfully request that the North Carolina Department of Health and Human Services, Division of Health Service Regulation (the “Department”) issue a declaratory ruling as to the applicability of provisions codified in Article 9 of Chapter 131E of the North Carolina General Statutes entitled Certificate of Need (“CON Law”), and of the Department’s rules to the facts set forth below. Petitioners ask the Department to confirm that the acquisition of the membership interests in WROS and the continued operation of the oncology treatment center, as described in more detail below (the “Proposed Transaction”), may proceed without first obtaining a certificate of need.

The Petitioners are requesting an expedited declaratory ruling because they would like to close the Proposed Transaction by September 15, 2010. To expedite the conclusion of the Proposed Transaction, the Petitioners would appreciate receiving the declaratory ruling before September 10, 2010 if at all possible.

GENERAL INFORMATION

To comply with 10A N.C.A.C. 14A .0103, the Petitioners provide the following general information.

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

2. Cancer Centers of North Carolina, P.C. ("CCNC") is a professional corporation organized under the laws of the State of North Carolina with its principal place of business located at 4101 Macon Pond Road, Raleigh, North Carolina 27607. CCNC employs physicians licensed to practice medicine in the State of North Carolina, who provide oncology treatment services, including radiation oncology services through the use of a linear accelerator located on Macon Pond Road.

3. US Oncology, Inc. ("USON") is a business corporation organized under the laws of the State of Delaware with its principal place of business located at 10101 Woodloch Forest, Woodlands, Texas 77380. Through its subsidiaries, US Oncology provides administrative support for, and furnishes medical equipment used by, oncology practices throughout the United States.

4. AOR Management Company of Virginia, LLC ("AOR") is a limited liability company, which is a subsidiary of USON and was organized under the laws of the State of

Delaware and authorized to do business in North Carolina. AOR provides administrative and other support services to CCNC under a Management Services Agreement with CCNC.

5. WakeMed is a North Carolina nonprofit corporation engaged in the provision of acute care services and other health care services in Wake County, with its principal place of business located at 3000 New Bern Avenue, Raleigh, North Carolina 27610.

6. The pertinent statutory provisions are found in the Certificate of Need Law including N.C. Gen. Stat. § 131E-175, N.C. Gen. Stat. § 131E-176(16), N.C. Gen. Stat. § 131E-178, and N.C. Gen. Stat. § 131E-184(a)(6) and (8).

7. The Petitioners would be aggrieved by a failure to issue the proposed declaratory ruling or by an interpretation of any part of the CON Law that concludes that any of the Petitioners must obtain a certificate of need ("CON") before completing the Proposed Transaction described below, because that would impede or delay the Proposed Transaction.

STATEMENT OF FACTS

Purchase of the Linear Accelerator and Simulator Pursuant to 1997 CON

In 1997, WROS received the certificate of need that authorized it to establish an oncology treatment center and to acquire a linear accelerator, simulator, and specialized computer systems. *See* Exhibit 1. WROS acquired this equipment and established its oncology treatment center on or about July 17, 1998. Since the establishment of its oncology treatment center, WROS has continuously operated the oncology treatment center established pursuant to the CON it received in 1997, as evidenced by the linear accelerator inventory in the annual State Medical Facilities Plan ("SMFP"). *See* Exhibit 2, Copy of Table 8Z from the 2000 SMFP and Exhibit 3, Copy of Table 9E from the 2010 SMFP.

In 1997, oncology treatment centers were among the services listed in the definition of "health service facility" in the CON Law, and a certificate of need was required for development

of an oncology treatment center. But with ratification of Senate Bill 740 in August 2005, the term "oncology treatment center" was deleted from the group of facilities defined as a "health service facility" under the CON Law. Senate Bill 740 also amended the list of new institutional health services in N.C. Gen. Stat. § 131E-176(16) to add purchases of linear accelerators or simulators, occurring on or after the effective date of the amendment, as activities for which a certificate of need is required, regardless of the cost of the purchase. When the CON Law was amended in 2005, WROS already was operating an existing oncology treatment center pursuant to the CON that it had obtained in 1997 and using a linear accelerator and simulator that had been recognized in the SMFP inventory for seven years. Since it already owned the equipment, it was not required to obtain a second CON to be able to continue to operate its linear accelerator and simulator. Purchase of that equipment already had been expressly authorized under the 1997 CON.

Conversion from PLLC to LLC

WROS was formed in 1996 as a North Carolina professional limited liability company ("PLLC") under the provisions of the North Carolina Limited Liability Company Act, N.C. Gen. Stat. § 57C-1-01, *et seq.* In a recent vote by its physician owners, WROS approved the transactions described in this Petition. Among the steps approved by the WROS physician owners was a conversion of WROS from a professional limited liability company to a limited liability company, to occur simultaneously with the sale of ownership interests to AOR that is described below.

Under North Carolina law, any limited liability company formed under the North Carolina Limited Liability Company Act, including a professional limited liability company like WROS, may convert to another form of business entity by following procedures that are outlined

in the North Carolina General Statutes. N.C. Gen. Stat. § 57C-9A-10. These statutory provisions expressly recognize that a conversion to a different business entity, like that approved by the WROS physicians, is simply a change in form; that there is no interruption in the existence of the legal entity; and that the legal entity remains in existence throughout the process with title to all its property and continuing responsibility for all its liabilities and obligations.

The statute specifically provides that when such a conversion takes effect:

- (1) The converting domestic limited liability company ceases its prior form of organization and continues in existence as the resulting business entity;
- (2) The title to all real estate and other property owned by the converting domestic limited liability company continues vested in the resulting business entity without reversion or impairment;
- (3) All liabilities of the converting domestic limited liability company continue as liabilities of the resulting business entity;

N.C. Gen. Stat. § 57C-9A-13(a)(1)-(3). Thus, by the express terms of the North Carolina statutes governing limited liability companies, this change in the business form of WROS that has been approved by its physician owners will not constitute a change in or dissolution of WROS, the legal entity that received the CON in 1997 and has continuously operated the oncology treatment center and the linear accelerator and simulator since they became operational.

The Proposed Transaction

WROS continues to be owned by the same physician owners but those physician owners have agreed to sell all of their individual membership interests in WROS to AOR. This sale will occur immediately upon the effective conversion of WROS from a physician owned professional limited liability company to a limited liability company. It also is likely that WROS will change its name, but that change also will not constitute a change in the entity that received the certificate of need and which has operated the oncology treatment center since its inception.

Subsequently, in a separate, distinct transaction, WakeMed anticipates purchasing a minority membership interest in the renamed WROS ("the LLC").

After these two transactions, the LLC will continue to exist as a legal and business entity, and will continue to own the oncology treatment center and the equipment that was authorized under the 1997 CON, including the linear accelerator and simulator. The oncology treatment center and its equipment will remain at the same location at 300 Ashville Avenue in Cary. There will be no purchase of additional equipment, or offering of any new services. The only change will be the membership composition of the LLC, with AOR initially purchasing all of the membership interests from the physicians, followed by a separate transaction in which WakeMed purchases a minority interest in the LLC from AOR.

The LLC will not offer any medical services. Oncology treatment services will be furnished by physicians associated with CCNC. The parties anticipate that the radiation oncologists who have been practicing with WROS and have supervised the care of a significant majority of the patients receiving treatment at the Oncology Treatment Center in the past will continue as employees of CCNC and thus would continue to be involved in supervising and directing the treatment of patients under their care. Under a Management Services Agreement that preserves the physicians' authority over all clinical and medical decisions, the LLC will make the linear accelerator and simulator available for treatment of patients by all of the radiation oncologists who are affiliated with CCNC.

ANALYSIS

The CON Law was enacted to prevent the development and operation of unneeded health services, equipment and facilities. *See* N.C. Gen. Stat. § 131E-175. It accomplishes this goal by regulating those "new institutional health services" that are identified in N.C. Gen. Stat. § 131E-176(16), and that entail the acquisition or establishment of new health services, equipment, and

facilities, and certain expansions and relocations of regulated services. In keeping with its fundamental goals, the CON Law also expressly recognizes that certain activities are not subject to review. Based on the clear terms of the CON Law and prior declaratory rulings by the Department, the Proposed Transaction does not require a certificate of need.

I. THE PROPOSED TRANSACTION IS NOT A NEW INSTITUTIONAL HEALTH SERVICE AND IS EXEMPT FROM CON REVIEW UNDER N.C. GEN. STAT. § 131E-184(a)(6).

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 definitions of “new institutional health service” in N.C. Gen. Stat. § 131E-176(16) address, directly or indirectly, the acquisition of membership interests in an existing LLC which holds a CON, that occurs after the project is complete and operational. This is an activity that is among the “administrative and other activities that are not integral to clinical management,” which the definition of “health service” in the CON Law specifically excludes. N.C. Gen. Stat. § 131E-176(9a). Therefore, the Proposed Transaction does not involve a new institutional health service at all and should be determined to be exempt from review under the provisions of N.C. Gen. Stat. § 131E-184(a)(6).

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, and “the obligation by any person of a capital expenditure exceeding two million dollars (\$2,000,000) to develop or expand a health service or a health service facility, or which relates to the provision of a health service,” N.C. Gen. Stat. § 131E-176(16)(b). Neither of these definitions applies to the Proposed Transaction. Prior declaratory rulings show that the Department has already determined that these definitions do not require an entity to obtain a CON to acquire membership interests in an

existing legal entity like WROS which owns and operates a linear accelerator or simulator.

A. Prior Declaratory Rulings Confirm That the Proposed Transaction Is Not an Equipment Acquisition.

The declaratory ruling requested by Petitioners is consistent with the Department's prior rulings that have interpreted the applicability of the CON Law to the purchase of ownership interests in health care organizations. In two rulings that were issued after the enactment of the August 2005 amendment to the CON Law that requires a certificate of need for the acquisition of a linear accelerator or simulator, the Department has determined that the transfer of ownership interests in organizations that own linear accelerators does not require a certificate of need.

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*, December 21, 2007 (Exhibit 4). Similarly, 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.*, September 14, 2007 (Exhibit 5). Each of these declaratory rulings was issued after the August 2005 enactment of Senate Bill 740.

In its declaratory ruling involving North Carolina Radiation Therapy Management Services in September of 2007, 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 which 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 Department ruled: "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.

The stock purchase proposed by CRTC is exactly analogous to the purchase of the interests of the LLC proposed by the Petitioners. WROS has operated a linear accelerator that is recognized in the SMFP inventory, along with a simulator, and the Proposed Transaction will entail acquisition by AOR of all of the LLC's ownership interests, followed by the separate purchase of a minority interest in the LLC by WakeMed. At each step, ownership interests in the LLC will be acquired. Ownership of the LLC's linear accelerator will remain with the LLC.

In the declaratory ruling involving Smithfield Radiation Oncology, the Department reached the same 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, in each case, the Department concluded that a purchase of the ownership interests of a company, which owned a linear accelerator that already was in operation, did not require a

CON. The Department also issued a similar ruling with regard to acquisition of the stock of a company that owned heart lung bypass equipment. *See In re: Request for Declaratory Ruling by New Hanover Perfusionists, Inc.*, January 24, 2008 (Exhibit 6) Heart-lung bypass machines are another type of medical equipment for which a certificate of need is required under N.C. Gen. Stat. § 131E-176 (16) (f1), the same portion of the definition of new institutional health services that applies to purchases of linear accelerators and simulators. The Department focused on the fundamental fact that the ownership of the equipment would not change, and so there was no purchase of equipment. The Department's determination in these rulings is firmly founded on the express terms of the CON Law.

B. The Proposed Transaction Is Not Subject to Review as an Acquisition of a Linear Accelerator or Simulator.

The proposed acquisition of 100% of the membership interests in the LLC by AOR does not constitute the acquisition of a linear accelerator or simulator because the entity that owns the linear accelerator and simulator will not change, and the same equipment will be used to provide the same radiation oncology services, in the same location. The LLC will continue to own the linear accelerator, the simulator, and all the oncology treatment center assets that were authorized under the 1997 CON and have been used to furnish oncology treatments to patients. Its membership composition initially will change from the present physician members to a single member, AOR, with the subsequent purchase of a minority interest by WakeMed. However, the LLC's legal status as an existing business entity will not change.

Since the LLC will remain the same legal entity, under the CON Law the same "person" will own the equipment and hold the CON. *See* N.C. Gen. Stat. § §131E-176(19) and 178. There will be no change in ownership of the regulated equipment or the operation of the oncology treatment center. Accordingly, there is no basis to require CON review of the

Proposed Transaction as an acquisition of a linear accelerator or simulator under the provisions of N.C. Gen. Stat. § 131E-176(16)(f)5a or 9.

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

The Proposed Transaction will involve expenditures by AOR and WakeMed; but these will simply be purchases of ownership interests in an existing limited liability company that owns the oncology treatment center. They 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 membership composition of the LLC, 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 the equipment and offering the 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 membership composition of the LLC is not integral to its clinical management, and its operations will not change as a result of this transaction. Therefore, the purchase of membership interests in the LLC 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).

II. ISSUANCE OF THE REQUESTED DECLARATORY RULING IS CONSISTENT WITH THE PURPOSES OF THE CON LAW.

The CON Law is intended to regulate new institutional health services and is not intended to impede routine business transactions such as an acquisition of a limited liability company's ownership interests. The only point when the CON Law does limit changes in ownership is "before completion of the project or operation of the facility." N.C. Gen. Stat. § 131E-189(c). WROS has operated the oncology treatment center for more than a decade, so this restriction in the CON Law clearly does not apply.

The Proposed Transaction does not involve the offering or expansion of any new facility, service or equipment, and the state's inventory of linear accelerators and simulators will not change. The oncology treatment center and its equipment have been established and operating for years, and have been recognized in the inventory of those services that is maintained by the Department. No new, or additional equipment will be acquired or placed in operation in the State. No new facility will be established nor new services offered. As a result, the Proposed Transaction does not implicate the fundamental objective of the CON Law--to control the development and expansion of health service facilities.

Failure to issue the requested ruling would delay and impede the parties that are requesting this declaratory ruling in proceeding with a lawful business transaction. The 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.")

In keeping with this approach, the CON Law actually contains a provision, in N.C. Gen. Stat. § 131E-184(a)(8), which recognizes that an outright purchase of all the assets of an entire health service facility is exempt from the requirement of obtaining a CON, even if the purchased facility contains equipment that would otherwise be subject to certificate of need review. Although the purchase of an individual unit of equipment, such as an MRI scanner, linear accelerator or CT simulator, standing alone, is subject to certificate of need review, acquisition of an entire facility or program where that equipment is located, is exempted from CON review. N.C. Gen. Stat. §§ 131E-176(16)(f1), 178 and 184(a)(8).

The exemption provision at N.C. Gen. Stat. § 131E-184(a)(8) expressly acknowledges that no additional review is required for existing facilities that already have gone through the CON review process and have been approved by the CON Section. By the same token, the purposes for which the CON Law was enacted are not served by regulating the purchase and sale of the underlying membership interests in organizations that own existing health service facilities or equipment which the CON Section has already determined to be needed. If ownership interests of an existing service provider or facility are purchased, without any accompanying addition, reduction, or relocation of the services offered, then none of the underlying policy concerns that are the basis for the CON Law come into play.

As stated above, since the establishment of the oncology treatment center pursuant to the 1997 CON, the linear accelerator, simulator and related equipment have been operated as part of an ongoing health care facility. After the completion of the Proposed Transaction, the same legal entity which received a CON in 1997, the same "person" under the CON Law, will continue to own the existing oncology treatment center.

For all of the foregoing reasons, the regulation of events like the Proposed Transaction, involving existing and previously reviewed and approved equipment or facilities, 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.

BASIS FOR EXPEDITED REVIEW

The Petitioners respectfully request that the Department issue a Declaratory Ruling on an expedited basis. Expediting the ruling will assist the Petitioners in consummating the Proposed Transaction as soon as possible. An expedited review is warranted for the following reasons:


- The proposed declaratory ruling is consistent with the Department's prior declaratory rulings that have construed the same provisions in the CON Law and have reached the same conclusion.
- The proposed declaratory ruling does not implicate any new arrangement for the development or offering of health services that would require analysis or interpretation of other facets of the CON Law. The Petitioners simply request confirmation that a change in the membership composition of an existing legal entity and CON holder that operates a health care service does not require certificate of need review.
- An expedited ruling will limit the transaction costs, reduce the effect of uncertainty on staff morale, and ensure the continuity of care and services to patients.

For the foregoing reasons, Petitioners respectfully request an expedited review of this request. The Petitioners do not request oral argument or a meeting with regard to this request, unless a third party comes forward and seeks to comment on the request. In that circumstance, the Petitioners request that the Department schedule a meeting at the earliest practicable time for all concerned parties to have an opportunity to present comments.

DECLARATORY RULING REQUESTED

The Petitioners respectfully submit that the purchase of membership interests in the LLC should not require a certificate of need because the same corporate entity will continue to own the oncology treatment center and its equipment, which will continue to serve patients at the same location as it has since the center first opened its doors in 1998 after the 1997 CON was issued to WROS. The Department's prior declaratory rulings cited in this Petition show that a purchase of membership interests in an existing and continuing health care organization does not constitute the acquisition of a linear accelerator or simulator or the development or expansion of a health service or health service facility. Accordingly, WROS, CCNC, USON, AOR and WakeMed request that the Department declare under the facts stated above, that the Proposed Transaction described in this Petition does not require a certificate of need.

This the 10th day of August, 2010.


Ronald I. Kirschbaum
N.C. State Bar No. 2556
*Attorneys for Wake Radiology Oncology,
PLLC*

OF COUNSEL:

KIRSCHBAUM, NANNEY, KEENAN & GRIFFIN, P.A.
2418 Blue Ridge Road
Suite 200
P.O. Box 19766
Raleigh, North Carolina 27607
Telephone: (919) 848.0420
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William R. Shenton

William R. Shenton
N.C. State Bar No. 8973
*Attorneys for U.S. Oncology, Inc. and AOR
Management Company of Virginia, LLC*

OF COUNSEL:

POYNER SPRUILL LLP
301 Fayetteville Street, Suite 1900
Raleigh, North Carolina 27601
Telephone: (919) 783.2947
Facsimile: (919) 783.1075

Larry E. Robbins

Larry E. Robbins
N.C. State Bar No. 9436
*Attorneys for Cancer Centers of North
Carolina, P.C.*

OF COUNSEL:

WYRICK ROBBINS YATES & PONTON, LLP
4101 Lake Boone Trail
Suite 300
P.O. Drawer 17803
Raleigh, North Carolina 27607
Telephone: (919) 781.4000
Facsimile: (919) 781.4865

Maureen Demarest Murray
Maureen Demarest Murray *by m*
N.C. State Bar No. 9195
Attorneys for WakeMed

OF COUNSEL:

SMITH MOORE LEATHERWOOD LLP
300 N. Greene Street, Suite 1400
Post Office Box 21927
Greensboro, North Carolina 27420
Telephone: (336) 378-5200
Facsimile: (336) 378-5400

CERTIFICATE OF SERVICE

I hereby certify that I have this day served a copy of the foregoing Petition for Declaratory Ruling upon the following parties at the address and in the manner indicated below.

Via Hand Delivery:

Drexdal Pratt, Director
Division of Health Service Regulation
Council Building
701 Barbour Drive
Raleigh, NC 27603

This the 10th day of August, 2010.

William R. Shenton
William R. Shenton

**INDEX
TO
EXHIBITS TO REQUEST FOR DECLARATORY RULING**

1. Certificate of Need issued July 6, 1997 to Wake Radiology Oncology Services, PLLC
2. Excerpt from 2000 State Medical Facilities Plan (Table 8Z – Hospital and Free-Standing Oncology Treatment Centers and Radiation Oncology Procedures)
3. Excerpt from 2010 State Medical Facilities Plan (Table 9E – Hospital and Free-Standing Linear Accelerators and Radiation Oncology Procedures)
4. *In Re: Request for Declaratory Ruling by Rex Healthcare, Inc. and Smithfield Radiation Oncology, LLC* (unsigned copy – printed from DHSR website)
5. *In Re: Request for Declaratory Ruling by Radiation Therapy Services, Inc. and North Carolina Radiation Therapy Management Services, Inc.*
6. *In Re: Request for Declaratory Ruling by New Hanover Perfusionists, Inc.*

Appendix 6

State Of North Carolina

Department Of Human Resources Division Of Facility Services

Certificate Of Need

Project Identification Number I-5464-96 Effective Date June 6, 1997
Issued to: Wake Radiology Oncology Services, PLLC
3614 Haworth Drive
Raleigh, NC 27609

The North Carolina Department of Human Resources, pursuant to the North Carolina Health Planning and Resource Development Act of 1978, G.S. § 131-175, et seq., as amended and recodified, G.S. § 131E-175, et seq., hereby finds and certifies that the new institutional health service proposed by the person listed above is consistent with, or as conditioned is consistent with the plans, standards, and criteria prescribed by the Act and the rules and regulations promulgated thereunder. The findings of the Department are attached hereto and incorporated by reference.

This Certificate affords the person listed above the opportunity to proceed with development of the proposed new institutional health service in a manner consistent with the plans, standards, and criteria prescribed by the Act and the rules and regulations promulgated thereunder. This Certificate includes and is limited to:

SCOPE: Wake Radiology Oncology Services, PLLC shall develop an oncology treatment center consisting of one medical linear accelerator, one therapeutic simulator and specialized computer systems, Wake County

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: Ashville Avenue, Cary, NC


MAXIMUM CAPITAL EXPENDITURE: \$2,086,152

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: September 1, 1997

This Certificate is limited to the person listed above and is not transferable or assignable. This Certificate may be withdrawn as provided in G.S. § 131E-189, and the rules and regulations promulgated thereunder.

Issuance of this Certificate does not supplant provisions or requirements embodied in codes, ordinances, statutes other than G.S. § 131E-175, et seq., rules regulations or guidelines administered or enforced by municipal, state or federal agencies or the agent thereof.


Eric D. Hoffner
Chief, Certificate of Need Section

CONDITIONS

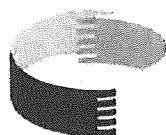
1. Wake Radiology Oncology Services, PLLC shall materially comply with the representations made in its certificate of need application, except as modified by the terms of this agreement and its correspondence received by the Certificate of Need Section on May 23, 1997.
2. Wake Radiology Oncology Services, PLLC shall acquire no more than one (1) linear accelerator and one (1) simulator.
3. The total capital expenditure for the project shall be \$2,086,152.
4. Wake Radiology Oncology Services, PLLC alone shall incur all capital expenditures necessary to acquire equipment and upfit and expand an office building for use as an oncology treatment center.

Conditions are pursuant to a Settlement Agreement signed by the applicant on May 30, 1997

TIMETABLE

| | |
|--|----------------|
| Completion of final drawings and specification | June 30, 1997 |
| Ordering equipment | June 30, 1997 |
| Completion of construction | March 1998 |
| Occupancy/offering of service | April 1, 1998 |
| Operation of equipment | March 15, 1998 |

Appendix 7



Cancer Centers *of North Carolina*

Medical Oncology

Neeraj Agrawal, M.D.
William R. Berry, M.D.
Elizabeth E. Campbell, M.D.
Roy Cromartie, M.D.
Alan D. Kritz, M.D.
Virgil L. Rose, M.D.
Stephen J. Tremont, M.D.
Mark Yoffe, M.D.

Radiation Oncology

John F. Reilly, Jr., M.D.
Scott L. Sailer, M.D.
Lewis Rosenberg, M.D.

ENT Surgical Oncology

Scott D. Meredith, M.D.

Gynecologic Oncology

Monica B. Jones, M.D.
Jennifer Rubatt, M.D.

August 1, 2014

Via Hand Delivery

Martha Frisone
Acting Chief
Certificate of Need Section
N.C. Division of Health Service Regulation
809 Ruggles Drive
Raleigh, NC 27603

RE: Support Letter for Proposed Transfer of Ownership Interests in Medical Oncology and Radiation Oncology Centers

Dear Ms. Frisone:

We are writing on behalf of Cancer Centers of North Carolina, P.C. ("CCNC") and AOR Management Company of Virginia, LLC ("AOR"), which is a subsidiary of US Oncology, Inc. ("USON"), in regard to the alternate proposed transactions described in a letter that is being submitted to the Certificate of Need Section on August 1, 2014 on behalf of Duke University Health System, Inc. d/b/a Duke Raleigh Hospital ("DUHS"). That letter (the "DUHS Request Letter") presents a Notice of Exempt Transaction and Request for No Review Determination.

As noted in the DUHS Request Letter, CCNC and AOR operate offices in Wake and Johnston Counties where CCNC has been providing a variety of services including medical oncology, radiation oncology, and ENT and gynecologic oncology. The details about these offices and equipment at CCNC's radiation oncology centers are presented in the DUHS Request Letter, which we have reviewed and approved.

CCNC and AOR have discussed the alternate proposed transactions described in the DUHS Request Letter and have reached agreement in principle with DUHS on those transactions. As you may be aware, CCNC is undergoing a transition, but we remain vitally interested in ensuring that needed diagnostic and therapeutic services for cancer patients residing in and around Wake and Johnston Counties are not interrupted. Continuity of patient care is a fundamental objective of the agreement in principle that we have reached with DUHS, and we believe that the transactions described in the DUHS Request Letter will ensure continued access to quality care for patients and their families in this area. CCNC and AOR fully support the exempt transaction notice and no review request set forth in the DUHS Request Letter.

In addition, a certificate of need was issued effective February 4, 2011 to CCNC and AOR to acquire a linear accelerator with stereotactic radiosurgery capabilities ("Trilogy Linac") to be located at the Macon Pond Center (Project I.D. No. J-7941-07). The Trilogy Linac project has not yet been fully developed. This letter also confirms that CCNC and AOR fully support DUHS' request for a determination that good cause exists to transfer the Trilogy Linac CON from CCNC and AOR to DUHS, for the reasons set forth in DUHS' Request for Transfer for Good Cause Letter dated August 1, 2014, which we have reviewed.


We hereby confirm that we are authorized to present the position of CCNC, AOR and USON with regard to the matters discussed above. Thank you for your attention to this matter.

Sincerely,

CANCER CENTERS OF NORTH CAROLINA, P.C.

By: 
Alan Kritz, President

AOR MANAGEMENT COMPANY OF VIRGINIA, LLC and US ONCOLOGY, INC.

By: 
Ella Friedman, SVP US Oncology Network Operns

Appendix 8

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

| | | |
|---------------------------------------|---|---------------------------|
| IN RE: REQUEST FOR DECLARATORY |) | |
| RULING BY JRH VENTURES, LLC, |) | |
| SMITHFIELD RADIATION |) | DECLARATORY RULING |
| ONCOLOGY, LLC and JOHNSTON |) | |
| RADIATION ONCOLOGY, LLC |) | |

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

JRH Ventures, LLC (hereinafter “JRH”), Smithfield Radiation Oncology, LLC (“SRO”), and Johnston Radiation Oncology, LLC (“JRO”) (collectively “the Applicants”) have requested a declaratory ruling to confirm that JRH’s acquisition of the membership interests of SRO and JRO may proceed without first obtaining a certificate of need. This ruling will be binding upon the Department and the entities requesting it, as long as the material facts stated herein are accurate. This ruling pertains only to the matters referenced herein. Except as provided by N.C.G.S. § 150B-4, the Department expressly reserves the right to make a prospective change in the interpretation of the statutes and regulations at issue in this Declaratory Ruling. David W. Strong of SRO has requested this ruling on behalf of the Applicants and has provided the material facts upon which this ruling is based.

STATEMENT OF THE FACTS

SRO owns and operates a linear accelerator (“linac”) in a building located on the campus of Johnston Memorial Hospital, at 509 N. Bright Leaf Blvd., Smithfield, Johnston County (“the Bright Leaf Blvd. Location”).

JRO owns and operates a linac in a medical office building located at 2186 NC Highway 42 West, in Clayton, Johnston County (“the Clayton Location”).

SRO is a North Carolina limited liability company (“LLC”) whose current sole member is Rex Hospital, Inc. (“Rex”). JRO is a North Carolina LLC whose current sole member is Johnston Health Enterprises, Inc.

JRH is a North Carolina LLC and consists of two members: Rex (50% member) and Johnston Health Enterprises, Inc. (50% member).

Rex now proposes to transfer its entire membership interest in SRO to JRH, and JRH will become SRO’s sole member. Thus, SRO will remain intact as the same LLC, but with a different membership composition.

Johnston Health Enterprises, Inc. will also transfer its entire membership interest in JRO to JRH, and JRH will become JRO’s sole member. Thus, JRO will remain intact as the same LLC, but with a different membership composition.

ANALYSIS

The CON law provides that no person shall offer or develop a “new institutional health service” without first obtaining a CON. N.C. Gen. Stat. § 131E-178. The list of new institutional health services includes “the acquisition by purchase, donation, lease, transfer or comparable arrangement” of a linear accelerator or simulator “by or on behalf of any person,” N.C. Gen. Stat. § 131E-176(16)(f)5a, 9, and “the obligation by any person of a capital

expenditure exceeding two million dollars (\$2,000,000) to develop or expand a health service or a health service facility, or which relates to the provision of a health service,” N.C. Gen. Stat. § 131E-176(16)(b).

Prior Declaratory Rulings show that the Department has already determined that these definitions do not require an entity to obtain a CON to acquire membership interests in existing legal entities like SRO and JRO which own and operate a linear accelerators or simulators. The Declaratory Ruling requested by the Applicants is consistent with the Department’s prior rulings that have interpreted the applicability of the CON Law to the purchase of ownership interests in health care organizations, for the following reasons:

The entity that owns the linear accelerator and simulator will not change, and the same equipment will be used to provide the same radiation oncology services, in the same location. The LLCs will continue to own their respective radiation therapy equipment.

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 locations, and no expansion of services is proposed.

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

CONCLUSION

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

This the _____ day of January, 2012.

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

CERTIFICATE OF SERVICE

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

CERTIFIED MAIL

David W. Strong
President, Smithfield Radiation Oncology, LLC
4420 Lake Boone Trail
Raleigh, NC 27607

This the _____ day of January, 2012.

Jeff Horton
Chief Operating Officer

Appendix 9

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

| | | |
|--|---|---------------------------|
| IN RE: REQUEST FOR |) | |
| DECLARATORY RULING BY |) | |
| THE CHARLOTTE-MECKLENBURG |) | |
| HOSPITAL AUTHORITY D/B/A |) | DECLARATORY RULING |
| CAROLINAS HEALTHCARE SYSTEM |) | |
| AND PINEVILLE RADIATION THERAPY |) | |
| CENTER, LLC |) | |

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

The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Healthcare System (“CMHA”) and Pineville Radiation Therapy Center, LLC (“PRTC”) have requested a Declaratory Ruling modifying a previous Declaratory Ruling issued on November 4, 2011, confirming that CMHA’s acquisition of the membership interests of University Radiation Oncology Center, LLC (“UROC”) and its continued operation of that facility may proceed without first obtaining a Certificate of Need (“CON”). This ruling will be binding upon the Department and the entities requesting it, as long as the material facts stated herein are accurate. This ruling pertains only to the matters referenced herein. Except as provided by N.C.G.S. § 150B-4, the Department expressly reserves the right to make a prospective change in the interpretation of the statutes and regulations at issue in this Declaratory Ruling. Gary S. Qualls of K&L Gates LLP has requested this ruling on behalf of CMHA and PRTC and has provided the material facts upon which this ruling is based.

STATEMENT OF THE FACTS

By declaratory ruling dated November 4, 2011, the Department ruled that CMHA could acquire, without a CON, the entire membership interest of UROC through transfer by Radiation Oncology Centers of the Carolinas, Inc. ("ROCC") and become UROC's sole member. CMHA has now decided to structure the proposed transaction differently, and CMHA asks that the Department approve this non-substantive change.

Instead of CMHA being the sole member of UROC, CMHA will be the sole member of PRTC, and PRTC will then be the sole member of UROC. Just as with the original transaction approved by the November 4, 2011 Declaratory Ruling, UROC will remain intact as the same LLC owning the linac operations, but with a different membership composition.

ANALYSIS

The November 4, 2011 Declaratory Ruling reasoned as follows in approving the request:

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

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

See Declaratory Ruling for the Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Healthcare System, November 4, 2011, p. 3.

The same rationale applies here. PRTC's acquisition of the membership interests in UROC does not constitute the acquisition of a linear accelerator or a simulator because the ownership of the equipment will not change. UROC will continue to own the two

pieces of equipment and UROC's legal status as a corporate entity will not change. No new institutional health service will be created and no new equipment will be added to the inventory.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that PRTC (with CMHA being the sole member in PRTC) may purchase ROCC's membership interests in UROC without a CON.

This the _____ day of January, 2012.

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

CERTIFICATE OF SERVICE

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

CERTIFIED MAIL

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

This the _____ day of January, 2012.

Jeff Horton
Chief Operating Officer

Appendix 10

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

**IN RE: REQUEST FOR DECLARATORY)
RULING BY RADIATION ONCOLOGY) DECLARATORY RULING
CENTERS OF THE CAROLINAS, INC.)**

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

Radiation Oncology Centers of the Carolinas, Inc. (“ROCC”) has requested a declaratory ruling to confirm that the transfer of two CON-approved radiation oncology facilities to two wholly owned subsidiaries (the “Proposed Transaction”) will not constitute a new institutional health service or require a CON. This ruling will be binding upon the Department and the entities requesting it, as long as the material facts stated herein are accurate. This ruling pertains only to the matters referenced herein. Except as provided by N.C.G.S. § 150B-4, the Department expressly reserves the right to make a prospective change in the interpretation of the statutes and regulations at issue in this Declaratory Ruling. S. Todd Hemphill of Bode, Call & Stroupe, L.L.P. has requested this ruling on ROCC’s behalf and have provided the material facts upon which this ruling is based.

STATEMENT OF THE FACTS

ROCC directly owns and operates two CON-approved radiation oncology facilities. University Radiation Oncology Center (“UROC”), located at 8310 University Executive Park, Suite 500, Charlotte, NC 28262, was acquired by ROCC in 1997 pursuant to an exemption.

Matthews Radiation Oncology Center (“MROC”), located at 1400 Matthews Township Parkway, Matthews, NC 28105, is a “grandfathered” facility, because it became operational in 1990, prior to the application of the CON law to oncology treatment centers or major medical equipment.

The radiation oncology equipment located at UROC includes a Varian 2100C linear accelerator and a GE Highspeed Advantage CT simulator. The radiation oncology equipment located at MROC includes a Varian 21Ex-d linear accelerator and a GE Brightspeed CT simulator. Acquisition of the linear accelerator and CT simulator equipment at each facility has been previously approved by the agency.

ROCC would like to transfer its interest in UROC and MROC to two wholly owned subsidiaries of ROCC.

ANALYSIS

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

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

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

The entity that owns the linear accelerator and simulator will not change, and the same equipment will be used to provide the same radiation oncology services, in the same location. The LLC will continue to own the linear accelerator, the simulator, and all the oncology treatment center assets that were authorized under the CON and have been used to furnish oncology treatments to patients.

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

CONCLUSION

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

This the _____ day of August, 2011.

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

CERTIFICATE OF SERVICE

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

CERTIFIED MAIL

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

This the _____ day of August, 2011.

Jeff Horton
Chief Operating Officer

Appendix 11

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

IN RE: REQUEST FOR)
DECLARATORY RULING BY REX)
HEALTHCARE, INC. AND SMITHFIELD) DECLARATORY RULING
RADIATION ONCOLOGY, LLC)

I, Robert J. Fitzgerald, Director of the Division of Health Service Regulation (the "Department"), hereby issue this declaratory ruling to Smithfield Radiation Oncology, LLC ("SRO") and Rex Healthcare, Inc. ("Rex") (collectively "Petitioners") pursuant to N.C.G.S. § 150B-4, 10A NCAC 14A.0103, and the authority delegated to me by the Secretary of the North Carolina Department of Health and Human Services. Petitioners have filed a Declaratory Ruling Request (the "Request") asking the Department to issue a declaratory ruling that Rex may increase its membership interest in SRO to 100% without certificate of need ("CON") review.

This ruling is binding on the Department and the person requesting it if the material facts stated in the Request are accurate and no material facts have been omitted from the request. The ruling applies only to this request. Except as provided by N.C.G.S. § 150B-4, the Department reserves the right to change the conclusions which are contained in this ruling. Gary S. Qualls of Kennedy Covington Lobdell & Hickman, L.L.P., counsel for Petitioners, has requested this ruling on behalf of Petitioners and has provided the statement of facts upon which this ruling is based. The material facts as provided by counsel for Petitioners are set out below.

STATEMENT OF THE FACTS

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

Petitioner SRO is a North Carolina limited liability company. Rex currently holds a 25% membership interest in SRO. The remaining members are the physician owners of Triangle Radiation Oncology Services. Petitioners state that Rex will be increasing its membership interest in SRO to 100%, thereby becoming the sole member of SRO.

SRO provides linear accelerator and radiation therapy services. Under prior law, because of the provisions in effect at the time, it was not subject to CON review either as an oncology treatment center or in connection with its acquisition of a linear accelerator.

Petitioners represent that ownership of SRO's linear accelerator will be unaffected by the proposed transaction; it will continue to be owned by SRO. They state that SRO will continue to provide cancer treatment services in materially the same manner as it has done for several years at its existing operational center.

ANALYSIS

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

The transaction described by Petitioners does not constitute the acquisition of a linear accelerator by any person because ownership of the linear accelerator here will not change. SRO will continue to be the owner of this equipment, and SRO's legal status as a limited liability company will not change.

Similarly, the transaction is not an obligation to develop or expand a health service or a health service facility, since Petitioners represent that SRO will continue to operate at the same location in a manner that is the same in all material respects as it operated prior to the transaction. In addition, pursuant to S.L. 2005-325, oncology treatment centers are not "health service facilities" for purposes of the CON law.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the Request to be true, I conclude that the acquisition by Rex of 100% of the membership interest of SRO, in the manner represented by Petitioners in the Request, is not subject to CON review.

This ruling is subject to the condition that, after the transaction, SRO continues to operate its radiation therapy center at the same location in Smithfield, Johnston County, North Carolina, in the same manner in which it operated prior to the transaction in all material ways.

This ruling is not intended to address, expand or validate any activities or status of SRO with respect to the requirements of the CON law as it relates to SRO. The ruling is limited to the specific facts presented in the Request.

This ____ day of December, 2007.

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

CERTIFICATE OF SERVICE

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

CERTIFIED MAIL

Gary S. Qualls
Kennedy Covington Lobdell & Hickman, L.L.P.
430 Davis Drive, Suite 400
Morrisville, NC 27560

This _____ day of December, 2007.

Jeff Horton
Chief Operating Officer

Appendix 12



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

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

Drexdal Pratt, Director

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

September 20, 2012

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

Jeff Shovelin
Director, Strategic Development
Vidant Health
PO Box 6028
Greenville, North Carolina 27835-6028

RE: No Review / East Carolina Health d/b/a Vidant Roanoke-Chowan Hospital / Change in Membership Interest in Radiation Services of North Carolina, LLC / Pitt County
FID # 923435


Dear Mr. Shovelin:


The Certificate of Need (CON) Section received your letter August 20, 2012 regarding the above referenced proposal. Based on the CON law in effect on the date of this response to your request, the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

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

In addition, you should contact the Acute Care Licensure & Certification Section, DHSR to determine if they have any requirements for development of the proposed project. 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,


Jane Rhoe-Jones
Project Analyst


Craig R. Smith, Chief
Certificate of Need Section

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

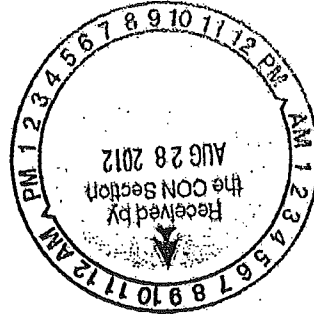




VIDANT HEALTH™

August 20, 2012

Love



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

Re: Notice of Change in Membership Interest in Radiation Services of North Carolina, LLC / Request for "No Review" Letter

Dear Mr. Smith:

This letter shall serve as notice that East Carolina Health d/b/a/ Vidant Roanoke-Chowan Hospital (VROA) intends to acquire 100% of the membership interest in Radiation Services of North Carolina, LLC (RSNC), an existing owner of a linear accelerator in Ahoskie, NC (Hertford County), on October 1, 2012. Currently, Alliance Oncology, LLC (Alliance) owns 100% of the membership interest. Before completing this transaction, we are requesting that the CON Section issue a letter determining VROA's acquisition of 100% membership interest of a linear accelerator and the subsequent provision of radiation therapy services in Ahoskie, North Carolina is not a new institutional health service, within the meaning of the certificate of need law.

RSNC originally acquired the Siemens 6700 linear accelerator in 1999. Prior to acquiring this linear accelerator, RSNC submitted a letter of no review requesting confirmation from the CON Section that its acquisition of the equipment and its provision of radiation therapy services did not require a CON (Exhibit A). The department's letter dated July 29, 1999 (Exhibit B) confirmed that no CON was required because the cost of acquiring the linear accelerator and making it operational was under the \$250,000 threshold for "oncology treatment centers," which was part of the CON Law at that time. Under current CON Law, "oncology treatment centers" are no longer a type of health service facility that is regulated. Instead, based on the changes to the law made in 2005, the CON Law directly regulates the acquisition of linear accelerators, regardless of cost (G.S. 131E-176(16)(f1)(5a)). Because RSNC acquired its linear accelerator in 1999 - six years prior to the current CON Laws pertaining to linear accelerators - RSNC's linear accelerator in "grandfathered" and is not subject to regulation under the CON Law.

In September 2008, Alliance filed a request for a declaratory ruling regarding its intent to purchase 100% of the membership interest in RSNC (Appendix C). Specifically the request asked, at that time, the Department of Health and Human Services to make the following declaration as to the applicability of the CON Law and the Department's rules to:

2100 Stantonsburg Road
Greenville, NC 27834-2818
PO Box 6028
Greenville, NC 27835-8028
252.847.4100
VidantHealth.com

- 1) The linear accelerator currently owned by RSNC is grandfathered equipment that is not subject to regulation under the CON law; and
- 2) Alliance 's acquisition of 100% of the membership interest of RSNC is not a new institutional health service since RSNC would continue to exist as the same corporate entity and would continue to own the same linear accelerator and Alliance's acquisition of 100% of the membership interest in RSNC was less than \$2,000,000.

In November 2008, Jeff Horton, at the time, the Acting Director of the Division of Health Service Regulation (Division), issued the declaratory ruling that concluded "the acquisition by Alliance Oncology, LLC of all the membership interests of RSNC, in the manner represented by Petitioner in the Request, is not subject to CON review (Appendix D). Upon this decision, Alliance purchased 100% of the membership interest in RSNC and continues to maintain 100% of the membership interest since. In December 2009, Alliance replaced the original Siemens 6700 linear accelerator with a Siemens Onco Impression linear accelerator (Serial Number 3753).

VROA believes the acquisition of 100% of the membership interest in RSNC from Alliance is not subject to CON review for the same reasons as determined in the Division's November 2008 declaratory ruling. Specifically,

- 1) The linear accelerator currently owned by RSNC would still be considered grandfathered equipment that is not subject to regulation under the CON law; and
- 2) VROA 's acquisition of 100% of the membership interest of RSNC is not a new institutional health service since RSNC would continue to exist as the same corporate entity and would continue to own the same linear accelerator and VROA's acquisition of 100% of the membership interest in RSNC will be less than \$2,000,000 (\$550,000).

If you have any questions or concerns, please feel free to contact me at (252) 847-3631

Sincerely,



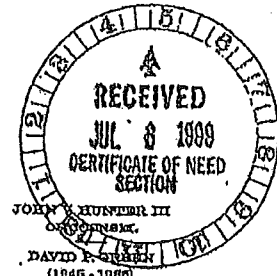
Jeffrey Shovelin
Director, Corporate Planning
Vidant Health

cc: Azzie Conley, Acute and Home Care Licensure and Certification Section

APPENDIX A

BODD, CALL & STROUPE, L.L.P.
ATTORNEYS AT LAW
2101 GLENWOOD AVENUE, SUITE 200
RALEIGH, NORTH CAROLINA 27612
(919) 881-0338
FACSIMILE (919) 881-9048

JOHN T. BODD
W. DAVIDSON CALL
ROBERT V. BODD
ODES L. STROUPE JR.
V. LANE WHARTON, JR.
S. TODD HEMPHILL
DIANA EVANS ROBERTS
JAMES N. JORGENSEN
ANTHONY D. TAIRI



MAILING ADDRESS
POST OFFICE BOX 6388
RALEIGH, NORTH CAROLINA
27622-6388

July 6, 1999

Via Hand Delivery

Lee B. Hoffman, Chief
Certificate of Need Section
Division of Facility Services
701 Barbour Drive
Raleigh, North Carolina 27603

Re: Radiation Services of North Carolina, LLC / Request for "No Review" Letter,
Hertford County

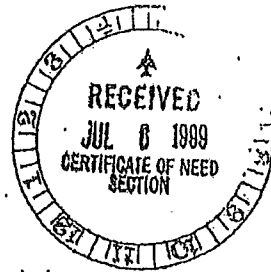
Dear Ms. Hoffman:

We are writing you on behalf of our client, Radiation Services of North Carolina, LLC (hereinafter, "RSNC"), requesting the CON Section to issue, pursuant to 10 NCAC 3R.0304, a letter determining that the following proposal by RSNC to acquire a linear accelerator and provide radiation therapy services in Ahsokle, Hertford County, North Carolina, is not a new institutional health service, within the meaning of the certificate of need law.

The operative statute in this regard is N.C. Gen. Stat. §131E-176(18a), which defines an oncology treatment center as follows:

"Oncology treatment center" means a facility, program, or provider, other than an existing health service facility that provides services for diagnosis, evaluation, or treatment of cancer and its aftereffects or secondary results and for which the total cost of all the medical equipment utilized by the center, exceeds two hundred fifty thousand dollars (\$250,000). In determining whether costs are more than two hundred fifty thousand dollars (\$250,000), the costs of equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making

Lee B. Hoffman
July 6, 1999
Page 2



operational the facility, program, or provider shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater.

Where the costs essential to the development of the facility do not exceed \$250,000, the facility is not an oncology treatment center, and therefore is not a new institutional health service. N.C.Gen.Stat. §§131E-176(9b), 131E-176(16)a., and 131E-178(a). For the reasons set forth below, the costs essential to the development of RSNC will not exceed \$250,000.

Facts

RSNC is a North Carolina limited liability corporation, established for the purpose of providing radiation oncology services in Ahoskie, North Carolina. Its Articles of Organization are attached hereto as Exhibit 1. The members of RSNC are Drs. Mark S. Sinesi and Christopher S. Sinesi. RSNC will lease space to provide its services in a building owned by Oncology Associates of North Carolina, PLLC (hereinafter, "OANC"), a North Carolina professional limited liability company. OANC's Articles of Organization are attached hereto as Exhibit 2. The members of OANC also are Drs. Mark S. Sinesi and Christopher S. Sinesi. OANC will own a physician office building in Ahoskie, to provide professional services to oncology patients. RSNC will acquire all essential radiation oncology equipment, and will be directly responsible to the contractor for all construction costs associated with the development of the radiation oncology service.

Attached as Exhibit 3 is a floor plan of the proposed physician office building to be constructed in Ahoskie. The spaces to be upfit for the radiation oncology service are the treatment room, the control room, a changing room and the dark room. The treatment room will house the linear accelerator, and will also contain space for construction and modification of molded cerrobend blocks, which provide the means to direct radiation to the specific site being treated. Radiation therapy procedures will be performed by staff operating from the control room. The darkroom will be used for developing x-rays used for treatment field verification and setup.

Services to be provided by the radiation oncology facility will include:

- treatment scheduling
- molded cerrobend block construction and modification; and
- radiation treatment with the use of high energy X-rays.

Treatment simulation and treatment planning will be performed off-site, through arrangements with The Cancer Center at Obici Hospital in Suffolk, Virginia, or through another existing radiation oncology facility in North Carolina.

Lee B. Hoffman
July 6, 1999
Page 3



RSNC's costs associated with the upfit of the above space and the acquisition of necessary equipment is estimated to be \$247,880, as set forth in the certified cost estimate attached hereto as Exhibit 4 and price quotes attached hereto as Exhibit 5. RSNC will acquire no other equipment with regard to this proposal.

OANC and/or other physician practices will separately provide professional services to cancer patients, including the following:

- patient consultation;
- patient examination;
- medical oncology treatment;
- nutritional counseling; and
- patient screening, education, early detection and public awareness programs.

The construction cost of the building is estimated to total \$370,550, as set forth in the certified cost estimate attached hereto as Exhibit 6. None of these capital costs will be borne by RSNC, and none of these costs directly relate to the provision of radiation therapy. RSNC will lease the treatment room, control room, changing room and darkroom from OANC pursuant to an operating lease, a draft of which is attached hereto as Exhibit 7. Pursuant to the lease, RSNC will have access to common areas used for patients and other visitors of OANC, including an examination room, waiting room and rest rooms, for a nominal cost. See Exhibit 7, ¶¶4(b) and 9. RSNC will have no obligation, however, for the construction or upfit of these common spaces. The lease is an operating, not a capital lease, and RSNC will have no right to purchase the premises (or any part thereof) at the conclusion of the lease term.

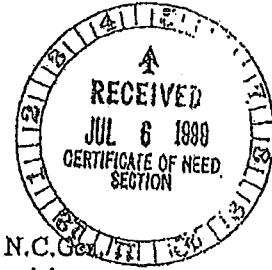
Although RSNC and OANC have common ownership, they are separate legal entities with separate provider numbers, and each will bill patients separately for the services provided under its own provider number. The relationship between the two entities will be arms-length, as landlord and tenant. As discussed below, the radiologist owners of OANC will not refer patients to the linear accelerator. Rather, referrals are and will be made by unaffiliated medical oncologists and general practitioners. Therefore, there should be no self-referral issues related to the operation of the radiation oncology facility. Further, as discussed more fully below, potential self-referral issues do not impact any issues under the CON law or regulations and therefore should not be considered in the context of a "no review" determination.

Discussion

New Institutional Health Service

To determine whether a proposed facility is an "oncology treatment center" under the above statute, the only costs to be considered are "the costs of equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities

Lee B. Hoffman
July 6, 1999
Page 4



essential to acquiring and making operational *the facility, program, or provider.*" N.C. Gen. Stat. §131E-176(18a) (emphasis added). The other separate capital costs of the physician office building which are not attributable to the service to be provided should not be considered. Indeed, a physician office building *per se* is exempt from certificate of need review, irrespective of the cost. N.C. Gen. Stat. §131E-184(9). Only when a particular service offered in that physician office building otherwise may be a new institutional health service, may the costs of such service be considered in making such a determination.

The facts presented show that the costs associated with the acquisition of the linear accelerator and other essential equipment, together with the construction and development costs associated with the radiation oncology facility, total \$247,880, which is below the statutory \$250,000 threshold. That being the case, the proposed service is not a new institutional health service, and would not require a certificate of need.

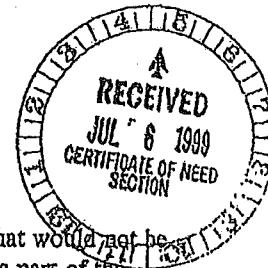
Self-Referral Issues

A question has been raised as to whether the proposed operation of RSNC in the same building as OANC's physician practice is consistent with applicable laws regarding self-referral under the Federal Stark law or North Carolina's similar self-referral provision. We respectfully submit that this question has no bearing on the question as to whether RSNC's proposal is a new institutional health service. However, because of the implications and/or possible misconceptions that could arise from a simultaneous analysis of these issues, we believe we should present our position on why these laws, even if applicable, present no issues which would impact our client's proposal.

The Stark law provides that a physician who has a financial relationship with an entity may not refer Medicare or Medicaid patients to that entity for the furnishing of certain health services (and the entity may not bill for the services) unless an applicable exemption exists. Thus, the Stark law specifically contemplates looking beyond the formal corporate structure to address these self-referral issues.

Conversely, under the CON law, the only issue which the CON Section may determine is whether the capital costs associated with the acquisition of equipment by the "facility, program or provider" at issue are \$250,000 or less. As set forth above, the "facility, program or provider" at issue is the radiation therapy facility owned by RSNC, a distinct legal entity. The capital costs associated with the acquisition of equipment and development of that facility will not exceed \$250,000. The separate physician practice owned by OANC is exempt under the CON law (N.C. Gen. Stat. §131E-184(a)(9)), and the capital costs associated with that portion of the building related to the physician practice may not be considered under the CON law and established CON Section precedent. Because the costs associated with RSNC's proposal will not exceed \$250,000, it is not a new institutional health service, and the CON Section has no authority to regulate it. N.C. Gen. Stat. §131E-178(a). Therefore, even if the

Lee B. Hoffman
July 6, 1999
Page 5



arrangement between RSNC and OANC were to raise self-referral concerns, that would not be an issue within the CON Section's jurisdiction, and should not be considered as part of the CON Section's determination.

However, to alleviate any concerns you may have on this issue, the Stark and North Carolina anti-self-referral laws in fact will not impact the proposal. No person or entity involved in the Ahoskie center will be making "referrals," because as a practical matter, radiation oncologists generally do not make referrals for radiation therapy. Rather, a general practitioner or medical oncologist refers a cancer patient to a radiation oncologist, to determine whether radiation therapy is an appropriate course of treatment. If the radiation oncologist recommends radiation therapy, the patient is then sent *back* to the initial referring physician, who then makes a referral to whatever radiation therapy center that physician and the patient agree is most appropriate. This has always been the procedure under which the physician owners of OANC have operated, and we can affirmatively represent to you that they will continue in this fashion, and that none of the physicians associated with OANC will make referrals to the RSNC linear accelerator. Therefore, the Stark law is not applicable.

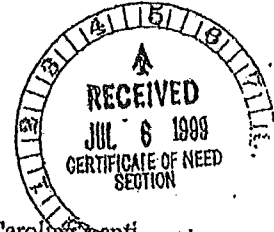
Further, even if those radiologists were to refer patients to the RSNC linear accelerator, such activity would not constitute a prohibited referral under the Stark law. Under the Stark law, a "referral" is defined as "the request by a physician for the item or service, including the request by a physician for a consultation with another physician (and any test or procedure ordered by, or to be performed by (or under the supervision of), that other physician)... " 42 U.S.C. § 1395nn(h)(5)(A). The request or establishment of a plan of care by a physician that includes the provision of designated health services also constitutes a referral by a referring physician; however, the Stark law defines as *not* being a referral "services integral to a consultation by certain specialists." Among those excluded services are radiation oncology services:

[A] request by a radiation oncologist for radiation therapy, if such services are furnished by (or under the supervision of) such . . . radiation oncologist pursuant to a consultation requested by another physician does not constitute a "referral" by a "referring physician."

42 U.S.C. § 1395nn(h)(5)(C). Thus, a radiation oncologist may direct a patient to a radiation therapy service in which he has a financial interest, so long as that physician is supervising the radiation treatment performed.

Similarly, the North Carolina anti-self-referral law provides that a prohibited referral by a health care provider does *not* include referral to a designated health care service where the provider or a member of his group practice will be directly supervising the provision of care. N.C. Gen. Stat. § 90-405(11).

Lee B. Hoffman
July 6, 1999
Page 6



As a practical matter, however, neither the federal Stark law nor North Carolina's anti-self-referral statute apply to this situation, since all referrals will be made by physicians who have no financial interest in OANC or RSNC.

Conclusion

Based upon our research and analysis of the facts, the proposed acquisition and provision of radiation services is exempt from review. It is our opinion that the CON Section should determine that RSNC's proposal is not subject to certificate of need review and issue its letter of "no review."

Please contact us if you have any questions or if you need any further information regarding this review. We would appreciate your attention to this request at your earliest convenience.

Very truly yours,

BODE, CALL & STROUPB, L.L.P.

A handwritten signature in cursive script, appearing to read "S. Todd Hemphill".

S. Todd Hemphill.

STH/sh: 3809.000

APPENDIX B



454 II
to review 135

North Carolina Department of Health and Human Services
Division of Facility Services
701 Barbour Drive - Post Office Box 29530 Raleigh, N.C. 27626-0530
Courier Number 56-20-05

James B. Hunt, Jr., Governor
H. David Bruton, M.D., Secretary
July 29, 1999

Lynda D. McDaniels, Director

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

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

RE: No Review/Radiation Services of North Carolina, LLC/ Acquire a linear accelerator and provide radiation oncology services/ Hertford County

Dear Mr. Hempill:

In response to your letters of July 6 and July 14, 1999, the above referenced proposal does not represent a new institutional health service within the meaning of N.C.G.S. 131B-176(16) and, therefore, you may proceed to offer, develop or establish the above referenced project without a certificate of need.

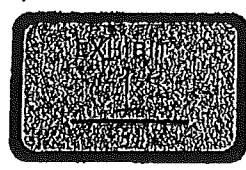
It should be noted that this Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this Agency and a separate determination. If you have any questions concerning this matter, please feel free to contact this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

Sincerely,

Louise A. Campbell by MCF
Louise A. Campbell, Project Analyst

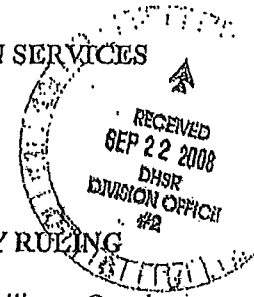
Lee B. Hoffman
Lee B. Hoffman, Chief
Certificate of Need Section

cc: Medical Facilities Planning Section, DRS



Appendix C

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



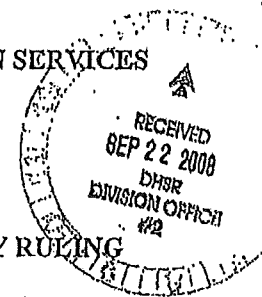
IN RE: REQUEST FOR)
DECLARATORY RULING BY) REQUEST FOR
ALLIANCE ONCOLOGY, LLC) DECLARATORY RULING

Pursuant to N.C. Gen. Stat. § 150B-4 and 10A N.C.A.C. 14A.0103, Alliance Oncology, LLC ("Alliance") requests that the North Carolina Department of Health and Human Services, Division of Health Service Regulation (the "Department") issue a declaratory ruling as to the applicability of Chapter 131E, Article 9 of the North Carolina General Statutes and of the Department's rules to the facts described below. Alliance requests a declaration that (1) the linear accelerator currently owned by Radiation Services of North Carolina, LLC ("RSNC") is grandfathered equipment that is not subject to regulation under the certificate of need ("CON") Law and (2) its acquisition of all of the membership interests of RSNC does not require a CON.

STATEMENT OF FACTS

RSNC currently owns a Siemens 6700 linear accelerator, which it acquired in 1999. Prior to acquiring this linear accelerator, RSNC requested confirmation from the CON Section that its acquisition of this equipment and its provision of radiation therapy services did not require CON review. By letter dated July 29, 1999, the CON Section confirmed that RSNC's acquisition of this linear accelerator did not require a CON. A copy of the July 1999 correspondence between counsel for RSNC and the CON Section regarding this matter is attached hereto as Exhibit 1. The Department's July 29, 1999 letter confirmed that no CON was required because the cost of acquiring the linear accelerator and making it operational was under the \$250,000 threshold for "oncology treatment centers," which was part of the CON Law at that time.

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



IN RE: REQUEST FOR)
DECLARATORY RULING BY) REQUEST FOR
ALLIANCE ONCOLOGY, LLC) DECLARATORY RULING

Pursuant to N.C. Gen. Stat. § 150B-4 and 10A N.C.A.C. 14A.0103, Alliance Oncology, LLC ("Alliance") requests that the North Carolina Department of Health and Human Services, Division of Health Service Regulation (the "Department") issue a declaratory ruling as to the applicability of Chapter 131E, Article 9 of the North Carolina General Statutes and of the Department's rules to the facts described below. Alliance requests a declaration that (1) the linear accelerator currently owned by Radiation Services of North Carolina, LLC ("RSNC") is grandfathered equipment that is not subject to regulation under the certificate of need ("CON") Law and (2) its acquisition of all of the membership interests of RSNC does not require a CON.

STATEMENT OF FACTS

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Alliance now proposes to acquire all of the membership interests of RSNC. Following the acquisition of these membership interests by Alliance, RSNC would continue to exist as the same corporate entity and would continue to own the same linear accelerator. Alliance's acquisition of all of the membership interests in RSNC will cost much less than \$2,000,000.

DISCUSSION

Under the current CON Law, "oncology treatment centers" are no longer a type of health service facility that is regulated. Instead, based on the changes to the law made in 2005, the CON Law directly regulates the acquisition of linear accelerators, regardless of cost. See N.C. Gen. Stat. § 131E-176(16)(f1)(5a). Because RSNC acquired its linear accelerator in 1999 – six years prior to the current requirement that any acquisition of a linear accelerator, regardless of cost, requires a CON – RSNC's linear accelerator is "grandfathered" and is not subject to regulation under the CON Law.

Following Alliance's proposed acquisition of all of the membership interests of RSNC, the current ownership of the linear accelerator would remain unchanged; it would continue to be owned by RSNC. Therefore, there will be no change in ownership of this linear accelerator.

The CON Law would require a full review of Alliance's proposal if it involved the development of a "new institutional health service." See N.C. Gen Stat. § 131E-178(a). However, Alliance's proposed acquisition of the membership interests in RSNC is not a new institutional health service as that term is defined in N.C. Gen. Stat. § 131E-176(16).

This proposal does not constitute the development of a "new institutional health service" pursuant to N.C. Gen. Stat. § 131E-176(16)(f1), which defines the acquisition of certain equipment, including a linear accelerator, as a new institutional health service. This statute does not apply here because RSNC will at all times continue to own the linear accelerator.

Additionally, Alliance's acquisition of the membership interests in RSNC will cost much less than the \$2,000,000 threshold established in N.C. Gen. Stat. § 131E-176(16)(b).

DECLARATORY RULING REQUESTED

Alliance requests that the Department of Health and Human Services make the following declaration as to the applicability of the CON Law and the Department's rules to the foregoing stated facts:

1. The linear accelerator currently owned by Radiation Services of North Carolina, LLC is grandfathered equipment that is not subject to regulation under the CON Law; and
2. Alliance Oncology, LLC's acquisition of all of the membership interests of Radiation Services of North Carolina, LLC is not a new institutional health service and does not require a certificate of need.

This the 22nd day of September, 2008.

NELSON MULLINS RILEY & SCARBOROUGH LLP

By: Wallace C. Hollowell, III
Wallace C. Hollowell, III
GlenLake One, Suite 200
4140 Parklake Avenue
Raleigh, North Carolina 27612
Telephone: (919) 329-3800

ATTORNEYS FOR ALLIANCE ONCOLOGY, LLC

Appendix D



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

Michael F. Basley, Governor
Dempsey Banton, Secretary

Jeff Horton, Acting Director
Phone: 919-855-3750
Fax: 919-733-2757

November 6, 2008

CERTIFIED MAIL

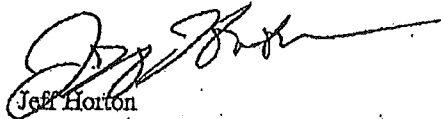
Wallace C. Hollowell, III, Esquire
GlenLake One, Suite 200
4140 Parklake Avenue
Raleigh, North Carolina 27612

RE: Declaratory Ruling for Alliance Oncology, LLC, Hertford County

Dear Mr. Hollowell:

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

Sincerely,



Jeff Horton

JH:JG:peb

Enclosure

cc: Jesse Goodman, Acting Chief Operating Officer, DHSR
Lee Hoffman, Chief, Certificate of Need Section
Azzie Conley, Chief, Acute and Home Care Licensure and Certification Section
Medical Facilities Planning Section
Marc Lodge, Special Deputy Attorney General, DOJ



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



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

IN RE: REQUEST FOR)
DECLARATORY RULING BY ALLIANCE) DECLARATORY RULING
ONCOLOGY, LLC)

I, Jeff Horton, Acting Director of the Division of Health Service Regulation (the "Department"), hereby issue this declaratory ruling to Alliance Oncology, LLC ("Petitioner") pursuant to N.C.G.S. § 150B-4, 10A NCAC 14A.0103, and the authority delegated to me by the Secretary of the North Carolina Department of Health and Human Services. Petitioner has filed a Declaratory Ruling Request (the "Request") asking the Department to issue a declaratory ruling that Alliance may acquire all of the membership interests of Radiation Services of North Carolina, LLC ("RSNC") without certificate of need ("CON") review.

This ruling is binding on the Department and the person requesting it if the material facts stated in the Request are accurate and no material facts have been omitted from the request. The ruling applies only to this request. Except as provided by N.C.G.S. § 150B-4, the Department reserves the right to change the conclusions which are contained in this ruling. Wallace C. Hollowell, III of Nelson Mullins Riley & Scarborough LLP, counsel for Petitioner, has requested this ruling on behalf of Petitioner and has provided the statement of facts upon which this ruling is based. The material facts as provided by counsel for the Petitioner are set out below.

STATEMENT OF THE FACTS

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

Petitioner Alliance Oncology is a North Carolina limited liability company. Petitioner states that Alliance will be acquiring all of the membership interests of RSNC.

RSNC provides linear accelerator and radiation therapy services. Under prior law, because of the provisions in effect at the time, it was not subject to CON review either as an oncology treatment center or in connection with its acquisition of a linear accelerator.

Petitioner represents that ownership of RSNC's linear accelerator will be unaffected by the proposed transaction; it will continue to be owned by RSNC.

ANALYSIS

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

The transaction described by the Petitioner does not constitute the acquisition of a linear accelerator by any person because ownership of the linear accelerator here will not change. RSNC will continue to be the owner of this equipment, and RSNC's legal status as a limited liability company will not change.

Similarly, the transaction is not an obligation to develop or expand a health service or a health service facility, since Petitioner represents that RSNC will continue to operate in the same manner and in all material respects as it operated prior to the transaction. In addition, pursuant to S.L. 2005-325, oncology treatment centers are not "health service facilities" for purposes of the CON law.

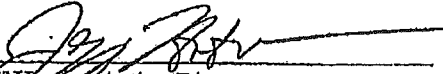
CONCLUSION

For the foregoing reasons, assuming the statements of fact in the Request to be true, I conclude that the acquisition by Alliance Oncology, LLC of all of the membership interests of RSNC, in the manner represented by Petitioner in the Request, is not subject to CON review.

This ruling is subject to the condition that, after the transaction, RSNC continues to operate its radiation therapy center in the same manner in which it operated prior to the transaction in all material ways.

This ruling is not intended to address, expand or validate any activities or status of RSNC with respect to the requirements of the CON law as it relates to RSNC. The ruling is limited to the specific facts presented in the Request.

This 6th day of November, 2008.



Jeff Horton, Acting Director
Division of Health Service Regulation
N.C. Department of Health and Human Services

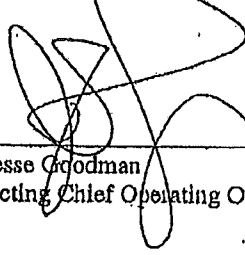
CERTIFICATE OF SERVICE

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

CERTIFIED MAIL

Wallace C. Hollowell, III
GlenLake One, Suite 200
4140 Parklake Avenue
Raleigh, North Carolina 27612

This the 6th day of November, 2008.



Jesse Goodman
Acting Chief Operating Officer

Appendix 13



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/dhshr

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

January 6, 2012

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

RE: No Review:

- Transfer by Cancer Centers of North Carolina – Asheville, P.C. (CCNC Asheville) of 100% of its ownership interests in the existing oncology treatment center located at 20 Medical Park Drive, Asheville (Oncology Center) to AHLC, LLC, a wholly-owned subsidiary of CCNC Asheville
 - Transfer by AOR Management Company of Virginia, LLC (AOR) of 100% of its ownership interests in the Oncology Center to Asheville CC, LLC, a wholly-owned subsidiary of AOR
 - Acquisition of 100% of AHLC, LLC by North Carolina Radiation Therapy Management Services, LLC (NCR TMS)
 - Acquisition of 100% of Asheville CC, LLC by NCR TMS
- Buncombe County


Dear Mr. Shenton:


The Certificate of Need (CON) Section received your letter of September 26, 2011 and an email dated December 28, 2011 regarding the above referenced proposals. Based on the CON law in effect on the date of this response to your request, the proposals described in your correspondence are not governed by, and therefore, do not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposals would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposals when the new law becomes effective.

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

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

Sincerely,


Martha J. Frisone
Assistant Chief


Craig R. Smith, Chief
Certificate of Need Section

cc: Medical Facilities Planning Section, DHSR



Frisone, Martha

From: S. Todd Hemphill [Hemphill@bcs-law.com]
Sent: Wednesday, December 28, 2011 9:57 AM
To: Smith, Craig; Frisone, Martha
Cc: William R. Shenton (wshenton@poynerspruill.com); Ouchley, Jeremy C
Subject: Request for No Review Determination - Asheville Oncology Treatment Center
Attachments: North Carolina Qualification - Asheville CC.pdf; ART-ORG - AHLC.pdf; CERT ORG - Asheville CC.pdf

Dear Craig and Martha,

Following up on Bill Shenton's September 26, 2011 letter regarding the above matter, please find attached Articles of Organization for AHLC, LLC (the entity owned by the physicians), and the Certificate of Organization and Application for Certificate of Authority for Asheville CC, LLC (the entity owned by AOR Management). I believe this is all the information you need to complete your review of the request, but please feel free to contact me if I can be of further assistance.

Todd

S. Todd Hemphill

Attorney

919.881.0338 Ext. 238

hemphill@bcs-law.com



Bode, Call & Stroupe, LLP

3105 Glenwood Ave, Suite 300

Raleigh, NC 27612

P: 919.881.0338 • F: 919.881.9548

www.bcs-law.com

This e-mail and any attachments hereto, is intended only for use by the addressee(s) named herein and may contain legally privileged and/or confidential information. If you are not the intended recipient of this e-mail, you are hereby notified that the dissemination, distribution or copying of this e-mail, and any attachments hereto, is strictly prohibited by law. If you have received this e-mail in error, please notify the foregoing sender immediately via return email or by telephone (919.881.0338), and delete this message and all attachments from your computer system. Thank you.



NORTH CAROLINA

Department of the Secretary of State

To all whom these presents shall come, Greetings:

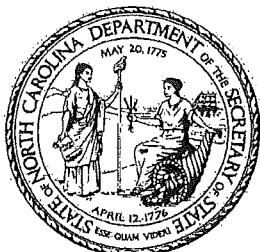
I, Elaine F. Marshall, Secretary of State of the State of North Carolina, do hereby certify the following and hereto attached to be a true copy of

APPLICATION FOR CERTIFICATE OF AUTHORITY

OF

ASHEVILLE CC, LLC

the original of which was filed in this office on the 3rd day of November, 2011.



IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal at the City of Raleigh, this 3rd day of November, 2011.

Elaine F. Marshall

Secretary of State

SOSID: 1228671
Date Filed: 11/3/2011 12:20:00 PM
Elaine F. Marshall
North Carolina Secretary of State
C201130600648

State of North Carolina
Department of the Secretary of State

APPLICATION FOR CERTIFICATE OF AUTHORITY
FOR LIMITED LIABILITY COMPANY

Pursuant to §57C-7-04 of the General Statutes of North Carolina, the undersigned limited liability company hereby applies for a Certificate of Authority to transact business in the State of North Carolina, and for that purpose submits the following:

1. The name of the limited liability company is Asheville CC, LLC;

and if the limited liability company name is unavailable for use in the State of North Carolina, the name the limited liability company wishes to use is Asheville CC, LLC

FICTITIOUS NAME NOT
FILED IN THIS OFFICE

2. The state or country under whose laws the limited liability company was formed is: Delaware

3. The date of formation was October 17, 2011; its period of duration is: Perpetual

4. Principal office information: (Select either a or b.)

a. The limited liability company has a principal office.

The street address and county of the principal office of the limited liability company is:

Number and Street 10101 Woodloch Forest Drive
City, State, Zip Code The Woodlands, TX 77380 County Montgomery

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

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

5. The street address and county of the registered office in the State of North Carolina is:

Number and Street 327 Hillsborough Street
City, State, Zip Code Raleigh, NC 27603 County Wake

6. The mailing address, *if different from the street address*, of the registered office in the State of North Carolina is:

7. The name of the registered agent in the State of North Carolina is: Corporation Service Company

APPLICATION FOR CERTIFICATE OF AUTHORITY

Page 2

8. The names, titles, and usual business addresses of the current managers of the limited liability company are:
(use attachment if necessary)

| <u>Name</u> | <u>Business Address</u> |
|--|---|
| AOR Management Company of Virginia, LLC | 10101 Woodloch Forest Drive, The Woodlands, TX 77380 |
| | |
| | |
| | |

9. Attached is a certificate of existence (or document of similar import), duly authenticated by the secretary of state or other official having custody of limited liability company records in the state or country of formation. The Certificate of Existence must be less than six months old. A photocopy of the certification cannot be accepted.

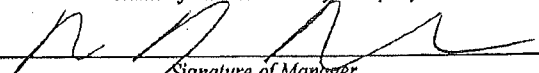
10. If the limited liability company is required to use a fictitious name in order to transact business in this State, a copy of the resolution of its managers adopting the fictitious name is attached.

11. This application will be effective upon filing, unless a delayed date and/or time is specified: _____

This the 15th day of Nov., 2011

Asheville CC, LLC
AOR Management Company of Virginia, LLC, Member

Name of Limited Liability Company



Signature of Manager

Bruce D. Broussard, President

Type or Print Name

Authorized to sign in accordance with NCGS 57c-3-24"

Notes:

1. Filing fee is \$250. This document must be filed with the Secretary of State.

CORPORATIONS DIVISION

P. O. BOX 29622

RALEIGH, NC 27626-0622

(Revised January 2002)

(Form L-09)

Delaware

PAGE 1

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ASHEVILLE CC, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIRST DAY OF NOVEMBER, A.D. 2011.

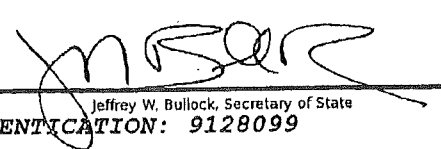
AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE NOT BEEN ASSESSED TO DATE.

5051933 8300

111155025

You may verify this certificate online
at corp.delaware.gov/authver.shtml




Jeffrey W. Bullock, Secretary of State
AUTHENTICATION: 9128099

DATE: 11-01-11



NORTH CAROLINA

Department of the Secretary of State

To all whom these presents shall come, Greetings:

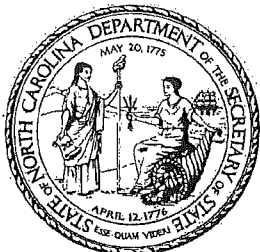
I, Elaine F. Marshall, Secretary of State of the State of North Carolina, do hereby certify the following and hereto attached to be a true copy of

ARTICLES OF ORGANIZATION

OF

AHLC, LLC

the original of which was filed in this office on the 20th day of December, 2011.



IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal at the City of Raleigh, this 20th day of December, 2011.

Elaine F. Marshall

Secretary of State

State of North Carolina
Department of the Secretary of State

SOSID: 1235047
Date Filed: 12/20/2011 1:48:00 PM
Elaine F. Marshall
North Carolina Secretary of State
C201135400200

Limited Liability Company
ARTICLES OF ORGANIZATION

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

1. The name of the limited liability company is: AHLC, LLC
2. If the limited liability company is to dissolve by a specific date, the latest date on which the limited liability company is to dissolve: *(If no date for dissolution is specified, there shall be no limit on the duration of the limited liability company.)*
3. The name and address of each person executing these articles of organization is as follows:
(State whether each person is executing these articles of organization in the capacity of a member, organizer or both. Note: This document must be signed by all persons listed here).
Don Jackson, M.D., Organizer, Member
20 Medical Park Dr.
Asheville, NC 28803
4. The street address and county of the initial registered office of the limited liability company is:
Number and Street 20 Medical Park Dr., Asheville, NC 28803
City, State, Zip Code Asheville, NC 28803 County Buncombe
5. The mailing address, *if different from the street address*, of the initial registered office is:

6. The name of the initial registered agent is Don Jackson, M.D.
7. Principal office information: *(Select either a or b.)*
 - a. The limited liability company has a principal office.
The street address and county of the principal office of the limited liability company is:
Number and Street 20 Medical Park Dr.
City, State, Zip Code Asheville, NC 28803 County Buncombe
The mailing address, *if different from the street address*, of the principal office of the corporation is:

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

8. Check one of the following:

(i) *Member-managed LLC*: all members by virtue of their status as members shall be managers of this limited liability company.

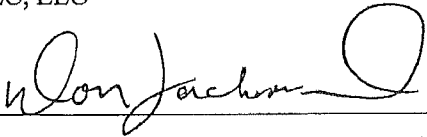
(ii) *Manager-managed LLC*: except as provided by N.C.G.S. Section 57C-3-20(a), the members of this limited liability company shall not be managers by virtue of their status as members.

9. Any other provisions which the limited liability company elects to include are attached.

10. These articles will be effective upon filing, unless a date and/or time is specified:

This is the 15 day of December 2011

AHLC, LLC



Don Jackson, M.D., Member-Manager

NOTES:

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

CORPORATIONS DIVISION
(Revised January 2002)

P.O. Box 29622

RALEIGH, NC 27626-0622
(Form L-01)

Instructions for Filing

Delaware

PAGE 1

The First State

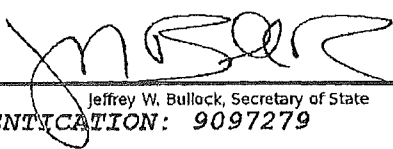
I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ASHEVILLE CC, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SEVENTEENTH DAY OF OCTOBER, A.D. 2011.



5051933 8300

111105649

You may verify this certificate online
at corp.delaware.gov/authver.shtml


Jeffrey W. Bullock, Secretary of State
AUTHENTICATION: 9097279

DATE: 10-17-11

State of Delaware
Secretary of State
Division of Corporations
Delivered 10:52 AM 10/17/2011
FILED 10:52 AM 10/17/2011
SRV 111105649 - 5051933 FILE

STATE of DELAWARE
LIMITED LIABILITY COMPANY
CERTIFICATE of FORMATION

First: The name of the limited liability company is Asheville CC, LLC

Second: The address of its registered office in the State of Delaware is 2711
Centerville Road, #400 in the City of Wilmington
Zip code 19808. The name of its Registered agent at such address is
Corporation Service Company

Third: (Use this paragraph only if the company is to have a specific effective date of
dissolution: "The latest date on which the limited liability company is to dissolve is
_____")

Fourth: (Insert any other matters the members determine to include herein.)

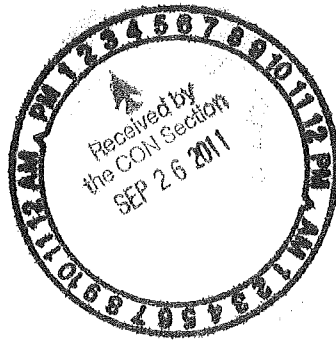
Sole Member: AOR Management Company of Virginia, LLC

In Witness Whereof, the undersigned have executed this Certificate of Formation this
17th day of October, 2011.

By: [Signature]
Authorized Person (s)

Name: Bruce b. Broussard

WSD



Poyner Spruill^{LLP}

September 26, 2011

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

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 Corporate Entities that Own Cancer Centers of North Carolina's Asheville Oncology Treatment Center

Dear Mr. Smith:

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 is a national provider of radiation oncology services which offers services at several locations in western North Carolina.

With this letter, NCRTMS is requesting a no-review determination regarding its acquisition of the ownership interests in the corporate entities that own an existing oncology treatment center and the associated equipment located in Asheville, North Carolina. Consistent with the longstanding approach of the Agency in finding that purchases of corporate ownership interests are not events requiring a certificate of need, NCRTMS now seeks confirmation that its acquisition of membership interests in the corporate entities owning the existing Asheville oncology treatment center, including a linear accelerator and computed tomography scanner, and its continued operation of that oncology treatment center and the same equipment, at the same site, may proceed without first obtaining a certificate of need.

FACTUAL BACKGROUND

The Parties

Since 2004, Cancer Centers of North Carolina – Asheville, P.C. ("CCNC-Asheville") and AOR Management Company of Virginia, LLC (f/k/a AOR Management Company of Virginia, Inc.) ("AOR"), an indirect, wholly-owned subsidiary of US Oncology, Inc. ("USON"), together have owned and operated an oncology treatment center that is located at 20 Medical Park Drive, Asheville, North Carolina (the "Oncology Center").¹ This Oncology Center uses a Varian 2100C linear accelerator (the "Linac") and a computed tomography scanner (the "CT Scanner") to provide radiation therapy services to patients. As discussed further below, the Linac and CT Scanner were acquired, and have been used to provide radiation therapy services, under an exemption from certificate of need ("CON") review that was recognized by the Certificate of Need Section ("CON Section"). After an appeal of this determination, the CON Section's decision to grant an exemption was upheld.

¹ CCNC-Asheville was formerly known as Asheville Hematology and Oncology Associates, P.A. ("AHO"). The corporate name was changed in 2009. See Exhibit 1. AOR was formerly a corporation, but has converted to a limited liability company. See Exhibit 2.

Mr. Craig R. Smith
Chief, CON Section
September 26, 2011
Page 2

Poyner Spruill^{LLP}

CCNC-Asheville is a professional corporation organized under the laws of the State of North Carolina with its principal place of business located at 20 Medical Park Drive, Asheville, North Carolina. It employs physicians licensed to practice medicine in the State of North Carolina, who provide oncology treatment services, including radiation oncology services through the use of the Linac and CT Scanner located at the Asheville Oncology Center on Medical Park Drive. CCNC-Asheville has served cancer patients in the Asheville area since 1982 when the practice (then AHO) was first formed and began providing medical oncology services. Its oncology treatment center is a "grandfathered" facility because it became operational before the CON Law was amended to apply to oncology treatment centers. See 2004 correspondence between AHO and CON Section (without exhibits) (Exhibit 3).

USON is a business corporation organized under the laws of the State of Delaware, with its principal place of business located at 10101 Woodloch Forest Drive, The Woodlands, Texas 77380. Through its subsidiaries, USON provides administrative support for oncology practices throughout the United States, and also furnishes medical equipment used by those practices. One of those subsidiaries is AOR, a Delaware limited liability company.

RTS (also known as 21st Century Oncology) operates several radiation therapy centers in western North Carolina, including one located in a medical office building in Asheville which was the site of a damaging fire that occurred on July 28, 2011, and which was reported to you in an earlier letter. Federal and State investigators have indicated they believe this fire may have been intentionally set; but because the investigation of the fire is still in process, RTS has not been able to access this center and assess the damage and determine when and how it might be re-opened. Once a damage assessment is completed, RTS will approach the CON Section about the status of the center, including any steps needed to repair or replace it. However, without a full assessment of the status of this site, RTS is uncertain at this point about the steps necessary to resume operations at that center.

Immediately following the fire, RTS successfully transitioned cancer patients who had been receiving treatment at its Asheville center to its other treatment centers in western North Carolina, where they are continuing to receive consultations and radiation therapy treatment. The transaction proposed in this letter would facilitate the resumption of RTS's provision of radiation therapy services to patients closer to Asheville, and accordingly RTS and NCRTMS request that the Agency expedite its consideration of this no-review request.

NCRTMS is a North Carolina limited liability company which is a wholly-owned subsidiary of RTS. NCRTMS provides management and administrative support services for RTS's radiation therapy centers in North Carolina.

RTS, NCRTMS, CCNC-Asheville and AOR (collectively, the "Parties") have discussed and reached agreement on a transaction that would involve the transfer of the membership interests in the corporate entities that own the Oncology Center and the equipment used to provide treatment for patients at the Oncology Center, including the Linac and CT Scanner (collectively, the "Equipment"). The transaction would be limited to a transfer of the underlying ownership interests in the corporate entities that own the Oncology Center and the Equipment (the "Proposed Transaction"). The Oncology Center 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 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 Services Regulation and by the CON Section, it is clear that the Proposed Transaction agreed upon by the Parties is not a "New Institutional Health Service," and should be permitted to proceed without first obtaining a certificate of need.

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

Background on the Oncology Center and Equipment

In 2005, AHO (now CCNC-Asheville) relocated its Asheville offices to establish the current Oncology Center. AHO acquired the Linac and CT Scanner to provide radiation therapy services to patients. The Linac that has been operated at the Oncology Center is recognized in the Linac Inventory in the State Medical Facilities Plan. See Draft 2012 State Medical Facilities Plan, p. 147 (Exhibit 4). As you will recall, the present Oncology Center was developed under an exemption from CON review recognized by the CON Section. In February 2005, AHO sought "no review" determinations for a proposed relocation and expansion of its oncology treatment center and acquisition of medical equipment that would allow AHO to provide radiation therapy. See AHO No-Review Requests and Related Correspondence (without exhibits) (Exhibit 5). AHO presented four proposals: (1) acquisition of a linear accelerator, (2) acquisition of a CT scanner, (3) acquisition of treatment planning equipment, and (4) relocation of its oncology treatment center. On August 2, 2005, the CON Section issued four "no review" letters, confirming that none of the proposals required a certificate of need. See CON Section No-Review Determinations (Exhibit 6).

The CON Section's determinations were challenged and following a lengthy contested case and appeal, the North Carolina Court of Appeals ultimately affirmed the Final Agency Decision, entered by the Acting Director of the Division of Faculty Services (the "Division") that AHO's acquisition of the Linac and CT scanner and expansion of the oncology treatment center did not require a CON. See *Mission Hospitals, Inc. v. N.C. DHHS*, 696 S.E.2d 163 (N.C. Ct. App. 2010) (Exhibit 7).

At the heart of the appeal challenging the CON Section's no-review determinations were amendments to the CON Law which took effect in late August 2005. Before late August 2005, oncology treatment centers were among the services regulated by the CON Law, and a certificate of need was required to develop an oncology treatment center. But on August 26, 2005, the CON Law was amended by deleting the term "oncology treatment center" from the group of facilities defined as a "health service facility" under N.C. Gen. Stat. § 131E-176. Along with this change, the list of new institutional health services for which a certificate of need is required was amended to add any acquisition of a linear accelerator occurring on or after the effective date of the amendment. AHO's no-review requests and the CON Section's subsequent no-review determinations preceded the August 26, 2005 amendment that eliminated the concept of oncology treatment centers and established a requirement for a certificate of need to acquire a linear accelerator.

In its decision, the Court of Appeals recognized that AOR provided substantial administrative support for AHO's day-to-day operations under a Management Services Agreement which also authorized AOR to acquire equipment for AHO. The Court of Appeals concluded that: (1) AHO's February 2005 requests seeking CON determinations regarding its proposals were made in good faith reliance on the CON Law then in existence; (2) AHO had acquired vested rights to develop its proposed services under the prior version of the CON Law because of the building lease entered into by AHO's managing agent, and AHO's acquisition by comparable arrangement of the Linac through a purchase contract entered into by AOR; and (3) the CON Section had issued its no-review determinations prior to

the effective date of the amendment to the CON Law. Accordingly, the Court of Appeals held that the CON Section and the Division in its Final Agency Decision properly applied the CON Law as it existed when AHO submitted its no-review requests. The Court of Appeals also affirmed the Final Agency Decision's determinations that AHO's acquisition of the CT Scanner did not require a CON because the total costs to buy the CT Scanner and make it operational were below the threshold dollar amount for a diagnostic center, and that the relocation and expansion of AHO's oncology treatment center did not require a CON because the costs related to such relocation and expansion did not exceed \$2,000,000. Thus, the Court of Appeals conclusively determined that the relocation and expansion of AHO's (now CCNC-Asheville's) oncology treatment center and AHO's acquisition of the Linac and CT Scanner did not require a certificate of need.

The Proposed Transaction

The Proposed Transaction to transfer the ownership interests in the corporate entities that own the Oncology Center and Equipment will proceed in two steps. First, CCNC-Asheville will transfer its interest in the Oncology Center and Equipment to a wholly-owned subsidiary ("CCNC Sub"), and AOR will transfer its interest in the Oncology Center and Equipment to a wholly-owned subsidiary (collectively with CCNC Sub, the "LLCs"). The transaction will be completed with NCRTMS purchasing all of the membership interests in those two LLCs as a second step.

After the Proposed Transaction is complete, the LLCs will continue to exist as legal business entities, and will continue to own the Oncology Center and Equipment, including the Linac and CT Scanner that the CON Section (and the Court of Appeals) determined were not subject to CON review. The Oncology Center and its Equipment will continue to serve patients at the same location at 20 Medical Park Drive in Asheville. There will be no purchase of additional equipment, nor will any new services be offered, as a result of the Proposed Transaction. The only change will be the membership composition of the corporate entities that own the Oncology Center and Equipment, with CCNC-Asheville and AOR initially transferring their ownership interests to the wholly-owned subsidiary LLCs, followed by a separate transaction in which NCRTMS will acquire all of the membership interests in the LLCs.

The LLCs will not offer any medical services. All medical services associated with oncology treatment at the center will be furnished by licensed physicians. The Parties anticipate that the radiation oncologists who have been practicing with CCNC-Asheville and have supervised the care of a significant majority of the patients receiving treatment at the Oncology Center in the past will continue to supervise and direct the treatment of patients under their care. Under an agreement that preserves the physicians' authority over all clinical and medical decisions, the LLCs will make the Linac and CT Scanner available for treatment of patients by the CCNC-Asheville radiation oncologists and other licensed physicians authorized to care for patients at the Oncology Center.

Based upon the long-standing approach that the Division and the CON Section have taken to the purchase of equity interests in existing North Carolina health care facilities when there is no change in the services offered or the equipment employed to offer the services, 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 very 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). 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. Based upon the clear terms of the CON Law and prior declaratory rulings by the Department, 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 membership 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 "by or on behalf of any person," N.C. Gen. Stat. § 131E-176(16)(f1)5a, 9, and "the obligation by any person of a capital expenditure exceeding two million dollars (\$2,000,000) to develop or expand a health service or a health service facility, or which relates to the provision of a health service," N.C. Gen. Stat. § 131E-176(16)(b). 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 transactions which are limited to an acquisition of underlying corporate membership interests in an existing legal entity which owns and operates an existing oncology center and its associated equipment, such as the Proposed Transaction, fall within the above-referenced exclusion recognized in the definition of "health service" in the CON Law. 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 own existing health care facilities. Over the course of North Carolina's Certificate of Need program, there have been a number of declaratory rulings which confirmed that the acquisition of ownership interests in companies which own existing health care facilities that already are offering services does not constitute the offering of a new institutional health service because such transactions do not implicate the creation of additional capacity and health service facilities which might lead to the "unnecessary use and expense of resources and overutilization of healthcare services," detailed in the legislative findings. See N.C. Gen. Stat. § 131E-175(4). Several examples of declaratory rulings which have upheld this principle of no review for acquisitions of corporate ownership interests are discussed below.

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 facilities 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 8).
- 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 9).
- 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 10).
- 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 11).

At issue in the August 2011 declaratory ruling involving Radiation Oncology Centers of the Carolinas, Inc. ("ROCC"), was the proposed transfer of two existing oncology facilities owned by ROCC to two wholly-owned subsidiaries of ROCC. The two oncology facilities each operated a linear accelerator and CT simulator, the acquisition of which had previously been approved by the CON Section. The Department concluded that this transaction was not subject to CON review. As the Declaratory Ruling explained, "The entity that owns the linear accelerator and simulator will not change, and the same equipment will be used to provide the same radiation oncology services, in the same location. . . . The Proposed Transaction does not involve the offering or expansion of any new facility, service or equipment, and the state's inventory of linear accelerators and simulators will not change." The transaction at issue in the ROCC declaratory ruling is very similar to the first step of the Proposed Transaction at issue in this request, under which CCNC-Asheville and AOR will transfer their interests in the existing Oncology Center and its associated Equipment to two wholly-owned subsidiary LLCs.

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 to Cancer Centers of North Carolina, P.C. 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 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 Linac 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." The transactions involved in the WROS declaratory ruling are analogous to the second step of the Proposed Transaction at issue in this request, under which NCRTMS will acquire ownership interests in two existing LLCs which own the Oncology Center and its associated Equipment which will continue to provide the same services to patients at the same location following the transaction.

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.

The purchase of LLC interests proposed by the Parties in this Request is analogous to the stock purchase that was proposed by CRTC. The Proposed Transaction will entail acquisition by NCRTMS of all of the ownership interests in the LLCs. Ownership of the Oncology Center and its associated Equipment, including the Linac and CT Scanner, will remain with the LLCs following the second step of the Proposed Transaction.

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 Department also issued a similar ruling with regard to acquisition of the stock of a company that owned heart lung bypass equipment. See *In re: Request for Declaratory Ruling by New Hanover Perfusionists, Inc.*, January 24, 2008 (Exhibit 12). Heart-lung bypass machines are another type of medical equipment for which a certificate of need is required under N.C. Gen. Stat. § 131E-176 (16) (f1), the same portion of the definition of new institutional health services that applies to purchases of linear accelerators. The Department focused on the fundamental fact that the ownership of the equipment would not change, and that there was no purchase of equipment, in ruling that this stock acquisition did not require a Certificate of Need. The Department's determination in these rulings is firmly founded on the express terms of the CON Law.

The Proposed Transaction Is Not an Acquisition of a Linear Accelerator

The proposed acquisition of 100% of the membership interests in the LLCs by NCR TMS 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 entities that own the existing Oncology Center and its associated Equipment. The Linac will continue to be used to provide the same radiation oncology services, in the same location, and the entity that owns the Linac will not change as a result of Step 2 of the Proposed Transaction. The LLCs will continue to own the Linac and the CT Scanner as well as all the Oncology Center assets that were found to be exempt from CON review and have been used to furnish oncology treatments to patients. The LLCs' membership composition will change to a single member, NCR TMS, but their legal status as existing business entities will not change.

Since the LLCs will remain the same legal entities, the same "person" will own the equipment and operate the Oncology Center and its Equipment following the Proposed Transaction's second step. See N.C. Gen. Stat. § §131E-176(19) and 178. There will be no change in the operation of the Oncology Center. 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 involve expenditures by NCR TMS, but these will simply be purchases of ownership interests in existing LLCs that own the Oncology Center. They 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 membership composition of the LLCs, 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 the equipment and offering the 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 membership composition of the LLCs is not integral to the clinical management of the Oncology Center, and the Center's operations will not change as a result of the Proposed Transaction. Therefore, the purchase of membership interests in the LLCs 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).

Issuance of the No-Review Determination Is Consistent with the Purposes of the CON Law

The CON Law is intended to regulate new institutional health services and is not intended to impede routine business transactions such as an acquisition of a limited liability company's ownership interests. The only point when the CON Law does limit changes in ownership is "before completion of the project or operation of the facility . . ." N.C. Gen. Stat. § 131E-189(c). CCNC-Asheville and AOR have operated the Oncology Center for more than a year², so this restriction in the CON Law clearly does not apply.

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. The Oncology Center and its Equipment have been established and operating for years. No new, or additional equipment will be acquired or placed in operation in the State. No new facility will be established nor new services offered. As a result, the Proposed Transaction does not implicate the fundamental objective of the CON Law -- to control the development and expansion of health service facilities. Although not applicable to the Parties' Proposed Transaction, in keeping with this overarching objective, the CON Law actually contains a provision, in N.C. Gen. Stat. § 131E-184(a)(8), which recognizes that an outright purchase of all the assets of an entire health service facility is exempt from the requirement of obtaining a CON, even if the purchased facility contains equipment that would otherwise be subject to CON review.

The purposes for which the CON Law was enacted are not served by regulating the purchase and sale of the underlying membership interests in corporate entities that own existing health service facilities or equipment which the CON Section has already determined to be needed. If membership interests in companies that own an existing health service facility are purchased, without any accompanying addition, expansion, reduction, or relocation of the services offered, then none of the underlying policy concerns that are the basis for the CON Law come into play.

CONCLUSION

For all of the foregoing reasons, the regulation of events like the Proposed Transaction, involving existing and previously reviewed and approved facilities 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 stated above, since the expansion of the Oncology Center pursuant to the exemption recognized by the CON Section, the Linac, CT Scanner, and related equipment have been operated as part of an ongoing health care facility and that will continue after completion of the Proposed Transaction.

The 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

² As you may be aware, AHO (now CCNC-Asheville) operated the Oncology Center in 2006, but the operation of the Equipment was stayed after the initial Final Agency Decision on AHO's no review request reversed the CON Section's initial determination and the Recommend Decision. CCNC-Asheville was not able to fully reinstate operation of the Equipment until after the Court of Appeals' decision in 2010 affirming the second Final Agency Decision which upheld the CON Section's initial determination.

Mr. Craig R. Smith
Chief, CON Section
September 26, 2011
Page 10

Poyner Spruill^{LLP}

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 materials 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. Thank-you for your attention to this and if there is any additional information you may require, it will be expedited upon receipt of your request.

Sincerely,



William R. Shenton
Partner

Enclosures

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