



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

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

Drexdal Pratt, Director

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

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

September 20, 2012

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.

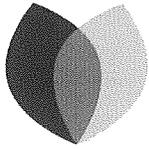
Sincerely,


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





Save

VIDANT HEALTH™



August 20, 2012

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 is "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 27835-6028
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.

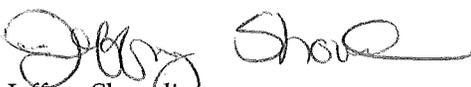
In November 2008, Jeff Horton, at the time, the Acting Director of the Division of Health Service Regulation (Division), issued the declaratory ruling that concluded "the acquisition by Alliance Oncology, LLC of all the membership interests of RSNC, in the manner represented by Petitioner in the Request, 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 Oncor 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

BODIE, CALL & STROUPE, L.L.P.

ATTORNEYS AT LAW

3101 GLENWOOD AVENUE, SUITE 200
RALEIGH, NORTH CAROLINA 27613

(919) 881-0338

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JOHN T. BODIE
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Y. LANE WHARTON, JR.
S. TODD HEMPHILL
DIANA EVANS RICHARDS
JAMES N. JORGENSEN
ANTHONY D. TATBI



MAILING ADDRESS
POST OFFICE BOX 6388
RALEIGH, NORTH CAROLINA
27628-6388

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 Ahoskie, 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.

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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
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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 & STROUPE, L.L.P.

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

S. Todd Hemphill

STH/sh: 3809.000

APPENDIX B



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(2) 2/11/99

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

Lynda D. McDaniel, Director

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

July 29, 1999

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. 131E-176(16) and, therefore, you may proceed to offer, develop or establish the above referenced project without a certificate of need.

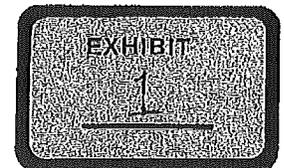
It should be noted that this Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this Agency and a separate determination. If you have any questions concerning this matter, please feel free to contact this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

Sincerely,

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

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

cc: Medical Facilities Planning Section, DFS



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
ALLIANCE ONCOLOGY, LLC

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)
)

REQUEST FOR
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
ALLIANCE ONCOLOGY, LLC

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)
)

REQUEST FOR
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.

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. Easley, Governor
Dempsey Benton, Secretary

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

November 6, 2008

CERTIFIED MAIL

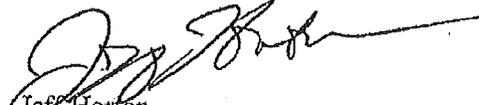
Wallace C. Hollowell, III, Esquire
GlenLake One, Suite 200
4140 Parklake Avenue
Raleigh, North Carolina 27612

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



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. § 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 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

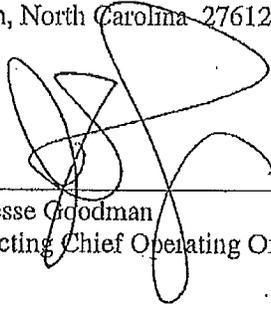
CERTIFICATE OF SERVICE

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