

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
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April 2, 2012

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

RE: No Review

- Transfer By MV-Photon of its membership interest in Sampson Regional Cancer Center LLC to Sampson Regional Medical Center
 - Transfer by Sampson Radiation Oncology, P.A. of its ownership interests in the Simulator currently located in the Sampson Regional Cancer Center LLC to a New LLC (a wholly owned subsidiary of Sampson Radiation Oncology, P.A.)
 - Transfer by Sampson Regional Medical Center of its ownership interests in the Linac currently located in the Sampson Regional Cancer Center LLC to SRMC Sub (a wholly-owned subsidiary limited liability company)
 - Acquisition of 100% of SRMC Sub by North Carolina Radiation Therapy Management Services, LLC
 - Acquisition of 100% of New LLC by North Carolina Radiation Therapy Management Services, LLC
- Sampson County

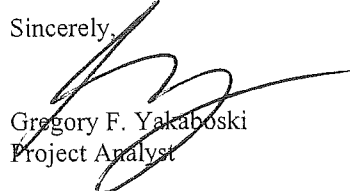
Dear Mr. Shenton:

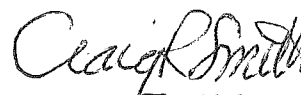
The Certificate of Need (CON) Section received your letters of February 29, 2012 and March 23, 2012 regarding the above referenced proposal. Based on the CON law **in effect on the date of this response to your request**, the proposal described in your correspondence is not governed by, and therefore, 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 Construction 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,


Gregory F. Yakaboski
Project Analyst


Craig R. Smith, Chief
Certificate of Need Section

cc: Medical Facilities Planning Section, DHSR





Greg

Poyner Spruill^{LLP}

March 23, 2012

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

VIA HAND DELIVERY

Mr. Greg Yakaboski
Project Analyst
CON Section
801 Ruggles Drive
Raleigh, NC

RE: Request for No Review Determination – Acquisition of Ownership Interests in Corporate Entities that Own Sampson Regional Cancer Center

Dear Greg:

I am writing to follow up on our telephone conversation earlier this week and enclose a series of charts that depict the current relationships of the parties involved in the operation of the Sampson Regional Cancer Center, the nature of the transactions that are described in the letter that I sent to Craig Smith and Martha Frisone on February 29, and the end result of the transactions proposed.

I hope that this meets your needs in analyzing this matter, and please do not hesitate to contact me if you have any questions concerning the enclosures or any other aspect of the proposed transaction.

Thank you once again for your attention to this.

With best wishes, I am

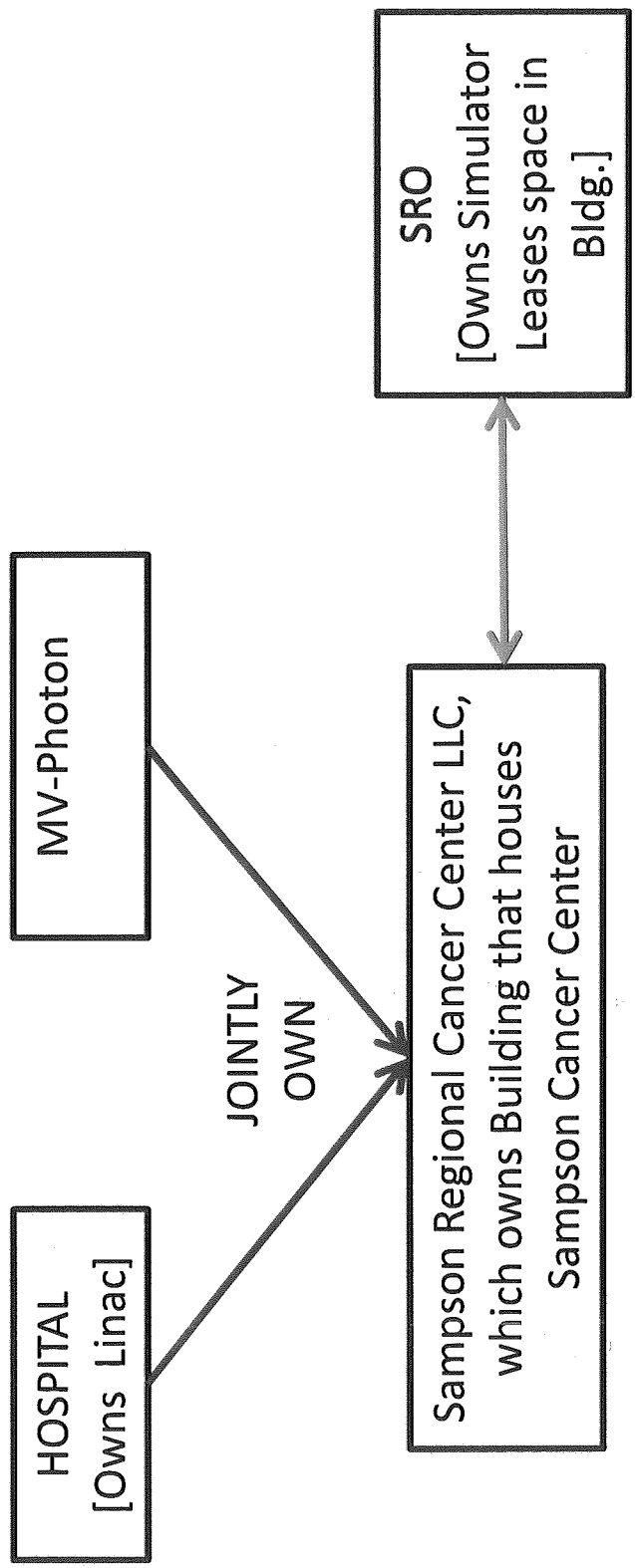
Very truly yours,

William R. Shenton
Partner

WRS:klh

Enc.

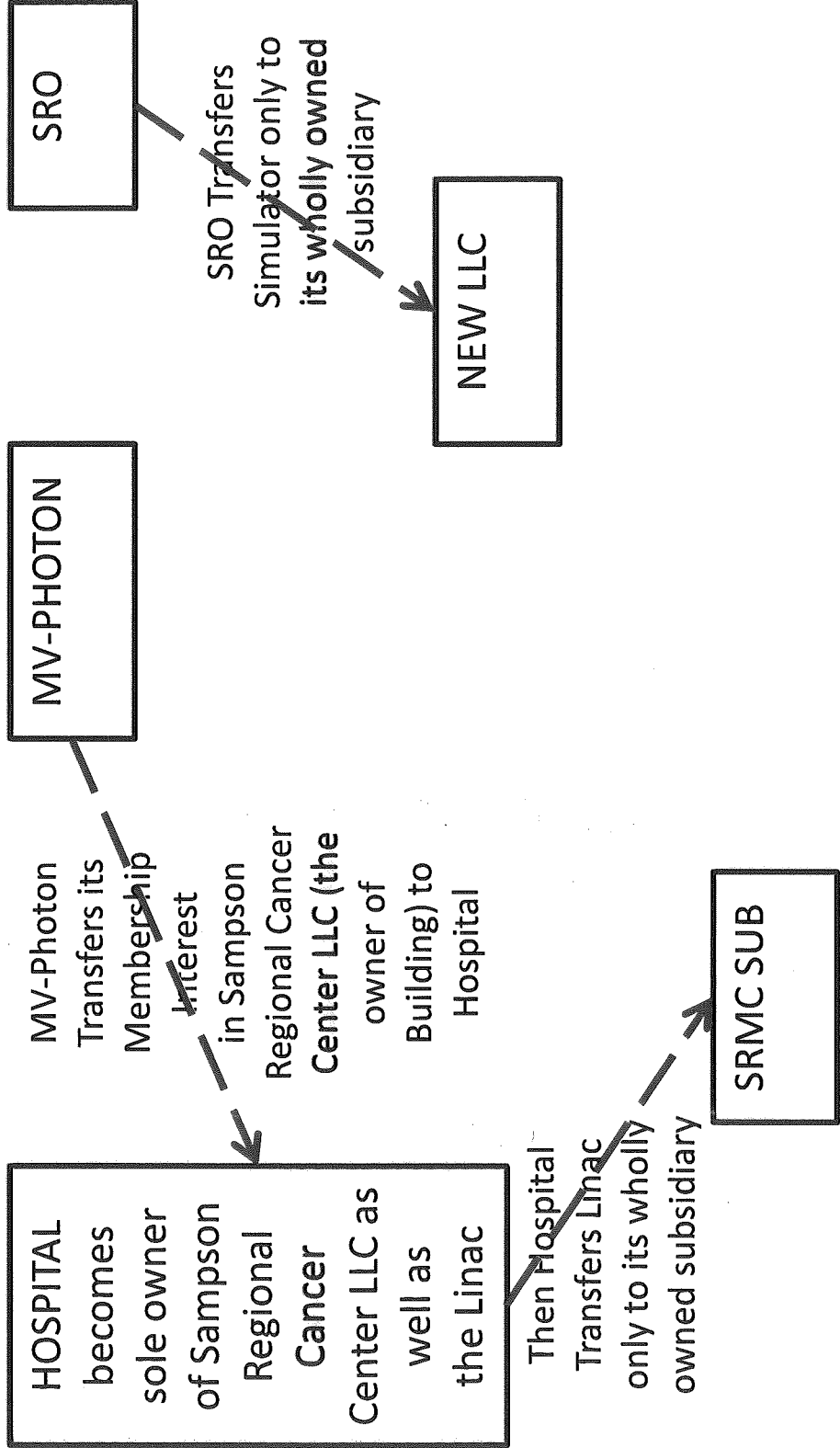
Current Ownership and Relationships to Sampson Cancer Center



Solid Blue Lines indicate an ownership relationship
Solid Green Lines indicate a lease relationship

Transfer of Membership Interests

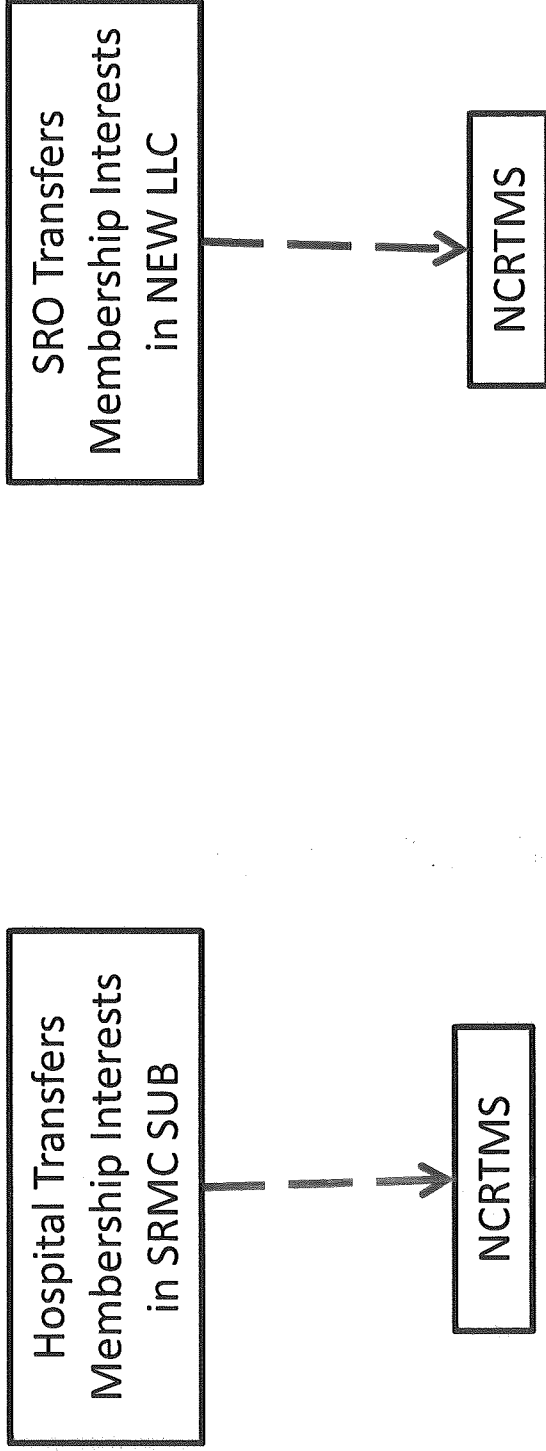
Phase 1



Dotted Red Lines indicate transfer

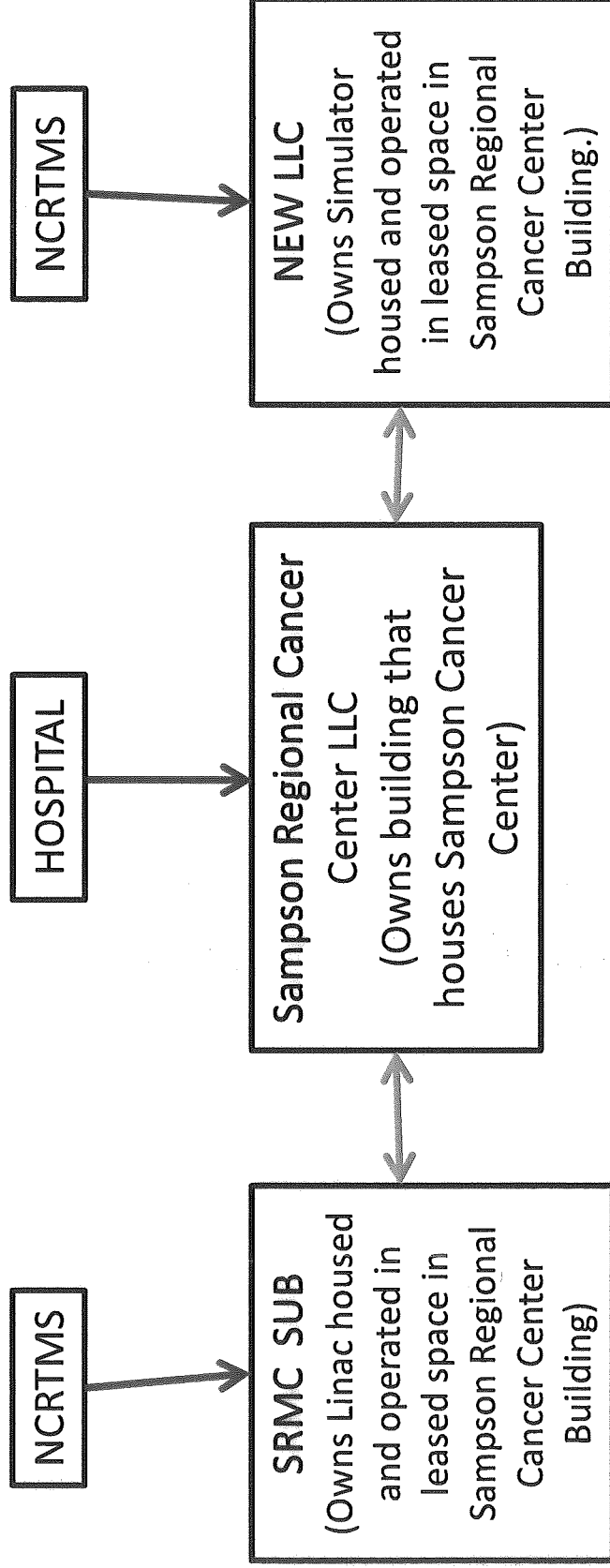
Transfer of Membership Interests

Phase 2



Dotted Red Lines indicate transfer

Resulting Ownership after Transfers



Solid Blue Lines indicate an ownership relationship

Solid Green Lines indicate a lease relationship

**Potential Pothole:
Written Objections to the Rule**

- If the RRC receives written objections to the rule from 10 or more persons, no later than 5:00pm on the day after the RRC meeting when the rule was approved, clearly requesting review by the legislature, the rule goes to the legislature.

They can...

- Pass a bill to stop the rule
- Take no action and let the rule go into effect
- The Governor, by Executive Order, may make effective a permanent rule that was approved by the Commission in order to protect public health, safety, or welfare.

Helpful Links

NC Administrative Procedure Act
http://www.ncga.state.nc.us/enactedlegislation/statutes/html/bychapter/chapter_150b.html

Executive Order 70
<http://www.governor.state.nc.us/newsItems/ExecutiveOrderDetail.aspx?newsitemID=1518>

NC Administrative Code
<http://reports.oah.state.nc.us/ncac.asp>

NC Register
<http://www.ncoah.com/rules/register/>

Office of Administrative Hearings, Rules Division
<http://www.ncoah.com/rules/>

DHSR Rule Actions
<http://www.ncdhhs.gov/dhsr/ruleactions.html>

OSBM, Regulatory Analysis Office
http://www.osbm.state.nc.us/ncosbm/economic_analysis/regulatory_analysis.shtm

DHSR Rulemaking Coordinator
Megan Lamphere, MSW, 919-855-3781 Megan.Lamphere@dhhs.nc.gov

RRC Standards for Review

What is the RRC looking at?

- o It is within the authority delegated to the agency by the General Assembly
- o It is clear and unambiguous
- o It is reasonably necessary to implement or interpret an act of the General Assembly, Congress, or a federal regulation
- o It was adopted in accordance with the APA (G.S. 150B)

A Bump in the Road: Staff Opinions & Technical Changes

- After RRC staff attorney review the rule, they can approve OR send back...
 - o Request for Technical Change
 - o Small changes that do not alter the intended or accepted meaning, interpretation, or application of the rule, such as:
 - o Change the word "will" to "shall" or "shall" to "must",
 - o Typographical or grammatical errors
 - o Clarifying ambiguous terms such as "appropriate", "thorough", etc.
 - o Staff Opinion
 - o More significant issue with the rule based on the Standards for Review
 - o Even if revisions are made, these will not go to the RRC meeting...will have to wait until the next meeting

RRC Decisions

- | | | |
|--|--------|---|
| Approve the rule | —————> | Goes to Codifier of Rules—
Published in the NC
Administrative Code and
becomes effective on 1 st day
of the next month |
| Objects to the rule | —————> | Agency changes rule,
heard at next meeting <u>OR</u>
Agency doesn't change
rule and rule dies |
| Extends period for
Review of the rule | —————> | Agency provides additional
information, heard at the
next RRC meeting if RRC is
satisfied |

Certification by OSBM

- OSBM conducts final review of proposed rule text and fiscal note
- Certifies that the Agency adhered to the "6 principles" in G.S. 150B-19.1 and E. O. 70.

Final Adoption by Agency

- Agency adopts rule
- Agency gives final approval to fiscal note
- Rules must be adopted by the Agency within 12 months of the end of the comment period.

Rules Review Commission (RRC)

- Who are they?
 - 10 members appointed by the General Assembly
 - Must approve all rules before they are entered into Code
 - May review not just your amendments, but the entire rule
- Proposed rule text is submitted to RRC
 - By the 20th of the month preceding the meeting
 - Meetings are the 3rd Thursday of the month at 10am
 - RMC and Section representative attend to answer questions

Public Hearing

- 60 day public comment period
- Must hold a public hearing to accept comments on the proposed rule and fiscal note (unless rule change is a 'technical change')
- RMC will work with Section staff to schedule the public hearing toward the end of the 60 day period
- RMC and Section staff attend public hearing

Potential Road Block: Substantial Changes

- Agency may not adopt a rule that differs substantially from the proposed text as published in the NC Register.

A rule differs substantially from the proposed rule if it:

1. Affects the interests of persons who, based on the proposed text published in the NC Register, could not have reasonably determined that the rule would affect their interests.
2. Addresses a subject matter or issue that is not addressed in the proposed rule text.
3. Produces an effect that could not reasonably have been expected based on the proposed rule text.

Fork in the Road: How to Proceed

- No substantial changes to proposed rule text → Agency for adoption
- Substantial changes → NC Register
- Agency decides not to adopt rule → Rule dies

Department Review & Approval

- Proposed rule text and fiscal note are reviewed by
 - DHHS Office of Legal Affairs
 - DHHS Division of Budget & Analysis
- Department has 45 days to review

Notice of Text to OAH

- RMC submits the Notice of Text and proposed rules to the Office of Administrative Hearings (OAH)
- Notice and rule text will be published in the next issue of the NC Register.
- NC Register is published twice per month

And at the same time.....

Interested Parties Letter & Website Posting

On the same day the Notice of Text is submitted to OAH,

- Section sends the Interested Parties letter to all 'interested parties'
 - Providers, professional or trade organizations, anyone who has requested to be notified of rule actions
- Webmaster posts the following information on the "Rule Actions" page of the DHSR website:
 - Text of the proposed rule
 - An explanation of the proposed rule and reason for it
 - Federal certification if required
 - Interested Parties letter
 - Any fiscal note prepared for the proposed rule
 - Dates that the rule and fiscal note were approved by OSBM and the rulemaking agency

First Steps: Fiscal Note

- **When is a fiscal note required? Always!**
E.O. 70 requires all Cabinet Agencies (that's us) to "quantify the costs and benefits to all parties of a rule to the greatest extent possible. The level of analysis shall be proportional to the significance of the rule."
- **3 Tiers of Fiscal Analysis**
 1. **Tier I: De Minimis Rules**
Rules with little or no impact on state, local or private funds.
 2. **Tier II: Non-substantial economic impact rules**
Rules that have (1) an aggregate economic impact less than \$500,000 in a 12 month period; and (2) impacts State or local government funds or have a significant policy impact.
 3. **Tier III: Substantial economic impact rules**
Rules with an aggregate economic impact on all persons affected of at least \$500,000 in a 12 month period.

Fiscal Notes continued...

- Email fiscal note to the RMC
- Fiscal note will be reviewed and approved by the Division Budget Office. (RMC will send)
- **Fiscal Note Assistance**
Megan Lamphere, DHSR RMC 855-3781
Kyle Fay, DHSR Budget Office 855-3753
Anca Grozav, OSBM 807-4740
- Fiscal note and proposed rule text sent by RMC to OSBM for review and approval.

Agency Review & Approval

- Agency must review and approve proposed rule changes and the fiscal note
- **Who is the "Agency"?**
 - o Depends on which agency has statutory authority to make/change those particular rules
 - o Look in the history note
 - Examples: NC Medical Care Commission, DHSR Director, Radiation Protection Commission, the Governor
- If Agency approves, rule moves forward in the rulemaking process

Six Principles for Developing & Drafting Proposed Rules

According to the APA (G.S. 150B 19.1)

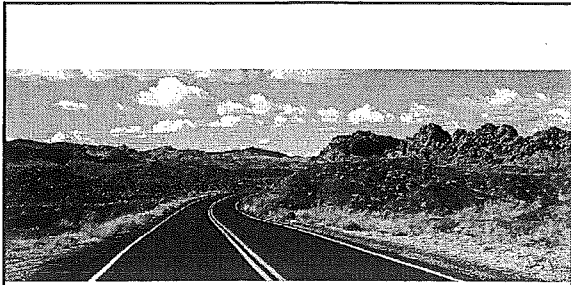
1. An agency may adopt only rules that are expressly authorized by federal or State law and that are necessary to serve the public interest.
2. An agency shall seek to reduce the burden on upon those persons or entities who must comply with the rule.
3. Rules shall be written in a clear and unambiguous manner and must be reasonably necessary to implement or interpret federal or State law.

Six Principles continued...

4. An agency shall consider the cumulative effect of all rules adopted by the agency related to the specific purpose for which the rule is proposed. The agency shall not adopt a rule that is unnecessary or redundant.
5. When appropriate, rules shall be based on sound, reasonably available scientific, technical, economic, and other relevant information.
6. Rules shall be designed to achieve the regulatory objective in a cost-effective and timely manner.

First Steps: Draft Your Proposed Rule Text

- Format rules according to the formatting rule
- Email draft of the proposed rule/rule changes to the Rulemaking Coordinator
- OAH Staff Attorneys (Bobby Bryan or Joe Deluca) conduct a preliminary review of proposed rule text (RMC will send)



The Road to Rulemaking

NC Department of Health & Human Services
Division of Health Service Regulation

March 6, 2012

Training Objective

- To understand the process for permanent rulemaking in accordance with the
 - Administrative Procedure Act (G.S. 150B),
 - Executive Order 70, and the
 - Office of State Budget and Management (OSBM).

Why Adopt a Rule?

- General Assembly enacts legislation
- Agency needs the rule to accomplish its purpose
- Federal mandate
- Court order
- Petition for rulemaking

- (F) one operating room technician or nurse with recent specialized training in open heart surgical procedures;
 - (G) if pediatric open heart surgical procedures are performed, a cardiac surgeon specially trained and clinically competent to perform pediatric open heart surgical procedures.
 - (H) staff for the dedicated cardiac surgical intensive care unit to ensure the availability of 1 RN for every 2 patients during the first 48 hours of post-operative care;
- (3) at least two fully-qualified cardiac surgeons on the staff, at least one of whom is board-certified; one of these surgeons shall be on-call at all times; if pediatric open heart surgical procedures are performed, one of these surgeons shall be specially trained and clinically competent to perform pediatric open heart surgical procedures.
- (c) An applicant shall demonstrate that it can provide the following staff training:
- (1) certification in cardiopulmonary resuscitation and advanced cardiac life support;
 - (2) an organized program of staff education and training which ensures improvements in technique and the proper training of new personnel.

History Note: Filed as a Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;

Authority G.S. 131E-177(1); 131E-183(b);

Eff. January 1, 1987;

Amended Eff. January 4, 1994; November 1, 1989.

- (1) a dedicated cardiac surgical intensive care unit that shall be a distinct intensive care unit and shall meet the requirements of 10A NCAC 14C .1200;
- (2) for facilities performing pediatric open heart surgery services, a pediatric intensive care unit that shall be a distinct intensive care unit and shall meet the requirements of 10A NCAC 14C .1300;
- (3) emergency room with full-time director, staffed for cardiac emergencies with acute coronary suspect surveillance area and voice communication linkage to the ambulance service and the coronary care unit; and
- (4) cardiac catheterization services including both diagnostic and interventional cardiac catheterization capabilities.

History Note: Filed as a Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Authority G.S. 131E-177(1); 131E-183(b);
Eff. January 1, 1987;
Amended Eff. January 4, 1994; November 1, 1989.

10A NCAC 14C .1705 STAFFING AND STAFF TRAINING

- (a) An applicant shall demonstrate that it can meet the following staffing requirements:
 - (1) at least two cardiac surgeons on the medical staff, at least one of whom is board-certified;
 - (2) one certified perfusionist per operational heart lung bypass machine and an additional certified perfusionist on standby;
- (b) An applicant that proposes to develop open-heart surgery services shall also demonstrate that it can meet the following staffing requirements:
 - (1) one cardiovascular surgeon who has been designated to serve as director of the open heart surgery program and who has the following special qualifications:
 - (A) certification by the American Board of Thoracic Surgery; and
 - (B) thorough understanding of and experience in basic medical and surgical knowledge and techniques of cardiac surgery, cardiopulmonary bypass and methods of myocardial management;
 - (2) at least one specialized open heart surgical team composed of at least the following professional and technical personnel:
 - (A) one cardiovascular surgeon board certified by the American Board of Thoracic Surgery;
 - (B) one assistant surgeon, preferably a cardiovascular or thoracic surgeon;
 - (C) one board certified anesthesiologist trained in open heart surgical procedures;
 - (D) one certified registered nurse anesthetist;
 - (E) one circulating nurse or scrub nurse, with recent specialized training in open heart surgical procedures;

- proposed equipment used to support scheduled open heart surgical procedures; or
- (iv) that the applicant will reduce costs by acquiring a heart-lung bypass machine and discontinuing use of an existing heart-lung bypass machine that it does not own; or
 - (v) that the applicant intends to use the heart-lung bypass machine for procedures performed in a location within the facility separate from any location in which open heart surgery services are performed, and that acquiring the additional machine will improve the efficiency, cost-effectiveness, or quality of clinical service to patients.

History Note: Authority G.S. 131E-177(1); 131E-183(b);
Eff. January 1, 1987;
Amended Eff. November 1, 1989;
Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Amended Eff. January 4, 1994;
Temporary Amendment January 1, 1999;
Temporary Eff. January 1, 1999 expired October 12, 1999;
Temporary Amendment Eff. January 1, 2000 and shall expire on the date the permanent amendment to this rule, approved by the Rules Review Commission on November 17, 1999, becomes effective;
Amended Eff. July 1, 2000;
Temporary Amendment Eff. January 1, 2002;
Amended Eff. April 1, 2003;
Temporary Amendment Eff. February 1, 2010;
Amended Eff. November 1, 2010.

10A NCAC 14C .1704 SUPPORT SERVICES

(a) An applicant shall demonstrate that the following services shall be available in the facility 24 hours per day, 7 days per week:

- (1) electrocardiography laboratory and testing services, including stress testing and continuous cardiogram monitoring;
- (2) echocardiography service;
- (3) blood gas laboratory;
- (4) nuclear medicine laboratory;
- (5) pulmonary function unit;
- (6) staffed blood bank;
- (7) hematology laboratory or coagulation laboratory;
- (8) microbiology laboratory; and
- (9) clinical pathology laboratory with facilities for blood chemistry.

(b) An applicant that proposes to develop open-heart surgery services shall also demonstrate that the following services shall be available in the facility 24 hours per day, 7 days per week:

- (G) the number of open heart surgery procedures performed by type of procedure during the twelve month period reflected in the most recent licensure form on file with the Division of Health Service Regulation; and
- (4) the number and composition of open heart surgical teams available to the applicant.

History Note: Filed as Temporary Amendment Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;

Authority G.S. 131E-177(1); 131E-183;

Eff. January 1, 1987;

Amended Eff. November 1, 1996; January 4, 1994; November 1, 1989;

Temporary Amendment January 1, 1999;

Temporary Eff. January 1, 1999 Expired on October 12, 1999;

Temporary Amendment Eff. January 1, 2000;

Temporary Amendment effective January 1, 2000 amends and replaces a permanent rulemaking originally proposed to be effective August 2000;

Amended Eff. April 1, 2001.

10A NCAC 14C .1703 PERFORMANCE STANDARDS

- (a) An applicant that proposes to develop open-heart surgery services shall demonstrate that the proposed project is capable of meeting the following standards:
 - (1) the applicant's projected utilization and proposed staffing patterns are such that each open heart surgical team shall perform at least 150 open heart surgical procedures in the third year following completion of the project;
 - (2) the applicant shall document the assumptions and provide data supporting the methodology used to make these projections.
- (b) An applicant that proposes to acquire a heart-lung bypass machine shall demonstrate either:
 - (i) if the equipment is proposed to be used solely for open-heart surgical procedures, that the applicant's existing, approved, and proposed heart-lung bypass machines (other than any machines proposed to be acquired pursuant to 10A NCAC 14C.1704(b)(iii) below) shall be utilized at an annual rate of 200 open heart surgical procedures per machine, measured in the third year following completion of the project; or
 - (ii) if the equipment is proposed to be used solely or in part for procedures other than open-heart surgical procedures, that the annual utilization of its existing, approved, and proposed heart-lung bypass machines (other than any machines proposed to be acquired pursuant to 10A NCAC 14C.1704(b)(iii) below), as measured in minutes in use or staffed on standby for all procedures, shall be at or above 900 hours per year during the third year following completion of the project; or
 - (iii) that the proposed machine is needed to assure appropriate coverage for open-heart surgery emergencies and in no instance shall be scheduled for use at the same time as the applicant's other existing, approved, or

any existing service area are expected to refer patients to the applicant, including the methodology and assumptions used to define the proposed service area.

- (c) An applicant shall also provide the following additional information:
- (1) the number of procedures using the applicant's existing, approved and proposed heart-lung bypass machines in each of the first three years following completion of the proposed, identified by ICD-9, ICD-10, or CPT code, including the methodology and assumptions used to make the projections;
 - (2) the number of patients from the proposed service area who are projected to receive procedures using the applicant's existing, approved, and proposed heart-lung bypass equipment by patient's county of residence in each of the first three years following completion of the proposed project, including the methodology and assumptions used to make these projections;
 - (3) the projected patient referral sources;
 - (4) evidence of the applicant's capability to communicate efficiently with emergency transportation agencies and with all hospitals serving the proposed service area; and
 - (5) evidence of the applicant's capability to perform both cardiac catheterization and open heart surgical procedures 24 hours per day, 7 days per week.
- (d) An applicant that proposes to develop open heart surgery services shall also provide the following additional information:
- (1) the projected number of open heart surgical procedures to be performed on each heart-lung bypass machine owned by or operated in the facility for each of the first three years following completion of the proposed project, including the methodology and assumptions used to make these projections;
 - (2) the projected number of cardiac catheterization procedures to be completed in the facility for each of the first three years following completion of the proposed project, including the methodology and assumptions used for these projections;
 - (3) the applicant's experience in treating cardiovascular patients at the facility during the past 12 months, including:
 - (A) the number of patients receiving stress tests;
 - (B) the number of patients receiving intravenous thrombolytic therapies;
 - (C) the number of patients presenting in the Emergency Room or admitted to the hospital with suspected or diagnosed acute myocardial infarction;
 - (D) the number of cardiac catheterization procedures performed, by type of procedure;
 - (E) the number of patients referred to other facilities for cardiac catheterization or open heart surgical procedures, by type of procedure;
 - (F) the number of patients referred to the applicant's facility for cardiac catheterization or open heart surgical procedures, by type of procedure; and

**SECTION .1700 - CRITERIA AND STANDARDS FOR OPEN-HEART
SURGERY SERVICES AND HEART-LUNG BYPASS MACHINES**

10A NCAC 14C .1701 DEFINITIONS

The following definitions shall apply to all rules in this Section:

- (1) "Capacity" of a heart-lung bypass machine means 400 adult-equivalent open heart surgical procedures per year. One open heart surgical procedure on persons age 14 and under is valued at two adult open heart surgical procedures. For purposes of determining capacity, one open heart surgical procedure is defined to be one visit or trip by a patient to an operating room for an open heart operation.
- (2) "Cardiac Surgical Intensive Care Unit" means an intensive care unit as defined in 10A NCAC 14C .1201(2) and which is for exclusive use by post-surgical open heart patients.
- (3) "Heart-lung bypass machine" shall have the same meaning as defined in G.S. 131E-176(10a).
- (4) "Open heart surgery services" shall have the same meaning as defined in G.S. 131E-176(18b).
- (5) "Open heart surgical procedures" means specialized surgical procedures which:
 - (a) utilize a heart-lung bypass machine (the "pump");
 - (b) are designed to correct congenital or acquired cardiac and coronary disease by opening the chest for surgery on the heart muscle, valves, arteries, or other parts of the heart.

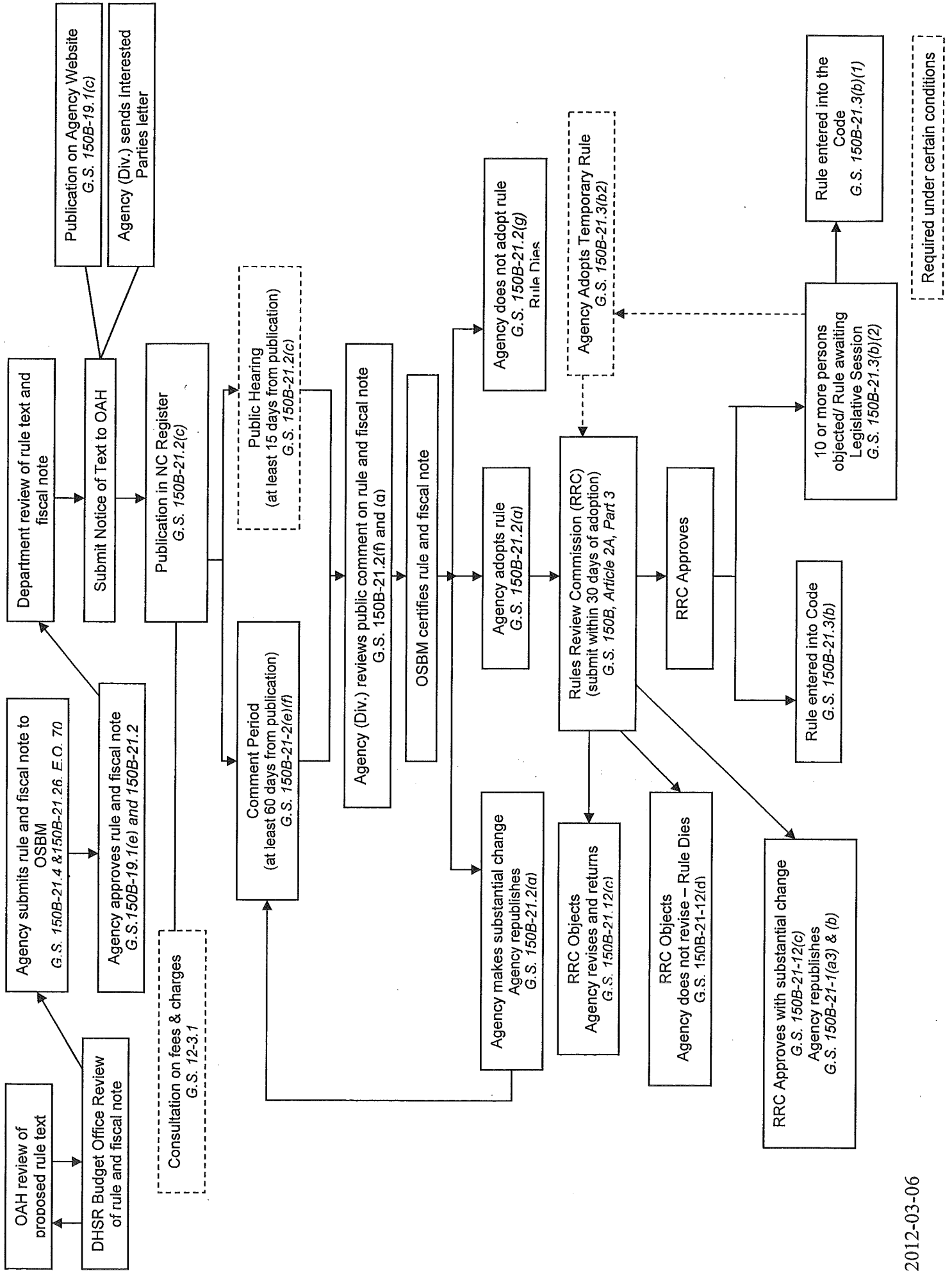
*History Note: Authority G.S. 131E-177(1); 131E-183;
Eff. January 1, 1987;
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on which the permanent amendment to this Rule, approved by the Rules
Review Commission on November 17, 1999, becomes effective;
Amended Eff. July 1, 2000;
Temporary Amendment Eff. March 1, 2010;
Amended Eff. November 1, 2010.*

10A NCAC 14C .1702 INFORMATION REQUIRED OF APPLICANT

- (a) An applicant shall use the acute care facility/medical equipment application form.
- (b) An applicant shall define the proposed service area for the proposed project which shall be similar to the applicant's existing or proposed service area for other existing or proposed health services, unless the applicant documents that other providers outside of

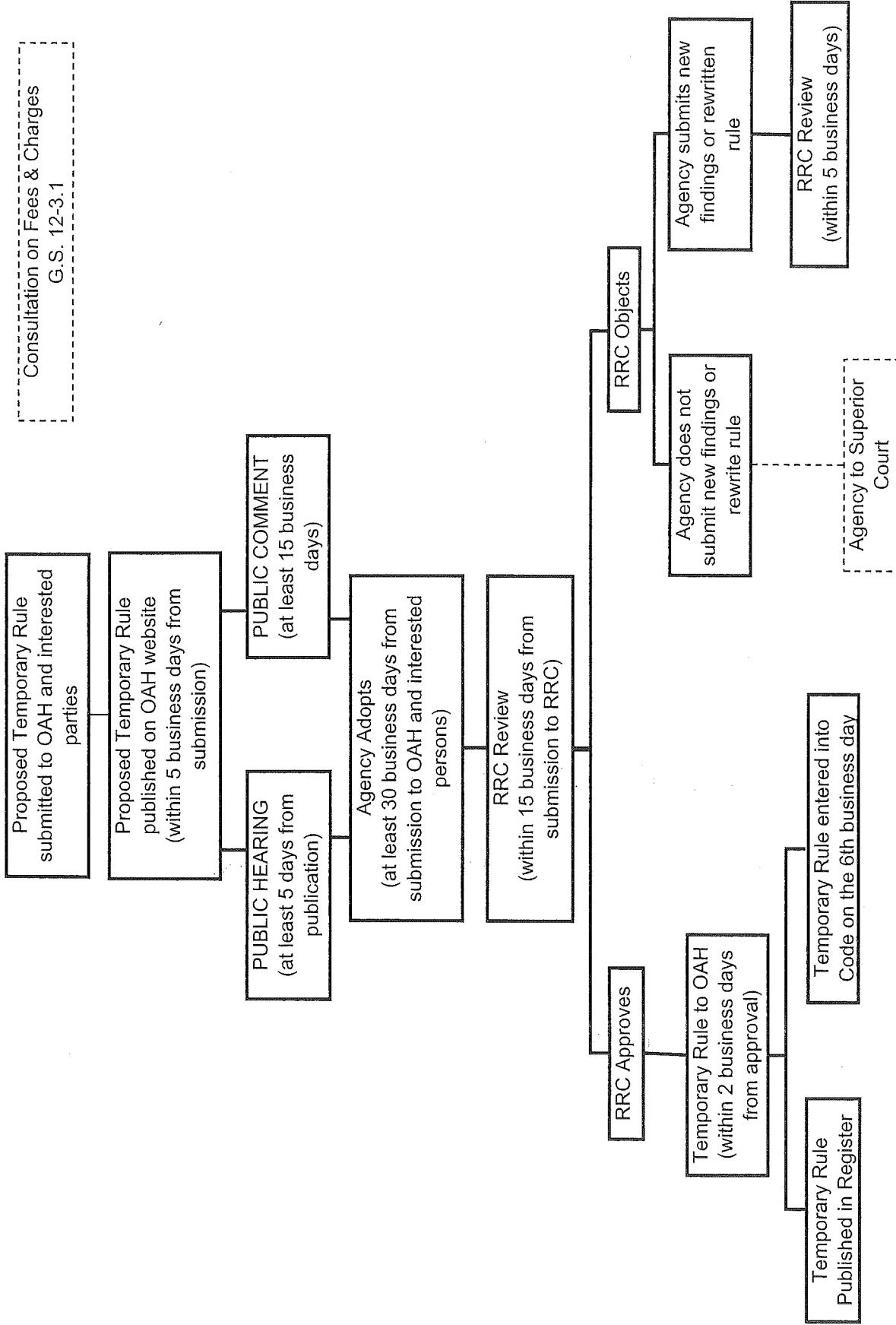
☆Start here!

DHSR Permanent Rulemaking Process



TEMPORARY RULEMAKING PROCESS

(G.S. 150B-21.1)



Office of State Budget & Management

Tiers of Fiscal Analysis/Types of Rules

7.3.2.1 Tier 1 - De Minimis Rules

There are many rule changes that propose minor changes to policy or have a small economic impact. These rule changes do not require nearly the same level of analysis as a larger rule change. Examples of such rule changes include technical changes, clarifications and updates to current rule language, and rules that have no impact on state or local funds and have a de minimis impact on the private sector.

For de minimis rule changes, a brief description of the rule change must be submitted to OSBM for review and approval. The brief description must include:

- ◆ The title of the rule change and North Carolina Administrative Code citation;
- ◆ The name of the agency proposing the rule and agency contact information;
- ◆ A citation to the statute authorizing the rule change or the federal law or regulation requiring the rule;
- ◆ A brief statement identifying whether or not the rule has State, local, federal government, or substantial economic impact;
- ◆ A brief description of the rule, its purpose, likely impact of costs and benefits, and how it would benefit the public interest;
- ◆ A copy of the proposed rule text; and
- ◆ The certification of federal requirement.

7.3.2.2 Tier II - Non-Substantial Economic Impact Rules

For permanent rule changes with (1) a non-substantial economic impact and (2) an impact on State or local government funds or a significant policy impact, the fiscal note must include the following information:

a) General Information

- ◆ The title of the rule change and North Carolina Administrative Code citation;
- ◆ The name of the agency proposing the rule and agency contact information;
- ◆ A citation to the statute authorizing the rule change or the federal law or regulation requiring the rule;
- ◆ A brief statement identifying whether or not the rule has State, local, federal government, or substantial economic impact;
- ◆ Information on the source of funds that would be used to cover new costs if the rule change requires disbursement of state funds so that OSBM can certify the existence of funds (see G.S. 150B-21.4(a));

- ◆ A copy of the proposed rule; and
- ◆ The certification of federal requirement.

b) Summary of the Proposed Regulation

- ◆ Description of the change – Given the broad intended audience for this analysis, this discussion must be clear, concise, and avoid technical jargon.
- ◆ Purpose of the rule change – Describe the need for the proposed action, including a clear description of the problem or issue a rule change is intended to address. Discuss any expected improvements in public health, safety, or welfare.

c) Economic Analysis – This section is the heart of the fiscal note and must describe how the agency estimated the impact of the rule change. The depth of the fiscal note must correspond to the complexity and impact of the rule. Below are some general considerations that must be taken into account when evaluating the economic impact of the proposed rule change:

- ◆ Scope of Analysis – The appropriate time frame for analysis is dependent on the nature of a specific rule change and must cover a period long enough to encompass the important costs and benefits likely to result from the rule change. For many rule changes, a per year estimate may be sufficient. For others, such as a rule change with phased implementation over a number of years, the appropriate time frame may be much longer.
- ◆ Baseline – The impacts identified must be measured against a baseline. This baseline must be the best assessment of the way the world would look if the rule change is not adopted. This assessment must account for effective N.C. General Statutes and rules contained in the N.C. Administrative Code. Informal agency policies not adopted as rules in compliance with G.S. 150B must be excluded from the assessment of the baseline.
- ◆ Cost Estimates – The economic impact of the rule change is the incremental difference between the baseline and the future condition expected after implementation of the regulation. Direct costs as well as opportunity costs must be included. How is the rule change expected to change the current state? What costs are associated with these changes? Agencies must include tables and schedules of the cost estimates. Cost estimates must be monetized to the greatest extent possible. Where costs are not quantified in dollars, they must be listed and described.
- ◆ Benefit Estimates – Explain how the actions required by the rule change are linked to the expected benefits. Benefit estimates must be quantified in dollars to the greatest extent possible. Where benefits are not quantified, they must be listed and described.
- ◆ Transparency and Reproducibility – A good fiscal note must clearly set out the basic assumptions, methods, and data used, enabling the reader to understand how conclusions were reached.

d) Persons Affected – The fiscal note must identify the persons affected by the rule change within the categories listed below. Within each category, describe the number of different entities impacted by the rule change and briefly summarize

how these units will be affected. In some cases, it may be useful to organize the discussion by type of entity affected, depending on the complexity of the rule change.

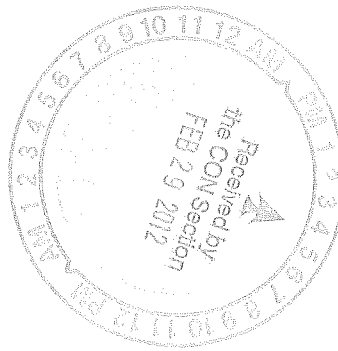
- ◆ State government entities,
- ◆ Local government entities,
- ◆ Federal government entities, and
- ◆ Private sector entities.

7.3.2.3 Tier III - Substantial Economic Impact Rules

A rule change is considered to have a substantial economic impact if the aggregate impact on all persons affected is of at least \$500,000 in a 12-month period. For example, a rule change with \$300,000 in estimated benefits and \$200,000 in estimated costs would have a substantial economic impact.

For rule changes with substantial economic impact, the agency must send OSBM the following:

- ◆ The information required for non-substantial economic impact rules.
- ◆ Alternatives – Agencies must identify at least two alternatives deserving consideration, evaluate their impacts to the extent possible, and state reasons for which they were rejected. The alternatives may have been identified by the agency or by members of the public. When there is a “continuum” of alternatives to address a particular problem, an agency must examine a preferred option, a more expensive or stringent option, and a less expensive or stringent option. Agencies must also consider alternatives involving economic incentives, information disclosure requirements, performance standards, and other actions that do not require rule-making. When the status-quo is a possible alternative, it may be used as one of the two required alternatives. (See G.S. 150B-21.4(b2)).
- ◆ Time Value of Money – Benefits and costs do not always take place in the same time period. When they do not, an agency may not simply add up all of the expected benefits or costs without accounting for when the impacts occur. Benefits or costs that occur sooner are generally more valuable. Given this preference, a discount factor of 7.0% must be used to adjust future benefits and costs when appropriate. At the discretion of OSBM, other discount rates may be used in addition to 7.0% for comparative purposes. Agencies must include a summary table of annualized costs and benefits. In constructing this summary table, it may be helpful to organize annual costs and benefits by rule provision and affected party. (See G.S. 150B-21.4(b1) and the U.S. Office of Management and Budget’s Circular A-4 on Regulatory Analysis.)
- ◆ Risk Analysis – A risk is a factor or possible event that may jeopardize anticipated benefits or increase the cost of a rule change. The agency must evaluate possible risks for their likelihood of occurrence and the impact of the occurrence. The impact must be described in terms of the costs and/or benefits it would affect. The risk analysis must tie into the assumptions and parameters used in the analysis of benefits and costs. Each significant risk must be listed and described. Given the uncertainty of various estimates, it may also be useful to provide a sensitivity analysis to reveal whether, and to what extent, the results of the analysis are sensitive to possible changes in key assumptions.



February 29, 2012

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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 Sampson Regional Cancer Center

Dear Mr. Smith:

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

With this letter, NCRRTMS is requesting a no-review determination regarding its acquisition of the ownership interests in the existing Sampson Regional Cancer Center located in Clinton, North Carolina and the associated equipment. Consistent with the longstanding approach of the CON Section in finding that other purchases of corporate ownership interests are not events requiring a certificate of need, NCRRTMS now seeks confirmation that its acquisition of membership interests in the corporate entities involved in the existing Sampson Regional Cancer Center, and the continued operation of that center by NCRRTMS at the same site, may proceed without first obtaining a certificate of need.

FACTUAL BACKGROUND

This request relates to the Sampson Regional Cancer Center ("Sampson Cancer Center"), which is located at 215 Beaman Street in Clinton, North Carolina, near the Sampson Regional Medical Center campus. The Sampson Cancer Center was established by Sampson Regional Medical Center, Inc. ("the Hospital"), MV-Photon, LLC ("MV-Photon") and Sampson Radiation Oncology, P.A. ("SRO") following a settlement agreement that was reached in contested cases arising from a 2003 linear accelerator review conducted by the North Carolina Certificate of Need Section. The Settlement Agreement was executed and approved by the Director of the North Carolina Division of Facility Services and the Chief of the Certificate of Need Section in May 2004; and it included no-review and exemption determinations pertaining to several aspects of the Sampson Cancer Center. See Global Settlement Agreement in Contested Cases Nos. 03 DHR 1710 and 03 DHR 1736 ("Settlement Agreement") (Exhibit 1).

Background on the Organizations Submitting this Request

The Hospital is a North Carolina non-profit corporation which has owned and operated an acute care hospital in Clinton for many years. In addition to acute care services, the Hospital offers a variety of outpatient services, including radiation therapy services provided for cancer patients on the Linac owned by the Hospital and operated at the Sampson Cancer Center as an outpatient department of the Hospital.

Sampson Regional Cancer Center, LLC is a North Carolina limited liability company whose members are the Hospital and MV-Photon. Sampson Regional Cancer Center, LLC owns the building in which the Sampson Cancer Center is located.

MV-Photon is a North Carolina limited liability company owned by Dr. Kevin J. Kerlin ("Dr. Kerlin"), a North Carolina licensed physician.

SRO is a professional corporation organized under the laws of the State of North Carolina, and its principal place of business is located at the Sampson Cancer Center. Its sole shareholder is Dr. Kerlin. SRO currently leases space in the Sampson Cancer Center from Sampson Regional Cancer Center, LLC. SRO and Dr. Kerlin have served cancer patients at the Sampson Cancer Center since it first opened in 2006.

Goldsboro Radiation Therapy Services, P.A. ("GRTS") was formed as a professional corporation under the laws of the State of North Carolina, with Dr. Kerlin as its sole shareholder, and its principal place of business located at 2802 McLamb Place, Goldsboro, North Carolina. Prior to the establishment of the Sampson Cancer Center, GRTS served Sampson County area patients at its Wayne Oncology Center located in Goldsboro, North Carolina. However, since establishment of the Sampson Cancer Center, Sampson County patients have received Dr. Kerlin's professional services through SRO. In connection with a separate transaction in December of 2011, GRTS converted to a business corporation, and it is now owned by NCRTMS.

Under a Professional Services Agreement with the Hospital, Dr. Kerlin has furnished professional services required to provide radiation therapy services, using the Linac, Simulator and other equipment in operation at the Sampson Cancer Center since the Center first opened. GRTS also has provided management and administrative support services for the Sampson Cancer Center. Currently, a Varian Clinac 2100C linear accelerator (the "Linac"), a Varian Ximatron CD-X CT Simulator (the "Simulator"), and other associated equipment are used to provide radiation therapy services to patients at the Sampson Cancer Center. The Linac was acquired by the Hospital following the CON Section's no-review determination, and the Simulator was acquired by SRO. SRO was formed so that Dr. Kerlin would have a separate professional corporation from GRTS through which he could furnish professional services to Sampson Cancer Center, and so SRO, rather than GRTS, acquired the Simulator.

The Proposed Transaction

RTS, NCRTMS, the Hospital, SRO, GRTS, and MV-Photon (collectively, the "Parties") have discussed and reached agreement in principle on a transaction (the "Proposed Transaction") that would involve the transfer of the ownership interests in the corporate entities that own interests in any facet of the Sampson Cancer Center and its associated equipment, including the Linac and Simulator (collectively, the "Equipment"). Ultimately, the Proposed Transaction (as more fully described on pages 3 and 4) would only involve the contribution of the Equipment to wholly owned subsidiaries followed by a transfer of the underlying ownership interests in the corporate entities that hold ownership interests in any facet of the Sampson Cancer Center and the Equipment. The Sampson Cancer 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 Sampson Cancer Center as a result of the Proposed Transaction. The Proposed Transaction does not involve the offering or expansion of any new facility, service or equipment, and the State's inventory of linear accelerators will not change as a result of the transaction. Based upon prior declaratory rulings and "no review" determinations that have been issued by the Office of the Director of the Division of Health Service Regulation ("DHSR") and by the CON Section, it is clear that the Proposed Transaction is not a "New Institutional Health Service," and should be permitted to proceed without first obtaining a CON. This letter describes the details of the Proposed Transaction and identifies the grounds for a determination that it is not subject to CON review.

Background on the Sampson Cancer Center and Equipment

As mentioned above, the Sampson Cancer Center was established following the execution and approval of the Settlement Agreement, in which the CON Section recognized that the following activities did not require a certificate of need:

- the Hospital's acquisition and installation of a linear accelerator and related items for less than the cost thresholds in the CON Law;
- Acquisition and installation of planning and simulation equipment and related items for less than \$250,000; and
- Development of medical office space exempt from CON review pursuant to N.C. Gen. Stat. § 131E-184(a)(9), by a joint venture between the Hospital and MV-Photon.

Settlement Agreement, p. 5, ¶¶ 3-5.

In accordance with the exemption recognized by the CON Section in the settlement, through a joint venture between the Hospital and MV-Photon, medical office space was constructed in a building located at 215 Beaman Street in Clinton, to be used in providing physician services to patients receiving treatment at the Sampson Cancer Center. Consistent with the no review determination recognized by the CON Section as part of the settlement, the Hospital acquired and installed the Linac at the Sampson Cancer Center in 2006.

The Linac and Simulator are the only oncology equipment that has been operated at the Sampson Cancer Center. The first treatment on the Linac was provided in October of 2006 over five years ago, and the Linac has been recognized each year in the linear accelerator inventory in the State Medical Facilities Plan. See State Medical Facilities Plan Excerpts for 2009-2012 (Exhibit 2).

The Proposed Transaction

The Proposed Transaction to transfer the ownership interests in the Sampson Cancer Center and the related Equipment will proceed in two phases, after receiving confirmation that no certificate of need is required for the Proposed Transaction. In the first phase, the Hospital will transfer its interest in the Linac to a wholly-owned subsidiary limited liability company ("SRMC Sub"). In addition, MV-Photon will transfer its interest in the Sampson Regional Cancer Center, LLC, which owns the building, to the Hospital, and SRO will transfer the simulator to a NEW LLC. In the final step of the transaction, NCRTMS will purchase all of the membership interests in SRMC Sub and NEW LLC.

After the Proposed Transaction is complete, the three LLCs, SRMC Sub, NEW LLC, and Sampson Regional Cancer Center LLC, all will continue to exist as legal business entities. Sampson Regional Cancer Center, LLC will continue to own the building that houses the Sampson Cancer Center, and will enter a long-term lease of the building to NCRTMS. Under an appropriate arrangement with NCRTMS that will be defined in writing, SRMC Sub and NEW LLC will continue to own and operate the equipment in the building, including the Linac and Simulator. It also is possible that at some point in the future, after the Proposed Transaction is complete, NCRTMS will determine that it is more convenient to merge SRMC Sub and NEW LLC into NCRTMS.

After all these steps, the Sampson Cancer Center and its Equipment will continue to serve patients at the same location at 215 Beaman Street in Clinton, in a manner that is the same in all material respects as the current operations of the Center and its associated Equipment. No additional equipment will be purchased as part of the Proposed Transaction, and no new services be offered as a result of the Proposed Transaction. The lease of Sampson Cancer Center to NCRTMS will not entail any new construction or associated capital expenditure, since the building already exists. Thus, the only change resulting from any aspect of the Proposed Transaction will be a change in the membership composition of the corporate entities that own the Sampson Cancer Center and Equipment.

Sampson Regional Cancer Center LLC, SRMC Sub and NEW LLC 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 SRO and GRTS and have supervised the care of a significant majority of the patients receiving treatment at the Sampson Cancer 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, SRMC Sub and NEW LLC will make the Linac and Simulator available for treatment of patients by Dr. Kerlin and other licensed physicians authorized to care for patients at the Sampson Cancer Center.

Based upon the longstanding approach by DHSR and the CON Section to the purchase of equity interests in existing health care facilities when there is no change in the services offered or the equipment employed to offer the services, NCRTMS respectfully submits that: 1) none of the steps in the Proposed Transaction constitutes a New Institutional Health Service requiring a CON; and 2) a subsequent merger of SRMC Sub and NEW LLC into NCRTMS also does not require a CON.

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). Accordingly, the CON Law essentially focuses on the development and offering of those "new institutional health services" that would create additional capacity, and which are catalogued in N.C. Gen. Stat. § 131E-176(16).

Each of these regulated new institutional health services entails in some way the acquisition or establishment of a *new* health service, *new* equipment, *new* facilities, or expansions and relocations of existing facilities or services (which also would have an impact on how health services are deployed and utilized). In keeping with its fundamental goals, the CON Law expressly recognizes that certain activities are not subject to review, such as acquisitions of existing facilities, or the repair or replacement of existing

facilities or equipment, since these actions do not change the overall capacity of the health care system. Based upon the clear terms of the CON Law and prior declaratory rulings by the Department that have recognized this fundamental principle, the Proposed Transaction does not require a CON.

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 addresses, directly or indirectly, the acquisition of ownership interests in an organization that already is operating a health service. Acquisitions of ownership interests are among the activities that are "administrative and other activities that are not integral to clinical management," and which are specifically excluded from the definition of "health service" in the CON Law. N.C. Gen. Stat. § 131E-176(9a). Therefore, an acquisition of corporate ownership interests, such as the Proposed Transaction at issue in this request, does not involve a new institutional health service at all and should not be subject to CON Review.

The list of new institutional health services does include "the acquisition by purchase, donation, lease, transfer or comparable arrangement" of a linear accelerator or simulator "by or on behalf of any person," N.C. Gen. Stat. § 131E-176(16)(f1)5a, 9; as well as "the obligation by any person of a capital expenditure exceeding two million dollars (\$2,000,000) to develop or expand a health service or a health service facility, or which relates to the provision of a health service," N.C. Gen. Stat. § 131E-176(16)(b). However, neither of these definitions applies to the Proposed Transaction. In prior declaratory rulings and no review determinations, the Department and CON Section have consistently recognized that other transactions with the same basic features as the Proposed Transaction, which involve only the acquisition of underlying corporate ownership interests in an existing legal entity which owns and operates an existing oncology center and its associated equipment, fall within the above-referenced exclusion recognized in the definition of "health service" in 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 Rulings Confirm the Transaction Does Not Require a CON

This No-Review Request is consistent with the Department's and the CON Section's prior 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. In at least five rulings issued after the enactment of the August 2005 amendment to the CON Law, which added acquisition of a linear accelerator to the definition of "new institutional health services" under N.C. Gen. Stat. § 131E-176, the Department has determined that the transfer of ownership interests in organizations that own and operate linear accelerators does not require a certificate of need.

- On January 6, 2012, the CON Section issued a no-review determination confirming that the transfer of ownership interests in Cancer Centers of North Carolina's Asheville radiation oncology treatment center to wholly-owned subsidiaries and the acquisition by NCRIMS of the membership interests in those subsidiaries did not require a CON. *See No-Review Determination Letter Re: Request by NCRIMS Pertaining to Cancer Centers of North Carolina Asheville Oncology Treatment Center* (Exhibit 3).
- 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 CON. See *In re: Request for Declaratory Ruling by Radiation Oncology Centers of the Carolinas, Inc.* (Exhibit 4).

- 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 CON. 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 5).
- 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 6).
- 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 7).

The August 2011 declaratory ruling relating to Radiation Oncology Centers of the Carolinas, Inc. ("ROCC"), involved a 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 the Hospital and MV-Photon will transfer their respective ownership interests in the existing Sampson Cancer Center and its associated Equipment to wholly-owned subsidiary LLCs.

The January 2012 no-review determination relating to Cancer Centers of North Carolina's Asheville oncology treatment center, involved a transaction very similar to the Proposed Transaction at issue in this request. CCNC and its management company proposed to transfer an existing oncology center and associated equipment to two wholly-owned subsidiary limited liability companies, and NCRTMS proposed to acquire 100% of the ownership interests in those subsidiaries. In their no-review request letter, the parties explained that the Asheville oncology center and its exempt linear accelerator and computed tomography scanner would continue to serve patients at the center's existing location. The structure and result of the Proposed Transaction at issue in this request mirror this Asheville oncology center transaction which the CON Section determined did not require a CON.

In the September 2010 declaratory ruling involving Wake Radiology Oncology Services, the Department reviewed a proposed transaction under which WROS would be converted from a professional limited liability company to a limited liability company, followed immediately by the sale of the ownership interests in WROS. Subsequently, in a separate transaction, WakeMed proposed purchasing a minority

membership interest in the renamed WROS entity. After the two transactions, the resulting LLC would continue to exist as a legal and business entity and would continue to own the oncology treatment center and equipment that was authorized by a previously issued CON. The Department concluded that these proposed transactions did not require a CON. In its Declaratory Ruling, the Department noted that the entity which owned the linear accelerator and simulator would not change and the same equipment would continue to be used to provide the same radiation oncology services at the same location. The Declaratory Ruling explained that although the proposed transaction involved expenditures by CCNC and WakeMed, "these will be purchases of ownership interests in an existing limited liability company that owns the oncology treatment center. There will be no capital expenditure to develop or expand a health service or health service facility because the same equipment will continue to be operated at the same location, and no expansion of services is proposed." 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 Sampson Cancer Center and its associated Equipment which will continue to provide the same services to patients at the same location following the transaction.

Similarly, 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 CON.

In the December 2007 declaratory ruling relating to 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 purchase of LLC interests proposed by the Parties in this Request is analogous to the transactions that were proposed by NCRTMS and Rex Healthcare in the above-described declaratory rulings and no-review determination. Under the Proposed Transaction, NCRTMS will acquire all of the ownership interests in the LLCs, and ownership of the Sampson Cancer Center and its associated Equipment, including the Linac and Simulator, will remain with the LLCs following the Transaction. The Sampson Cancer Center will continue to use the Equipment to provide the same radiation therapy services to patients at the same location following the Proposed Transaction.

The Proposed Transaction Is Not an Acquisition of a Linear Accelerator or Simulator

The proposed acquisition of 100% of the membership interests in the LLCs by NCRTMS does not constitute the acquisition of a linear accelerator or simulator. As explained above, the transaction is limited to the acquisition of the underlying ownership interests in the corporate entities that own the existing Sampson Cancer Center and its associated Equipment. The Linac and Simulator will continue to be used to provide the same radiation oncology services, in the same location, and the entity that owns the Linac and Simulator will not change as a result of Step 2 of the Proposed Transaction. The LLCs will continue to own the Linac and the Simulator as well as all the Sampson Cancer Center assets that have been used to furnish oncology treatments to patients. The LLCs' membership composition will change to a single member, NCRTMS, 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 Sampson Cancer 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 Sampson Cancer 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 and simulator under the provisions of N.C. Gen. Stat. § 131E-176(16)(f1)5a and 9.

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

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

As the Department and CON Section must have determined in the prior 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 Sampson Cancer 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).

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 does not implicate the fundamental purposes of the CON Law and should not require a CON. As stated above, since 2006, the Sampson Cancer Center and its associated Equipment have been operated as part of an ongoing health care facility and that will continue after completion of the Proposed Transaction. Similarly, a subsequent merger of SRMC Sub and NEW LLC into NCRTMS also should not require a CON.

Mr. Craig R. Smith
Chief, CON Section
February 29, 2012
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Poyner Spruill^{LLP}

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.") Failure to issue the requested no-review determination would delay and impede the Parties that are requesting this determination in proceeding with a lawful business transaction.

We have enclosed a copy of the Exhibits referenced in this letter (see attached Index). We request your earliest possible attention to this request and look forward to your confirmation that the Proposed Transaction is not a new institutional health service and may proceed without a certificate of need. The Parties are aiming to close on the Proposed Transaction within approximately 30 days, and accordingly, we request a response from you by March 2, 2012, 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,



William R. Shenton



Pamela A. Scott

Enclosures

cc: Martha Frisone, Assistant Chief, CON Section
Norton L. Travis, General Counsel for RTS
Lee Spinks, Counsel for SRO, GRTS and MV-Photon
Lew Starling, Counsel for Sampson Regional Medical Center, Inc.

Index to Exhibits

1. Settlement Agreement in Contested Case Nos. 03 DHR 1710 and 03 DHR 1736
2. State Medical Facilities Plan Excerpts, 2009-2012
3. January 6, 2012 No Review Determination re: Request by Radiation Therapy Services, Inc. and September 26, 2011 Request Letter (without Exhibits)
4. August 18, 2011 Declaratory Ruling, *In re: Request for Declaratory Ruling by Radiation Oncology Centers of the Carolinas, Inc.*
5. September 27, 2010 Declaratory Ruling, *In re: Request for Declaratory Ruling by Wake Radiology Oncology Services, PLLC, Cancer Centers of North Carolina, P.C., US Oncology, Inc. et al.*
6. December 21, 2007 Declaratory Ruling, *In re: Request for Declaratory Ruling by Rex Healthcare, Inc. and Smithfield Radiation Oncology, LLC*
7. September 14, 2007 Declaratory Ruling, *In re: Request for Declaratory Ruling by Radiation Therapy Services, Inc. and North Carolina Radiation Therapy Management Services, Inc.*

EXHIBIT 1

STATE OF NORTH CAROLINA

IN THE OFFICE OF
ADMINISTRATIVE HEARINGS

COUNTY OF SAMPSON

03 DHR 1710

SAMPSON REGIONAL MEDICAL)
CENTER, INC.,)

Petitioner,)

v.)

N.C. DEPARTMENT OF HEALTH)
AND HUMAN SERVICES, DIVISION OF)
FACILITY SERVICES, CERTIFICATE OF)
NEED SECTION,)

Respondent,)

and)

CUMBERLAND COUNTY HOSPITAL)
SYSTEM, INC. d/b/a CAPE FEAR VALLEY)
HEALTH SYSTEM, and GOLDSBORO)
RADIATION THERAPY SERVICES, P.A.)
d/b/a SAMPSON RADIATION)
ONCOLOGY(lessee) and MV PHOTON,)
LLC (lessor),)

Respondent-Intervenors.)

STATE OF NORTH CAROLINA

IN THE OFFICE OF
ADMINISTRATIVE HEARINGS

COUNTY OF CUMBERLAND

03 DHR 1736

GOLDSBORO RADIATION THERAPY)
SERVICES, P.A., d/b/a SAMPSON)
RADIATION ONCOLOGY (lessee))
and MV PHOTON, LLC (lessor),)

Petitioners,)

v.)

N.C. DEPARTMENT OF HEALTH)
AND HUMAN SERVICES, DIVISION OF)
FACILITY SERVICES, CERTIFICATE OF)
NEED SECTION,)

Respondent,)
)
 and)
)
 SAMPSON REGIONAL MEDICAL)
 CENTER, INC., and CUMBERLAND)
 COUNTY HOSPITAL SYSTEM, INC. d/b/a)
 CAPE FEAR VALLEY HEALTH SYSTEM,)
)
 Respondent-Intervenors.)

SETTLEMENT AGREEMENT

This agreement is entered into by and among Cumberland County Hospital System, Inc. d/b/a Cape Fear Valley Health System ("Cape Fear"); Sampson Regional Medical Center, Inc. ("SRMC"); Goldsboro Radiation Therapy Services, P.A.; MV Photon, LLC; and the North Carolina Department of Health and Human Services, Division of Facility Services, Certificate of Need Section (the "Agency" or the "CON Section") (collectively referred to hereinafter as "the parties").

RECITALS

WHEREAS, on or about April 15, 2003, Cape Fear, SRMC and Goldsboro Radiation Therapy Services, P.A. d/b/a Sampson Radiation Oncology (lessee) and MV Photon, LLC (lessor) (collectively referred to as "GRTS") each filed an application with the Agency to acquire a linear accelerator. The three applications were subsequently determined complete for review and identified as: Project I.D. No. M-6804-03 (the "Cape Fear Project" or "Cape Fear's application"); Project I.D. No. M-6808-03 (the "SRMC Project" or "SRMC's application"); and Project I.D. No. M-6809-03 (the "GRTS Project" or "GRTS' application"). The applications were included in the next scheduled review cycle that began on May 1, 2003;

WHEREAS, by letter dated September 10, 2003, and the Required State Agency Findings issued September 10, 2003, the Agency approved Cape Fear's application and denied SRMC's application and GRTS application;

WHEREAS, on October 8, 2003, SRMC challenged the approval of Cape Fear's application and the denial of its application by initiating a contested case in the Office of Administrative Hearings, identified as 03 DHR 1710 ("the SRMC Contested Case");

WHEREAS, on October 10, 2003, GRTS challenged the approval of Cape Fear's application and the denial of its application by initiating a contested case in the Office of Administrative Hearings, identified as 03 DHR 1736 ("the GRTS Contested Case");

WHEREAS, on November 17, 2003, Cape Fear was allowed to intervene in both Contested Cases and on November 18, 2003 the two cases were consolidated by Order of Chief Administrative Law Judge Julian Mann, II (collectively referred to as the "Contested Cases");

WHEREAS, Goldsboro Radiation Therapy Services, P.A. is no longer doing business as Sampson Radiation Oncology and Sampson Radiation Oncology, P.A. is a separate legal entity independent from Goldsboro Radiation Therapy Services, P.A.

WHEREAS, pursuant to N.C. Gen. Stat. § 150B-22, it is the policy of the State to settle disputes between State agencies and other persons whenever possible;

WHEREAS, pursuant to this policy, the parties have discussed settlement of these Contested Cases;

WHEREAS, the execution of this Settlement Agreement does not constitute an admission of error by any party and does not constitute a concession by any party regarding any issue in the Contested Cases;

WHEREAS, in exchange for the mutual promises and agreements contained herein which the parties agree constitute good and satisfactory consideration to resolve all issues among the parties involving these Contested Cases and to resolve other issues, disputes, and potential disputes described herein;

NOW THEREFORE, pursuant to N.C. Gen. Stat. §§150B-22 and 31(b), and subject to the approval of the Director of the Division of Facility Services (the "Director"), the parties agree to resolve these Contested Cases in the manner set forth below.

AGREEMENT

1. Voluntary Dismissal with Prejudice. Within five business days after this Agreement is approved and adopted by the Director, SRMC and GRTS shall file notices of voluntary dismissal, with prejudice, in the Contested Cases in the Office of Administrative Hearings. Cape Fear consents to SRMC's dismissal and GRTS' dismissal of these Contested Cases and agrees that these cases shall terminate immediately upon the petitioner's filing Notices of Voluntary Dismissal With Prejudice, and that no filing by Cape Fear or other parties is required to terminate the case.

2. Issuance of Certificate of Need to Cape Fear. Within five (5) business days after the Agency receives file-stamped copies of the Notice of Voluntary Dismissal With Prejudice in the Contested Cases, the Agency shall issue Cape Fear a CON for the project described in Cape Fear's application, as modified by this Agreement and the conditions and timetable contained in Exhibit A to this Agreement.

3. No Review Determination for SRMC project. By executing this Agreement, the Agency determines that the SRMC proposal to acquire and install a linear accelerator and related items for less than the cost thresholds contained in the CON Law, as described in its request dated February 12, 2004, is not a new institutional health service and therefore does not require a certificate of need. After the project is complete, SRMC shall submit all actual costs associated with the project to the Agency so that the Agency may verify such costs.

4. No Review Determination for Goldsboro Radiation Therapy Services, P.A. project. By executing this Agreement, the Agency determines that the Goldsboro Radiation Therapy Services, P.A. project to acquire and install planning and simulation equipment and related items for less than \$250,000, as described in its request dated February 13, 2004 is not a new institutional health service and therefore does not require a certificate of need. After this project is complete, Goldsboro Radiation Therapy Services, P.A. shall submit all actual costs associated with the project to the Agency so that the Agency may verify the costs.

5. Exemption From Review. By executing the Agreement, the Agency determines that the project proposed by the limited liability company comprised of MV Photon, LLC and SRMC to develop office space, which is not part of the projects described in paragraphs 3 and 4 above, is exempt from review pursuant to N.C.G.S. 131E-184(a)(9). After this project is complete, the limited liability company referenced above shall submit all actual costs associated with the project to the Agency so that the Agency may verify such costs.

6. Release of Bond. Cape Fear consents to the release of SRMC's bond and

Goldsboro Radiation Therapy Services' bond posted with the Cumberland County Clerk of Court in connection with their appeal of Cape Fear's application.

7. Release. Each party hereby releases all other parties, their officials, employees, and representatives, from any and all liability or claims that have arisen or might arise out of: (a) the Agency's review of Cape Fear's application; (b) the Agency's review of SRMC's application; (c) the Agency's review of GRTS' application; or (d) this appeal.

8. Expenses. The parties agree that each shall bear its own expenses, including attorneys' fees, and that no claim for such costs or expenses shall be made by one party against the other.

9. Effect of Approval. If approved by the Director, this Agreement shall resolve all issues involved in, or arising out of, the Contested Cases, and other issues and disputes described herein.

10. Effect of Disapproval. If this Agreement is not approved by the Director, it shall be null and void and the parties shall be entitled to proceed with the Contested Cases. In that event, the Director's review of this Agreement as provided herein shall not prejudice his authority to render the final Agency decision following the hearing in these Contested Cases in accordance with Article 3 of Chapter 150B of the North Carolina General Statutes. In addition, if this Agreement is not approved by the Director, the parties agree that it shall be inadmissible at the contested case hearing for any purpose.

11. Waiver of Right to Appeal Agreement. The parties irrevocably waive any right to initiate an appeal from this Agreement, assuming that any such right exists; provided that nothing in this Agreement shall be construed to waive any claim for

enforcement or breach of this Agreement. The parties reserve the right to intervene in any appeal of this Agreement that might be filed by any third parties.

12. Merger. The parties further agree and acknowledge that this written Agreement sets forth all of the terms and conditions among all of them concerning the subject matter of this Agreement, superseding all prior oral and written statements and representations and that there are no terms and conditions among all four of the parties except as specifically set forth in this Agreement.

13. Modification or Waiver. No modification or waiver of any provision of this Agreement shall be effective unless it is in writing. Any modification or waiver must be signed by authorized representatives of the parties and must be adopted and approved by the Director.

14. No Strict Interpretation Against Draftsman. Each of the parties has participated in the drafting of this Agreement and has had the opportunity to consult with counsel concerning its terms. This Agreement shall not be interpreted strictly against any one party on the ground that it drafted the Agreement.

15. Recitals and Headings. All parts and provisions of this Agreement, including the recitals and paragraph headings, are intended to be material parts of the Agreement.

16. Authority to Settle. The undersigned represent and warrant that they are authorized to enter into this Agreement on behalf of the parties to this Agreement.

17. Ex Parte Presentation. Cape Fear, SRMC and GRTS authorize counsel for the Agency to present this Agreement to the Director *ex parte*.

18. Effective Date. This Agreement shall be effective as of the day and year which is adopted and approved by the Director of the Division of Facility Services.

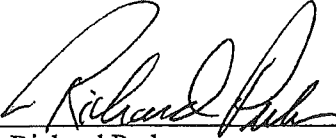
19. Binding Effect. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective legal representatives, successors, and assigns.

20. Material Compliance Determination. The Parties agree that all of the following determinations shall be within the sole discretion of the Agency, such determinations to be rendered consistent with the provisions of N.C. Gen. Stat. § 131E-178, 183, 184, 189: (a) whether any Party's subsequent performance materially complies with the representations in its certificate of need application, no review request, or exemption request, as modified or approved by this Settlement Agreement; (b) whether any Party's subsequent performance materially complies with any conditions imposed on its certificate of need; (c) whether any Party is meeting, or is making good faith efforts to meet, its timetable; and (d) whether any Party's actual costs related to its certificate of need application, no review request, or exemption request exceed the cost thresholds which would otherwise require a new certificate of need.

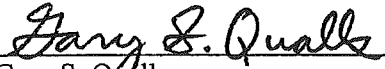
IN WITNESS WHEREOF, the parties have executed four originals of this Settlement Agreement, with one original copy being retained by each party.

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CUMBERLAND COUNTY HOSPITAL SYSTEMS, INC. d/b/a CAPE FEAR VALLEY HEALTH SYSTEM

By:  4/12/04
Richard Parks
Chief Executive Officer
Date

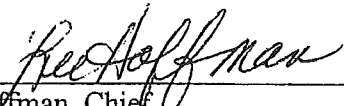
KENNEDY COVINGTON LOBDELL & HICKMAN LLP

By:  4/13/04
Gary S. Qualls
2801 Slater Road, Suite 120
Morrisville, NC 27560
Date

Attorneys for Cumberland County Hospital Systems, Inc. d/b/a Cape Fear Valley Health System

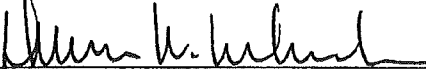
**NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF FACILITY SERVICES**

CERTIFICATE OF NEED SECTION

By: 
Lee Hoffman, Chief

Date: 5/4/04

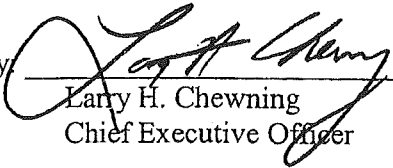
**ROY COOPER
Attorney General**

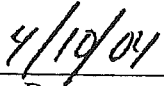
By: 
T. Matthew Woodward
N.C. Department of Justice
P.O. Box 629
Raleigh, NC 27602-0629

Date: 5/3/04

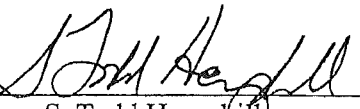
Counsel for the North Carolina Department of Health and Human Services, Division of
Facility Services, Certificate Need Section

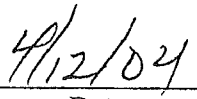
SAMPSON REGIONAL MEDICAL CENTER, INC.

By: 
Larry H. Chewning
Chief Executive Officer


Date

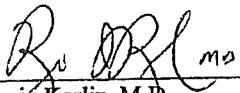
BODE, CALL & STROUPE, LLP

By: 
S. Todd Hemphill
3105 Glenwood Ave, Suite 300
Raleigh, NC 27612


Date

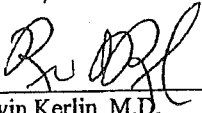
Attorneys for Sampson Regional Medical Center, Inc.

GOLDSBORO RADIATION THERAPY SERVICES, P.A

By: 
Kevin Kerlin, M.D.

4-26-04
Date

MV PHOTON, LLC

By: 
Kevin Kerlin, M.D.

4-21-04
Date

SMITH MOORE, L.L.P.

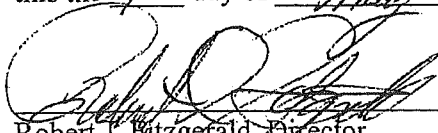
By: Susan Fradenburg
Susan Fradenburg
300 N. Greene Street, Suite 1400
P. O. Box 21927
Greensboro, NC 27420

4/26/04
Date

Attorneys for Goldsboro Radiation Therapy Services, P.A. and MV Photon, LLC

APPROVAL AND ADOPTION

The foregoing Settlement Agreement is hereby APPROVED AND ADOPTED
this the 4th day of May, 2004.



Robert J. Fitzgerald, Director
Division of Facility Services

EXHIBIT A
TIMETABLE

Certificate of Need

- | | | |
|-----|---|------------------|
| (a) | Anticipated Date of Decision
(90 to 150 days from beginning date of review period) | |
| (b) | Date of Issuance of the Certificate of Need (Date may not be less than 31 days following the decision date) | <u>4/30/04</u> |
| 1. | <u>Financing</u> | |
| (a) | Obtaining construction financing | <u>Available</u> |
| (b) | Obtaining permanent financing | <u>Available</u> |
| (c) | Obtaining funds necessary to undertake project | <u>Available</u> |
| 2. | <u>Design</u> | |
| (a) | Completion of preliminary drawings | |
| (b) | Completion of final drawings and specifications | <u>5/04/04</u> |
| (c) | Approval of final drawings and specifications by the Construction Section, Division of Facility Services | <u>7/01/04</u> |
| 3. | <u>Construction</u> | |
| (a) | Approval of Site by Construction Section, DFS | <u>7/01/04</u> |
| (b) | Contract award (Notice to Proceed) | <u>8/03/04</u> |
| (d) | 25% completion of construction (25% of the dollar value of the contract in place) | <u>11/03/04</u> |
| (d) | 50% completion of construction | <u>02/15/05</u> |
| (e) | 75% completion of construction | <u>05/15/05</u> |
| (f) | Completion of construction | <u>09/01/05</u> |
| (g) | Occupancy /offering of service(s) | <u>10/01/05</u> |
| 4. | <u>Acquisition of Medical Equipment</u> | |
| (a) | Ordering equipment - beds | <u>05/30/05</u> |
| (b) | Arrival equipment | <u>09/01/05</u> |
| (c) | Operation of equipment | <u>10/01/05</u> |
| 5. | <u>Other Milestones</u> | |
| (a) | Licensure of Facility | _____ |
| (b) | Certification of beds | _____ |
| (c) | Other (Specify) | _____ |

Exhibits A to Settlement Agreement p. 2
Conditions

The application submitted by Cape Fear Valley Health System is approved subject to the following conditions.

1. **The Cumberland County Hospital System, Inc. d/b/a Cape Fear Valley Health System shall materially comply with all representations made in the certificate of need application.**
2. **The Cumberland County Hospital System, Inc. d/b/a Cape Fear Valley Health System shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application or that would otherwise require a certificate of need.**
3. **Prior to issuance of the certificate of need, Cumberland County Hospital System, Inc. d/b/a Cape Fear Valley Health System shall submit to the Certificate of Need Section the projected number of patient treatments by county for the each of first eight calendar quarters following completion of the proposed project.**
4. **Prior to issuance of the certificate of need, the applicant shall provide to the Certificate of Need Section documentation of the fair market value of each piece of radiation therapy equipment and the purchase price quotations and fair market value for each item of related equipment proposed to be acquired.**
5. **The Cumberland County Hospital System, Inc. d/b/a Cape Fear Valley Health System shall acknowledge acceptance and compliance with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**

EXHIBIT 2

NORTH CAROLINA 2009 STATE MEDICAL FACILITIES PLAN

Effective January 1, 2009

Prepared by the

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Medical Facilities Planning Section

Under the direction of the

North Carolina State Health Coordinating Council

For information or copies, contact the

North Carolina Division of Health Service Regulation
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

<http://www.ncdhhs.gov/dhsr/ncsmfp/index.html>

(919) 855 - 3865 Telephone Number
(919) 715 - 4413 FAX Number



The North Carolina Department of Health and Human Services does not discriminate on the basis of race, color, national origin, sex, religion, age or disability in employment or the provision of services.

**Table 9E: Hospital and Free-Standing Linear Accelerators
and Radiation Oncology Procedures**

Facility Name	Service Area #	County	LIN	PROCEDURES (ESTVs)	
			ACC	2006-2007	Average per Unit
New Hanover Radiation Oncology	19	New Hanover	2	24,737	12,369
New Hanover Regional Med Ctr	19	New Hanover	1	8,388	8,388
South Atlantic Radiation Oncology, LLC (c)	19	Brunswick	1	NA	0
2007 SMFP Need Determination	20		1		
Cancer Centers of NC - Raleigh Hematology	20	Wake	1	10,062	10,062
Duke Raleigh Hospital	20	Wake	1	6,923	6,923
Rex Hospital	20	Wake	4	18,838	4,710
Wake Radiology / Oncology Services	20	Wake	1	5,597	5,597
Smithfield Radiation Oncology LLC	21	Johnston	1	3,053	3,053
2006 SMFP Need Determination	21	Johnston	1		
Lenoir Memorial	22	Lenoir	1	7,267	7,267
Wayne Radiation Oncology Center	22	Wayne	1	5,535	5,535
Carteret General (g)	23	Carteret	1	3,750	3,750
Craven Regional Med Ctr	23	Craven	2	13,590	6,795
Onslow Radiation Oncology, LLC ("ORO") and Onslow County Hospital Authority	24	Onslow	1		
Nash Day Hospital	25	Nash	2	8,194	4,097
Roanoke Valley Cancer Center	25	Halifax	1	3,578	3,578
Wilson Memorial Hospital	25	Wilson	1	5,525	5,525
Ahoskie Cancer Center	26	Hertford	1	2,679	2,679
Carolina Radiation Medicine, P.A. (f) (S)	26	Pitt	1	8,711	8,711
Pitt County Memorial Hospital (S)	26	Pitt	3	18,097	6,032
Albemarle Hospital	27	Pasquotank	1	3,666	3,666
Outer Banks Cancer Center	27	Dare	1	3,643	3,643
TOTALS (67 Facilities)			114	612,989	5,377

- (a) Cape Fear Valley Health System received a CON in May 2004 for one additional linac bringing their total to 4 linacs.
- (b) Mission Hospitals received a CON in September 2004 to initiate CyberKnife linac service; to be operational in October 2005.
- (c) South Atlantic Radiation Oncology received a CON in August 2005 to initiate linac service; operation effective May 2007.
- (d) Hugh Chatham Memorial Hospital became operational in March 2000 with a leased linac from NC Baptist Hospitals.
- (e) Maria Parham Hospital received a CON in July 2001 to lease and install one linac.
- (f) Carolina Radiation Medicine, P.A. became operational in July 1998.
- (g) Carteret General Hospital received a no review in June 1999 to replace a linear accelerator and purchase a simulator.
- (h) Gaston Memorial Hospital received a CON in August 1999 to add one linac; operation projected for April 2001.
- (i) Union Regional Medical Center received a CON in April 2000 to acquire one linac; operation projected for September 2001.
- (j) Alamance Regional Medical Center received a CON in August 2002 to add one linac; operation projected for July 2003.
- (k) Forsyth Medical Center received a CON in August 2002 to add one linac; operational in October 2004.
- (l) Scotland Memorial Hospital became operational in August 2003.
- (m) Randolph Cancer Center received a CON in June 2006 to initiate linac service.
- (n) Pineville Radiation Therapy Center received a CON in June 2007 to initiate linac service.
- (o) Cancer Center of Davidson County, LLC received a CON in July 2007 to initiate linac service.
- (p) East Carolina University Brody School of Medicine (Pitt Memorial) received a CON in December 2007 to replace an existing linear accelerator with a CyberKnife linear accelerator; to be operational June 2008.
- (q) UNC Hospitals received a CON in October 2006 to replace an existing linear accelerator with a CyberKnife linear accelerator; to be operational in April 2007.
- (r) Carolinas Medical Center - NorthEast received a CON in February 2006 to acquire a CyberKnife linear accelerator; to be operational in October 2007.
- (s) Lincoln Radiation Oncology Associates received CON 10/27/08 to acquire existing linear accelerator through ownership transfer from Gaston Memorial Hospital, replace the linear accelerator and relocate to Lincoln Radiation Oncology Center.

CPT Code 77427 - Weekly radiation therapy management. These procedure numbers from Freestanding (fixed non-hospital) Centers were removed from the count for purposes to determine need.
 NA - Not Applicable, not in operation for appropriate time frame.
 NR - No report
 S - Has at least one Linear Accelerator configured for Stereotactic Radiosurgery

16

NORTH CAROLINA 2010 STATE MEDICAL FACILITIES PLAN

Effective January 1, 2010

Prepared by the

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Medical Facilities Planning Section

Under the direction of the

North Carolina State Health Coordinating Council

For information contact the

North Carolina Division of Health Service Regulation
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

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(919) 855 - 3865 Telephone Number
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450 copies of this document were printed at a cost of \$9,376.73 or \$20.85 per copy.

Table 9E: Hospital and Free-Standing Linear Accelerators and Radiation Oncology Procedures

Facility Name	Service Area #	County	Number of Linear Accelerators	Number of Procedures (ESTVs) 10/1/2007-9/30/2008	Average # of Procedures per Unit
Cape Fear Valley Medical Center (a)	18	Cumberland	5	21,340	4,268
Southeastern Regional Medical Center (v)	18	Robeson	1	6,705	6,705
Sampson Regional Medical Center	18	Sampson	1	2,365	2,365
New Hanover Radiation Oncology	19	New Hanover	2	23,613	11,807
New Hanover Regional Med Center	19	New Hanover	1	7,186	7,186
South Atlantic Radiation Oncology, LLC (c)	19	Brunswick	1	3,694	3,694
Raleigh Hematology Oncology Associates/Cancer Centers of NC (u)	20	Wake	2	11,277	5,639
Duke Health Raleigh Hospital	20	Wake	1	7,566	7,566
Rex Hospital	20	Wake	4	16,970	4,242
Wake Radiology / Oncology Services Rex Healthcare (Smithfield Radiation Oncology)	20	Wake	1	6,216	6,216
Johnston Memorial Hospital Authority (t)	21	Johnston	1	3,706	3,706
Lenoir Memorial	21	Johnston	1	NR	NR
Lenoir Memorial	22	Lenoir	1	6,911	6,911
Goldsboro Radiation Therapy Services dba Wayne Radiation Oncology Center	22	Wayne	1	5,955	5,955
Carteret General Hospital (g)	23	Carteret	1	4,162	4,162
CarolinaEast Medical Center	23	Craven	2	12,771	6,386
Onslow Radiation Oncology, LLC	24	Onslow	1	NR	NR
Nash Day Hospital	25	Nash	2	8,183	4,091
Roanoke Valley Cancer Center	25	Halifax	1	3,844	3,844
Wilson Medical Center	25	Wilson	1	4,526	4,526
Beaufort County Hospital	26	Beaufort	1	3,470	3,470
Ahoskie Cancer Center	26	Hertford	1	2,048	2,048
NC Radiation Therapy Management Services (prev Carolina Radiation Medicine, P.A.) (f) (S)	26	Pitt	1	7,668	7,668
ECU Brody School of Medicine (S)	26	Pitt	3	14,929	4,976
Albemarle Hospital	27	Pasquotank	1	4,696	4,696
Alliance Oncology dba Outer Banks Cancer Center	27	Dare	1	2,323	2,323
TOTALS (72 Facilities)			116	587,798	5,067

* Murphy Medical Center stopped operating, and decommissioned, this linear accelerator on May 20, 2009.

** CMC will move one linear accelerator to CMC-Union per CON F-007525-06

(a) Cape Fear Valley Health System received a CON in May 2004 for the fourth linac, and a CON on 12/18/2009 for the fifth linac, which will be a CyberKnife.

(b) Mission Hospitals received a CON in September 2004 to initiate CyberKnife linac service; operational in October 2005.

(c) South Atlantic Radiation Oncology received a CON in August 2005 to initiate linac service; operation effective May 2007.

(d) Hugh Chatham Memorial Hospital became operational in March 2000 with a leased linac from NC Baptist Hospitals.

(e) Maria Parham Hospital received a CON in July 2001 to lease and install one linac.

(f) Carolina Radiation Medicine, P.A. became operational in July 1998.

(g) Carteret General Hospital received a no review in June 1999 to replace a linear accelerator and purchase a simulator.

(h) Gaston Memorial Hospital received a CON in August 1999 to add one linac.

NORTH CAROLINA 2011 STATE MEDICAL FACILITIES PLAN

Effective January 1, 2011

Prepared by the

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Medical Facilities Planning Section

Under the direction of the

North Carolina State Health Coordinating Council

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Table 9E: Hospital and Free-Standing Linear Accelerators and Radiation Oncology Procedures

Facility Name	Service Area #	County	Number of Linear Accelerators	Number of Procedures (ESTVs) 10/1/2008-9/30/2009	Average # of Procedures per Unit
Southeastern Regional Medical Center (v)	18	Robeson	1	7,404	7,404
Sampson Regional Medical Center	18	Sampson	1	2,519	2,519
New Hanover Radiation Oncology	19	New Hanover	2	21,634	10,817
New Hanover Regional Medical Center	19	New Hanover	1	6,954	6,954
South Atlantic Radiation Oncology (c)	19	Brunswick	1	7,640	7,640
Raleigh Hematology Oncology Associates/Cancer Centers of NC (u)	20	Wake	2	11,923	5,962
Duke Raleigh Hospital	20	Wake	1	7,268	7,268
Rex Hospital	20	Wake	4	16,932	4,233
Wake Radiology / Oncology Services	20	Wake	1	4,718	4,718
Rex Healthcare (Smithfield Radiation Oncology)	21	Johnston	1	2,432	2,432
Johnston Memorial Hospital Authority (t)	21	Johnston	1	NR	NR
Lenoir Memorial	22	Lenoir	1	5,860	5,860
Goldsboro Radiation Therapy Services dba Wayne Radiation Oncology Center	22	Wayne	1	4,799	4,799
Carteret General Hospital (g)	23	Carteret	1	119	119
CarolinaEast Medical Center	23	Craven	2	12,036	6,018
Onslow Radiation Oncology	24	Onslow	1	NR	NR
Nash Day Hospital	25	Nash	2	8,491	4,246
Roanoke Valley Cancer Center	25	Halifax	1	3,996	3,996
Wilson Medical Center	25	Wilson	1	5,178	5,178
Beaufort County Hospital	26	Beaufort	1	4,308	4,308
Ahoskie Cancer Center	26	Hertford	1	1,758	1,758
NC Radiation Therapy Management Services (prev Carolina Radiation Medicine, P.A.) (f) (S)	26	Pitt	1	8,228	8,228
ECU Brody School of Medicine (S)	26	Pitt	3	18,786	6,262
Albemarle Hospital	27	Pasquotank	1	5,276	5,276
Alliance Oncology dba Outer Banks Cancer Center	27	Dare	1	2,049	2,049
TOTALS (71 Facilities, including Murphy Medical Center)			119	593,531	4,988

* Murphy Medical Center stopped operating, and decommissioned, this linear accelerator on May 20, 2009.

** CMC will move one linear accelerator to CMC-Union per CON F-007525-06

(a) Cape Fear Valley Health System received a CON in May 2004 for the fourth linear accelerator, and CON M-008133-08 on 12/18/2009 to retain a linear accelerator, for a total of five, including a CyberKnife.

(b) Mission Hospitals received a CON in September 2004 for a CyberKnife linear accelerator; operational in October 2005.

(c) South Atlantic Radiation Oncology received a CON in August 2005 for a linear accelerator; operational in May 2007.

(d) Hugh Chatham Memorial Hospital became operational in March 2000 with a leased linear accelerator from NC Baptist Hospitals.

(e) Maria Parham Hospital received a CON in July 2001 to lease and install one linear accelerator.

(f) Carolina Radiation Medicine, P.A. became operational in July 1998.

(g) Carteret General Hospital received a no review in June 1999 to replace a linear accelerator and purchase a simulator. Also received a no-review for a replacement linear accelerator in 2009.

(h) Gaston Memorial Hospital received a CON in August 1999 to add one linear accelerator.

**NORTH CAROLINA
2012 STATE MEDICAL FACILITIES PLAN**

Effective January 1, 2012

Prepared by the

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Medical Facilities Planning Branch

Under the direction of the

North Carolina State Health Coordinating Council

For information contact the

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Table 9E: Hospital and Free-Standing Linear Accelerators and Radiation Oncology Procedures

Facility Name	Service Area #	County	Number of Linear Accelerators	Number of Procedures (ESTVs) 10/1/2009-9/30/2010	Average # of Procedures per Unit
Duke University Hospital	16	Durham	8	34,771	4,346
Durham Regional Hospital	16	Durham	1	5,750	5,750
Maria Parham Hospital	16	Vance	1	6,642	6,642
FirstHealth Moore Regional	17	Moore	2	19,954	9,977
Scotland Memorial Hospital	17	Scotland	1	3,907	3,907
Cape Fear Valley Medical Center	18	Cumberland	5	19,668	3,934
Southeastern Regional Medical Center	18	Robeson	1	9,046	9,046
Sampson Regional Medical Center	18	Sampson	1	2,134	2,134
New Hanover Radiation Oncology	19	New Hanover	2	12,987	6,494
New Hanover Regional Medical Center	19	New Hanover	1	6,078	6,078
South Atlantic Radiation Oncology	19	Brunswick	1	4,838	4,838
Franklin County Cancer Center (included in inventory by letter of no review 5/09/2011)	20	Franklin	1	NR	NR
Raleigh Hematology Oncology Associates/Cancer Centers of NC	20	Wake	2	11,506	5,753
Duke Raleigh Hospital	20	Wake	1	7,572	7,572
Rex Hospital	20	Wake	4	19,636	4,909
Wake Radiology / Oncology Services	20	Wake	1	5,633	5,633
Rex Healthcare (Smithfield Radiation Oncology)	21	Johnston	1	3,015	3,015
Johnston Radiation Oncology dba Clayton Radiation Oncology	21	Johnston	1	863	863
Lenoir Memorial	22	Lenoir	1	5,041	5,041
Goldsboro Radiation Therapy Services dba Wayne Radiation Oncology Center	22	Wayne	1	5,269	5,269
Carteret General Hospital	23	Carteret	1	4,319	4,319
CarolinaEast Medical Center	23	Craven	2	8,353	4,177
Onslow Radiation Oncology	24	Onslow	1	NR	NR
Nash Day Hospital	25	Nash	2	8,174	4,087
Roanoke Valley Cancer Center	25	Halifax	1	3,278	3,278
Wilson Medical Center	25	Wilson	1	5,407	5,407
Beaufort County Hospital	26	Beaufort	1	3,458	3,458
Ahoskie Cancer Center	26	Hertford	1	2,199	2,199
NC Radiation Therapy Management Services (prev Carolina Radiation Medicine, P.A.)	26	Pitt	2	10,705	5,353
ECU Brody School of Medicine [On 12/30/2010 related entity NewCo Cancer Services acquired two existing linear accelerators (Q-008562-10) and Pitt County Memorial Hospital acquired one existing linear accelerator (Q-008558-10)]	26	Pitt	3	14,512	4,837
Albemarle Hospital	27	Pasquotank	1	5,426	5,426
Alliance Oncology dba Outer Banks Cancer Center	27	Dare	1	3,370	3,370
TOTALS (72 Facilities)			123	600,749	4,884

EXHIBIT 3



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

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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 (NCRRTMS)
- Acquisition of 100% of Asheville CC, LLC by NCRRTMS
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



WSP



Poyner Spruill^{LLP}

September 26, 2011

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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 (“NCR-TMS”). RTS is a national provider of radiation oncology services which offers services at several locations in western North Carolina.

With this letter, NCR-TMS 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, NCR-TMS 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.

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 NCRTMS does not constitute the acquisition of a linear accelerator. As explained above, the transaction is limited to the acquisition of the underlying ownership interests in the corporate 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, NCRTMS, 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)(f)5a.

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

The Proposed Transaction will involve expenditures by NCRTMS, 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

cc: Martha Frisone, Assistant Chief, CON Section
Norton L. Travis, General Counsel for RTS
S. Todd Hemphill, Counsel for CCNC-Asheville and AOR
Jeremy C. Ouchley, Counsel for AOR

EXHIBIT 4



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

August 18, 2011

CERTIFIED MAIL

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

RE: Declaratory Ruling for Radiation Oncology Centers of the Carolinas, Inc.

Dear Mr. Hemphill:

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

Sincerely,

Drexdal Pratt

DP:JH:peb

Enclosure

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



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

**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 18th day of August, 2011.



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

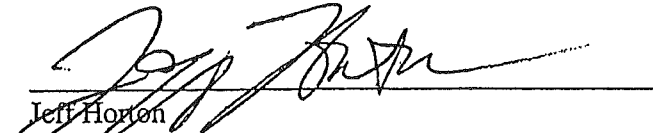
CERTIFICATE OF SERVICE

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

CERTIFIED MAIL

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

This the 18th day of August, 2011.



Jeff Horton
Chief Operating Officer

EXHIBIT 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.



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

CERTIFICATE OF SERVICE

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

CERTIFIED MAIL

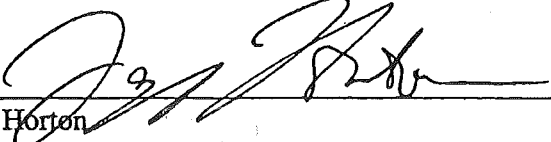
William R. Shenton, Esquire
Poyner Spruill LLP
301 Fayetteville Street, Suite 1900
Raleigh, NC 27601
Attorneys for U.S. Oncology, Inc. and AOR Management
Company of Virginia, LLC

Ronald I. Kirschbaum, Esquire
Kirschbaum, Nanney, Keenan & Griffin, P.A.
Post Office Box 19766
Raleigh, NC 27607
Attorneys for Wake Radiology Oncology, PLLC

Larry E. Robbins, Esquire
Wyrick Robbins Yates & Ponton, LLP
Post Office Drawer 17803
Raleigh, NC 27607
Attorneys for Cancer Centers of North Carolina, P.C.

Maureen Demarest Murray, Esquire
Smith Moore Leatherwood LLP
Post Office Box 21927
Greensboro, NC 27420
Attorneys for WakeMed

This the 27th day of September, 2010.



Jeff Horton
Chief Operating Officer

EXHIBIT 6

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.C.G.S. § 131E-176(16) defines "new institutional health service" to include: (1) "The acquisition by purchase, donation, lease, transfer, or comparable arrangement" of a linear accelerator "by or on behalf of any person," N.C.G.S. § 131E-176(16)f1.5a, and (2) "The obligation by any person of a capital expenditure exceeding two million dollars (\$2,000,000) to develop or expand a health service or a health service facility, or which relates to the provision of a health service," N.C.G.S. § 131E-176(16)b.

The transaction described by Petitioners does not constitute the acquisition of a linear accelerator 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

EXHIBIT 7



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

COPY

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

Michael F. Easley, Governor
Dempsey Benton, Secretary

Robert J. Fitzgerald, Director
Phone: 919-855-3750
Fax: 919-733-2757

September 18, 2007

CERTIFIED MAIL

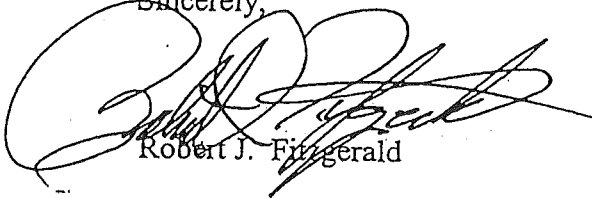
Susan H. Hargrove, Esquire
Smith, Anderson, Blount, Dorsett
Mitchell & Jernigan, L.L.P.
P.O. Box 2611
Raleigh, NC 27602-2611

RE: Declaratory Ruling for Radiation Therapy Services, Inc. and North Carolina Radiation
Therapy Management Services, Inc.

Dear Ms. Hargrove:

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

Sincerely,



Robert J. Fitzgerald

RJF:JH:peb

Enclosure

cc: Jeff Horton, Chief Operating Officer, DHSR
Lee Hoffman, Chief, Certificate of Need Section, DHSR
Azzie Conley, Chief, Acute and Home Care Licensure and Certification Section, DHSR
Marc Lodge, Special Deputy Attorney General, DOJ



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

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

I, Robert J. Fitzgerald, Director of the Division of Health Service Regulation (the "Department"), hereby issue this declaratory ruling to Radiation Therapy Services, Inc. d/b/a/ 21st Century Oncology ("RTS") and North Carolina Radiation Therapy Management Services, Inc. ("NC Radiation") (collectively "Petitioners") pursuant to N.C.G.S. § 150B-4, 10A NCAC 14A.0103, and the authority delegated to me by the Secretary of the North Carolina Department of Health and Human Services. Petitioners have filed a Declaratory Ruling Request (the "Request") asking the Department to issue a declaratory ruling that they may acquire all of the stock of Carolina Radiation and Cancer Treatment Center, Inc. ("CRTC") without certificate of need ("CON") review.

This ruling is binding on the Department and the person requesting it if the material facts stated in the Request are accurate and no material facts have been omitted from the request. The ruling applies only to this request. Except as provided by N.C.G.S. § 150B-4, the Department reserves the right to change the conclusions which are contained in this ruling. Susan H. Hargrove, Sean A. Timmons, and Jennifer B. Markhan of Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan, L.L.P., counsel for Petitioners, have requested this ruling on behalf of Petitioners and have provided the statement of facts upon which this ruling is based. The material facts as provided by counsel for Petitioners are set out below.

STATEMENT OF THE FACTS

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

Petitioner RTS is a Florida corporation. NC Radiation is a North Carolina corporation that is a wholly-owned subsidiary of RTS. Both have their principal business address in Fort Myers, Florida.

Petitioners wish to acquire 100% of the issued and outstanding stock of CRTC, which they state is a North Carolina corporation owned by Dr. Gordon Koltis that operates a radiation therapy facility for cancer patients. Petitioners describe CRTC as an oncology treatment center that, prior to 26 August 2005, would have been a "health service facility" as defined in N.C.G.S. § 131E-176(9b). S.L. 2005-325 eliminated oncology treatment centers from the category of "health service facilities," effective 26 August 2005.

Petitioners also state that CRTC "owns and operates two linear accelerators" and "one simulator." Request, p. 3. Footnote 1 to the Request states:

CRTC has represented to Petitioners that it entered into binding obligations to acquire the second linear accelerator prior to August 26, 2005, and that the acquisition of the second linear accelerator cost less than \$750,000, including the cost of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the second linear accelerator.

I note from the files of the Department that the inventory report of linear accelerator equipment submitted by Carolina Radiation Medicine, P.A., certified and dated by Gordon G. Koltis on April 6, 2007, identifies only one linear accelerator owned by CRTC. The Department files do not contain any information concerning the purported second linear accelerator.

Petitioners represent that they have executed a stock purchase agreement by which NC Radiation will acquire 100% of the issued and outstanding capital stock of CRTC from Dr. Koltis. After closing the transaction, Petitioners state that CRTC will remain a separate corporate entity that is a wholly-owned subsidiary of NC Radiation. They state that CRTC will continue to operate its freestanding radiation therapy facility at the same location in Greenville, Pitt County, North Carolina, in the same manner in which it operated prior to the transaction in all material ways. Petitioners will pay more than two million dollars to purchase the CRTC stock. The closing of the transaction is conditioned on receiving confirmation from the Department that acquisition of the stock will not require a certificate of need.

ANALYSIS

N.C.G.S. § 131E-178 provides that no person shall offer or develop "a new institutional health service" without first obtaining a CON. N.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 or a simulator by any person because ownership of the one reported linear accelerator and one reported simulator here will not change. CRTC will continue to be the owner of these two pieces of equipment, and CRTC's legal status as a corporate entity will not change.

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

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

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Finally, on the specific facts of this case, the transaction proposed by Petitioners is not "a capital expenditure . . . which relates to the provision of a health service" within the meaning of N.C.G.S. § 131E-176(16)b. The definition of "health service" specifically "does not include administrative and other activities that are not integral to clinical management." Petitioners' representations indicate that stock ownership of CRTC is not integral to the clinical management of CRTC, because in all material respects the operations of CRTC will not change.

I specifically except from this Ruling any conclusions as to the status or legality of the ownership of a purported second linear accelerator by CRTC. The Department has no notice of the existence or ownership of the second linear accelerator, and I make no finding that CRTC may acquire or operate, or has properly acquired and operated, a second linear accelerator without CON review.

CONCLUSION

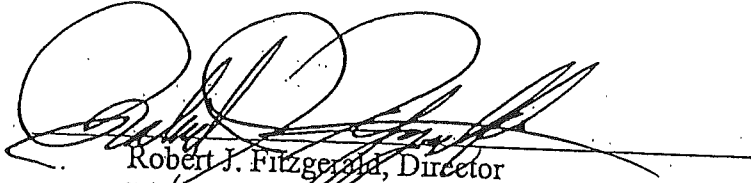
For the foregoing reasons, assuming the statements of fact in the Request to be true, I conclude that the acquisition by Petitioners of 100% of the outstanding and issued stock of CRTC, in the manner represented by Petitioners in the Request, is not subject to CON review.

This ruling is subject to the condition that, after the transaction, CRTC continues to operate its freestanding radiation therapy facility at the same location in Greenville, Pitt County, North Carolina, in the same manner in which it operated prior to the transaction in all material ways.

This ruling is not intended to address, expand or validate any activities or status of CRTFC with respect to the requirements of the CON law as it relates to CRTFC. The ruling is limited to the specific facts presented in the Request. It specifically does not address the status of any linear accelerator that CRTFC may own or claim to own.

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This 14th day of September 2007.



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

CERTIFICATE OF SERVICE


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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

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

This the 14th day of September, 2007.



Jeff Horton
Chief Operating Officer