

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

IN RE: REQUEST FOR DECLARATORY)
RULING BY NEW HANOVER REGIONAL) **DECLARATORY**
MEDICAL CENTER AND SOUTH ATLANTIC) **RULING**
RADIATION ONCOLOGY, LLC)
FID# 050139)

I, Mark Payne, Director, Division of Health Service Regulation, North Carolina Department of Health and Human Services (the “Department” or “Agency”), do hereby issue this Declaratory Ruling pursuant to North Carolina Gen. Stat. §150B-4 and 10A N.C.A.C. 14A.0103 under the authority granted me by the Secretary of the Department of Health and Human Services.

New Hanover Regional Medical Center (“NHRMC”) and South Atlantic Radiation Oncology, LLC (“SARO”) (collectively the “Parties”) have requested that the North Carolina Department of Health and Human Services, Division of Health Service Regulation (the “Department”) issue a declaratory ruling as to the applicability of Chapter 131E, Article 9 of the North Carolina General Statutes, and of the Department’s rules, to the facts described below. Specifically, the Parties request a determination that the Redesignation (without relocation) of SARO’s Cancer Center, including the linear accelerator and simulator located therein, to an unlicensed, provider-based outpatient department of NHRMC: (1) is permitted by the Hospital Licensure Act; and (2) does not require a Certificate of Need (“CON”). This ruling will be binding upon the Department and the entities requesting it, as long as the material facts stated herein are accurate. This ruling pertains only to the matters referenced herein. Except as provided by N.C. Gen. Stat. § 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. Denise Gunter

of Nelson Mullins Riley & Scarborough LLP has requested this ruling on behalf of the Parties, and has provided the material facts upon which this ruling is based.

STATEMENT OF FACTS

NHRMC operates an integrated health care delivery system with its main hospital campus located at 2131 S. 17th Street in Wilmington, New Hanover County, North Carolina. NHRMC currently owns fifty percent of SARO. NHRMC also owned fifty percent of SARO when SARO applied for and was issued a certificate of need effective August 30, 2005 to develop an oncology treatment center in Brunswick County by acquiring a linear accelerator and a simulator.

SARO developed and currently operates the freestanding radiation oncology treatment center in a single building located at 545 Ocean Highway West, Supply, North Carolina 28462. SARO's Cancer Center Space measures 9,847 square feet and houses a linear accelerator in a linear accelerator vault and a CT area used by physicians, physicists and dosimetrists for generating images for treatment planning and radiation dosage.

The Parties now propose to continue operation of the radiation oncology treatment center in the same building at the same physical address, but wish to Redesignate the 9,847 square feet currently operated as SARO's Cancer Center from a freestanding radiation oncology treatment center to a provider-based, unlicensed location of NHRMC.

The parties further represent the following:

- a. The SARO Cancer Center Space is already designated as a Business Occupancy in Brunswick County;
- b. The SARO Cancer Center does not administer anesthesia;
- c. The SARO Cancer Center does not provide emergency or urgent care;

- d. No more than three (3) patients will be simultaneously rendered incapable of self-preservation under emergency conditions without the assistance of others;
- e. The requested re-designation will not involve the offering or expansion of any new facility, service or equipment;
- f. No assets will physically move as a result of the re-designation;
- f. The requested re-designation will not change the inventory of linear accelerators and simulators in Brunswick County or in New Hanover County or the State.

The Cancer Center Space and the linear accelerator will remain in the precise same location in the same building at 545 Ocean Highway West, Supply, North Carolina. NHRMC will enter into a Resources and Services Agreement to operate the Cancer Center Space, including the linear accelerator.

ANALYSIS

The Redesignation entails the Parties shifting the designation of the Cancer Center Space from a provider-based licensed location of SARO to a provider-based, unlicensed location of NHRMC. No assets are physically moving as a result of the Re-designation.

A. Licensure Discussion

Pursuant to the proposed Agreement, the Cancer Center Space, and the linear accelerator therein, will be provider-based to NHRMC, and is permitted to be operated as an unlicensed outpatient location under the North Carolina Hospital Licensure Act's Business Occupancy Exception, contained in N.C. Gen. Stat. § 131E-76(3). That statute defines "hospital" as follows for licensure purposes:

“Hospital’ means any facility which has an organized medical staff and which is designed, used, and operated to provide health care, diagnostic and therapeutic services, and continuous nursing care primarily to inpatients where such care and services are rendered under the supervision and

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

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

Because outpatient Business Occupancy locations are not part of a licensed hospital under the Business Occupancy Exception, they are not restricted by the “County Line Licensure Rule” at 10A N.C.A.C. 13B.3101(f), and thus can be located in a county other than the county in which the hospital is located. Therefore, the SARO Cancer Center Space (in Brunswick County) can operate as a non-licensed, provider-based outpatient department of NHRMC (main campus located in New Hanover County) consistently with the Hospital Licensure Act.

The North Carolina Hospital Licensure Act’s “hospital” definition in N.C. Gen. Stat. § 131E-76(3) incorporates by reference the definitions in the 2000 Life Safety Code of the National Fire Protection Association (the “Life Safety Code”). That Life Safety Code designates whether hospital space is classified as:

1. Health Care Occupancy;
2. Ambulatory Care Occupancy; or
3. Business Occupancy (so as to meet the Business Occupancy Exception).

The Life Safety Code at NFPA 101 Section 3.3.134.1 defines what functionally constitutes occupancy for Ambulatory Health Care. The Life Safety Code classifies “Ambulatory Health

Care” as a “building or portion thereof used to provide services or treatment simultaneously to four or more patients that (1) provides, on an outpatient basis, treatment for patients that renders the patients incapable of taking action for self-preservation under emergency conditions without the assistance of others; or (2) provides, on an outpatient basis, anesthesia that renders the patients incapable of taking action for self-preservation under emergency conditions without the assistance of others.” See NFPA 101 Section 3.3.134.1A.

Because Business Occupancy classification is a functional step below Ambulatory Health Care (i.e., fewer requirements), the Department’s Construction Section looks at what falls below the Ambulatory Health Care standard to determine what is classified as Business Occupancy under the Life Safety Code. Thus, a Business Occupancy classification is appropriate when a building or portion thereof is used to provide outpatient services where treatment renders three (3) or fewer patients simultaneously incapable of self-preservation under emergency conditions without the assistance of others. The SARO Cancer Center Space is already designated as Business Occupancy. NHRMC and SARO represent that no more than three (3) patients will be simultaneously rendered incapable of self-preservation under emergency conditions without the assistance of others. In addition, SARO does not administer anesthesia to its patients.

Given the foregoing features, the Department confirms that the Redesignation (without relocation) of SARO’s Cancer Center Space to unlicensed, provider-based space of its co-owner hospital, NHRMC is permitted by the Business Occupancy Exception in N.C. Gen. Stat. § 131E-76(3) of the Hospital Licensure Act.

B. CON Discussion

The Redesignation does not trigger any of the definitions of a “new institutional health service,” which would implicate CON review. N.C. Gen. Stat. § 131E-178(a) provides that no

person shall offer or develop a “new institutional health service” without first obtaining a CON. The term “new institutional health service” is defined in numerous ways in N.C. Gen. Stat. § 131E-176(16).

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

. . . [T]he obligation by any person of a capital expenditure exceeding two million dollars (\$2,000,000) to develop or expand a health service or a health service facility, or which relates to the provision of a health service

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

The parties represent that there is no capital cost associated with the proposed Redesignation. The inventory of linear accelerators and simulators will not change as a result of the proposal. Neither will ownership of the equipment change as a result of the proposal.

Because no beds are involved, the Redesignation does not constitute a “change in bed capacity” under N.C. Gen. Stat. § 131E-176(16)(c). Because no operating rooms are involved, the Redesignation does not implicate N.C. Gen. Stat. § 131E-176(16)(u). Nor does the Redesignation constitute a “new institutional health service” under any other CON trigger in N.C. Gen. Stat. § 131E-176(16).

NHRMC owned fifty percent of SARO at the time SARO applied for and received the CON to develop the SARO Cancer Center and continues to own fifty percent of SARO. NHRMC will enter into a Resources and Services Agreement to operate the Cancer Center Space, including the linear accelerator. Because of the parties’ relationship, the Redesignation does not trigger any of the “acquisition-related” new institutional health service definitions in N.C. Gen. Stat. § 131E-176(16).

The Redesignation does not involve the offering or expansion of any new facility, service or equipment, and will not alter the inventory of linear accelerators in Brunswick County, New Hanover County or the State.

It is a well-established principle of statutory construction that the intent of the Legislature controls the interpretation of the statute. *See State v. Fulcher*, 294 N.C. 503, 520, 243 S.E.2d 338, 350 (1978). Prohibiting this simple intra-organizational Redesignation of existing services would not advance the goal of avoiding costly duplication because the Radiation Therapy Equipment and the Cancer Center Space already exist and are used to provide the same services they will provide after the Redesignation. Construing the statute otherwise would lead to absurd results that the General Assembly could not have intended. *See King v. Baldwin*, 276 N.C. 316, 325, 172 S.E.2d 12, 18 (1970) (“It is presumed that the legislature acted in accordance with reason and common sense and that it did not intend an unjust or absurd result.”)

This proposal is similar to a UNC Health Care proposal that the Agency has found to be non-reviewable. On March 24, 2016, the Agency determined that no CON review was necessary for UNC Health Care to Redesignate (without relocation) Caldwell Memorial Hospital, Incorporated’s (“CMHI”) Cancer Center Space (including one linear accelerator) on Caldwell Memorial Hospital’s license and located on that hospital’s campus in Caldwell County to unlicensed, provider-based outpatient department of its sister hospital, UNC Hospitals, which is located in Orange County. UNC Hospitals and Caldwell Memorial Hospital are both owned by The University of North Carolina Health Care System.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that that the Redesignation (without relocation) of SARO's Cancer Center Space, and Radiation Therapy Equipment located therein, to unlicensed, provider-based space of NRHMC: (1) is permitted by the Hospital Licensure Act; and (2) does not require a Certificate of Need.

This the _____ day of December, 2016.

Mark Payne, Director
Division of Health Service Regulation
N.C. Department of Health and Human Services

CERTIFICATE OF SERVICE

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

Denise Gunter
NELSON MULLINS RILEY & SCARBOROUGH LLP
380 Knollwood Street
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Winston-Salem, NC 27103

This the _____ day of December, 2016.

Cheryl Ouimet
Chief Operating Officer