

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

IN RE: REQUEST FOR DECLARATORY)
RULING BY THE UNIVERSITY OF NORTH)
CAROLINA HEALTH CARE SYSTEM, THE)
UNIVERSITY OF NORTH CAROLINA)
AT CHAPEL HILL D/B/A UNC HOSPITALS)
AND HIGH POINT REGIONAL HEALTH)

**DECLARATORY
RULING**

I, Mark Payne, Assistant Secretary, Audit and 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.

The University of North Carolina Health Care System (“UNC Health Care”), the University of North Carolina at Chapel Hill d/b/a UNC Hospitals (“UNC Hospitals”), and High Point Regional Health (“HPRH”) (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 HPRH’s Cancer Center Space, and Radiation Therapy Equipment located therein, to unlicensed, provider-based space of its sister hospital, UNC Hospitals: (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 entity 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. Gary S. Qualls, of K&L Gates 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

By statute (N.C. Gen. Stat. § 116-37), UNC Hospitals is an operating component entity of UNC Health Care. HPRH operates an acute care hospital (“High Point Regional”) in High Point, Guilford County. Effective May 2, 2013, UNC Health Care became the sole corporate member of HPRH. Thus, UNC Health Care owns, as the parent, both HPRH and UNC Hospitals.

While UNC Health Care is the parent of both, HPRH and UNC Hospitals are each distinct entities. Thus, while UNC Health Care owns HPRH, it owns HPRH indirectly, via being the sole owner of the subsidiary that owns HPRH, and UNC Health Care owns UNC Hospitals, but indirectly, via being the sole owner of the subsidiary that operates UNC Hospitals.

The Parties now wish to redesignate 27,112 square feet of radiation therapy space and outpatient medical oncology space currently operated at High Point Regional (the “Cancer Center Space”) to unlicensed, provider-based space of its sister hospital, UNC Hospitals (the “Redesignation”). UNC Health Care proposes to have its subsidiary, UNC Hospitals, lease the cancer center space from its other subsidiary, HPRH. In doing so, HPRH will no longer have the Cancer Center Space on its license. While UNC Health Care owns both UNC Hospitals and HPRH, it is not a part of the transaction itself. The transaction is between UNC Hospitals and HPRH, two distinct entities that have common ownership.

The Cancer Center Space is situated in a single building, the Hayworth Cancer Center Building, at 302 Westwood Avenue, High Point, NC, 27262. The Cancer Center Space includes the following services in the following locations within the Hayworth Cancer Center Building:

1. The First Floor Space delineated within the red lines in the supplemental line drawing submitted contains 11,961 square feet of space. That is the “Radiation Therapy Space.” The First Floor Space includes:
 - a. two (2) linear accelerators;
 - b. one (1) PET Scanner; and
 - c. one (1) CT simulator.(the “Radiation Therapy Equipment”).
2. The Second Floor Space is delineated within the green, red, and blue lines in the line drawing attached as Exhibit 4 to the Request. The Second Floor Space includes:
 - a. 4800 square feet of hematology / oncology clinic space;
 - b. 3348 square feet of infusion center space;
 - c. 1174 square feet of pharmacy space;
 - d. 570 square feet of clinical research space; and
 - e. 4026 square feet of oncology support and administration space.
3. The Third Floor Space delineated within the green lines in the line drawing attached as Exhibit 5 to the Request contains 1233 square feet of oncology care team office suite space.

The Cancer Center Space and the Radiation Therapy Equipment will remain in the precise same location in the same Hayworth Cancer Center Building at 302 Westwood Avenue, High Point, NC, 27262. UNC Hospitals will lease the Cancer Center Space, including the Radiation Therapy Equipment, from HPRH through operating leases.

ANALYSIS

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

A. Licensure Discussion

Pursuant to the proposed lease, the Cancer Center Space, and the Radiation Therapy Equipment therein, will be provider-based to UNC Hospitals, 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 Cancer Center Space (in Guilford County) can operate as a

non-licensed, provider-based outpatient department of UNC Hospitals (otherwise predominantly located in Orange 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. Business Occupancy (so as to meet the Business Occupancy Exception);
2. Ambulatory Care Occupancy; or
3. Health Care Occupancy.

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. In the proposed UNC Hospitals Cancer Center Space, no more than three (3) patients will be simultaneously rendered incapable of self-preservation under emergency conditions without the assistance of others. Moreover, UNC Hospitals' Cancer Center Space will be space dedicated to this use, within the Hayworth Cancer Center Building.

The Cancer Center Space on the First and Second Floors is already designated as Business Occupancy. The Cancer Center Space on the Third Floor (the office space) is currently designated as Healthcare Occupancy, but will be redesignated as Business Occupancy. No more than three (3) patients will be simultaneously rendered incapable of self-preservation under emergency conditions without the assistance of others in all areas designated as Business Occupancy.

Given the foregoing features, the Department confirms that the Redesignation (without relocation) of HPRH's Cancer Center Space to unlicensed, provider-based space of its sister hospital, UNC Hospitals 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).

However, the Redesignation does not constitute a “new institutional health service” under N.C. Gen. Stat. § 131E-176(16)(b), because the capital expenditures being incurred as part of this Redesignation are far less than \$2,000,000. The Parties’ submissions show the \$1,564,031 in non-exempt capital costs that UNC Hospitals projects to spend for this Redesignation. Moreover, UNC has incurred exempt expenditures, some of which may continue to be incurred during the timeframe of the Redesignation, related to information systems. Those costs do not count toward this Redesignation because: (a) they are not incurred as a result of this Redesignation; and (b) they are exempt in any event.

The lease for the Cancer Center Space and the CON-regulated Radiation Therapy Equipment will be operating leases from HPRH to its sister entity, UNC Hospitals. Additionally, this is an intra-organizational Redesignation within UNC Health Care’s two controlled affiliates, HPRH and UNC Hospitals.

Nor does the Redesignation of the Cancer Center Space trigger any of the “acquisition-related” new institutional health service definitions in N.C. Gen. Stat. § 131E-176(16). Ordinarily, if a health care entity wanted to acquire a cancer center from another entity, via lease, it would require a CON. N.C. Gen. Stat. § 131E-178(b) states:

...No person shall make an acquisition by donation, lease, transfer, or comparable arrangement without first obtaining a certificate of need from the Department, if the acquisition would have been a new institutional health service if it had been made by purchase...

..

See N.C. Gen. Stat. § 131E-178(b).

Here, the Radiation Therapy Equipment is not being acquired, because no legal entity outside of the UNC Health Care controlled affiliates is acquiring anything. Rather, this

Redesignation is an intra-organizational redesignation within UNC Health Care controlled affiliates. 10A N.C.A.C. 14C.0502 states:

...(b) Ownership of a certificate of need is transferred when any person acquires a certificate from the holder by purchase, donation, lease, trade, or any comparable arrangement, except that ownership of a certificate of need is not transferred when:

- (1) the holder of the certificate is a corporation and the identity of the holder changes because of a corporate reorganization; or
- (2) the holder of the certificate is a partnership and the identity of the holder changes because the same partners reorganize as a new partnership...

..

See 10A N.C.A.C. 14C.0502.

Because the current holder of the CON for the Cancer Center Space and the Radiation Therapy Equipment is a corporation, HPRH, and because UNC Health Care now owns HPRH, transferring ownership of the CON from HPRH to UNC Hospitals qualifies as a corporate reorganization.

The Redesignation does not constitute the establishment of a new health service facility under N.C. Gen. Stat. § 131E-176(16)(a) because the existing Cancer Center Space is transitioning from outpatient space at one existing hospital to outpatient space at another existing, sister hospital. 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).

This Redesignation does not involve the offering or expansion of any new facility, service or equipment, and the inventory of linear accelerators, PET Scanners, and simulators in Guilford

County, Health Service Area (“HSA”) II, and the State overall will not change. No new radiation therapy equipment or services will be placed in operation in Guilford County, HSA II, or the State as a result of this Project.

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 another UNC Health Care proposal that the Agency has found to be non-reviewable. On March 12, 2015, 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, and Radiation and Medical Oncology Equipment located therein, to unlicensed space at its sister hospital, UNC Hospitals.

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 HPRH’s Cancer Center Space, and Radiation Therapy Equipment located therein, to unlicensed, provider-based space of its sister hospital, UNC Hospitals: (1) is permitted by the Hospital Licensure Act; and (2) does not require a Certificate of Need.

This the _____ day of March, 2016.

Mark Payne, Assistant Secretary
Audit and 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:

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

This the _____ day of March, 2016.

Cheryl Ouimet
Chief Operating Officer