

**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) DECLARATORY RULING
AT CHAPEL HILL D/B/A UNC HOSPITALS,)
AND CALDWELL MEMORIAL HOSPITAL,)
INCORPORATED)
FID#: 933051)**

I, Drexdal Pratt, Director of the 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 General Statute §150B-4 and 10A NCAC 14A.0103 under the authority granted me by the Secretary of the Department of Health and Human Services.

The 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 Caldwell Memorial Hospital, Incorporated (“CMHI”) (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 CMHI’s Cancer Center Space, and Radiation and Medical Oncology Equipment located therein, to unlicensed space at 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.G.S. § 150B-4, the Department expressly reserves the right to make a prospective change in the interpretation of the statutes and regulations at issue in this Declaratory Ruling. Gary S. Qualls of K&L Gates LLP has requested this ruling on behalf of 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. CMHI operates an acute care hospital -- “Caldwell Memorial” -- in Lenoir, Caldwell County. Effective April 29, 2013, UNC Health Care became the sole corporate member of CMHI. Thus, UNC Health Care owns, as the parent, both Caldwell Memorial and UNC Hospitals.

The Parties now wish to redesignate radiation and medical oncology space currently operated as CMHI’s McCreary Cancer Center (the “Cancer Center Space”) to unlicensed space of its sister hospital, UNC Hospitals (the “Redesignation”). The Cancer Center Space is situated at 212 Mulberry Street, SW, Lenoir, Caldwell County, and includes the following:

1. One (1) linear accelerator and one (1) CT scanner capable of simulation (the “Radiation Oncology Equipment”);
2. 10 private chemotherapy bays (the “Medical Oncology Equipment”);
3. Lab services; and
4. Provider-based physician offices.

The Cancer Center Space, and the Radiation and Medical Oncology Equipment therein, will remain in the precise same location, in the same building at 212 Mulberry Street, SW.

The Cancer Center Space comprises 13,446 square feet. UNC Hospitals will lease the Cancer Center Space, the Radiation Oncology Equipment, and the Medical Oncology Equipment from CMHI through operating leases.

ANALYSIS

The Redesignation entails the Parties shifting the designation of the Cancer Center Space from a provider-based licensed location of CMHI to an 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, the Radiation Oncology Equipment, and the Medical Oncology Equipment will be permitted to be operated by UNC Hospitals 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 Caldwell County) can operate as a non-licensed outpatient department of UNC Hospitals (otherwise 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), we understand that 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 located in a building dedicated to such space, the McCreary Cancer Center Building at 212 Mulberry Street, SW. The Cancer Center Space will not be contiguous to any space operated as part of Caldwell Memorial's licensed hospital, which is located at 321 Mulberry Street, SW. Per the Certificate of Occupancy for the Cancer Center Space, that space is already classified as Business Occupancy as of July 31, 2012.

Given the foregoing features, the Department confirms that the Redesignation (without relocation) of CMHI's Cancer Center Space to unlicensed 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 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 no capital expenditures (other than nominal signage costs)¹ are being incurred as part of this Redesignation. Those expenditures were incurred years ago as the Cancer Center Space was developed. 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, the Radiation Oncology Equipment, and the Medical Oncology Equipment will be operating leases from CMHI to its sister entity, UNC Hospitals. Additionally, this is purely an intra-organizational Redesignation within UNC Health Care’s two controlled affiliates, CMHI 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). The Cancer Center Space, the Radiation Oncology Equipment, and the Medical Oncology Equipment are not being acquired, because no legal entity outside of the UNC Health Care controlled affiliates is

¹ UNC Hospitals projects that approximately \$3,000 may be expended to change the signage to UNC Hospitals signage.

acquiring anything. Rather, this Redesignation is purely an intra-organizational Redesignation within UNC Health Care controlled affiliates. See 10A NCAC 14C.0502.

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 simply 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 and CT scanners in Caldwell County and the State overall will not change. No new radiation oncology equipment or services will be placed in operation in Caldwell County 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 Oncology 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. *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 other proposals that the Agency has found to be non-reviewable. For example, the Agency recently determined that no CON review was necessary for a transaction involving Heart-Lung Bypass Machines (“Bypass Machines”) in Wake County (the “Wake Bypass Transaction”). In Stage #1 of the Wake Bypass Transaction, eight Bypass Machines were redesignated from CSA Medical Services, LLC (“CSA”) to two separate subsidiaries -- CSAMS Lake Boone Trail, LLC (“CSA Lake Boone”) and CSAMS New Bern Avenue, LLC (“CSA New Bern”). Thus, in Stage #1, the eight Bypass Machines (reviewable *per se* if “acquired” per § 131E-176(16)(f1)(5)) were shifted from one related company to another without a CON. In Stage #2 of the Wake Bypass Transaction, CSA Lake Boone and CSA New Bern became controlled affiliates of Rex Hospital, Inc, and WakeMed, respectively. Even though the Bypass Machines technically changed ownership (from one related company to another), no CON was required.

As the requesting parties emphasized, the Wake Bypass Transaction resulted in:

1. No increase in the Bypass Machine inventory in Wake County;
2. No physical relocation of Bypass Machines in Wake County; and
3. No creation of any new health service facilities anywhere.

This UNC/Caldwell Redesignation is also similar to another proposal that the Agency has found to be non-reviewable, the Ruling in *In Re: Request for Declaratory Ruling by The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Healthcare*, November 24, 2011

This UNC/Caldwell Redesignation is even further removed from reviewability than the Wake Bypass Transaction or the *Carolinas Healthcare* Ruling because the UNC/Caldwell Redesignation retains ultimate operational control of the equipment under a single parent, whereas the parent entity changed in Stage 2 of the Wake Bypass Transaction and in the *Carolinas Healthcare* Ruling Transaction.

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 CMHI's Cancer Center Space, and Radiation and Medical Oncology Equipment located therein, to unlicensed space of its sister hospital, UNC Hospitals: (1) is permitted by the Hospital Licensure Act; and (2) does not require a Certificate of Need.

Submitted this ____ day of _____, 2015.

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

CERTIFICATE OF SERVICE

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

CERTIFIED MAIL

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

This the _____ day of March, 2015.

Cheryl Ouimet
Chief Operating Officer