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 THE UNIVERSITY OF NORTH
CAROLINA HEALTH CARE SYSTEM, THE
UNIVERSITY OF NORTH CAROLINA AT
CHAPEL HILL d/b/a UNC HOSPITALS, AND
UNC ROCKINGHAM HEALTH CARE, INC.

DECLARATORY RULING

I, Mark Payne, as 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 Statutes § 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.

On February 15, 2018, 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 UNC Rockingham Health Care, Inc. ("UNC Rockingham") (collectively, the "Parties"), requested a declaratory ruling as to the applicability of Chapter 131E, Article 5 (Hospital Licensure Act) and Article 9 (Certificate of Need Law) 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 re-designation (without relocation) of UNC Rockingham's Cancer Center Space, and the 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 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 North Carolina General

Statutes § 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 THE FACTS

Pursuant to N.C. Gen. Stat. § 116-37, UNC Hospitals, located in Chapel Hill, Orange County, North Carolina, is an operating component entity of UNC Health Care. UNC Rockingham operates an acute care hospital ("UNC Rockingham Health Care") in Eden, Rockingham County, North Carolina. UNC Health Care is the sole corporate member of UNC Rockingham. Therefore, UNC Health Care, as the parent entity, owns both UNC Hospitals and UNC Rockingham.

While UNC Health Care is the parent of both, UNC Hospitals and UNC Rockingham are each distinct entities. Thus, while UNC Health Care owns UNC Hospitals, it owns it indirectly via being the sole owner of the subsidiary that owns UNC Hospitals. Similarly, while UNC Health Care owns UNC Rockingham, it owns it indirectly via being the sole owner of the subsidiary that owns UNC Rockingham. Effective January 1, 2018, UNC Health Care, through UNC Rockingham, acquired the assets of the former Morehead Memorial Hospital.

The Parties now wish to renovate and re-designate 11,267 square feet of radiation therapy space and outpatient medical oncology space currently operated at UNC Rockingham (the "Cancer Center Space") to unlicensed, provider-based space of its sister hospital, UNC Hospitals (the "Re-designation"). The Cancer Center Space is situated in a single building, the Rockingham Cancer Center Building, located at 516 South Van Buren Road, Eden, Rockingham County, North Carolina. The Cancer Center Space includes one (1) linear accelerator (the "Radiation Therapy

Equipment"); two (2) private chemotherapy bays and six (6) chemotherapy chairs (the "Medical Oncology Equipment"); pharmacy and lab services; and provider-based physician offices.

Pursuant to the Re-designation, the Cancer Center Space, and the Radiation Therapy Equipment therein, will remain in the precise same location in the Rockingham Cancer Center Building, located at 516 South Van Buren Road, Eden, Rockingham County, North Carolina. UNC Rockingham will continue to own the Cancer Center Space, including the Radiation Therapy and Medical Oncology Equipment, and UNC Hospitals will lease the Cancer Center Space, including the Radiation Therapy Equipment, from UNC Rockingham through operating leases.

ANALYSIS

The Re-designation entails the Parties shifting the designation of the Cancer Center Space from a provider-based licensed location of UNC Rockingham to a provider-based, unlicensed location of UNC Hospitals. No assets will be physically moved as a result of the Re-designation.

A. <u>Licensure Discussion</u>

Pursuant to the proposed lease, the Cancer Center Space, and the Radiation Therapy and Medical Oncology 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). N.C. Gen. Stat. § 131E-76(3) defines "hospital" as follows:

> "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. <u>The term does not include...any</u> <u>outpatient department[,] including a portion of a hospital operated as</u> <u>an outpatient department, on or off of the hospital's main campus, that</u>

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"

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 Rockingham 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." <u>See NFPA 101 Section 3.3.134.1A</u>.

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, the UNC Hospitals Cancer Center Space will be dedicated to this use.

Given the foregoing features, the Department confirms that the Re-designation (without relocation) of UNC Rockingham'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. <u>CON Discussion</u>

Pursuant to N.C. Gen. Stat. § 131E-178(a), 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). The Re-designation does

not trigger any of the definitions of a "new institutional health service," which would implicate CON review.

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

"...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, the Re-designation 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 Re-designation are less than \$2,000,000. UNC Hospitals projects expenditures of \$1,918,840 in non-exempt capital costs for the Re-designation. In addition, the operating leases for the Cancer Center Space and the CON-regulated Radiation Therapy Equipment is purely an intra-organizational re-designation within UNC Health Care's two controlled affiliates, UNC Hospitals and UNC Rockingham.

In addition, the Re-designation of the Cancer Center Space does not trigger any of the "acquisition-related" new institutional health service definitions in N.C. Gen. Stat. § 131E-176(16). Pursuant to N.C. Gen. Stat. § 131E-178(b):

"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...."

N.C. Gen. Stat. § 131E-178(b). Here, the Cancer Center Space and the CON-regulated Radiation Therapy Equipment are not being acquired because no legal entity outside of the UNC Health Care controlled affiliates is acquiring anything. Rather, the Re-designation is an intra-organizational re-designation within UNC Health Care controlled affiliates. Further, pursuant to 10A N.C.A.C. 14C. 0502(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."

10A N.C.A.C. 14C .0502(b). Because the existing Cancer Center Space is simply transitioning from being designated as outpatient space at one existing hospital to outpatient space at its existing, sister hospital, both of which entities are owned by UNC Health Care, the Re-designation does not constitute the transfer of ownership of the CON.

Moreover, because no beds are involved, the Re-designation does not constitute a "change in bed capacity" under N.C. Gen. Stat. § 131E-176(16)(c). Because no operating rooms are involved, the Re-designation does not implicate N.C. Gen. Stat. § 131E-176(16)(u). And, finally, the Re-designation does not constitute a "new institutional health service" under any other definition in N.C. Gen. Stat. § 131E-176(16).

This proposal is similar to other UNC Health Care proposals that the Department determined to be non-reviewable. On March 12, 2015, the Department determined that no CON review was necessary for the re-designation (without relocation) of Caldwell Memorial Hospital, Inc.'s ("CMHI") Cancer Center Space, and the Radiation and Medical Oncology Equipment located therein, to unlicensed space of its sister hospital, UNC Hospitals. Similarly, on March 24, 2016, the Department determined that no CON review was necessary for UNC Health Care to re-designate (without relocation) of High Point Regional Health's ("HPRH") Cancer Center Space,

and the Radiation and Medical Oncology Equipment located therein, to unlicensed space of its sister hospital, UNC Hospitals.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that the Re-designation (without relocation) of UNC Rockingham's Cancer Center Space, and the 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 April, 2018.

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

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that I have this day served the foregoing Declaratory Ruling upon the PETITIONER by certified mail, return receipt requested, by causing a copy of same to be placed in the United States Mail, first-class, postage pre-paid envelope addressed as follows:

CERTIFIED MAIL

Gary S. Qualls K&L GATES, LLP 430 Davis Drive, Suite 400 Morrisville, North Carolina 27560 ATTORNEY FOR THE UNC HEALTH CARE SYSTEM, THE UNIVERSITY OF NORTH CAROLINA d/b/a UNC HOSPITALS, and UNC ROCKINGHAM HEALTH CARE, INC.

This the _____ day of April, 2018.

Diana Barbry Executive Assistant to the Director Division of Health Service Regulation