



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

March 5, 2021

CERTIFIED MAIL

Terri Harris
Fox Rothschild LLP
230 N. Elm Street
Greensboro, NC 27401

RE: **The Moses Cone Memorial Hospital Operating Corporation
HeartCare-Kernersville**

Dear Ms. Harris:

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

Sincerely,

Mark Payne

MP:pdb

Enclosure

cc: Emery E. Milliken, Deputy Director
Kimberly Randolph, Assistant Attorney General, DOJ
Bethany Burgon, Assistant Attorney General, DOJ
Lisa Pittman, Acting Chief, Certificate of Need
Azzie Conley, Chief, Acute and Home Care Licensure
Jeff Harms, Chief, DHSR Construction Section

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

**IN RE: REQUEST FOR DECLARATORY)
RULING BY THE MOSES H. CONE MEMORIAL)
HOSPITAL OPERATING CORPORATION AND) DECLARATORY RULING
MOSES CONE AFFILIATED PHYSICIANS, INC.)**

I, Mark Payne, 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 N.C.G.S. § 150B-4 and 10A NCAC 14A .0103, under the authority granted me by the Secretary of the Department of Health and Human Services.

On December 18, 2020, The Moses H. Cone Memorial Hospital Operating Corporation (“Cone Health”) and Moses Cone Affiliated Physicians, Inc. (“MCAP”) (hereinafter 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 requested a determination that the redesignation (without relocation) of MCAP d/b/a Cone Health Medical Group HeartCare at Kernersville (“HeartCare Kernersville”) as unlicensed, provider-based space of Cone Health: 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. Terrill Johnson Harris of Fox Rothschild 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

Cone Health operates licensed acute care hospitals in Guilford and Rockingham Counties. In Guilford County, its main campus location is known as The Moses H. Cone Memorial Hospital located at 1200 North Elm Street, Greensboro, NC 27401, and is operated under License #H0159. MCAP currently operates a cardiology practice, HeartCare Kernersville, at 1635 NC-66, Suite 155, Kernersville, Forsyth County, NC 27284. HeartCare Kernersville currently occupies 1,603 square feet of space on the first floor of the two story medical office building at 1635 NC-66, Kernersville, NC (the “HeartCare Kernersville Space”). MCAP employs the physicians practicing at HeartCare Kernersville and owns the equipment in use at that location. Cone Health currently owns the building in which the practice is located. The HeartCare Kernersville Space has a separate and distinct waiting room for patients. Physicians see patients in the HeartCare Kernersville Space each Wednesday for four hours.

Cone Health now wishes to designate the HeartCare Kernersville Space as unlicensed, provider-based space of The Moses H. Cone Memorial Hospital/Cone Health. The HeartCare Kernersville Space will remain in the same location, in the same building, at 1635 NC-66, Kernersville, NC, and Cone Health will remain the owner of the building. Cone Health will become the employer for the physicians practicing at this location and the owner of the equipment used at this location. None of the equipment owned by MCAP is separately reviewable under the Certificate of Need Act. There are no capital expenditures associated with this redesignation.

ANALYSIS

The redesignation entails the Parties shifting the designation of the HeartCare Kernersville Space from a provider-based cardiology practice to an unlicensed, provider-based space of Cone

Health. There are no capital costs associated with the redesignation and no assets are physically moving as a result of the redesignation.

A. Licensure Discussion

Cone Health plans to redesignate the Business Occupancy, provider-based HeartCare Kernersville Space, and the equipment therein, to unlicensed, provider-based space of Cone Health, permitting the space 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).

The 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. **Provided, however, if the Business Occupancy outpatient location is to be operated within 30 feet of any hospital facility, or any portion thereof, which is classified as Health Care Occupancy or Ambulatory Health Care Occupancy under the Life Safety Code of the National Fire Protection Association, the hospital shall provide plans and specifications to the Department for review and approval** as required for hospital construction or renovations in a manner described by the Department.

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 NCAC 13B .3101(f), which states that a hospital license can only include facilities within

a single county. Thus, the HeartCare Kernersville Space can be located in a county other than the county in which the hospital is located pursuant to the Business Occupancy Exception. Additionally, the HeartCare Kernersville Space has at least 30 feet of separation from any hospital facility classified as Health Care Occupancy or Ambulatory Health Care Occupancy, and thus, would not have to be licensed as part of any hospital. Therefore, the HeartCare Kernersville Space (in Forsyth County) currently meets the Business Occupancy Exception and can operate as a non-licensed, provider-based outpatient department of Cone Health (located in Guilford County) consistent 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 3.3.134.1.

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 building located at 1635 NC-66, Kernersville, NC, is classified as Business Occupancy and is a fully sprinklered, two story building. Throughout the building and in the HeartCare Kernersville Space located on the first floor, no more than three (3) patients will be simultaneously rendered incapable of self-preservation under emergency conditions without the assistance of others.

The Parties reported there was no sedation, anesthesia, or procedures performed in the Heartcare Kernersville Space that would render more than three (3) patients simultaneously incapable of self-preservation under emergency conditions without the assistance of others. Thus, a Business Occupancy classification is currently appropriate because a portion of the building 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.

However, Cone Health Imaging Service, which contains an MRI, CT, and Mobile MRI, is also located in a separate suite on the first floor of the building at 1635 NC-66, Kernersville, NC. This imaging equipment renders three patients incapable of self-preservation under emergency conditions without the assistance of others. Therefore, any additional diagnostic or imaging

equipment, procedures, or any other use of the building that renders any additional patient incapable of self-preservation under emergency conditions without the assistance of others, could not be added to the building located at 1635 NC-66, Kernersville, NC, without triggering the Ambulatory Health Care Occupancy per the requirements of NFPA 101, rather than Business Occupancy per N.C. Gen. Stat 131E-76(3), since four (4) or more patients would be simultaneously incapable of self-preservation under emergency conditions without the assistance of others. See N.C. Gen. Stat. § 131E-76(3).

Given the foregoing features and the facts provided by the Parties, the Department confirms that the redesignation (without relocation) of the HeartCare Kernersville Space to unlicensed, provider-based space of Cone Health 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 of the HeartCare Kernersville Space 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 are N.C. Gen. Stat. § 131E-176(16)(a) and (b), which define a “new institutional health service” as:

- a. The construction, development, or other establishment of a new health service facility.
- b. ... [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)(a), (b).

The redesignation of the HeartCare Kernersville Space as unlicensed, provider-based space of Cone Health does not constitute a “new institutional health service” under N.C. Gen. Stat. § 131E-176(16)(a) or (b), because Cone Health is not constructing, developing or establishing a new health service facility by this redesignation, and the Parties’ submission indicates there are no capital expenditures being incurred as part of this redesignation. Additionally, as a physician’s office, the HeartCare Kernersville Space does not meet the definition of a health service facility according to N.C. Gen. Stat. § 131E-176(9b).

The proposal also does not trigger any of the “acquisition-related” new institutional health service definitions in N.C. Gen. Stat. § 131E-176(16). There are no beds involved, so the redesignation does not constitute a “change in bed capacity” under N.C. Gen. Stat. § 131E-176(16)(c). The redesignation does not constitute the acquisition of major medical equipment under N.C. Gen. Stat. § 131E-176(16)(p) since none of the medical equipment in the HeartCare Kernersville Space has an individual value greater than \$750,000 to constitute “major medical equipment” under N.C. Gen. Stat. § 131E-176(7a). Similarly, the medical diagnostic equipment at the HeartCare Kernersville Space, counting each item with a value over \$10,000, totaled less than \$500,000, and therefore would not be considered a diagnostic center according to N.C. Gen. Stat. § 131E-176(14o). 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) since the redesignation does not involve the offering or expansion of any new facility, service or equipment.

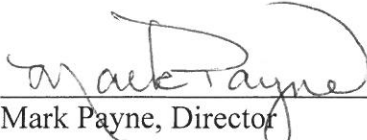
This proposal is similar to two other proposals, a UNC Health Care proposal and a New Hanover Regional Medical Center proposal, that the Agency found to be non-reviewable. On

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, provider-based space of its sister hospital, UNC Hospitals. On December 9, 2016, the Agency also determined that no CON review was necessary for New Hanover Regional Medical Center to redesignate (without relocation) Southern Atlantic Radiation Oncology's ("SARO") Cancer Center Space, and Radiation and Medical Oncology Equipment located therein, to an unlicensed, provider-based location of New Hanover Regional Medical Center. These projects involved space that housed CON-reviewable services and equipment, unlike HeartCare Kernersville.

CONCLUSION

For the foregoing reasons, assuming the statement of facts and representations in the request to be true, I conclude that redesignation (without relocation) of HeartCare Kernersville Space, and any equipment located therein, to unlicensed, provider-based space of Cone Health: (1) is permitted by the Hospital Licensure Act; and (2) does not require a Certificate of Need.

This the 5th day of March, 2021.



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 non-agency party by certified mail, return receipt requested, by depositing the copy in an official deposit of the United States Postal Service in first-class, postage pre-paid envelope addressed as follows:

CERTIFIED MAIL

Terrill Johnson Harris
Fox Rothschild LLP
230 N. Elm Street, Suite 1200
Greensboro, NC 27401

This the 5th day of March, 2021.



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