



NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

VIA EMAIL ONLY

November 16, 2021

Gary S. Qualls
Gary.Qualls@klgates.com

No Review

Record #: 3729
Date of Request: November 5, 2021
Business Name: The Charlotte-Mecklenburg Hospital Authority
Business #: 1770
Project Description: Redesignate Levine Cancer Institute-Union as an unlicensed provider-based location of Carolinas Medical Center
County: Union

Dear Mr. Qualls:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the project described above. Based on the CON law in effect on the date of this response to your request, the project as described is not governed by, and therefore, does not currently require a certificate of need. If the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

This determination is binding only for the facts represented in your correspondence. If changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by this office.

Please do not hesitate to contact this office if you have any questions.

Sincerely,

Handwritten signature of Julie M. Faenza

Julie M. Faenza
Project Analyst

Handwritten signature of Micheala Mitchell

Micheala Mitchell
Chief

cc: Acute and Home Care Licensure and Certification Section, DHSR

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION
HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704
https://info.ncdhhs.gov/dhsr/ • TEL: 919-855-3873

November 5, 2021

Gary S. Qualls
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gary.qualls@klgates.com

Via Hand Delivery

Micheala Mitchell, Chief
N.C. Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section
809 Ruggles Drive
Raleigh, NC 27603

Re: No Review Letter Regarding Redesignation of Oncology Provider-Based Outpatient Department of Atrium Health Union to a Provider-Based Outpatient Department of CMC

Dear Ms. Mitchell:

Our client, The Charlotte-Mecklenburg Hospital Authority (“CMHA”), is requesting a “no review” determination that the North Carolina Certificate of Need (“CON”) law does not require CON review of already developed and operational provider-based medical oncology space being redesignated in status, effective December 4, 2021, as follows:

1. The space being redesignated has historically been operated as an unlicensed provider-based location of Atrium Health Union (“AH Union”) on the AH Union Campus and has historically been called Levine Cancer Institute-Monroe.
2. The space described above (collectively the “Medical Oncology Space”) is being redesignated to be operated as an unlicensed provider-based location of Carolinas Medical Center (“CMC”) in Charlotte, yet physically remaining on the AH Union Campus. Signage for the Medical Oncology Space will say, and the location will be called, “Levine Cancer Institute-Union, a facility of Carolinas Medical Center.”

CMHA is a North Carolina hospital authority. CMHA owns and operates several hospitals. Among those hospitals, CMHA operates CMC, a hospital in Charlotte, Mecklenburg County and AH Union, a hospital in Monroe, Union County. Both CMC and AH Union are directly under the organizational umbrella of CMHA, as operating divisions of CMHA. Neither is a separate legal entity.

For many years, AH Union has been operating medical oncology services in the Medical Oncology Space in a building (the “Medical Oncology Building”) on the AH Union Campus at 1550 Faulk Street. See Floor Plan for Medical Oncology Space in dark blue coloring on attached Exhibits A and B.¹ That Oncology Space contains the following services: medical oncology; infusion; lab; and pharmacy. The Medical Oncology Space does not include radiation oncology services or equipment.

CMHA is shifting the designation of that Medical Oncology Space from a provider-based licensed location of AH Union to a provider-based, unlicensed location of CMC (the “Redesignation”). No assets are physically moving as a result of the Redesignation.

The Medical Oncology Space will be provider-based to CMC, and is permitted to be operated as an unlicensed outpatient location under the Business Occupancy Exception, in accordance with N.C. Gen. Stat. § 131E-76(3).² 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 Medical Oncology Space (in Union County) can operate as a non-licensed, provider-based outpatient department of CMC (in Mecklenburg County).

¹ For ease of reference and viewing, we have attached the floor plans for Floor 1 (Ex. A) and Floor 2 (Ex. B) as Word documents so that the Agency may enlarge them for viewing.

² 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).

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 four million dollars (\$4,000,000) 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 are being incurred as part of this Redesignation. Those expenditures were incurred many years ago as the Oncology Building (and the Medical Oncology Space therein) was being developed. Moreover, this is purely an intra-organizational Redesignation within CMHA. No legal entity is acquiring anything from any other legal entity.

Moreover, none of the equipment in the Medical Oncology Space is either “major medical equipment” under N.C. Gen. Stat. § 131E-176(14o) or *per se* reviewable pursuant to N.C. Gen. Stat. § 131E-176(16)(f1). However, even if it were, the Medical Oncology Space (and any equipment therein) is not being acquired because no legal entity is acquiring anything from any other legal entity in this Redesignation as this is purely an intra-organizational Redesignation within CMHA.

Finally, 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 space is simply transitioning from CMHA-owned outpatient space at one existing hospital to outpatient space at another existing 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).

Accordingly, the Redesignation does not require CMHA to obtain a CON pursuant to any provision of the CON statutes. Thus, based upon the foregoing information and the attached documents, CMHA hereby requests that the Agency provide a written response confirming that the Redesignation described herein does not require a CON.

Ms. Micheala Mitchell
November 5, 2021
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Please let us know if you need additional information. We thank you for your consideration of this submission.

Sincerely,



Gary S. Qualls

Enclosures

Exhibits

- A. Floor Plan for Level 1 of Medical Oncology Space in dark blue coloring per the color key
- B. Floor Plan for Level 2 of Medical Oncology Space in dark blue coloring per the color key



Atrium Health
 PROJECT & CONSTRUCTION MANAGEMENT
 8401 Arrowpoint Boulevard
 Charlotte, NC 28273

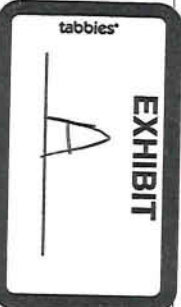
Cost Center Name

- Base Building Areas
- Charlotte Radiology
- Breast Cir
- Common Area
- ONCOLOGY - LCI
- PHYSICIAN OFFICE
- Vertical Penetrations

Company Name	Cost Center Name	Ca-Cp Unit #	Cost Center #	Area
LEVIN CANCER INSTITUTE	ONCOLOGY - LCI	280110411	32850	5,484 SF
UNION SURGICAL ASSOCIATES	PHYSICIAN OFFICE	315810411	33175	6,712 SF
CAC-Clum Medical Office Bldg	Base Building Areas	UI_100B	BASEBLDG	1,687 SF
3rd Party Tenants	Charlotte Radiology Breast Cir	3100PRTY	CHL TRADRC	3,451 SF
CAC-Clum Medical Office Bldg	Common Area	UI_100B	COMMON	904 SF
CAC-Clum Medical Office Bldg	Vertical Penetrations	UI_100B	VERTICAL	639 SF
				19,187 SF



1 ARCHIBUS PLAN - LEVEL 01
 1/16" = 1'-0"



2/15/2021 12:53:56 PM
 CAC-Clum MOB II
 Atrium Health Facility # 0163
 1550 Park Street
 Moses, NC 28110

SHEET NAME
 ARCHIBUS PLAN - LEVEL
 01

SHEET NUMBER
 ARCH-01



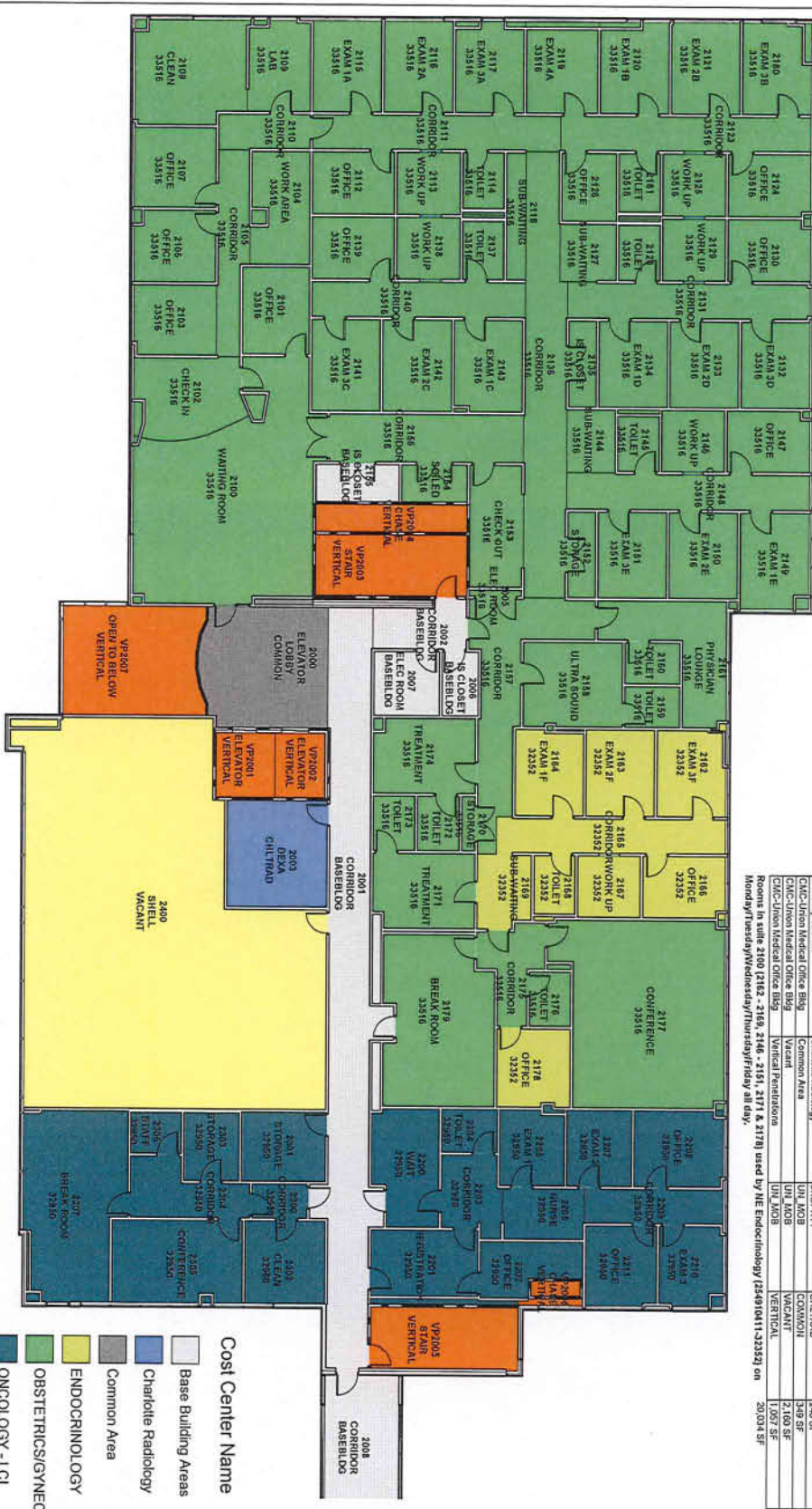
Atrium Health
PROJECT & CONSTRUCTION MANAGEMENT
9401 Arrowpoint Boulevard
Charlotte, NC 28273

Company Name	Cost Center Name	Comp. Unit #	Cost Center #	Area
LEWIS CANCER INSTITUTE	ONCOLOGY - LCI	280110411	32650	2,693 SF
NORTHEAST ENDOCRINOLOGY	ENDOCRINOLOGY	284910411	32352	1,077 SF
UNION TOBACCO	OBSTETRIC/GYNECOLOGY	282610411	33516	10,506 SF
CNC-Union Medical Office Bldg	Base Building Areas	UN_1008	BASEBLDG	1,951 SF
San Pary Tenants	Charlotte Radiology	3069PRTY	CHLTRAD	249 SF
CNC-Union Medical Office Bldg	Common Area	UN_1008	COMMON	349 SF
CNC-Union Medical Office Bldg	Vacant Penetrations	UN_1008	VACANT	2,103 SF
CNC-Union Medical Office Bldg	Vacant	UN_1008	VERTICAL	1,091 SF
				20,004 SF

Monday/Tuesday/Wednesday/Thursday/Friday all day.

Reserved under 2100, 2112, 2118, 2146, 2151, 2171, 2171 & 2172 used by NE Endocrinology (284910411-32352) on

Archibus Level 02



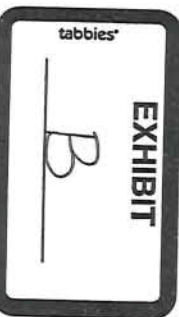
1 ARCHIBUS PLAN - LEVEL 02
1/16" = 1'-0"

- Cost Center Name**
- Base Building Areas
 - Charlotte Radiology
 - Common Area
 - ENDOCRINOLOGY
 - OBSTETRIC/GYNECOLOGY
 - ONCOLOGY - LCI
 - Vacant
 - Vertical Penetrations

2/15/2021 12:54:04 PM

CNC-Union MOB II
Atrium Health Facility # 0163
1250 Park Street
Morris, NC 28110

SHEET NAME
ARCHIBUS PLAN - LEVEL
02
SHEET NUMBER
ARCH-02



From: [Faenza, Julie M](#)
To: [Waller, Martha K](#)
Subject: FW: [External] No Review Request for LCI-Monroe
Date: Friday, November 5, 2021 2:49:35 PM
Attachments: [EXHIBIT B - CMC-Union MOB II 1550 Faulk ARCHIBUS PLAN LEVEL2.pdf](#)
[EXHIBIT A - CMC-Union MOB II 1550 Faulk ARCHIBUS PLAN LEVEL1.pdf](#)
[20211105 K&L GATES 001.pdf](#)

Julie M. Faenza, Esq.

Project Analyst, Certificate of Need

[Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section](#)
[NC Department of Health and Human Services](#)

Office: 919-855-3873 (*I am working remotely most of the time; email is the best way to reach me.*)

Julie.Faenza@dhhs.nc.gov

Pronouns: She/her/hers

Don't wait to vaccinate. Find a COVID-19 vaccine location near you at [MySpot.nc.gov](https://www.myspot.nc.gov).

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From: Qualls, Gary <Gary.Qualls@klgates.com>
Sent: Friday, November 5, 2021 2:43 PM
To: Mitchell, Micheala L <Micheala.Mitchell@dhhs.nc.gov>; Faenza, Julie M <Julie.Faenza@dhhs.nc.gov>
Subject: [External] No Review Request for LCI-Monroe

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to [Report Spam](#).

Micheala and Julie:

Please accept for filing a No Review Request for LCI-Monroe. As we indicate in the letter, we have attached Exhibits A and B as separate Word documents so that you can enlarge if needed.

Please acknowledge receipt for my records.

Thanks

Gary

Gary S. Qualls

Partner
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