



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor

KODY H. KINSLEY • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

November 27, 2024

Gary S. Qualls
Gary.qualls@klgates.com

No Review

Record #: 4658
Date of Request: November 13, 2024
Facility Name: Carolinas Medical Center
FID #: 943070
Business Name: The Charlotte-Mecklenburg Hospital Authority
Business #: 1770
Project Description: Redesignate freestanding Atrium Health Levine Cancer Center Institute-Gaston as an unlicensed provider-based location of Carolinas Medical Center and rename the facility Atrium Health Levine Cancer Institute, a facility of Carolinas Medical Center
County: Mecklenburg

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 representation in your request and 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. **As a reminder, it is unlawful to offer or develop a new institutional health service without first obtaining a certificate of need. The Department reserves the right to impose sanctions, including civil penalties and the revocation of a license, upon any entity that offers or develops a new institutional health service without first obtaining a certificate of need.**

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

Sincerely,

Gregory F. Yakaboski, Project Analyst

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

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

November 12, 2024

Gary S. Qualls
D 919.466.1182
F 919.516.2072
gary.qualls@klgates.com

Via Email 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 Freestanding Gaston County Oncology Practice to a Provider-Based Outpatient Department of Carolinas Medical Center

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, freestanding oncology space (the “Medical Oncology Space”) being redesignated in status to provider-based space at Carolinas Medical Center (“CMC”), effective December 16, 2024, as follows:

1. The Medical Oncology Space being redesignated has historically been operated as a freestanding cancer center in Gaston County and has historically been called Atrium Health Levine Cancer Institute-Gaston (“AHLCI-Gaston” or “the Center”). The Center and the Medical Oncology Space is already directly owned by CMHA.
2. 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 in Gastonia, Gaston County. Signage for the Medical Oncology Space will say, and the location will be called, “Atrium Health Levine Cancer Institute, 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. CMC and the Center are both operating divisions of CMHA.

Since 2018, AHLCI-Gaston has been operating medical oncology services in the Medical Oncology Space in a building (the “Medical Oncology Building”) at 2610 Aberdeen Blvd., Gastonia, Gaston County. See Floor Plan for Medical Oncology Space in blue coloring on attached Exhibit A. 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 freestanding unlicensed location 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).¹ 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 Gaston County) can operate as a non-licensed, provider-based outpatient department of CMC (in Mecklenburg County).

¹ 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).²

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 because 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 freestanding outpatient space to outpatient space operated as part an existing CMHA 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).

² The current capital cost threshold is specifically \$4,119,200 based on Medical Care Index adjustments pursuant to the CON Statute.

Ms. Micheala Mitchell
November 12, 2024
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Accordingly, the Redesignation does not require CMHA to obtain a CON pursuant to any provision of the CON statute. 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.

Please let us know if you need additional information. We thank you for your consideration of this submission.

Sincerely,



Gary S. Qualls

Ms. Micheala Mitchell
November 12, 2024
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Exhibits

- A. Floor Plans for Level 1, 2, and 3 of the Medical Oncology Space in blue coloring per the color key.



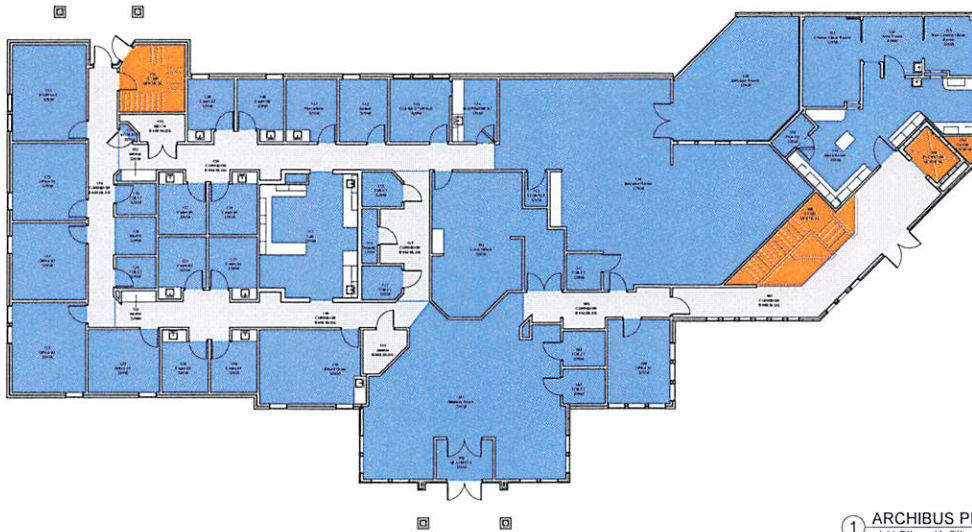
ARCHIBUS LEVEL 01				
Company Name	Cost Center Name	Co/Op Unit #	Cost Center #	Area
LEVINE CANCER INSTITUTE	ONCOLOGY - LCI	280110312	32950	7,338 SF
2010 Aberdeen Blvd	Base Building Areas	81557	BASEBLDG	1,687 SF
2010 Aberdeen Blvd	Vertical Penetrations	81557	VERTICAL	410 SF
				9,435 SF



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

Cost Center Name

- Base Building Areas
- ONCOLOGY - LCI
- Vertical Penetrations



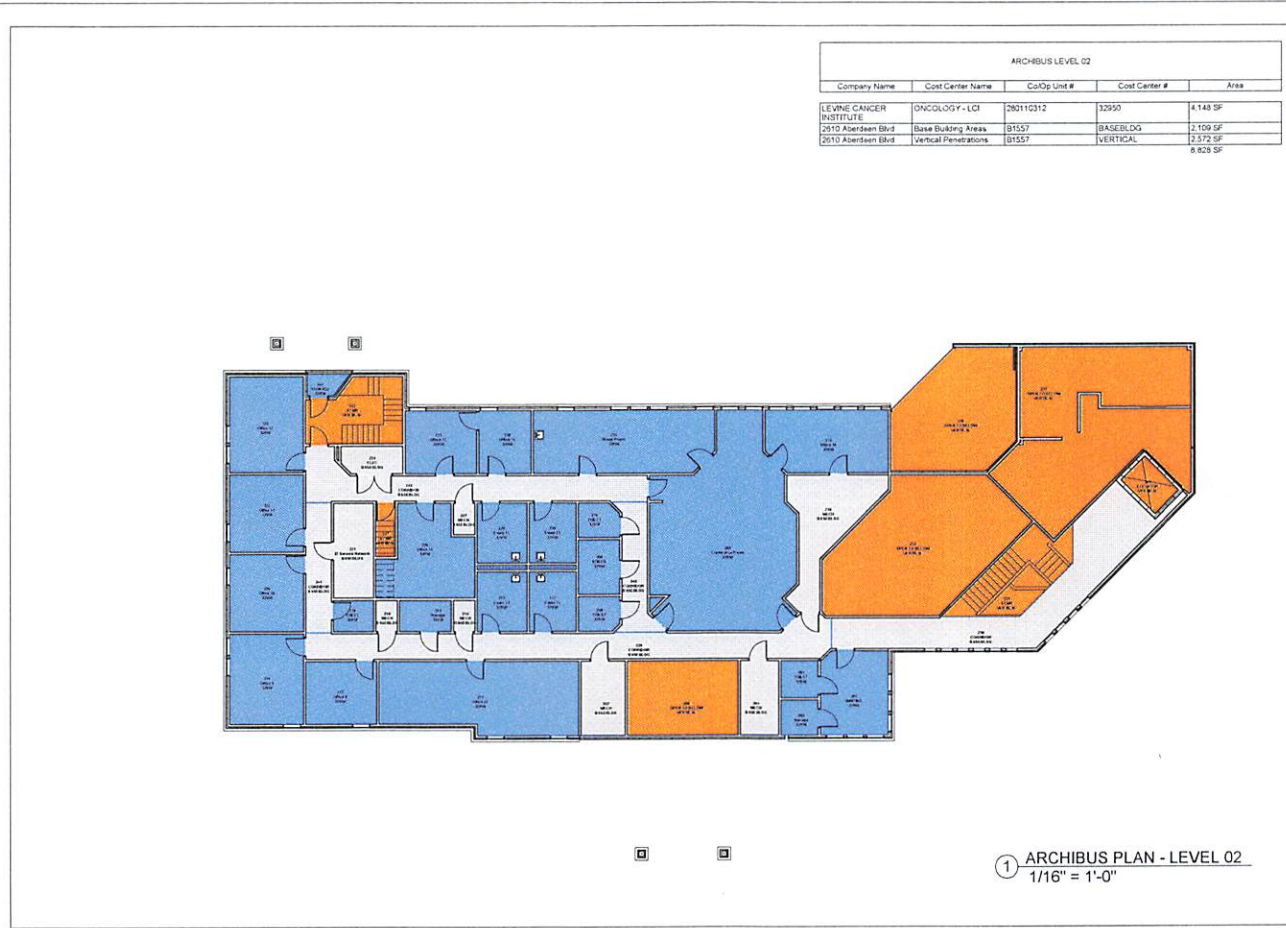
① ARCHIBUS PLAN - LEVEL 01
 1/16" = 1'-0"

3/1/2021 5:32:28 PM
 2010 ABERDEEN
 Atrium Health Facility # 1557
 2010 ABERDEEN BLVD

SHEET NAME
 ARCHIBUS PLAN - LEVEL
 01

SHEET NUMBER
 ARCH-01

3/1/2021 5:32:28 PM



Atrium Health

PROJECT & CONSTRUCTION MANAGEMENT
 4401 Arrowpoint Boulevard
 Charlotte, NC 28273

Cost Center Name

- Base Building Areas
- ONCOLOGY - LCI
- Vertical Penetrations

3/1/2021 5:32:35 PM

2610 ABERDEEN
 Atrium Health Facility # 1557
 2610 ABERDEEN BLVD

SHEET NAME
 ARCHIBUS PLAN - LEVEL
 02

SHEET NUMBER
ARCH-02

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

3/1/2021 5:32:35 PM

ARCHIBUS LEVEL 00				
Company Name	Cost Center Name	Co/Op Unit #	Cost Center #	Area
LEVINE CANCER INSTITUTE	ONCOLOGY - LCI	28015312	12850	993 SF
2610 Aberdeen Blvd	Base Building Areas	B1557	BASEBLDG	79 SF
2610 Aberdeen Blvd	Vertical Penetrations	B1557	VERTICAL	68 SF
				1,129 SF

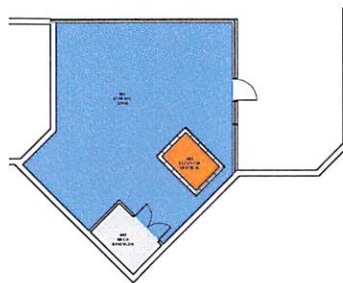


Atrium Health

PROJECT & CONSTRUCTION MANAGEMENT
 9401 Arrowpoint Boulevard
 Charlotte, NC 28273

Cost Center Name

- Base Building Areas
- ONCOLOGY - LCI
- Vertical Penetrations



① ARCHIBUS PLAN - LEVEL 00
 1/16" = 1'-0"

3/1/2021 5:32:15 PM

2610 ABERDEEN
 Atrium Health Facility # 1557
 2610 ABERDEEN BLVD

SHEET NAME
 ARCHIBUS PLAN - LEVEL
 00

SHEET NUMBER
 ARCH-00

3/1/2021 5:32:15 PM

From: [Pittman, Lisa](#)
To: [Stancil, Tiffany C](#)
Cc: [Mitchell, Micheala L](#)
Subject: FW: [External] FW: Atrium -- LCI Gaston Redesignation
Date: Tuesday, November 12, 2024 6:03:20 PM
Attachments: [11122024_K&L_GATES_002.pdf](#)

Tiffany,

Please log this no review request and assign it to Greg.

Note- Gary sent this to Micheala first, so she may have forwarded this to you as well.

Lisa Pittman
Assistant Chief
Division of Health Service Regulation, Healthcare Planning & CON Section
NC Department of Health and Human Services

Office: 919-855-3989 *I work from home and in the office. Email is the best way to contact me.*
Lisa.Pittman@dhhs.nc.gov

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From: Qualls, Gary <Gary.Qualls@klgates.com>
Sent: Tuesday, November 12, 2024 4:42 PM
To: Pittman, Lisa <lisa.pittman@dhhs.nc.gov>
Subject: [External] FW: Atrium -- LCI Gaston Redesignation

CAUTION: External email. Do not click links or open attachments unless verified. Report suspicious emails with the Report Message button located on your Outlook menu bar on the Home tab.

Lisa:

I sent this attached letter for filing earlier this afternoon and saw that Micheala is out until the 18th. Thus, I wanted to forward to you to make sure it is routed properly in the meantime.

Thanks

Gary

From: Qualls, Gary <Gary.Qualls@klgates.com>
Sent: Tuesday, November 12, 2024 3:33 PM
To: micheala.mitchell@dhhs.nc.gov
Subject: FW: Atrium -- LCI Gaston Redesignation

Micheala:

Attached for filing is a No Review Request by Atrium to redesignate existing space.

Thanks

Gary



Gary S. Qualls
Partner
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Morrisville, NC 27560
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