



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

JOSH STEIN • Governor

DEV DUTTA SANGVAI • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

November 18, 2025

Gary S. Qualls

Gary.qualls@klgates.com

No Review

Record #: 4992
Date of Request: October 22, 2025
Facility Name: Atrium Health Lake Norman
FID #: 190513
Business Name: The Charlotte-Mecklenburg Hospital Authority
Business #: 1770
Project Description: Expansion of the acute inpatient dialysis program
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.

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

Sincerely,



Gregory F. Yakaboski
Project Analyst



Micheala Mitchell
Chief

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

October 22, 2025

Gary S. Qualls
D 919.466.1182
F 919.516.2182
gary.qualls@klgates.com

Via Email

Micheala Mitchell, Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
N.C. Department of Health and Human Services
1915 Health Services Way
Raleigh, NC 27607

Re: No Review Request For Dialysis Services at Atrium Health University City's Lake Norman Campus

Dear Ms. Mitchell:

The Charlotte-Mecklenburg Hospital Authority ("CMHA") seeks confirmation that the following proposal to add three (3) inpatient dialysis equipment units (the "Dialysis Equipment") for use in four (4) inpatient rooms, as needed, at CMHA's Atrium Health Lake Norman Hospital Campus (the "Lake Norman Campus") does not require a Certificate of Need ("CON"). As you know, the Lake Norman Campus is licensed as part of Atrium Health University City ("University City"), also in Mecklenburg County. As you also know, University City already performs inpatient dialysis services, and has done so within the last 12 months.

I. No New Institutional Health Services Are Triggered by Offering Dialysis Services at University City's Lake Norman Campus.

Acquiring and implementing the Dialysis Equipment (the "Dialysis Equipment Addition") does not trigger any new institutional health service definitions that would require a CON.

A. No Non-Cost-Based New Institutional Health Services Are Triggered.

CMHA's Dialysis Equipment Addition is not a CON reviewable event because such an event is not expressly addressed in any of the new institutional health service "CON triggers" in N.C. Gen. Stat. § 131E-176(16). The provisions of N.C. Gen. Stat. § 131E-176(16)(d) require a CON in the following context: "The offering of dialysis services or home health services by or on behalf of a

health service facility if those services were not offered within the previous 12 months by or on behalf of the facility.”

Here, the “facility” is the licensed hospital. *See* N.C. Gen. Stat. § 131E-176(9b) (Health service facility defined to include “A hospital . . .”). Inpatient dialysis services have been performed at University City in the last 12 months. The Lake Norman Campus is part of University City, being on the same hospital license. Thus, since University City has performed dialysis services in the last 12 months, this provision does not require a CON in this instance simply because such services will also be offered on University City’s Lake Norman Campus.

The No Review Approval that this Agency issued to WakeMed on March 7, 2024 (attached as Exhibit 1) is directly analogous to Atrium’s situation here. There, the Agency recognized that the initiation of inpatient dialysis services at the WakeMed North Campus was not CON regulated because WakeMed already operated dialysis services at WakeMed’s main campus in Raleigh and the two campuses operated under the same license. The same is true of Atrium Health University City and its Lake Norman Campus.

B. No Cost-Based New Institutional Health Services Are Triggered.

The capital costs for this Dialysis Equipment Addition will be minimal. All three pieces of Dialysis Equipment together will total \$165,000 each. The four inpatient rooms are already plumbed to accommodate such equipment. All costs associated with operationalizing the Dialysis Equipment – including acquiring the equipment itself – are projected to be below \$500,000.

II. Conclusion.

Pursuant to the maxim of statutory construction *expressio unius est exclusio alterius*, those transactions not included in N.C. Gen. Stat. § 131E-176(16) -- such as this Dialysis Equipment Addition -- do not require a CON. *See e.g., In re Miller*, 357 N.C. 316, 325, 584 S.E.2d 772, 780 (2003) (stating that “[u]nder the doctrine of *expressio unius est exclusio alterius*, when a statute lists the situation to which it applies, it implies the exclusion of situations not contained in the list”); *see also Jackson v. A Woman’s Choice, Inc.*, 130 N.C. App. 590, 594, 503 S.E.2d 422, 425 (1998) (internal citations omitted) (“[W]here a statute is explicit on its face, the courts have no authority to impose restrictions that the statute does not expressly contain.”).

Therefore, we request your confirmation that the Dialysis Equipment Addition is not subject to CON review.

Micheala Mitchell, Chief
October 22, 2025
Page 3

We thank you for your consideration of this request. Do not hesitate to contact me if you have any questions.

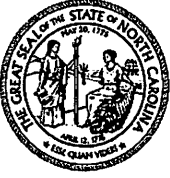
Sincerely,



Gary S. Qualls

Exhibits

1. March 7, 2024 No Review Approval for WakeMed to operate inpatient dialysis services at the WakeMed North Campus and March 4 Request from WakeMed



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

March 7, 2024

Robbie Roberts
rroberts@wakemed.org

No Review

Record #: 4393
Date of Request: March 4, 2024
Facility Name: WakeMed North Hospital
FID #: 990974
Business Name: WakeMed
Business #: 2018
Project Description: Expansion of the acute dialysis program to inpatients at the WakeMed North Hospital campus
County: Wake

Dear Robbie Roberts:

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,

Crystal Kearney (handwritten signature)

Crystal Kearney, Project Analyst

Micheala Mitchell (handwritten signature)

Micheala Mitchell, Chief

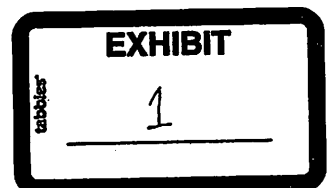
cc: Acute and Home Care Licensure and Certification Section, DHSR

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION

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WakeMed Health & Hospitals

3000 New Bern Avenue

Raleigh, North Carolina 27610

919-350-8000

March 4, 2024

Via electronic mail to Crystal.kearney@dhhs.nc.gov

Ms. Crystal Kearney, Project Analyst

Healthcare Planning and Certificate of Need Section

Division of Health Service Regulation

2704 Mail Service Center

Raleigh, NC 27699-2704

Re: Request for No Review/WakeMed to Extend Acute Dialysis Program to WakeMed North Hospital/Wake County

Dear Ms. Kearney:

This letter is to inform the Healthcare Planning and Certificate of Need Section of WakeMed's intent to extend Acute Dialysis services to WakeMed North Hospital, located at 10000 Falls of Neuse Road, Raleigh, NC 27614. WakeMed North Hospital operates as a remote campus under the WakeMed license (H0199) and CMS Certification Number (340069). WakeMed North began offering Emergency services as a remote campus of WakeMed Raleigh in accordance with Project No, J-6940-03, and Inpatient services via Project Nos. J-7843-07 and J-8180-08. WakeMed North Hospital is currently licensed for 77 acute care beds and 4 operating rooms.

WakeMed has operated an Acute Dialysis Program at the Raleigh Campus in partnership with Fresenius Kidney Care since 1980. WakeMed North, as a remote campus of WakeMed, plans to provide Acute Dialysis to patients admitted to the hospital as needed during their inpatient stay. Expansion of this existing program to a hospital campus operating under the same license does not constitute a "new service".

Because Acute Dialysis Programs are not governed by the CON Statute, WakeMed believes this project is not subject to certificate of need review and is requesting that the Agency confirm that WakeMed may proceed without first obtaining a CON.

Thank you for your attention to this matter. If you have questions or require additional information, please contact me at 919-350-8023 or rroberts@wakemed.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Robbie Roberts".

Robbie Roberts

Manager, Market Planning

From: [Mitchell, Micheala L](#)
To: [Stancil, Tiffany C](#)
Subject: FW: [External] No Review for Inpatient Dialysis Services at Atrium University City's Lake Norman Campus
Date: Wednesday, October 22, 2025 3:06:19 PM
Attachments: [10222025 K&L GATES 001.pdf](#)

Tiffany,

Would you mind logging and assigning to Greg, please?

Thanks,

Micheala

Micheala Mitchell, JD
[NC Department of Health and Human Services](#)
[Division of Health Service Regulation](#)
Section Chief, Healthcare Planning and CON Section
809 Ruggles Drive, Edgerton Building
2704 Mail Service Center
Raleigh, NC 27699-2704
Office: 919 855 3879
Micheala.Mitchell@dhhs.nc.gov

From: Qualls, Gary <Gary.Qualls@klgates.com>
Sent: Wednesday, October 22, 2025 12:29 PM
To: Mitchell, Micheala L <Micheala.Mitchell@dhhs.nc.gov>
Subject: [External] No Review for Inpatient Dialysis Services at Atrium University City's Lake Norman Campus

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.

Micheala:

Please see attached for filing a No Review Request for Inpatient Dialysis Services at Atrium University City's Lake Norman Campus. Please confirm receipt for my records.

Don't hesitate to let me know if you have any questions.

Thanks

Gary



Gary S. Qualls

Partner
K&L Gates LLP
430 Davis Drive, Suite 400
Morrisville, NC 27560
Phone: 919-466-1182
Fax: 919-516-2072
gary.qualls@klgates.com
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