



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

October 22, 2020

Gary S. Qualls
Gary.Qualls@klgates.com

Exempt from Review

Record #: 3389
Facility Name: Carolinas Medical Center
FID #: 943070
Business Name: The Charlotte-Mecklenburg Hospital Authority
Business #: 1770
Project Description: Replace existing non-medical equipment (pharmacy robot)
County: Mecklenburg

Dear Mr. Qualls:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of October 19, 2020, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(g). Therefore, you may proceed to offer, develop, or establish the above referenced project without a certificate of need.

However, you need to contact the Agency's Construction and Acute and Home Care Licensure and Certification Sections to determine if they have any requirements for development of the proposed project.

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Agency. Changes in a project include but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Handwritten signature of Julie M. Faenza

Julie M. Faenza
Project Analyst

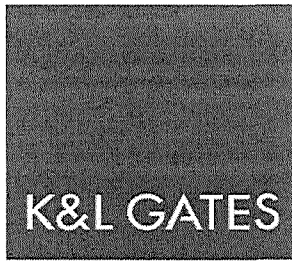
Handwritten signature of Martha J. Frisone

Martha J. Frisone
Chief

cc: Construction Section, DHSR
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



Gary S. Qualls
gary.qualls@klgates.com

October 19, 2020

T +1 919 466 1182
F +1 919 516.2072

Via E-Mail to disraeliza.flores@dhhs.nc.gov

Martha J. Frisone, Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
N.C. Department of Health and Human Services
809 Ruggles Drive
Raleigh, NC 27603

RE: The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center's
No Review Request and Exemption Notice Regarding Replacement of its
Pharmacy Robot

Dear Ms. Frisone:

On behalf of our client, The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center ("CMC"), we request a determination by the Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (the "Agency") that CMC be permitted to replace its existing Pharmacy Robot ("Original Pharmacy Robot" or "Existing Equipment") with a new Omnicell Pharmacy Robot Workstation ("New Pharmacy Robot" or "Replacement Equipment") without a Certificate of Need ("CON"). The proposed New Pharmacy Robot is either:

1. not CON reviewable as major medical equipment under N.C. Gen. Stat. § 131E-176(14o) – despite exceeding \$750,000 -- and exempt under the general "Main Campus Exemption" in N.C. Gen. Stat. §131E-184(g) given that the associated costs exceed \$2 Million; or

K&L GATES LLP
POST OFFICE BOX 14210 RESEARCH TRIANGLE PARK NC 27709-4210 430 DAVIS DRIVE SUITE 400 MORRISVILLE NC 27560
T +1 919 466 1190 F +1 919 831 7040 klgates.com

2. exempt from CON review pursuant to the “Main Campus Replacement Equipment Exemption” under N.C. Gen. Stat. §131E-184(f).

Exhibit 1 contains marketing materials describing the functionality of the New Pharmacy Robot. The Quote in Exhibit 2 shows the cost of the New Pharmacy Robot to be \$1,901,112.17, including shipping, installation, and de-installation of the Original Pharmacy Robot. The certified cost estimate in Exhibit 3 shows that associated construction costs for the New Pharmacy Robot are projected to be \$77,300. Associated taxes are estimated to be \$133,035. Therefore, the New Pharmacy Robot will cost in excess of \$2 Million to acquire and implement.

I. No Review Request and Main Campus Exemption.

The proposed New Pharmacy Robot is not required to undergo CON review because: (a) it is not CON reviewable under the major medical equipment definition in N.C. Gen. Stat. § 131E-176(14o); and (b) it is exempt under the Main Campus Exemption in N.C. Gen. Stat. §131E-184(g).

Pharmacy robot workstations such as the New Pharmacy Robot are not reviewable *per se* under the CON statute. Moreover, the New Pharmacy Robot does not meet the definition of “major medical equipment” under N.C. Gen. Stat. § 131E-176(14o) even though the cost of the New Pharmacy Robot exceeds \$750,000. The statutory definition of “major medical equipment” under N.C. Gen. Stat. § 131E-176(14o) is:

"Major medical equipment" means a single unit or single system of components with related functions which is used to provide medical and other health services and which costs more than seven hundred fifty thousand dollars (\$750,000). In determining whether the major medical equipment costs more than seven hundred fifty thousand dollars (\$750,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the major medical equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater. Major medical equipment does not include replacement equipment as defined in this section.

N.C. Gen. Stat. § 131E-176(14o)(emphasis added).

Pharmacy robot workstations such as the New Pharmacy Robot are not “used to provide medical and other health services” within the definition of “major medical equipment” under N.C. Gen. Stat. § 131E-176(14o). Rather, the function of the New Pharmacy Robot is to provide pharmacy packaging, dispensing, compounding functions, and pharmacy inventory control. The New Pharmacy Robot (like the Old Pharmacy Robot it will replace) automates what is traditionally a backroom manual process.

Unlike units of major medical equipment, the New Pharmacy Robot (like the Old Pharmacy Robot) will not operate on, or interact directly with, patients. Rather, the New Pharmacy Robot is a backroom item that will increase operating efficiencies in the pharmacy. Since the New Pharmacy Robot is not the type of equipment contemplated by the major medical equipment definition, it is not reviewable as such, despite its cost exceeding \$750,000.

Thus, based upon the above facts, the New Pharmacy Robot does not meet the definition of “major medical equipment” under N.C. Gen. Stat. § 131E-176(14o) and is not reviewable as such.

Moreover, since the New Pharmacy Robot costs would only otherwise be reviewable pursuant to the \$2 Million threshold in N.C. Gen. Stat. §131E-176(16)(b), such costs are exempt under the general “Main Campus Exemption” in N.C. Gen. Stat. §131E-184(g). That section reads as follows:

- (g) The Department shall exempt from certificate of need review any capital expenditure that exceeds the two million dollar (\$2,000,000) threshold set forth in G.S. 131E-176(16)b. if all of the following conditions are met:
 - (1) The sole purpose of the capital expenditure is to renovate, replace on the same site, or expand the entirety or a portion of an existing health service facility that is located on the main campus.
 - (2) The capital expenditure does not result in (i) a change in bed capacity as defined in G.S. 131E-176(5) or (ii) the addition of a health service facility or any other new institutional health service other than that allowed in G.S. 131E-176(16)b.
 - (3) The licensed health service facility proposing to incur the capital expenditure shall provide prior written notice to the Department, along with supporting documentation to demonstrate that it meets the exemption criteria of this subsection.

The term “main campus,” as used in Subsection 184(g)(1) above, is defined at N.C. Gen. Stat. § 131E-176(14n)) as follows:

(14n) “Main campus” means all of the following for the purposes of G.S. 131E-184(f) and (g) only:

- a. The site of the main building from which a licensed health service facility provides clinical patient services and exercises financial and administrative control over the entire facility, including the buildings and grounds adjacent to that main building.
- b. Other areas and structures that are not strictly contiguous to the main building but are located within 250 yards of the main building.

The Original Pharmacy Robot is currently housed in CMC’s existing pharmacy on the CMC Main Campus. The New Pharmacy Robot will be located, and the associated renovations will occur, in the same location. Specifically, the site is on the second floor of CMC’s main hospital building.

Thus, CMC is requesting a determination that its purchase of the New Pharmacy Robot is exempt from CON review under the general Main Campus Exemption provisions contained in N.C. Gen. Stat. §131E-184(g).

II. Main Campus Replacement Equipment Exemption Request (In The Alternative)

As explained in Part I above, CMC seeks to acquire a New Pharmacy Robot (i.e., the Replacement Equipment) to replace the Original Pharmacy Robot (i.e., the Existing Equipment). Thus, in the alternative, CMC seeks confirmation that this acquisition is exempt from CON review under the Replacement Equipment Exemption provisions contained in N.C. Gen. Stat. §131E-184(f).

A. CMC's Proposed Replacement Equipment Meets The Main Campus Replacement Equipment Exemption Test Under Section 184(f).

CMC seeks confirmation that this acquisition is exempt from CON review under the Main Campus Replacement Equipment Exemption provisions contained in N.C. Gen. Stat. §131E-184(f), as follows:

- (f) The Department shall exempt from certificate of need review the purchase of any replacement equipment that exceeds the two million dollar (\$2,000,000) threshold set forth in G.S. 131E-176(22) if all of the following conditions are met:
1. The equipment being replaced is located on the main campus.
 2. The Department has previously issued a certificate of need for the equipment being replaced. This subdivision does not apply if a certificate of need was not required at the time the equipment being replaced was initially purchased by the licensed health service facility.
 3. The licensed health service facility proposing to purchase the replacement equipment shall provide prior written notice to the Department, along with supporting documentation to demonstrate that it meets the exemption criteria of this subsection.

B. Cost of the Replacement Equipment

As described in the introduction, the New Pharmacy Robot will cost in excess of \$2 Million to acquire and implement. To recap:

1. The purchase price of the Replacement Equipment is \$1,901,112.17. See Exhibit 2 (Quote).
2. The construction cost to install the Replacement Equipment is \$77,300. See Exhibit 3 (Cost Certification Letter).
3. Associated taxes are estimated to be \$133,035.
4. There will be no other construction costs or other capital costs associated with this Replacement Equipment.

C. Equipment Being Replaced is Located on the Main Campus

As explained under the Main Campus Exemption discussion in Part I above, the Existing Equipment is currently housed in CMC's existing pharmacy on the CMC Main Campus, which qualifies as the "main campus" as defined in N.C. Gen. Stat. § 131E-176(14n).

The Existing Equipment was acquired over 20 years ago and CMC's Material Resources Management personnel have been unable to find any documentation regarding the purchase of that equipment. However, we assume that the Existing Equipment was not CON reviewable at the time of acquisition.

D. Comparable Equipment

Assuming that replacement equipment under N.C. Gen. Stat. §131E-184(f) – as contrasted with Section 131E-184(a) -- is required to meet the comparability test,¹ the Replacement Equipment must be "comparable" to the equipment it replaces and must be "sold or otherwise disposed of when replaced." CMC's proposal meets these tests as well. The CON rule codified as 10A N.C.A.C. 14C.0303 (the "Regulation") defines "comparable medical equipment" in subsection (c) as follows:

"Comparable medical equipment" means equipment which is functionally similar and which is used for the same diagnostic or treatment purposes.

10A N.C.A.C. 14C.0303(c).

CMC intends to use the Replacement Equipment for substantially the same pharmaceutical services for which CMC currently uses the Existing Equipment. The Existing Equipment has been used for approximately twenty years and is currently in use.

¹ The "replacement equipment" definition in N.C. Gen. Stat. §131E-176(22a) does not apply to Main Campus Replacement Equipment Exemptions because such exemptions are for replacement equipment exceeding \$2 Million. Section 131E-176(22a) only covers replacement equipment under Section 131E-184(a), because it specifically refers to equipment costing less than \$2 Million, as follows:

"Replacement equipment" means equipment that costs less than two million dollars (\$2,000,000) and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced.

See N.C. Gen. Stat. §131E-176(22a).

The Replacement Equipment will serve the same function as the Existing Equipment. Although it possesses some expanded capabilities due to technological improvements, the Replacement Equipment will perform the same general range of functions as the Existing Equipment. See Equipment Comparison Chart, attached as Exhibit 4. The Replacement Equipment is therefore “comparable medical equipment” as defined in Subsection (c).

Furthermore, CMC does not intend to increase patient charges or per procedure operating expenses more than 10% within the first 12 months after acquiring the Replacement Equipment.

Subsection (d) of the regulation further provides:

- (1) it has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements; and
- (2) it is functionally similar and is used for the same diagnostic or treatment purposes as the equipment currently in use and is not used to provide a new health service; and
- (3) the acquisition of the equipment does not result in more than a 10% increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.

10A N.C.A.C. 14C.0303(d).

The Replacement Equipment will meet all three of the tests set out in Subsection (d). The Replacement Equipment satisfies the technology and functionality tests in Subsection (1) and (2) as discussed above and identified in the Comparison Chart. See Exhibit 4. Moreover, CMC represents that use of the Replacement Equipment will not result in the types of expense or charge increase described in Subsection (d)(3).

E. Disposition of Equipment

As part of the proposal to acquire the Existing Equipment, Omnicell will de-install and dispose of the Existing Equipment. See Exhibit 2 Quote (De-installation Line Item priced at \$30,000).

Martha J. Frisone, Chief
October 19, 2020
Page 8

III. Conclusion

CMC hereby requests that the Agency provide a written response confirming that the acquisition of the New Pharmacy Robot described herein is exempt from CON review. If the Agency needs additional information to assist in its consideration of this request, please let us know.

Sincerely,

/s/ Gary S. Qualls

Gary S. Qualls

Martha J. Frisone, Chief
October 19, 2020
Page 9

Exhibits

1. Marketing Materials Describing New Pharmacy Robot
2. New Pharmacy Robot Quote
3. Cost Certification Letter
4. Equipment Comparison Chart

EXHIBIT 1

EXHIBIT 1

How Will Pharmacy Revolutionize Patient Care? XR2 Automated Central Pharmacy System

Pharmacy should be an integral part of the care team. But manual and disjointed processes often keep your staff bogged down with lower value tasks. Omnicell's new XR2 Automated Central Pharmacy System is a revolutionary approach to medication inventory management, allowing you to make a meaningful shift from operational demands to clinical contributions that impact patient outcomes.

The XR2 system, designed with input from leading health system pharmacies, automates critical workflows to maximize inventory control, improve operational efficiency, and increase medication safety. Its scalable and flexible technology streamlines any medication distribution model, and is customizable to the unique needs of your pharmacy operations.

Scalability and Flexibility Designed to Meet Your Evolving Needs

- Supports both cartless and cartfill distribution strategies through unit dose and multi-dose dispensing capabilities
- One-touch design reduces handling of medications by technicians and pharmacists
- Advanced algorithms ensure earliest expiring medications are picked first, reducing medication waste
- Extremely configurable and scalable architecture can easily be tailored to meet your needs, fit your space, and expand as you grow



Addressing the Financial and Clinical Challenges of Inventory Management

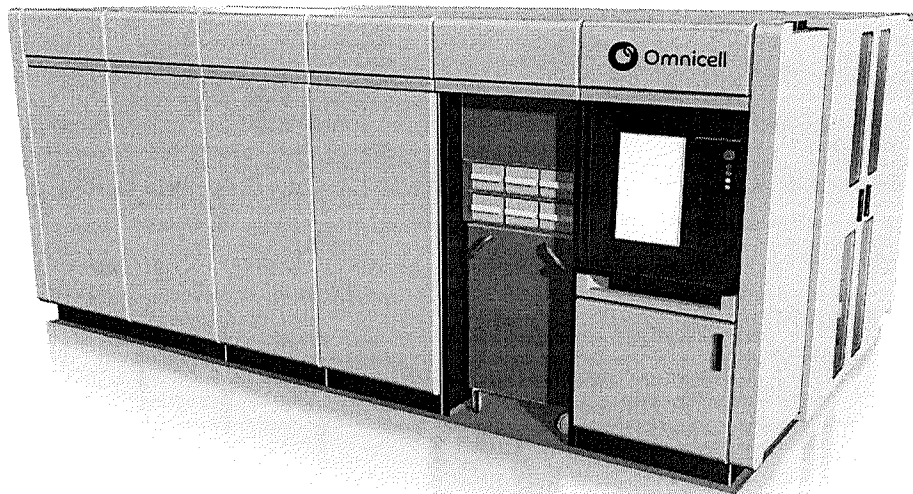
Slow-moving inventory is a challenge for traditional pharmacy automation. Not only does it make up a high percentage of inventory value, but slow movers also present a safety risk, since they are handled infrequently. The unique storage design of the XR2 system enables efficient management of slow moving inventory, allowing you to:

- Eliminate human error through 100% barcode scanning
- Maintain accurate inventory control and minimize discrepancies
- Dispense soonest-to-expire medications for reduced waste

Performance that Drives Safety and Efficiency

- Supports 90% of non-IV and non-narcotic formulary in a variety of form factors: individual blisters, blister cards, vials, cups, packets, syringes, and others
- Does not require the time and expense of repackaging
- Stores 200%-300% more doses compared with conventional pharmacy robots of similar size

The XR2 system is part of Omnicell's autonomous approach to medication management, leveraging hardware and workflow solutions, real-time predictive intelligence, and performance-driven partnerships to drive ongoing satisfaction and transform patient-centered care.



Learn more about how the XR2 Automated Central Pharmacy System is revolutionizing the patient medication experience at www.omnicell.com/XR2.



Omnicell and the Omnicell design mark are registered trademarks of Omnicell, Inc. in the United States and internationally. All other trademarks and trade names are the property of their respective owners.
©2020 All rights reserved. PN1014 Rev B 03/20

EXHIBIT 2



QUOTATION - PURCHASE

Print Date: 06/18/2020

EXHIBIT 2

Master Agreement ID: 37777CMA-01
Pricing Supplement ID: 5388607
Quote: 00031514 CMC Main XR2
Ship To ID: 10166
Carolinas Medical Center
1000 Blythe Boulevard
Charlotte North Carolina 28203

Start Date: 12/04/2019
Expiration Date: 12/31/2020
Price List: USA Price List
Bill To ID: 50809
Atrium Health Accounts Payable
/PO BOX 5379
Portland Oregon 97228-5379

Support Services Term / Level: 60 Months / Standard

Product	Description	Qty	Unit Price	Extended Price
CRX-WKS-002	XR2 PHARMACY WORKSTATION	2	\$4,864.70	\$9,729.40
XR2-BDS-001	XR2 AUTO PACKAGER	1	\$162,156.53	\$162,156.53
XR2-CTM-002	CART MODULE WITH QUICK PICK DRAWERS	1	\$113,509.57	\$113,509.57
XR2-KIT-005	RESTOCK CART TRAY KIT	1	\$19,458.78	\$19,458.78
XR2-KIT-009	DISPENSE TRAY KIT- LIONVILLE	1	\$5,837.64	\$5,837.64
XR2-KIT-011	RESTOCK TRAY STORAGE RACK KIT	1	\$16,215.65	\$16,215.65
XR2-LAB-001	ROBOT-RX DEINSTALLATION	1	\$30,000.00	\$30,000.00
XR2-LIC-001	UL INSPECTION CERTIFICATION	1	\$5,000.00	\$5,000.00
XR2-OPT-003	RESTOCK CART	3	\$5,189.01	\$15,567.03



QUOTATION - PURCHASE

Print Date: 06/18/2020

Product	Description	Qty	Unit Price	Extended Price
XR2-RBT-005	XR2 5 BAY SYSTEM	1	\$735,542.03	\$735,542.03
XR2-SPM-002	SPACER MODULE, FULL WIDTH (6')	1	\$7,783.51	\$7,783.51
XR2-STM-002	STORAGE MODULE FULL WIDTH (6')	7	\$107,023.31	\$749,163.17
			Product	\$1,869,963.31
			Shipping	\$31,148.86
			Total	\$1,901,112.17

1. Omnicell has made no commitment with regard to any functionality not generally available to the commercial marketplace as of the Pricing Supplement Effective Date or on the availability of any future version of the Licensed Software or purchased/leased Delivered Product.
2. A purchase order for Support Services in the amount shown as Total Service Fees is included with this Pricing Supplement.
3. Omnicell shall not be liable for any delays in the provision of Support Services if Omnicell is unable to obtain access to the Delivered Product due to a Customer provided padlock on the Omnicell Padlock Cabinet Kit.

EXHIBIT 3



July 1, 2020

EXHIBIT 3

Brigid Knoll Huber
Atrium Health
Strategic Services Group

Re: AH CMC Main Medication Robot Replacement
Charlotte, NC
OSR: 3440670
WMBA: 3409

Ms. Huber,

Having worked with Atrium Health to develop the design for the referenced project, Wright McGraw Beyer Architects, p.a. is pleased to provide the cost certification letter. The probable cost is based on the drawings included with the CON submittal. The estimated construction cost has been provided by Rodgers Builders. Wright McGraw Beyer Architects, p.a. certifies to the best of our knowledge the construction cost of \$77,300.

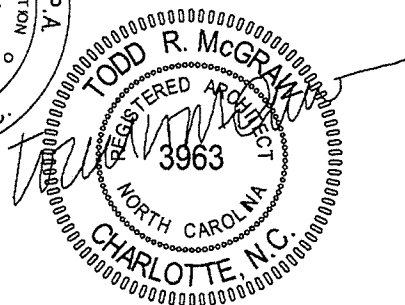
Please call me if you have any questions or comments.

Sincerely,

Wright McGraw Beyer Architects, p.a.

Todd McGraw
Managing Principal
North Carolina License #3963

SC/tm



2105 Water Ridge
Parkway Suite 450
Charlotte, NC
28217

704.535.6374
www.wmba.net

H:\3409 CMC Main Carousel Replacement\01-Predesign\1.B - Statements of Probable Cost\340670_AH CMC Main Robot Replacement - Cost Certification Letter.docx

EXHIBIT 4

EXHIBIT 4

EQUIPMENT COMPARISON – 2020 CMC Pharmacy Robot Replacement

	Existing Equipment	Replacement Equipment
Type of Equipment (List each component)	Automated Central Pharmacy System	Automated Central Pharmacy System
Manufacturer of Equipment	McKesson	Omniceil
Tesla Rating for MRIs	N/A	N/A
Model Number	APS II	XR2
Serial Number	1243010RB	Not Available Until Installed
Provider’s Method of Identifying Equipment	Internal Asset # / Serial #	Internal Asset # / Serial #
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #	N/A	N/A
Mobile Tractor Serial Number/VIN #	N/A	N/A
Date of Acquisition of Each Component	2000	2020
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	Title
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.)	Due to system transition, this information is not available	\$2,111,447
Total Cost of Equipment	Due to system transition, this information is not available	\$2,034,147
Fair Market Value of Equipment	N/A	\$2,034,147
Net Purchase Price of Equipment	N/A	\$2,034,147
Locations Where Operated	CMC, 2 nd Floor (main pharmacy)	CMC, 2 nd Floor (main pharmacy)
Number Days in Use/To Be Used in N.C. per Year	365 days / year	365 days / year
Percent of Change in Patient Charges (by procedure)	0%	0%
Percent of Change in Per Procedure Operating Expenses (by procedure)	0%	0%
Type of Procedures Currently Performed on Existing Equipment	Medication inventory management	N/A
Type of Procedures New Equipment is Capable of Performing	N/A	Medication inventory management

From: [Norwood, Connie](#)
To: [Waller, Martha K](#)
Cc: [Qualls, Gary](#)
Subject: [External] The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center"s No Review Request and Exemption Notice Regarding Replacement of its Pharmacy Robot
Date: Monday, October 19, 2020 12:43:34 PM
Attachments: [20201019123144195.PDF](#)

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to report.spam@nc.gov

Good afternoon Ms. Waller,

At Gary Qualls' request and on behalf of his client, The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center, please find attached a No Review Request and Exemption Notice Regarding Replacement of its Pharmacy Robot. If you wouldn't mind, at your convenience, acknowledging receipt, I would greatly appreciate it.

If you have any problems accessing this document, please do not hesitate to let me know.

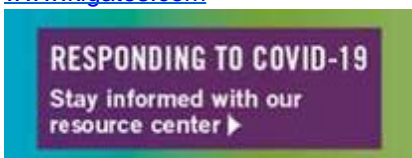
Best regards,

Connie Norwood



Connie J. Norwood
Practice Specialist
and Office Coordinator
K&L Gates LLP
430 Davis Drive, Suite 400
Morrisville, North Carolina 27560

Post Office Box 14210
Research Triangle Park, North Carolina 27709-4210
Phone: 919.466.1244
Fax: 919.516.2134
Connie.norwood@klgates.com
www.klgates.com



This electronic message contains information from the law firm of K&L Gates LLP. The contents may be privileged and confidential and are intended for the use of the intended addressee(s) only. If you are not an intended addressee, note that any disclosure, copying, distribution, or use of the contents of this message is prohibited. If you have received this e-mail in error, please contact me at Connie.Norwood@klgates.com.