



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

January 5, 2022

Kenneth Burgess
kburgess@bakerdonelson.com

No Review

Record #: 4104
Date of Request: December 9, 2022
Facility Name: Mission Hospital
FID #: 943349
Business Name: MH Mission Hospital, LLLP
Business #: 3045
Project Description: Acquire daVinci Dual Xi Surgical System
County: Buncombe

Dear Mr. Burgess:

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,

Ena Lightbourne, 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

KENNETH LEE BURGESS, SHAREHOLDER
Direct Dial: 919-294-0802
Direct Fax: 919-338-7696
E-Mail Address: kburgess@bakerdonelson.com

December 9, 2022

VIA EMAIL

micheala.mitchell@dhhs.nc.gov
ena.lightbourne@dhhs.nc.gov

Micheala Mitchell, Chief
Ena Lightbourne, Project Analyst
Healthcare Planning & Certificate of Need Section
N.C. Department of Health and Human Services
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

RE: MH Mission Hospital, LLP Request for No Review
Determination Regarding Acquisition of DaVinci Surgical System

Dear Micheala and Ena:

I am writing on behalf of our client, MH Mission Hospital, LLLP (“Mission”) to notify the N.C. Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (“the CON Section” or “the Agency”) of Mission’s plans to acquire a da Vinci Surgical System to be located in operating room (“OR”) 28 in the main Mission Hospital OR suite in Asheville, North Carolina. Mission Hospital’s license number is H0036. Details regarding the equipment being acquired and its cost are set forth below. The purpose of this letter is to request that the Agency issue a “No Review Determination” and thereby confirm in writing that Mission’s acquisition of the da Vinci system, on the terms described herein, is not subject to CON Section review and does not require that Mission obtain a certificate of need (“CON”) before acquiring the da Vinci System.

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Project Description

Mission plans to acquire a da Vinci Dual Xi Surgical System. This will represent Mission's sixth (6th) da Vinci surgical robotics system. The cost of the da Vinci Xi System will be \$1,738,750.00. The da Vinci Xi will be acquired through a capital lease which, for CON purposes, is the equivalent of an equipment purchase. The acquisition will include an Integrated Table Motion Upgrade designed to work with the da Vinci Xi System at a cost of \$25,500.00. Together, Mission's combined capital expenditure totals \$1,738,750.00. **See Attachment 1** (Projected Capital Cost Form). See also, **Attachment 2** (Statement of Mission Hospital Chief Operating Officer).

Applicable Legal Authorities

The CON Law precludes any person from offering or developing a "new institutional health service" without first obtaining a CON. N.C. Gen. Stat. § 131E-178(a). The definition of "new institutional health service" includes, *inter alia*, the following:

- Incurring an obligation for a capital expenditure that exceeds \$4,000,000.00 to develop or expand a health service or health service facility, or which "relates" to the provision of a health service; and
- The acquisition by purchase, donation, lease, transfer or comparable arrangement of "major medical equipment," which is defined as a single unit or single system of components used to provide medical and health services which costs more than \$2,000,000.00, including the costs of the equipment and all studies, drawings, installation and any other activities essential to acquiring and making the equipment operational.¹

N.C. Gen. Stat. §§ 131E-176(16)(b), (16)(p) and (14o). Conversely, the acquisition of medical equipment that does not cost more than \$2,000,000.00 does not qualify as "major medical equipment;" does not constitute a "new institutional health service; and is not subject to Agency review or the requirement to obtain a CON.

Because Mission's new da Vinci Xi System costs less than \$2 million dollars, it does not constitute major medical equipment under the CON Statute. Therefore, no further review of the proposed acquisition by the CON Section is required and Mission is not required to obtain a

¹ In calculating construction costs, our clients relied upon prior Agency determinations that the construction costs "essential to acquiring and making operational the replacement equipment" should include only those costs directly related to removing the old equipment, installing the new equipment and making sure that equipment operates properly. In the case of a CT scanner, for example, such cost should include upfit of the CT room related solely to the operation of the CT scanner (e.g., shielding, extra electrical connections), but need not include other construction costs associated with that room. Similarly, the Agency has previously determined that costs associated with the installation of equipment in the control room for the CT scanner should be included only to the extent that those costs would be different from construction related to general office space. *Mission Hospitals, Inc. v. NC DHHS*, ___ N.C.App. ___, 696 S.E.2d 163 (2010).

CON before acquiring the equipment. Further, surgical robotics systems are not a type of equipment identified as a “new institutional health service” by N.C. Gen. Stat. § 131E-176(16)f which, if listed in that statutory section, require a CON regardless of cost.²

Mission’s proposed new da Vinci Xi System does not qualify as a new institutional health service under any other provision of the CON Statute either.

The Agency Has Issued Previous No Review Letters for DaVinci Acquisitions

The Agency has recently approved the acquisition of da Vinci Surgical Systems for other health care providers in response to No Review or Exemption Requests. Recent examples of those include:

1. January 6, 2020 approval of an Exemption Request to acquire a da Vinci Surgical System by New Hanover Regional Medical Center. **See Attachment 3**
2. March 16, 2020 approval of a No Review Request to acquire a da Vinci Surgical System by Rex Hospital, Inc. **See Attachment 4.**
3. August 31, 2022 approval of an Exemption Request to acquire a da Vinci Surgical System by Novant New Hanover Regional Medical Center. **See Attachment 5.**³

Conclusion

Based on the information provided in this No Review Determination Request, and in keeping with the Agency’s recent practice regarding the determination that da Vinci Surgical Systems which cost less than \$2,000,000.00 are not subject to CON Section Review and do not require a CON, Mission respectfully requests that the Agency confirm in writing at its earliest opportunity that Mission’s acquisition of an additional da Vinci Surgical System is not subject to further CON Section review and does not require a CON.

Please let us know if you have any questions regarding this request.

Sincerely,


Kenneth L. Burgess

² Mission acknowledges that medical equipment which costs less than \$2,000,000.00 may also qualify as a new institutional health service under other provisions of the CON Statute, such as N.C. Gen. Stat. § 131E-176 (7a) (governing diagnostic centers). The da Vinci Surgical System being acquired by Mission does not fall within the ambit of that statutory provision or any other provision of the CON Statute defining “new institutional health services.”

³ Mission does not believe that an Exemption Request is the appropriate vehicle for obtaining confirmation that da Vinci Surgical Systems are not subject to CON Section review because they are not the subject of a statutory exemption from provisions of the CON Statute that would otherwise make them “new institutional health services.” As a result, Mission is requesting a No Review Determination in this case.

Micheala Mitchell
Ena Lightbourne
Page 4

Attachments

Attachment 1

**Projected Capital Cost Form
Mission Hospital Acquisition of da Vinci Robot (#6)**

Building Purchase Price	\$0.00
Purchase Price of Land	\$0.00
Closing Costs	\$0.00
Site Preparation	\$0.00
Construction/Renovation Contract(s)	\$0.00
Landscaping	\$0.00
Architect / Engineering Fees	\$0.00
Medical Equipment	\$1,600,000.00
Non-Medical Equipment	\$25,000.00
Furniture	\$0.00
Consultant Fees (specify)	\$0.00
Financing Costs	\$0.00
Interest during Construction	\$0.00
Other (specify)	\$113,750.00
Total Capital Cost	\$1,738,750.00

CERTIFICATION BY A LICENSED ARCHITECT OR ENGINEER

I certify that, to the best of my knowledge, the projected capital cost for the proposed project is complete and correct.

N/A
Signature of Licensed Architect or Engineer

Date Signed: N/A

CERTIFICATION BY AN OFFICER OR AGENT FOR THE PROPONENT

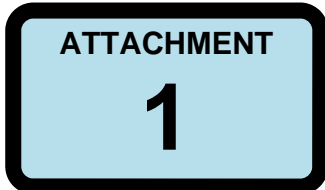
I certify that, to the best of my knowledge, the projected total capital cost for the proposed project is complete and correct and that it is our intent to carry out the proposed project as described.

Joseph R. Rudisill Digitally signed by Joseph R. Rudisill
Date: 2022.12.08 15:37:32 -05'00'

Signature of Officer/Agent

Date Signed: _____

Joseph R. Rudisill
Chief Operating Officer



Attachment 2

STATEMENT OF JOSEPH R. RUDISILL

1. I am the Chief Operating Officer for MH Mission Hospital, LLLP (“Mission”). I am personally familiar with Mission Hospital’s plan to acquire an additional DaVinci Surgical System which will be installed in operating room 28 in the main Mission OR suite on Mission’s main campus, license number H0036. I make this statement in support of Mission’s No Review Determination Request to the N.C. Certificate of Need Section.

2. As part of my duties as Chief Operating Officer, I am responsible for the oversight of all operations for Mission Hospital, which includes the surgical program.

3. I am personally familiar with the proposed project which involves the acquisition of a sixth DaVinci Surgical System by Mission to be located in OR 28.

4. Under pain of perjury, I certify that the total costs of the project are approximately ONE MILLION, SEVEN HUNDRED THIRTY-EIGHT THOUSAND, SEVEN HUNDRED AND FIFTY DOLLARS (\$ 1,738,750.00).

5. Furthermore, as part of this project, Mission Hospital will not acquire any new major medical equipment, increase total bed capacity, increase total operating room capacity or develop any other new institutional health services described in N.C. Gen. Stat. §131E-176 (16).

This the 9 day of December, 2022.

**Joseph R.
Rudisill** Digitally signed by
Joseph R. Rudisill
Date: 2022.12.09
08:44:45 -05'00'

JOSEPH R. RUDISILL
Chief Operating Officer
MH Mission Hospital, LLLP

ATTACHMENT

2

Attachment 3



NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

January 6, 2020

Kristy Hubard
2131 S. 17th Street
Wilmington, NC 28401

No Review

Record #: 3174
Facility Name: New Hanover Regional Medical Center
FID #: 943372
Business Name: New Hanover Regional Medical Center
Business #: 1308
Project Description: Acquire DaVinci XI Surgical System
County: New Hanover

Dear Ms. Hubard:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the above referenced proposal. Based on the CON law in effect on the date of this response to your request, the proposal described in that correspondence 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.

You may need to contact the Agency's Acute and Home Care Licensure and Certification Section to determine if they have any requirements for development of the proposed project.

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,

Tanya M. Saporito
Project Analyst

Martha J. Frisone
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



Waller, Martha K

From: dlegarth@nc.rr.com
Sent: Tuesday, November 26, 2019 5:59 PM
To: Tanya, Saporito; Waller, Martha K
Cc: 'Nancy O'Dacre'
Subject: [External] Letters of CON Exemption
Attachments: NHRMC daVinci Acquisition Letter.pdf; NHRMC SENCA Acquisition Letter.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 Evening,

Attached please find two Letters of CON Exemption. One letters pertains to the acquisition of limited assets of SENCA Properties, LLC and the other letter pertains to the acquisition of a DaVinci surgical robot.

Have a great Thanksgiving!

David Legarth



Mail Address:
P.O. Box 1936
Apex, NC 27502

FedEx/UPS Address:
108 Curely Maple Court
Apex, NC 27502

Phone:
(919)244-7609



November 25, 2019

Ms. Martha Frisone, Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
NC Department of Health and Human Services
2704 Mail Service Center
Raleigh, North Carolina 27699-2704

RE: Request for Exemption to Certificate of Need Review for Acquisition of an Intuitive daVinci Xi Surgical System / New Hanover County

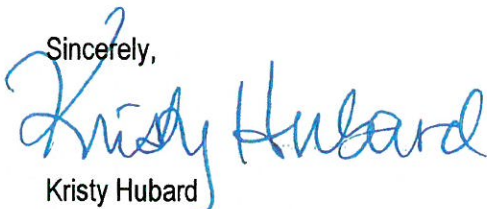
Dear Ms. Frisone,

This letter is intended to provide advance notice to the Healthcare Planning and Certificate of Need ("CON") Section that New Hanover Regional Medical Center ("NHRMC") is planning to acquire medical equipment, specifically, an Intuitive daVinci Xi Surgical System for use at the hospital. The total cost of the medical equipment is \$725,000. There are no other project costs associated with the acquisition of the medical equipment.

Under the CON statute, robotic surgical system equipment is not specifically subject to CON review unless the cost of acquiring the equipment meets the \$750,000 threshold for "Major Medical Equipment" set forth in N.C.G.S. 131E-176(140). Here the cost of the equipment, including all costs to make the equipment operational, will not exceed \$750,000. Accordingly, NHRMC requests that the Section issue a written determination confirming that its proposed acquisition of an Intuitive daVinci Xi Surgical System to be located on its main campus is not subject to CON review.

If you have any questions or need additional information, please do not hesitate to contact me at (910) 667-7000.

Sincerely,



Kristy Hubard
Chief Strategy Officer
New Hanover Regional Medical Center

NHRMC 943372
NR id 3174
BUS 1308

Attachment 4



NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

March 16, 2020

Elizabeth Runyon, System Director of Regulatory Affairs & Special Counsel
UNC Health Care
Hedrick Building
211 Friday Center Drive, Suite G014
Chapel Hill NC 27517

No Review

Record #: 3242
Facility Name: Rex Hospital
FID #: 953429
Business Name: Rex Hospital, Inc.
Business #: 1554
Project Description: Acquisition of da Vinci Xi Surgical System
County: Wake

Dear Ms. Runyon:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency) received your correspondence regarding the above referenced proposal. Based on the CON law in effect on the date of this response to your request, the proposal described in that correspondence 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.

You may need to contact the Agency's Acute and Home Care Licensure and Certification Section to determine if they have any requirements for development of the proposed project.

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,
Michael J. McKillip
Project Analyst

Martha J. Frisone
Martha J. Frisone
Chief

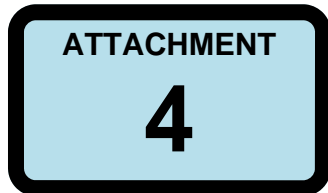
cc: Acute and Home Care Licensure and Certification Section, DHSR

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





March 5, 2020

VIA ELECTRONIC MAIL

Mr. Michael J. McKillip
Certificate of Need Section
Division of Health Service Regulation
Department of Health and Human Services
809 Ruggles Drive
Raleigh, NC 27603
mike.mckillip@dhhs.nc.gov

Re: Request for No Review Determination / Acquisition of da Vinci Xi Surgical System/
Rex Hospital / Wake County

Dear Mr. McKillip:

Rex Hospital, Inc. ("UNC Rex") is planning to purchase a da Vinci Xi Surgical System, which is a robotic system used to assist in minimally invasive laparoscopic surgical procedures. The purchase price of this system is \$725,000 and the delivery charge is \$10,000, resulting in a total cost of \$735,000 which UNC Rex will incur to acquire the equipment and make it operational. *See* Exhibit 1. No renovations or upfit are required in order for the robotic system to be accommodated and operationalized within the hospital, and there are no other costs that UNC Rex must incur to acquire the equipment and make it operational.

UNC Rex is requesting written confirmation that this proposed acquisition of the da Vinci Xi Surgical System does not require CON review, because the acquisition does not meet the definition of "major medical equipment" as contained in N.C. Gen. Stat. § 131E-176(14f), and it does not constitute any other type of "new institutional health service" requiring a CON as that term is defined in N.C. Gen. Stat. § 131E-176(16).

If you require any additional information regarding this project, please do not hesitate to contact me at 984-215-3622 or elizabeth.runyon@unchealth.unc.edu.

Sincerely,

A handwritten signature in cursive script that reads "Elizabeth Runyon".

Elizabeth Runyon
System Director of Regulatory Affairs & Special Counsel
UNC Health Care



Intuitive Surgical, Inc.
1020 Kifer Road
Sunnyvale, CA 94086
800-876-1310

Quote Details

Quote ID	131032.0
Quote Date	1/28/2020
Valid Until	3/16/2020
Sales Rep	Ryan Carlson
Phone Number	1(727) 698-5339
Email	Ryan.Carlson@intusurg.com

Company Information

Hospital Name	Rex Healthcare
SF ID / IDN Affiliation	13742/UNC Health Care
Address	4420 Lake Boone Trail
City, State, Zip	Raleigh, NC, 27607-6599
Contact Name	
Telephone	

Please submit orders electronically via GHX or fax to 408-523-2377

Items

Part Number	Qty	Item	Price	Discount	Subtotal
da Vinci Systems					
	1	da Vinci Xi® Single Console System One (1): da Vinci Xi System Surgeon Console One (1): da Vinci Xi System Patient Cart One (1): da Vinci Xi System Vision Cart da Vinci Xi System Documentation da Vinci Xi System Software Training Instrument Starter Kit Accessory Starter Kit Drapes Vision Equipment (All Kits subject to change without notice)	\$1,900,000.00	\$1,175,000.00	\$725,000.00
Freight					
	1	System Freight - East (AL, CT, DC, DE, FL, GA, IN, KY, MA, MD, ME, MI, MS, NC, NH, NJ, NY, OH, PA, RI, TN, SC, VA, VT, WV)	\$10,000.00	\$0.00	\$10,000.00
Total					\$735,000.00
Service					
Part Number	Qty	Item	Price	Subtotal	
	1	Da Vinci Xi® dVComplete Care Service Plan (single console) Years 2-5, per year		\$328,000.00	\$328,000.00
	1	Year One System Service (Included in System Fee unless an amount is listed)		\$328,000.00	\$328,000.00

Leasing Terms

Leasing options are available through Intuitive Surgical on systems and select upgrades. Please contact your Intuitive representative for additional details.

Terms and Conditions

1) System Terms and Conditions:

1.1 A signed Sales, License, and Service Agreement ("SLSA") or equivalent is required prior to shipment of the System(s). All site modifications and preparation are the Customer's responsibility and are to be completed to the specification given by Intuitive Surgical prior to the installation date. Delivery is subject to credit approval. Payment terms are net 30 days from Intuitive Surgical's invoice date. Each System includes the patient side cart, vision cart, and surgeon console(s). System enhancements required to support new features may be purchased at Intuitive Surgical's then current list price. The price of the da Vinci® Surgical System includes the initial installation of the System at Customer's facility and a one (1) year warranty for manufacture defect. All taxes and shipping charges are the responsibility of the Customer and will be added to the invoice, as appropriate.

1.2 Intuitive makes no representation with regard to Certificate of Need requirements for this purchase. It is your (the Customer's) responsibility to determine whether this purchase complies with your State's Certificate of Need laws and what Certificate of Need filing, if any, needs to be made with regard to this purchase.

1.3 Customer acknowledges that the cleaning and sterilization equipment, not provided by Intuitive, is required to appropriately reprocess da Vinci instruments and endoscopes. Please refer to the Intuitive Surgical Reprocessing website: <https://reprocessing.intuitivesurgical.com>. Customer is responsible for ensuring that its' cleaning and sterilization program comply with all health and safety requirements.

2) System Upgrade Terms and Conditions:

2.1 A signed Purchase Order and/or an addendum to the existing Sales, License, and Service Agreement ("SLSA") is required prior to shipment of the System upgrade. All site modifications and preparation are the Customer's responsibility and are to be completed with the specification given by Intuitive Surgical prior to the installation date.

2.2 Payment terms are net 30 days from Intuitive Surgical's invoice date. The price includes: the System upgrade, the initial installation at Customer's facility and a one (1) year warranty for manufacture defect. All taxes and shipping charges are the responsibility of the Customer and will be added to the invoice, as appropriate. Delivery is subject to credit approval and inventory availability. Standard shipping terms are FCA from Intuitive Surgical™ warehouse. A \$9.95 handling charge will be applied for any shipments using a customer designated carrier.

3) I&A Terms and Conditions:

3.1 To place an order, please fax Purchase Order to Intuitive Surgical Customer Service at 408-523-2377 or submit through the Global

Waller, Martha K

From: Runyon, Elizabeth <Elizabeth.Runyon@unhealth.unc.edu>
Sent: Thursday, March 5, 2020 9:48 AM
To: Mckillip, Mike
Cc: Waller, Martha K
Subject: [External] Rex No Review Request
Attachments: 2020.3.5 Rex daVinci No Review.pdf; Exhibit 1 - Quote 131032 Rex Healthcare.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

Mike,

Please see the attached No Review request for Rex Hospital. Let me know if you have any questions. Thank you!

Elizabeth

Elizabeth Frock Runyon

System Director of Regulatory Affairs and Special Counsel

UNC Health

211 Friday Center Drive, Chapel Hill, NC 27517

p (984) 215-3622

elizabeth.runyon@unhealth.unc.edu

----- Confidentiality Notice -----

The information contained in (or attached to) this electronic message may be legally privileged and/or confidential information. If you have received this communication in error, please notify the sender immediately and delete the message.

Attachment 5



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

August 31, 2021

Kristy Hubard
Kristy.hubard@nhrmc.org

No Review

Record #: 3670
Date of Request: August 19, 2021
Facility Name: Novant Health New Hanover Regional Medical Center
FID #: 943372
Business Name: Novant Health New Hanover Regional Medical Center, LLC
Business #: 3330
Project Description: Acquire two Intuitive daVinci Xi Surgical Systems
County: New Hanover

Dear Ms. Hubard:

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 Tanya M. Saporito]

Tanya M. Saporito

[Handwritten signature of Micheala Mitchell]

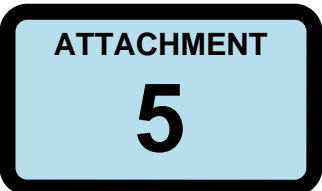
Micheala Mitchell
Chief

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
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AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER



August 19, 2021

Ms. Micheala Mitchell, Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
NC Department of Health and Human Services
2704 Mail Service Center
Raleigh, North Carolina 27699-2704

RE: Request for Exemption to Certificate of Need Review for Acquisition of an Intuitive daVinci Xi
Surgical System / New Hanover County
FID # 943372


Dear Ms. Mitchell,

This letter is intended to provide advance notice to the Healthcare Planning and Certificate of Need ("CON") Section that Novant Health New Hanover Regional Medical Center ("NHNHRMC") is planning to acquire medical equipment, specifically, two Intuitive daVinci Xi Surgical Systems for use at the hospital. The individual cost of each medical equipment is \$725,000. There are no other project costs associated with the acquisition of the medical equipment.

Under the CON statute, robotic surgical system equipment is not specifically subject to CON review unless the cost of acquiring the equipment meets the \$750,000 threshold for "Major Medical Equipment" set forth in N.C.G.S. 131E-176(14o). Here the cost of the equipment, including all costs to make the equipment operational, will not exceed \$750,000 each. Accordingly, NHNHRMC requests that the Section issue a written determination confirming that its proposed acquisition of two Intuitive daVinci Xi Surgical Systems to be located on its main campus are not subject to CON review.

If you have any questions or need additional information, please do not hesitate to contact me at (910) 667-5908.

Sincerely,



Kristy Hubard
Chief Strategy Officer
Novant Health New Hanover Regional Medical Center

From: [Mitchell, Micheala L](#)
To: [Stancil, Tiffany C](#)
Cc: [Lightbourne, Ena](#)
Subject: FW: [External] No Review Determination For MH Mission Hospital, LLLP: Acquisition of da Vinci Surgical System
Date: Friday, December 9, 2022 3:32:54 PM
Attachments: [4872-7000-5315 v.1 No Review Determination Request daVinci System w-attachments -2022-12-09.pdf](#)

Would you mind logging this as a no review? It goes to Ena.

Thank you!

Micheala Mitchell, JD

(she/her/hers)

Section Chief, Healthcare Planning and CON Section

[NC Department of Health and Human Services](#)

[Division of Health Service Regulation](#)

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From: Burgess, Ken <kburgess@bakerdonelson.com>

Sent: Friday, December 9, 2022 3:25 PM

To: Mitchell, Micheala L <Micheala.Mitchell@dhhs.nc.gov>; Lightbourne, Ena <ena.lightbourne@dhhs.nc.gov>

Subject: [External] No Review Determination For MH Mission Hospital, LLLP: Acquisition of da Vinci Surgical System

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Hi Micheala and Ena and Happy Friday. Attached please find a No Review Determination I am filing for our client MH Mission Hospital, LLLP in connection with Mission's acquisition of a da Vinci surgical robotics system. Please let me know if you have questions or need additional information

regarding this Notice. Thanks so much, Ken Burgess

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