



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

September 28, 2021

Kenneth Burgess

[kburgess@poynerspruill.com](mailto:kburgess@poynerspruill.com)

**Exempt from Review**

**Record #:** 3686  
**Date of Request:** September 13, 2021  
**Facility Name:** Mission Hospital  
**FID #:** 943349  
**Business Name:** MH Mission Hospital, LLLP  
**Business #:** 3045  
**Project Description:** Renovate and expand the existing pharmacy located on the main hospital campus  
**County:** Buncombe

Dear Mr. Burgess:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the above referenced proposal is exempt from certificate of need review in accordance with G.S. 131E-184(g). Therefore, you may proceed to offer, develop or establish the above referenced project without a certificate of need.

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,

Ena Lightbourne  
Project Analyst

Micheala Mitchell  
Chief, Certificate of Need

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

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

September 13, 2021

Kenneth L. Burgess  
Partner  
D: 919.783.2917  
F: 252.783.1075  
kburgess@poynerspruill.com

VIA E-MAIL

Micheala Mitchell, Chief  
Lisa Pittman, Assistant Chief  
N.C. Department of Health and Human Services  
Division of Health Service Regulation  
Certificate of Need Section  
809 Ruggles Drive, Raleigh, N.C. 27603  
Via email to: [lisa.pittman@dhhs.nc.gov](mailto:lisa.pittman@dhhs.nc.gov)  
[Micheala.mitchell@dhhs.nc.gov](mailto:Micheala.mitchell@dhhs.nc.gov)

**With copy to:**

Ena Lightbourne  
Project Analyst  
N.C. Department of Health and Human Services  
Division of Health Service Regulation  
Certificate of Need Section  
809 Ruggles Drive, Raleigh, N.C. 27603  
Via email to: [ena.lightbourne@dhhs.nc.gov](mailto:ena.lightbourne@dhhs.nc.gov)

RE: ***Notice of Exemption: Renovation of Mission Hospital's Existing Main Pharmacy, Facility I.D. No. 943349***

Dear Micheala, Lisa and Ena:

I am writing on behalf of our client MH Mission Hospital, LLLP ("Mission" or "the Hospital") to provide the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Certificate of Need Section ("the CON Section" or "the Agency") with prior written notice of Mission's intent to renovate and expand the Hospital's main pharmacy located in the main building on the Mission Hospital main campus ("the Project"). We believe the proposed project is exempt from further CON Section review, and does not require a certificate of need ("CON"), pursuant to N.C. Gen. Stat. section 131E-184(g).

**Background and Project Description**

The Project will involve the renovation and expansion of the Hospital's main pharmacy to ensure compliance with Chapters 700 and 800 of the *United States Pharmacopeia* requirements for compounding medications and ensuring a sterile environment for medication compounding. Compliance with the *United States Pharmacopeia* recommendations is a requirement of the Joint Commission on the Accreditation of Healthcare Organizations and is consistent with Mission's ongoing commitment to quality assurance and improvement. Mission's main pharmacy has not been renovated or upgraded in more than 20 years. The Project will enable Mission to ensure ongoing compliance with the *United States Pharmacopeia* and implement badly-needed upgrades to and expansion of its main pharmacy.

Micheala Mitchell  
September 13, 2021  
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Total project costs are estimated at approximately \$2,935,437.00 **See Exhibits A** (Projected Capital Cost Form) and **B** (Statement of Mission's Chief Operating Officer), both documenting estimated project costs.<sup>1</sup>

For the reasons stated below, we believe that the Proposed Project is exempt from CON Section review pursuant to N.C. Gen. Stat. § 131E-184(g), and thus Mission is not required to obtain a CON before proceeding with the Proposed Project.

### **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 \$2,000,000.00 to develop or expand a health service or health service facility, or which "relates" to the provision of a health service.

N.C. Gen. Stat. §§ 131E-176(16)(b). However, the CON Law includes a specific exemption for health-related capital expenditures in excess of \$2,000,000.00 where 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 located on the main campus." N.C. Gen. Stat. § 131E-184(g). That exemption, where applicable, eliminates the need to obtain a CON before incurring the capital expenditure. As described further below, the Proposed Project which is the subject of this Exemption Notice involves a capital expenditure in excess of \$2,000,000.00. However, the project is exempt from CON Section review based upon the exemption at N.C. Gen. Stat. § 131E-184(g). That exemption is described below.

### **The Statutory Exemption For Renovation, Replacement Or Expansion Of An Existing Health Facility On The Main Campus**

N.C. Gen. Stat. § 131E-184(g) provides an express exemption from CON Section review for capital expenditures that exceed \$2,000,000.00 where:

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 located on the main campus;
2. So long as the capital expenditure does not result in:
  - a. A change in bed capacity as defined in G.S. 131E-176(5); or
  - b. The addition of a health service facility or any other new institutional health service other than that allowed by G.S. 131E-176(16)b; and
  - c. The CON Section receives prior written notice of the planned expenditure along with documentation demonstrating that the provider meets the exemption.

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<sup>1</sup> Because the statutory exemption under which Mission is proceeding is not dependent on Mission being above or below a designated capital expenditure, a Projected Capital Cost Form is technically not required for this Exemption but we are including one to provide a general cost overview of the Project.

**The Proposed Project Involves The Renovation And Expansion Of Existing  
Space On Mission's Main Campus**

The Proposed Project which is the subject of this Exemption Notice is projected to cost in excess of \$2,000,000.00. The total project cost is anticipated to be approximately \$2,935,437.00. Of that amount, approximately \$2,082,007.00 will be expended on construction to renovate and expand the existing main pharmacy in the Service Wing (Wing B) of the main building at Mission Hospital. The remaining anticipated expenditures will be allocated to equipment, information technology system costs, miscellaneous costs and a contingency to cover any unanticipated cost increases. As previously noted, we have included a statement from Joseph R. Rudisill, Mission's Chief Operating Officer, attesting that the estimated total project costs are approximately \$2,935,437.00. **See Exhibit B.**

Even though total projected costs exceed \$2,000,000.00, the Proposed Project qualifies for the statutory exemption at N.C. Gen. Stat. § 131E-184(g) because the sole purpose of the project and related expenditure is to renovate or expand a portion of an existing health service facility on the hospital's main campus. The Proposed Project consists of renovating existing space located in the main hospital building at Mission Hospital on the hospital's main campus.

The term "campus" is defined at N.C. Gen. Stat. § 131E-176(2c) as "the adjacent grounds and buildings, or grounds and buildings not separated by more than a public right-of-way, of a health service facility and related health care entities." For the purposes of the exemption at N.C. Gen. Stat. § 131E-184(g), "main campus" is defined as:

- 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; and
- b. Other areas and structures that are not strictly contiguous to the main building but are located within 250 yards of the main building.

N.C. Gen. Stat. § 131E-176(14n).

The Project will be developed in the main Mission Hospital building on the hospital's main campus at 509 Biltmore Avenue in Asheville, North Carolina. Mission's Chief Executive Officer, Chief Operating Officer and Chief Financial Officer are all located in the main hospital building. Together, they exercise all financial and administrative control over Mission Hospital and its services, which includes the Hospital's pharmacy services. The main hospital building is also the location from which Mission provides clinical patient services. As such, the Proposed Project will be located in the main hospital building and so clearly is on the "main campus" within the meaning of N.C. Gen. Stat. § 131E-176(14n).

The Proposed Project does not involve a change in bed capacity as defined by N.C. Gen. Stat. § 131E-176(5). That section defines "change in bed capacity" in pertinent part as: (i) any relocation of health service facility beds from one licensed facility or campus to another, or (ii) any redistribution of health service facility bed capacity among the categories of health service facility beds defined in N.C. Gen. Stat. § 131E-176(9c), or (iii) any increase in the number of health service facility beds. The Proposed Project involves only the renovation existing space on Mission's main campus. The Project does not involve any relocation of health service facility beds from one licensed campus to another, any increase in the number of health service beds or any redistribution of health service facility beds among the categories identified at N.C. Gen. Stat. § 131E-176(9c). Further, the Project does not involve the development or

Micheala Mitchell  
September 13, 2021  
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addition of any bed capacity, operating rooms, health services or facilities that fall within the definition of “new institutional health services” at N.C. Gen. Stat. section 131E-176(16).

**The Project Does Not Involve the Acquisition of Equipment Which Qualifies as Major Medical Equipment Under The CON Statute**

The CON Statute treats as a “new institutional health service” requiring a CON the acquisition of major medical equipment. N.C. Gen. Stat. § 131E-176(16)p. Major medical equipment is defined as “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.” N.C. Gen. Stat. 131E-176(14o).

Mission’s Proposed Project does not involve the acquisition of medical equipment which meets the definition of “major medical equipment” under the CON Statute. See **Exhibits A** (Projected Capital Cost Worksheet) and **B** (Statement of Mission’s Chief Operating Officer). Total medical equipment costs for the Project are estimated at \$384,000.00, far below the major medical equipment threshold of \$750,000.00.

Also, the Proposed Project does not include the acquisition of any of the equipment defined at N.C. Gen. Stat. § 131E-176(16)f1 as a “new institutional health service” which, if listed there, would require Mission to obtain a CON before acquiring the equipment, regardless of the cost of the equipment.

**Mission’s Proposed Project Is Not A New Institutional Health Service Under Any Other Provision Of N.C. Gen. Stat. § 131E-176(16)**

The Proposed Project does not qualify as a “new institutional health service” under any other provision of the CON Statute, specifically including N.C. Gen. Stat. section 131E1-17(16). The Proposed Project does not involve a change in bed capacity, the construction or other development of a new health service or health service facility, the acquisition of major medical equipment or any other item or service which qualifies as a new institutional health service. Other than the proposed project expenditure which exceeds \$2,000,000.00, and from which Mission qualifies for an exemption pursuant to N.C. Gen. Stat. 131E-184(g), there are no other “new institutional health service” definitional elements that apply to the Proposed Project.

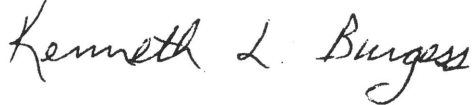
**Conclusion**

For the reasons recited herein, the proposed project qualifies under the exemption from CON Section review set forth at N.C. Gen. Stat. § 131E-184(g). Please allow this letter to serve as the advance written notice required by N.C. Gen. Stat. § 131E-184(g). We would appreciate the CON Section acknowledging at its earliest opportunity that the proposed project, as described herein, is not subject to CON Section Review and that Mission may proceed with the project without first obtaining a CON.

Please let me know if you have questions or need further information regarding this notice.

Micheala Mitchell  
September 13, 2021  
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Very truly yours,

A handwritten signature in black ink that reads "Kenneth L. Burgess". The signature is written in a cursive style with a large initial 'K' and a long, sweeping tail on the 's'.

**Kenneth L. Burgess**  
*Partner*

cc: Joseph R. Rudisill  
Cathi Durham  
Sondra Smith

Exhibits

# EXHIBIT A

**Projected Capital Cost Form  
Mission Hospital USP800 Pharmacy Upgrade**

Building Purchase Price	NA
Purchase Price of Land	NA
Closing Costs	NA
Site Preparation	NA
Construction/Renovation Contract(s)	\$2,082,007
Landscaping	NA
Architect / Engineering Fees	\$230,250.00
Medical Equipment	\$384,000
Non-Medical Equipment	\$190,000
Furniture	\$0.00
Consultant Fees (specify)	\$0.00
Financing Costs	NA
Interest during Construction	NA
Other (Associated Dev Costs)	\$49,180
<b>Total Capital Cost</b>	<b>\$2,935,437</b>

**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.



\_\_\_\_\_  
Signature of Licensed Architect or Engineer

Date Signed: Sept, 10, 2021

**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.



\_\_\_\_\_  
Signature of Officer/Agent

Date Signed: Sept. 10, 2021

Director, Facility Planning, Design & Construction  
Title of Officer/Agent



## EXHIBIT B

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**STATEMENT OF JOSEPH R. RUDISILL**

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1. I am the Chief Operating Officer for MH Mission Hospital, LLLP (“Mission). I am providing this Statement in support of Mission Hospital’s Notice of Exemption to the N.C. Certificate of Need Section in connection with Mission’s main pharmacy renovation project.

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

3. I am personally familiar with the Proposed Project which involves renovating and expanding the hospital’s main pharmacy which is located in the hospital’s main building on the main campus at 509 Biltmore Avenue, Asheville, N.C.

4. I certify that the total costs of the project are approximately TWO MILLION, NINE HUNDRED THIRTY-FIVE THOUSAND, FOUR HUNDRED AND THIRTY-SEVEN DOLLARS (\$2,935,437.00).

5. Furthermore, as part of this Proposed Project, Mission Hospital will not acquire any new major medical equipment as defined in the CON Statute, increase total bed capacity, redistribute health service facility beds among categories designated in the CON Statute or develop any other new institutional health services described in N.C. Gen. Stat. §131E-176 (16).

This the 8th day of September, 2021.

**Joseph R.  
Rudisill**

Digitally signed by Joseph R.  
Rudisill  
Date: 2021.09.08 10:56:10  
-04'00'

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

**From:** [Lightbourne, Ena](#)  
**To:** ["Burgess, Kenneth L."](#); [Mitchell, Micheala L](#); [Pittman, Lisa](#); [Waller, Martha K](#)  
**Subject:** RE: [External] Mission Hospital Pharmacy Renovation Exemption Notice  
**Date:** Monday, September 13, 2021 10:13:56 AM  
**Attachments:** [image002.png](#)  
[image003.png](#)  
[image004.png](#)

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Received. Thanks Ken.

Martha, can you log this? Thank you.

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**From:** Burgess, Kenneth L. <KBurgess@poynerspruill.com>  
**Sent:** Monday, September 13, 2021 10:07 AM  
**To:** Mitchell, Micheala L <Micheala.Mitchell@dhhs.nc.gov>; Pittman, Lisa <lisa.pittman@dhhs.nc.gov>; Lightbourne, Ena <ena.lightbourne@dhhs.nc.gov>  
**Subject:** [External] Mission Hospital Pharmacy Renovation Exemption Notice

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

Good morning Micheala, Lisa and Ena. Attached please find an Exemption Notice I am filing on behalf of my client MH Mission Hospital, LLLP in connection with the renovation of Mission's main pharmacy at the hospital's main building. Please let me know if you have any questions or need additional information regarding the Exemption Notice. Thanks, Ken Burgess

Kenneth L. Burgess | Partner

**Poyner Spruill**<sup>LLP</sup>  
ATTORNEYS AT LAW

1151 Falls Road, Suite 1000

Rocky Mount, N.C. 27804

**D:** 919 783 2917 | **M:** 919 449 4754

[Kburgess@poynerspruill.com](mailto:Kburgess@poynerspruill.com) | [www.poynerspruill.com](http://www.poynerspruill.com)



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