



North Carolina Department of Health and Human Services  
Division of Health Service Regulation

Pat McCrory  
Governor

Aldona Z. Wos, M.D.  
Ambassador (Ret.)  
Secretary DHHS

Drexdal Pratt  
Division Director

April 30, 2015

Catharine W. Cumber, Regulatory Counsel, Strategic Planning  
Duke University Health System  
3100 Tower Blvd, Suite 1300  
Durham NC 27707

**Exempt from Review**

Facility: Duke Raleigh Hospital  
Project Description: Renovation of the pharmacy  
County: Wake  
FID #: 923421

Dear Ms. Cumber:

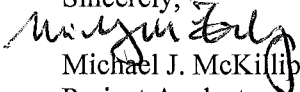
The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of April 16, 2015, the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-184(a)(1b). Therefore, you may proceed to 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,

  
Michael J. McKillip  
Project Analyst

  
Martha J. Frisone, Assistant Chief  
Certificate of Need

cc: Construction Section, DHSR  
Acute and Home Care Licensure and Certification Section, DHSR  
Assistant Chief, Healthcare Planning



**Healthcare Planning and Certificate of Need Section**

www.ncdhhs.gov

Telephone: 919-855-3873 • Fax: 919-733-8139

Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

An Equal Opportunity/ Affirmative Action Employer



 **Duke University Health System**

**Catharine W. Cummer**  
Regulatory Counsel, Strategic Planning

April 16, 2015

Via Electronic Mail

Michael J. McKillip, Project Analyst  
Certificate of Need Section  
Division of Health Service Regulation  
2704 Mail Service Center  
Raleigh, NC 27699-2704

Re: Exemption Notice

Dear Mr. McKillip:

On behalf of the Duke University Health System d/b/a Duke Raleigh Hospital, I am writing to provide notice of a project to renovate and upgrade the pharmacy at the Duke Cancer Center Macon Pond facility. The facility was acquired by DUHS in 2014, and was designated as a hospital provider-based clinic on January 20, 2015.

This renovation project is necessary for the pharmacy at this site to comply with state board of pharmacy standards and to comply with accreditation and certification standards under Title XVIII of the Social Security Act. Specifically, Board of Pharmacy regulations at 21 NCAC 46 .2801(e) (amended effective January 1, 2015) require that "The preparation, labeling, and dispensing of sterile compounded preparations shall comply with standards established by United States Pharmacopeia chapter 797, including all United States Pharmacopeia chapters and standards incorporated into chapter 797 by reference and including all subsequent amendments and editions of the same, governing both the sterile compounded products and the physical and environmental conditions under which sterile compounded products are prepared, labeled, and dispensed." As a hospital facility, Duke Raleigh Hospital is required to have a pharmacy permit to compound medication at the Macon Pond site and therefore must meet the standards established in Chapter 797. 42 CFR 482.25 includes as a condition of participation a requirement that "All compounding, packaging, and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with State and Federal laws." Until the renovation project is completed, Duke Raleigh Hospital must contract with a mobile pharmacy to ensure compliance with these requirements.



Michael J. McKillip  
April 16, 2015

The necessary pharmacy upgrades included in this project to meet the Chapter 797 requirements include increasing HEPA filtered airflow to provide sufficient positive and negative airflow, separating ante and buffer space from the general pharmacy area, and creating a location for donning proper protective equipment before entering the buffer space for compounding medication.

We seek confirmation that this project is exempt from CON requirements pursuant to NCGS Section 131E-184(a)(1a) and (1b) as necessary to comply with State licensure standards and to comply with accreditation or certification standards which must be met to receive reimbursement under Title XVIII of the Social Security Act or payments under a State plan for medical assistance approved under Title XIX of that act.

Thank you for your attention to this notice and request. Please let me know if you have any questions.

Very truly yours,

A handwritten signature in cursive script, appearing to read "Catharine W. Cummer".

Catharine W. Cummer