



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

July 8, 2015

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

Exempt from Review – Replacement Equipment

Record #: 1632
Facility Name: Duke University Hospital
FID #: 943138
Business Name: Duke University Health System
Business #: 639
Project Description: Replace chemistry analyzer
County: Durham

Dear Ms. Cummer:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of June 23, 2015, the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-184(f). Therefore, you may proceed to acquire, without a certificate of need, the Beckman Chemistry Analyzer. This determination is based on your representations that the unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need.

Moreover, 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 the Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this office and a separate determination. 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
Assistant Chief, Healthcare Planning
Acute and Home Care Licensure and Certification Section, DHSR



Healthcare Planning and Certificate of Need Section

www.ncdhhs.gov

Telephone: 919-855-3873 • Fax: 919-715-4413

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



June 23, 2015

Via Electronic Mail and United States Mail

Martha Frisone
Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

Re: Exempt Replacement Project at Duke University Hospital

Dear Ms. Frisone:

The purpose of this letter is to request the Section's written confirmation that the acquisition of a Beckman chemistry analyzer satisfies the requirements under N.C.G.S. 131E-184(f) for "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.

As set forth below, we believe that Duke University Hospital's project is now exempt from certificate of need review.

(1) Main Campus

The purpose of this project is to replace existing chemistry analysis equipment that, after replacement, will be located in the part of Duke University Hospital identified as the Hudson Building, which is located on the main campus of Duke University Hospital. The "main

Martha Frisone
June 23, 2015

campus” of the facility is defined in N.C.G.S. 131E-176(14n) to include both “[t]he 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 “[o]ther areas and structures that are not strictly contiguous to the main building but are located within 250 yards of the main building.”

In this case, Duke University Hospital is a licensed health service facility (see License attached as Exhibit A), and the main hospital building from which Duke University Hospital provides its clinical services and exercises financial and administrative control is the physically contiguous structure that includes Duke South, Duke North, the Duke Children’s Hospital, the Duke Medical Pavilion, the Morris Clinic, the Duke Cancer Center, the Wadsworth Building, and the new Hudson Building. A map of the hospital showing the location of the replacement equipment is attached as Exhibit B.

(2) Previous Certificate of Need.

As set forth in the correspondence attached as Exhibit C, Duke received confirmation in 2006 that the existing equipment did not require certificate of need review.

(3) Replacement equipment

The new equipment will replace two existing analyzers. The equipment qualifies as replacement equipment pursuant to the existing statutory and regulatory definitions. A completed Equipment Comparison form is enclosed as Exhibit D. Both the existing equipment and the replacement equipment provide chemistry tests. The total project cost exceeds \$2,000,000 reflecting equipment and installation expenses. A copy of the equipment quotation is available upon request. Duke will not acquire any other major medical equipment or develop any other new institutional health services other than those described in Section 131E-176(16)(b).

Thank you for your attention to this request. If you have questions about this information, please let me know.

Very truly yours,



Catharine W. Cummer

Enclosures

State of North Carolina

Department of Health and Human Services Division of Health Service Regulation

Effective January 01, 2015, this license is issued to

Duke University Health System, Inc.

to operate a hospital known as

Duke University Hospital

located in Durham, North Carolina, Durham County.

*This license is issued subject to the statutes of the
State of North Carolina, is not transferable and shall remain
in effect until amended by the issuing agency.*

Facility ID: 943138

License Number: H0015

Bed Capacity: 957

General Acute 938, Psych 19,

Dedicated Inpatient Surgical Operating Rooms: 4

Dedicated Ambulatory Surgical Operating Rooms: 9

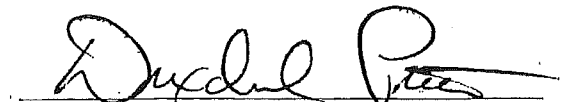
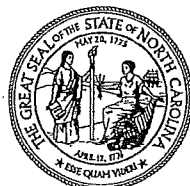
Shared Surgical Operating Rooms: 36

Dedicated Endoscopy Rooms: 10

Authorized by:



**Secretary, N.C. Department of Health and
Human Services**



Director, Division of Health Service Regulation

EX A



Campus Plan

5.12.2016



North Carolina Department of Health and Human Services
Division of Facility Services
Certificate of Need Section

2704 Mail Service Center ■ Raleigh, North Carolina 27699-2704

Michael F. Easley, Governor
Carmen Hooker Odom, Secretary

<http://facility-services.state.nc.us>

Lee Hoffman, Section Chief
Phone: 919-855-3873
Fax: 919-733-8139

October 26, 2006

Duncan Yaggy, Chief Planning Officer
Duke University Health System
3100 Tower Boulevard
Suite 600, Box 80
Durham, NC 27707

RE: Exempt from Review - Replacement Equipment/Duke University Health System/Acquisition of analyzers for the clinical laboratories/Durham County

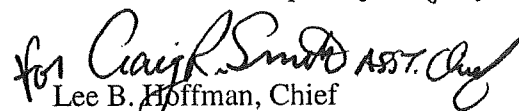
Dear Mr. Yaggy:

In response to your letter of October 12, 2006, the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(7). Therefore, you may proceed to acquire, without a certificate of need, the Beckman Coulter lab analyzers to replace the existing lab analyzers. This determination is based on your representations that the existing unit will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need. Further please be advised that as soon as the replacement equipment is acquired, you must provide the CON Section and the Medical Facilities Planning Section with the serial number of the new equipment to update the inventory, if not already provided.

It should be noted that this Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this Agency and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,


Michael J. McKillip, Project Analyst


Lee B. Hoffman, Chief
Certificate of Need Section

cc: Medical Facilities Planning Section, DFS



EX C



DUKE UNIVERSITY HEALTH SYSTEM

Duncan Yaggy
Chief Planning Officer

October 12, 2006

Mr. Michael J. McKillip, Project Analyst
Ms. Lee B. Hoffman, Chief
Certificate of Need Section
Division of Facility Services
Department of Health & Human Services
2704 Mail Services Center
Raleigh, NC 27699-2704

Re: Request for Letter of No Review for Replacement of Analyzers

Dear Mr. McKillip and Ms. Hoffman:

This letter requests your written confirmation that the acquisition and installation of 21 analyzers to replace 30 existing analyzers in 10 clinical laboratories operated by Duke University Health System (DUHS) will not require certificate of need review.

The distribution of the existing analyzers and the proposed analyzers among DUHS laboratories is described on the first sheet attached and on page 3 of the enclosed quotation from Beckman Coulter (under the heading "Analytical Equipment"). The price of the components is shown on the second sheet attached. (See the items marked "E" for "Equipment".)

Altogether, the components forming the 21 analyzers will cost a total of \$3,647,704, or an average of \$173,700 per analyzer. None of the analyzers, fully assembled, will cost as much as \$400,000.

We believe that the replacement of 30 existing analyzers with 21 new analyzers performing the same tests better and faster is exempt from CON review because:

Page Two

1. The analyzers operate separately and independently of one another. The replacement of one or two existing analyzers by a new analyzer does not entail the replacement of any other analyzer(s). The replacement project is therefore appropriately described as 21 separate projects, grouped together in a single project, partly for convenience and partly for the discount that buying all 21 at once makes possible. But we could certainly purchase and install them one at a time.

2. Fully installed, none of the new analyzers will cost as much as \$400,000.

3. The new analyzers will perform the same tests and procedures as those the existing analyzers now perform. The new analyzers will not be used to perform a new health service.

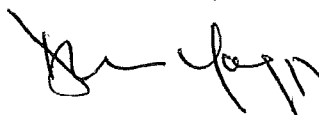
4. The replacement of the existing analyzers with new analyzers will not cause an increase of as much as 10% in the charges for laboratory tests or the costs incurred in performing the tests.

To document this request and facilitate its consideration I enclose a completed comparison table showing relevant information for one of the new analyzers and the analyzer it will replace. I also enclose:

- Brochures describing the existing analyzer and its proposed replacement;
- The quotations from Beckman Coulter, and
- A letter from Jeff Myers attesting to the fact that the 30 existing analyzers are still in use.

Thank you for your consideration of this request. If you would like further information, please let me know.

Sincerely,



Duncan Yaggy

DY:dw

Enclosures

A X W

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	Chemistry Analyzer	Chemistry Analyzer
Manufacturer of Equipment	Beckman Coulter	Beckman Coulter
Tesla Rating for MRIs	NA	NA
Model Number	DXC 800 (2 analyzers)	TBD
Serial Number	2271 and 2307	TBD
Provider's Method of Identifying Equipment	150451 and 150452	Asset # TBD
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN #	NA	NA
Mobile Tractor Serial Number/VIN #	NA	NA
Date of Acquisition of Each Component	09/14/2007	TBD
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	Capital Lease
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>	NA	NA
Total Cost of Equipment	\$3,746,104 *	NA
Fair Market Value of Equipment	\$3,746,104*	\$6,185,000 (purchase quote price)
Net Purchase Price of Equipment	\$3,746,104*	NA
Locations Where Operated	DUH Main Campus CARL Bldg	DUH Main Campus Hudson Bldg
Number Days In Use/To be Used in N.C. Per Year	365	365
Percent of Change in Patient Charges (by Procedure)	N/A	0
Percent of Change in Per Procedure Operating Expenses (by Procedure)	N/A	0
Type of Procedures Currently Performed on Existing Equipment	Chemistry Tests	N/A
Type of Procedures New Equipment is Capable of Performing	N/A	Chemistry Tests

*Total cost of existing equipment included 21 analyzers used at multiple locations. This project is replacing 2 analyzers at one of those locations.