

# DEPARTMENT OF HEALTH AND HUMAN SERVICES DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER GOVERNOR MANDY COHEN, MD, MPH SECRETARY

> MARK PAYNE DIRECTOR

November 15, 2017

Gary S. Qualls K & L Gates 430 Davis Drive, Suite 400 Morrisville NC 27560

Exempt from Review - Replacement Equipment

Record #: 2438

Facility Name: UNC Rex Hospital

FID #: 953429

Business Name: Rex Hospital, Inc.

Business #: 1554

Project Description: Replace an existing mobile cardiac catheterization unit by upgrading an existing vascular

imaging unit to be capable of performing cardiac catheterization procedures

County: Wake

Dear Mr. Qualls:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of November 9, 2017, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(a)(7). Therefore, you may proceed to acquire without a certificate an upgrade of the existing vascular imaging equipment to replace the existing mobile cardiac catheterization equipment. This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

Moreover, you 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.

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,

cc:

Michael J. McKillip

Project Analyst

Martha J. Frisone

Chief, Healthcare Planning and Certificate of Need Section

Sharetta Blackwell, Program Assistant, Healthcare Planning, DHSR

Acute and Home Care Licensure and Certification Section, DHSR

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

WWW.NCDHHS.GOV TELEPHONE 919-855-3873

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





November 9, 2017

Gary S. Qualls D 919.466.1182 F 919.516.2182 gary.qualls@klgates.com

# Via Hand Delivery

Martha Frisone Chief, Certificate of Need Department of Health and Human Services Division of Health Service Regulation Health Planning and Certificate of Need Section 809 Ruggles Drive Raleigh, North Carolina 27603

RE: Rex Hospital, Inc. – Exemption Notice for Acquisition of Replacement Cardiac Catheterization Equipment at Rex Hospital's Main Campus, Wake County

#### Dear Ms. Frisone:

Our client, Rex Hospital, Inc. d/b/a UNC REX ("Rex"), seeks to acquire a Mobile Cardiac Catheterization Unit from FirstHealth of the Carolinas, Inc. ("FirstHealth"). This Mobile Cardiac Catheterization Unit is grandfathered under the Certificate of Need ("CON") law because it was in use in the State prior to March 18, 1993 and has been in use continuously. See Exhibits 1 and 2, Exempt from Review Letters dated October 29, 1998 and November 9, 1998. Thus, this "Grandfathered Cath Unit" is also considered a grandfathered mobile Diagnostic Center under N.C. Gen. Stat. § 131E-176(7a) because it is a grandfathered mobile diagnostic program. Currently this Grandfathered Cath Unit is serving Rex two days a week through a contract between FirstHealth and Rex.

#### Rex intends to:

- (1) acquire the Grandfathered Cath Unit from FirstHealth as an exempt acquisition of an existing grandfathered mobile Diagnostic Center pursuant to N.C. Gen. Stat. §§ 131E-184(a)(8) and 131E-176(7a);
- then replace the Grandfathered Cath Unit (also referred to herein as the "Existing Equipment") with a different cardiac cath unit (the "Replacement Equipment") and will house the Replacement Equipment in Rex Hospital rather than in the mobile coach that currently houses the Grandfathered Cath Unit.

# I. Step #1: Acquire the Grandfathered Cath Unit as an Exempt Diagnostic Center

As a first step, Rex will acquire the Grandfathered Cath Unit from FirstHealth as an exempt acquisition of an existing grandfathered mobile Diagnostic Center pursuant to N.C. Gen. Stat. §§ 131E-184(a)(8) and 131E-176(7a). Exhibits 1 and 2 are attached as proof of grandfathered status. As referenced above, FirstHealth's Grandfathered Cath Unit is a grandfathered mobile Diagnostic Center under N.C. Gen. Stat. § 131E-176(7a). The Section 176(7a) definition of Diagnostic Center specifically includes mobile diagnostic programs.

# II. Step #2: Replacement Equipment Exemption

After the acquisition in Step #1 above, Rex intends to then replace the Grandfathered Cath Unit (also called the "Existing Equipment") with a different cardiac cath unit (the "Replacement Equipment") and will house the Replacement Equipment in Rex Hospital's Heart Tower on its Main Campus<sup>1</sup> rather than in the mobile coach which currently houses the Grandfathered Cath Unit.

Instead of acquiring a new piece of cardiac cath equipment, Rex will instead denominate a unit of existing vascular equipment at Rex as the "Replacement Equipment" and will convert that Replacement Equipment to cardiac cath use by adding software to enable that use. The Replacement Equipment is identified by serial number in Exhibit 3, which is the CON Replacement Equipment Comparison Form ("Comparison Form"). The Replacement Equipment will be located in the same location where it is currently used as a vascular unit.

This letter is to provide the Agency with notice and to request confirmation that:

- Rex may acquire the Grandfathered Cath Unit from FirstHealth as an exempt acquisition of an existing grandfathered mobile Diagnostic Center pursuant to N.C. Gen. Stat. §§ 131E-184(a)(8) and 131E-176(7a);
- 2) Rex's Replacement Equipment described herein is exempt from CON review pursuant to N.C. Gen. Stat. § 131E-184(a)(7); and
- Rex will have the right to reconvert the grandfathered Replacement Equipment to mobile use again without a CON so long as no relevant cost thresholds or other CON new institutional health service definitions are triggered in the process.

<sup>&</sup>lt;sup>1</sup> Even though this equipment replacement will be on Rex's Main Campus, Rex does not need to invoke the main campus replacement equipment provisions contained in N.C. Gen. Stat. § 131E-184(f) because the costs for the Replacement Equipment here do not exceed \$2 Million.

The General Assembly has chosen to exempt certain, otherwise reviewable events from CON review. Among those exemptions is the acquisition of "replacement equipment," defined as follows in the CON law:

"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).

In addition to the foregoing, to qualify for this exemption, the replacement equipment must be "comparable" to the equipment it replaces and must be "sold or otherwise disposed of when replaced." Rex's proposal qualifies for this exemption.

# A. Cost of the Replacement Equipment

The total cost to acquire, install, and make operational the Replacement Equipment is \$13,000. See Exhibit 4 (this shows the costs to upgrade the Existing Equipment -- vascular equipment -- to cardiac cath use). No additional capital costs will be expended regarding the Replacement Equipment because Rex already owns it, having purchased the Replacement Equipment in 2015, where it has since been used as non-cardiac cath vascular equipment.

### B. Comparable Equipment

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).

Rex intends to use the Replacement Equipment for substantially the same types of services for which the Existing Equipment it currently used. The Existing Equipment (i.e., the Grandfathered Cath Unit) performs a wide range of cardiac cath procedures, as will the Replacement Equipment.

The Replacement Equipment will perform all procedures currently performed on the Existing Equipment. Although it possesses some expanded capabilities due to technological improvements, the Replacement Equipment will perform the same general range of

procedures as the Existing Equipment. <u>See</u> Exhibit 3, Comparison Form. The Replacement Equipment is therefore "comparable medical equipment" as defined in Subsection (c).

Furthermore, Rex does not intend to increase patient charges or per procedure operating expenses more than 10% within the first 12 months after its acquisition. For further equipment comparison, please refer to Exhibit 3, the Comparison Form.

Subsection (d) of the Regulation further provides that the Replacement Equipment must meet the following tests:

- (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 Form  $\underline{See}$  Exhibit 3. Moreover, Rex represents that use of the Replacement Equipment will not result in the types of expense or charge increase described in Subsection (d)(3).

# D. <u>Disposition of Existing Equipment</u>

As part of the proposal, Rex will decommission the Existing Equipment acquired from FirstHealth and put it in storage. Rex will not operate the Existing Equipment without further authorization from the Agency.

# **CONCLUSION**

Based on the foregoing information, Rex provides exemption notices under N.C. Gen. Stat. §§ 131E-184(a)(7) and (a)(8), and hereby requests that the Agency provide a written response confirm the following:

- Rex may acquire the Grandfathered Cath Unit from FirstHealth as an exempt acquisition of an existing grandfathered mobile Diagnostic Center pursuant to N.C. Gen. Stat. §§ 131E-184(a)(8) and 131E-176(7a);
- 2) Rex's Replacement Equipment described herein is exempt from CON review pursuant to N.C. Gen. Stat. § 131E-184(a)(7); and
- Rex will have the right to reconvert the grandfathered Replacement Equipment to mobile use again without a CON so long as no relevant cost thresholds or other CON new institutional health service definitions are triggered in the process.

If the Agency needs additional information to assist in its consideration of this request, please apprise us as soon as possible. We thank you for your consideration of this notice.

Sincerely,

Dary S. Qualls

# **Exhibits**

- Notice of Exempt Acquisition by FirstHealth of the Carolinas, Inc. dated October 29, 1998
- 2. Exempt from Review Letter dated November 9, 1998
- 3. CON Equipment Comparison Form
- 4. Documentation of Purchase Price of Replacement Equipment (software upgrades to existing equipment)



# KILPATRICK STOCKTON LLP

Attorneys at Law
Suite 400
4101 Lake Boone Trail
Raleigh, North Carolina 27607-6519
Telephone: 919.420.1700
Facsimile: 919.420.1800
Web site: www.kilstock.com

NOAH H. HUFFSTETLER, III E-mail: nhuffstetler@kilstock.com Direct Dial: 919.420.1812

October 29, 1998

# HAND DELIVERED

Ms. Lee B. Hoffman, Chief North Carolina Department of Health and Human Services Division of Facilities Management Certificate of Need Section 701 Barbour Drive - Council Bldg. Raleigh, NC 27602-0629

Re: Notice of Exempt Acquisition by FirstHealth of the Carolinas, Inc.

Dear Ms. Hoffman:

As we have discussed by telephone, Riverside Health System of Newport News, Virginia, currently owns and operates a mobile cardiac catheterization laboratory which was located and in use in North Carolina prior to March 18, 1993, and has been continuously located and utilized in North Carolina to the present date. At the present time this laboratory is used by Riverside to provide services at Roanoke-Chowan Hospital, in Ahoskie, North Carolina. Riverside plans to create a new wholly-owned corporate subsidiary to be known as Riverside North Carolina Catheterization Services, Inc. ("the Provider"). The above-referenced cardiac catheterization laboratory, which is the only equipment of this kind that Riverside currently operates in North Carolina, will be owned by the Provider and any contracts for its use by North Carolina hospitals will be assigned to the Provider. Our client, FirstHealth of the Carolinas, Inc., ("FirstHealth") will purchase the Provider from Riverside and will locate its mobile cardiac catheterization laboratory on the campus of FirstHealth Moore Regional Hospital in Pinehurst, North Carolina. The Provider will thereafter be a wholly owned corporate subsidiary of FirstHealth. At some time in the future, FirstHealth may elect to merge the Provider into FirstHealth or one of its other corporate subsidiaries.

The purposes of this letter are as follows:

 to notify the Department of Human Resources ("Department") of the transaction described above, as provided in N.C.G.S. § 131E-184(a);

## KILPATRICK STOCKTON LLP

Ms. Lee B. Hoffman, Chief October 29, 1998 Page 2

- (2) to explain briefly the reasons for the transaction; and
- to request that the Department confirm that the transaction is exempt from certificate of need review under N.C.G.S. § 131E-184(a)(8).

FirstHealth desires to acquire the Provider from Riverside in order to increase patient access to cardiac catheterization services in its service area. Utilization of cardiac catheterization equipment as a diagnostic and interventional tool continues to increase. As the only tertiary facility in a six county service area, the demand for cardiac catheterization services at FirstHealth Moore Regional Hospital has continued to see significant increases -- approximately 17% per year over the past four years.

FirstHealth believes that this transaction should not require it to first obtain a certificate of need, as provided in N.C.G.S. § 131E-178. As you know, N.C.G.S. § 131E-184(a)(8) provides an exemption from certificate of need review for a proposal to "acquire an existing health service facility, including equipment owned by the health service facility at the time of acquisition." Under N.C.G.S. § 131E-176(9b), the term "health service facility" is defined to include a "diagnostic center." In turn, the term "diagnostic center" is defined by N.C.G.S. § 131E-176(7a) to mean "a freestanding facility, program, or provider, including, but not limited to . . . mobile diagnostic programs, in which the total cost of all the medical diagnostic equipment utilized by the facility which cost ten thousand dollars (\$10,000) or more exceeds five hundred thousand dollars (\$500,000)." Because this transaction involves the acquisition of a mobile diagnostic program in which the total cost of the medical diagnostic equipment utilized by the facility which costs ten thousand dollars (\$10,000) or more is \$1,124,554, this transaction qualifies for the above-referenced exemption.

This notice is timely, because FirstHealth has not yet incurred "an obligation for a capital expenditure which is a new institutional health service," as that term is defined in N.C.G.S. § 131E-178(c), with respect to the proposed acquisition. However, FirstHealth and Riverside hope to conclude the transaction described in this notice on or before December 1, 1998. Therefore, pursuant to this prior written notice, FirstHealth requests the Department to confirm as soon as possible that the proposed acquisition is exempt from certificate of need review under N.C.G.S. § 131E-184(a). Also, please let us know as soon as possible if you need additional information to assist in your consideration of this request.

# KILPATRICK STOCKTON LLP

Ms. Lee B. Hoffman, Chief October 29, 1998 Page 3

Thank you for your prompt consideration of this matter. To confirm the timely submission of this notice, we would appreciate your returning to us the enclosed copy of this letter, stamped with the date of its filing. With best regards, we are

Very truly yours,

KILPATRICK STOCKTON LLP

Noah H. Huffstetler, III

cc: Ms. Lynn DeJaco

Ms. Caroline Martin

Mr. Peter S. Brunstetter

RALLIB01:484444.02

# North Carolina Department of Health and Human Services Division of Facility Services

701 Barbour Drive - Post Office Box 29530 Raleigh, N.C. 27626-0530 Courier Number 56-20-05

James B. Hunt, Jr., Governor H. David Bruton, M.D., Secretary

Lynda D. McDaniel, Director

Certificate of Need Section Phone: (919) 733-6360 Fax: (919) 733-8139

November 9, 1998

Noah H. Huffsteler, III Kilpatrick Stockton LLP Attorneys at Law 4101 Lake Boone Trail, Suite 400 Raleigh, NC 27607-6519

RE: Exempt from Review/ Acquisition by Riverside North Carolina Catheterization Services, Inc. ("Riverside NC"), of Riverside Health System's mobile diagnostic cardiac catheterization program/ Hertford County

RE: Exempt from Review/ Acquisition by FirstHealth of the Carolinas, Inc. ("FirstHealth"), of Riverside North Carolina Catheterization Services, Inc. ("Riverside NC"), including all equipment owned by Riverside NC/ Moore County

## Dear Mr. Huffstetler:

In response to your letter of October 29, 1998, the above referenced proposal is exempt from certificate of need review in accordance with N.C.G.S 131E-184(a)(8). Therefore, FirstHealth may proceed to acquire Riverside Health System's entire cardiac catheterization program in North Carolina, including all cardiac catheterization equipment owned by Riverside Health System that is operated in North Carolina, without first obtaining a certificate of need. This determination is based on the following findings and conclusions:

- 1. Riverside Health System is located in Virginia and has a mobile diagnostic cardiac catheterization program in North Carolina. The mobile cardiac catheterization equipment currently operated by Riverside Health System is not a "mobile diagnostic program" or a "diagnostic center". Rather, Riverside Health System's entire mobile cardiac catheterization program in North Carolina is the "diagnostic center" as defined in N.C.G.S. 131E-176(7a), which would also be the case if Riverside Health System had more than one piece of mobile cardiac catheterization equipment in North Carolina.
- 2. Riverside Health System proposes to create a wholly-owned subsidiary to be known as Riverside North Carolina Catheterization Services, Inc. This company will own all cardiac catheterization equipment operated by Riverside Health System in North Carolina. Further, all contracts for

provision of cardiac catheterization services between Riverside Health System and North Carolina Hospitals will be assigned to Riverside NC. Therefore, Riverside Health System will no longer be a diagnostic center in North Carolina. Rather, Riverside North Carolina Catheterization Services, Inc. will acquire Riverside Health System's entire mobile cardiac catheterization program in North Carolina and consequently, will become the diagnostic center.

- 3. There will be no net increase in the number of diagnostic centers in North Carolina because Riverside Health System's diagnostic center in North Carolina, is being acquired by Riverside North Carolina Catheterization Services, Inc., which will become the new diagnostic center.
- 4. After Riverside NC becomes a diagnostic center, FirstHealth will acquire Riverside NC, including all equipment owned by Riverside NC. Riverside NC will become a wholly owned corporate subsidiary of FirstHealth.

Note that pursuant to N.C.G.S. §131E-181(b): "A recipient of a certificate of need, or any person who may subsequently acquire, in any manner whatsoever permitted by law, the service for which that certificate of need was issued, is required to materially comply with the representations made in its application for that certificate of need."

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,

cc:

Lee B. Hoffman, Chief

Certificate of Need Section

Section Chief, Licensure and Certification Section, DFS

# EQUIPMENT COMPARISON

	EXISTING	REPLACEMENT
	EQUIPMENT	EQUIPMENT
Type of Equipment (List Each Component)	Floor Mounted Single	Ceiling Mounted Single
	Plane X-ray	Plane X-ray
Manufacturer of Equipment	Siemens	Philips
Tesla Rating for MRIs	n/a	n/a
Model Number	Axiom Artis 7412807	Allura Xper FD20
Serial Number	35610	71267710
Provider's Method of Identifying Equipment	Room Number Location	Room Number Location
Specify if Mobile or Fixed	Mobile	Fixed
Mobile Trailer Serial Number/VIN #	1TKH05126XB027601	n/a
Mobile Tractor Serial Number/VIN #	unknown	n/a
Date of Acquisition of Each Component	Not Yet Acquired	Not Yet Acquired
Does Provider Hold Title to Equipment or Have a Capital Lease?	Yes	Yes
Specify if Equipment Was/Is New or Used When Acquired	Used	New
Total Capital Cost of Project (Including Construction, etc.) <use attached="" form=""></use>	n/a	n/a
Total Cost of Equipment	<\$50,000	\$13,000.00
Fair Market Value of Equipment	n/a	
Net Purchase Price of Equipment	n/a	
Locations Where Operated	UNC REX Healthcare	UNC REX Healthcare
Number Days In Use/To be Used in N.C. Per Year	365	365
Percent of Change in Patient Charges (by Procedure)	n/a	n/a
Percent of Change in Per Procedure Operating Expenses (by Procedure)	n/a	n/a
Type of Procedures Currently Performed on Existing Equipment	Cardiac Catheterization	n/a
	and Vascular Imaging	
Type of Procedures New Equipment is Capable of Performing	n/a	Cardiac Catheterization
		and Vascular Imaging



Page: 1 of 1

EXHIBIT

4

PO DATE: 10/17/2017

Acknowledge by email to <u>purchase@unchealth.unc.edu</u> ( preferred ) or fax 919-957-5786 with availability, Ship date, and Reference Nbr upon receipt of this PO.

If shipping charges contractually apply, ship Bill 3<sup>rd</sup> Party via FedEx account # 321417647, FOB Destination. If weight exceeds 150lbs, call 888-457-5851 for instructions.

PHILIPS MEDICAL SYSTEMS
CONTRACTS ADMINISTRATION
22100 BOTHELL-EVERETTE HWY
BOTHELL WA 98041-3003
ACCOUNT:

Contact Susan Phillippi (Agent) Phone 984-974-6590

PRODUCT TOTAL: \$13,000.00

# **PURCHASE ORDER NUMBER**

#### 95100004687-0-9

SHOW PO NUMBER ON ALL SHIPPING LABELS, INVOICES, PACKING LIST, BILLS OF LADING. COPIES OF PACKING LIST MUST ACCOMPANY ALL SHIPMENTS. FAILURE TO COMPLY WILL RESULT IN REJECTION OF SHIPMENTS AND NONPAYMENT OF INVOICES.

REX Healthcare

MAIL Accounts Payab

MAIL Accounts Payable Department 4400 Emperor Boulevard

TO: Suite 100

Durham, NC 27703

SHIP TO: REX HEALTHCARE

4420 LAKE BOONE TRAIL

REX HEART & VASCULAR TOWER ATTN JASON DUBRAY 919.357.7154

PO 95100004687-0-9 RALEIGH NC 27607

TOTAL

SHIP	rerms: F	ree On	Board Destination SHIP VIA: INSTALLED		
TERM	S: NET 30	0	FREIGHT TERMS: Vendor Expense	PRICE	TOTAL
LINE	QTY	UOM	DESCRIPTION		
1	1.0000	LO	Purchase Order Currency: US Dollars Invoice by mail QUOTE 1-1085JCP  DATED 9.23.2017 ATTN: BETHANN GRIFFITH-SUBIK  18-241500.01 101000-200700-510018241500.01-15002  NCVA VENTRICULAR QUANT SW PKG Deliver on November 3, 2017 SOFTWARE LICENSE UPGRADE	13,000.0000	13,000.00

\$13,000.00