



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 3, 2014

Lynn DeJaco
155 Memorial Drive
P.O. Box 3000
Pinehurst, NC 28374

Exempt from Review - Replacement Equipment

Facility: FirstHealth Moore Regional Hospital
Project Description: Replace cardiac catheterization unit located at FirstHealth Moore Regional Hospital
County: Moore
FID #: 943358

Dear Ms. DeJaco:

In response to your letter of June 4, 2014, 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 Toshiba Infinix-I Dual Plane cardiac catheterization unit, serial number to be determined at purchase, to replace the existing Toshiba Infinix CS cardiac catheterization unit, serial number 212480. 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. Furthermore, please be advised that as soon as the replacement equipment is acquired, you must provide the CON Section with the serial number of the new equipment to update the inventory.

Moreover, you need to contact the 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 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,

Tanya S. Rupp
Project Analyst

Martha J. Frisone, Interim Chief
Certificate of Need Section

cc: Acute and Home Care Licensure and Certification Section, DHR
Construction Section, DHR
Medical Facilities Planning Branch, DHR



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



June 4, 2014

Ms. Martha Frisone
Chief, Certificate of Need Section
Department of Health Service Regulation
809 Ruggles Drive
Raleigh, NC 27603



RE: Request for No Review Determination for Replacement of Cardiac Catheterization Unit located at FirstHealth Moore Regional Hospital / Moore County

Dear Mr. Smith:

Pursuant to T10 NCAC 3R.0304(a), FirstHealth Moore Regional Hospital (FMRH) intends to replace an existing cardiac catheterization unit and requests a determination that such replacement falls within the definition of NCGS 131E-184 (a)(7) and the regulations set out in T10.3R.0214, as exempt from review.

Statement of Facts

FRMH proposes to replace an existing Toshiba Infinix CS cardiac catheterization unit that was purchased in January 2004. The existing cardiac catheterization unit is outdated and has limited capabilities in its ability to be upgraded. FMRH has determined that it would be most effective to replace the existing cardiac catheterization unit with state-of-the-art technology that can be further upgraded in the future.

Exemption from Review

Pursuant to NCGS 131E-184(a)(7) "The department shall exempt from certificate of need review a new institutional health service if it receives prior written notice from the entity proposing the new institutional health service, when notice includes an explanation of why the new institutional health service is required, for any of the following: ... (7) To provide replacement equipment."

NCGS 131E-176(22a) defines "replacement equipment" as equipment that cost less than \$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.

Applicable Regulations

NCAC T10: 03R .0214 defines "comparable medical equipment" as equipment that is functionally similar and which is used for the same diagnostic or treatment purposes. Replacement equipment is comparable if:

- (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.

Replacement equipment is not comparable to the equipment being replaced if the replacement equipment is capable of performing procedures that could result in the provision of a new health service or type of procedure that has not been provided with the existing equipment.

Compliance

FirstHealth Moore Regional Hospital hereby certifies that:

1. The estimated replacement cost for the cardiac catheterization unit is \$1,174,250. This assumes purchase of a Toshiba Infinix-I Dual Plane cardiovascular system per the attached quotations (Exhibit A). Renovation and A/E costs are \$98,000 for a total project cost of \$1,272,250 (Exhibit B).
2. The replacement equipment will be purchased for the sole purpose of replacing comparable equipment currently in use, which will be dismantled by Toshiba Medical Systems. A comparison of the existing and replacement equipment is provided in Exhibit C.
3. The replacement equipment is functionally similar to existing equipment and will be used for the same diagnostic and/or treatment procedures as the equipment currently in use.
4. No increase in charges will occur within the first twelve months after the replacement equipment is acquired.
5. The average cost per cardiac catheterization procedure increases by \$0 (0%) as a result of the replacement.

Determination Requested

FirstHealth Moore Regional Hospital requests that the Division of Health Service Regulation make a determination that replacement of existing cardiac catheterization unit as proposed herein does not constitute a new institutional health service and is thus exempt from certificate of need review.

If you require additional information concerning this request, please contact me at 910-715-1981.

Sincerely,

A handwritten signature in black ink, appearing to read 'Lynn DeJaco', with a long horizontal flourish extending to the right.

Lynn DeJaco
Chief Financial Officer

Attachments: Exhibit A - Vendor Quotes
 Exhibit B - Proposed Total Capital Cost of Project
 Exhibit C - Existing/Replacement Equipment Comparison

TOSHIBA

Leading Innovation >>>

TOSHIBA AMERICA MEDICAL SYSTEMS, INC.

**QUOTATION/ORDER
ORDER SUMMARY**

PRESENTED TO: (COMPLETE LEGAL NAME)
FIRSTHEALTH MOORE REGIONAL
HOSPITAL
35 MEMORIAL DR
PINEHURST, NC. 28374

DATE: 3/6/2014
DELIVER TO:
FIRSTHEALTH MOORE REGIONAL HOSPITAL
35 MEMORIAL DR
PINEHURST, NC. 28374

SID NO: 30012973
QUOTE NO: 46248

EQUIPMENT SUMMARY:

DPI8/1216.000

**INFINIX-I DUAL PLANE
CARDIOVASCULAR SYSTEM**

VASCULAR DP-I/FD2 SYSTEM WITH CAT-850B TABLE

DP-I/FD2 MAIN SYSTEM WITH CAT-850B TABLE

STEPPING UNIT FOR CAT-850B

SITE LAYOUT TO BE DETERMINED

21 INCH COLOR MONITOR

VGA CONNECTION ADAPTER

LCD FLAT-PANEL COLOR MONITOR 21"

CABLE CARRIER KIT, 8'

ARMREST SET

This quotation shall remain valid until March 28, 2014.

All prices are F.O.B. destination.

Payment terms are: Cash - 0% down payment, 80% upon shipment, 20% net 30 days after shipment or upon availability for first use by purchaser, whichever comes first.

Additional terms and conditions appear at the end of this quotation. McKesson Agreement Required Yes No
Vital Software License Agreement Required Yes No

Please return signed quotation to: Toshiba America Medical Systems, 2441 Michelle Drive, Tustin, CA 92780.

ACCEPTED AGREED AND ORDERED:

CUSTOMER REQUESTED DELIVERY DATE:


PURCHASER'S SIGNATURE/TITLE

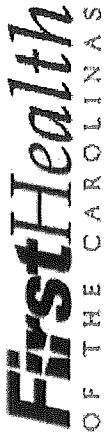
DATE


TOSHIBA REP/CONTACT

ZONE SALES MANAGER

2 Apr 2014
DATE

DATE



PO Number: 606836C
PO Date: 04/02/2014

Vendor:
TOSHIBA AMERICA MEDICAL SYSTEMS INC
2441 MICHELLE DR

TUSTIN, CA 92780
Phone: 8005211968
Fax:

Ship To:
FIRSTHEALTH MOORE REGIONAL HOSPITAL
ATTN RECEIVING
110 PAGE ROAD NORTH

PINEHURST, NC 28374
GLN:
Phone:
Fax: 910-715-1088

Bill To:
ACCOUNTS PAYABLE - FHC
FIRSTHEALTH MOORE REGIONAL HOSPITAL
ATTN ACCOUNTS PAYABLE
P.O. BOX 3000
PINEHURST, NC 28374

Phone:
Fax: 910-715-1088

Terms & Conditions :

THE PURCHASE AND ACCEPTANCE OF THE EQUIPMENT LISTED BY THIS PURCHASE ORDER IS SUBJECT TO EVALUATION FOR SAFETY AND SUITABILITY FOR INTENDED USE IN ACCORDANCE WITH NATIONALLY RECOGNIZED STANDARDS. THE EVALUATION SHALL BE CONDUCTED BY A QUALIFIED TESTING LABORATORY APPROVED BY THE COMMISSIONER OF INSURANCE OF THE STATE OF NORTH CAROLINA, OR BY ANY SPECIFIC ALTERNATIVE EVALUATION AUTHORIZED BY THE ENGINEERING DIVISION OF THE DEPARTMENT OF INSURANCE.


ORDER TO INCLUDE:

- ONE EACH SERVICE MANUAL
- ONE EACH OPERATOR'S MANUAL
- AT NO CHARGE FirstHealth Hospitals

if shipment cannot be made at these prices, notify purchasing prior to shipping. No item may be substituted on this order without our permission. Electrical equipment used in a hospital environment must comply with NC General statute 66-23 through 66-27, Article 4.



PO Number: 606836C
PO Date: 04/02/2014

Vendor: TOSHIBA AMERICA MEDICAL SYSTEMS INC 2441 MICHELLE DR TUSTIN, CA 92780 Phone: 8005211968 Fax:		Ship To: FIRSTHEALTH MOORE REGIONAL HOSPITAL ATTN RECEIVING 110 PAGE ROAD NORTH PINEHURST, NC 28374 GLN: Phone: Fax: 910-715-1088		Bill To: ACCOUNTS PAYABLE - FHC FIRSTHEALTH MOORE REGIONAL HOSPITAL ATTN ACCOUNTS PAYABLE P.O. BOX 3000 PINEHURST, NC 28374 Phone: Fax: 910-715-1088			
Vendor Code: 767 PO Type: CAP PO Status: On Order Customer No: 102933/8374		Comment: CONTINGENT UPON BOARD AND CON APPROVAL PLEASE FAX 910-715-1088 OR EMAIL GBULLARD@FIRSTHEALTH.ORG CONFIRMATION THANKS AND HAVE A BLESSED DAY AND WEEK WEEKEND PHONE 910-715-1074					
Composed By: BULLARD GERALYN Terms: NET 30 FOB: DEST Delivery Date: Tax ID Number: 561936354							
Line Modified	Vendor Catalog	Order Quantity	Mfr Catalog Contract	Charge Dept. Sub-Ledger	Project Sub-Project	Price Discount List Price	Ext. Price Tax Ext Price w/ Tax
1	DPI8/1216.000	1 EA	DPI8/1216.000	10-1350-15500		\$1,100,000.00	\$1,100,000.00 \$74,250.00 \$1,174,250.00
Item: [non-catalog] INFINIX-I DIJAL PLANE CARDIOVASCULAR SYSTEM AND COMPONENTS							
PO Sub Total: \$1,100,000.00 Tax Total: \$74,250.00 Purchase Order Total: \$1,174,250.00							
CONTINGENT UPON BOARD AND CON APPROVAL QUOTE NO: 46248 SID NO: 30012973 Signature(s): 							

PROPOSED CAPITAL COSTS

Project name: Cardiac Catheterization Replacement

Proponent: FirstHealth Moore Regional Hospital

Site Costs		
(1)	Full purchase price of land _____ Acres at \$_____ per acre	N/A
(2)	Closing costs	N/A
(3)	Site inspection and survey	N/A
(4)	Legal fees/subsoil investigation	N/A
(5)	Site preparation costs	N/A
(6)	Other (Demolition)	N/A
(7)	Sub-Total Site Costs	N/A
Construction Contract		
(8)	Cost of materials	\$110,000
(9)	Other (Specify)	N/A
(10)	Sub-Total Construction Contract	\$110,000
Miscellaneous Project Costs		
(11)	Building purchase	N/A
(12)	Fixed equipment purchase/lease	\$1,174,250
(13)	Movable equipment purchase/lease	N/A
(14)	Furniture	N/A
(15)	Landscaping	N/A
(16)	Consultant fees	N/A
(17)	Financing costs (e.g. bond, loan, etc.)	N/A
(18)	Interest during construction	N/A
(19)	Other (Contingency)	N/A
(20)	Sub-Total Miscellaneous	\$1,174,250
(21)	TOTAL CAPITAL COST OF PROJECT	\$1,284,250

EQUIPMENT COMPARISON

Exhibit C

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	Cardiac Catheterization	Cardiac Catheterization
Manufacturer of Equipment	Toshiba	Toshiba
Tesla Rating for MRIs	N/A	N/A
Model Number	Infinix CS	Infinix-I Dual Plane
Serial Number	212480	TBD at purchase
Provider's Method of Identifying Equipment	Research, Quality and Price	Research Quality and Price
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN#	N/A	N/A
Mobile Tractor Serial Number/VIN#	N/A	N/A
Date of Acquisition of Each Component	January 2004	June 2014
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	Title
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.)	N/A	\$1,284,250
Total Cost of Equipment	N/A	\$1,174,250
Fair Market Value of Equipment	\$0	\$1,174,250
Net Purchase Price of Equipment	N/A	\$1,174,250
Locations Where Operated	FirstHealth Moore Regional	FirstHealth Moore Regional
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	Cardiac Catheterization Procedures	N/A