



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

February 21, 2014

James Roskelly
Cone Health
1200 North Elm Street
Greensboro, NC 27401-1020

Exempt from Review – Replacement Equipment

Facility: Cone Health
Project Description: Replace Heart-Lung Bypass Equipment
County: Guilford
FID #: 943494

Dear Mr. Roskelly:

In response to your February 12, 2014 letter received on February 20, 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 System 1 Heart-Lung Machine with T-Link Data Management to replace the existing Cobe/Century Perfusion Pump, Serial # CCB-184. 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 Branch 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,

Celia C. Inman
Project Analyst

Martha J. Frisone, Interim Chief
Certificate of Need Section



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

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CONE HEALTH

The Network for Exceptional Care

Celia

1200 North Elm Street
Greensboro, NC 27401-1020
336.832.8199
www.conehealth.com

February 12, 2014

Received by
the CON Section
FEB 20 2014

Ms. Martha Frisone, Interim Section Chief
Ms. Celia Inman, Project Analyst
Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

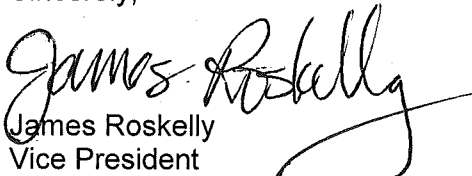
Dear Ms. Frisone and Ms. Inman:

Pursuant to Section § 131E-184 (a)(7) – Exemptions From Review – of the Certificate of Need Statute, I am writing to inform you of Cone Health's plans to replace one of its existing heart-lung bypass machines operating at The Moses H. Cone Memorial Hospital. The replacement project will not increase the total inventory of heart-lung bypass machines owned and operated by Cone Health. Exhibit 1 attached to this letter provides a comparison of the relevant information and specifications for the existing equipment and the planned replacement equipment. Of particular note, the replacement perfusion pump will cost well below \$2M, and will be functionally comparable to the equipment being taken out of service. The proposed capital costs for the planned equipment replacement are detailed in Exhibit 2.

The new heart-lung bypass machine, which will continue to be owned and operated by Cone Health, will be placed in service in March 2014. The equipment being replaced will be removed and disposed of by the vendor. Cone Health is simply updating an important piece of equipment. The proposed quote from Comprehensive Care Services for the advanced perfusion system, including detailed specifications, is attached as Exhibit 3.

Please let me know if I can answer any questions for you regarding this planned heart-lung bypass replacement.

Sincerely,


James Roskelly
Vice President
Corporate Planning and Development

Attachments

Exhibit 1

Comparison of Existing Equipment and Planned Replacement Equipment

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	Cobe/Century Heart-Lung Machine	System 1 Heart-Lung Machine with T-Link Data Management
Manufacturer of Equipment	Cobe	Tereumo
Tesla Rating for MRIs	N/A	N/A
Model Number	Cobe Century Perfusion Pump	Advanced Perfusion 1 System
Serial Number	CCB-184	TBD
Provider's Method of Identifying Equipment	Serial number	Serial number
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	August 1997	February 2014
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	Will hold title
Specify if Equipment Was/Is New or Used When Acquired	New	New
Total Capital Cost of Project (Including Construction, etc.) <Use Attached Form>	N/A	N/A
Total Cost of Equipment	Approximately \$50,000	\$211,961
Fair Market Value of Equipment	Approximately \$1,000	\$211,961
Net Purchase Price of Equipment	Approximately \$50,000	\$211,961
Locations Where Operated	The Moses H. Cone Memorial Hospital	The Moses H. Cone Memorial Hospital
Number Days In Use/To be Used in N.C. Per Year	365 days/year	365 days/year
Percent of Change in Patient Charges (by Procedure)	N/A	None
Percent of Change in Per Procedure Operating Expenses (by Procedure)	N/A	None
Type of Procedures Currently Performed on Existing Equipment	Open heart procedures	Open heart/cardiovascular procedures
Type of Procedures New Equipment is Capable of Performing	N/A	Transcatheter aortic valve replacement and electronic data management

Exhibit 2

Proposed Capital Costs

PROJECT CAPITAL COST

A. Site Costs

(1)	Full purchase price of land	\$	<u>0</u>	
	# Acres _____ Price per Acre \$ _____			
(2)	Closing costs	\$	<u>0</u>	
(3)	Site Inspection and Survey	\$	<u>0</u>	
(4)	Legal fees and subsoil investigation	\$	<u>0</u>	
(5)	Site Preparation Costs [Include]			
	Soil Borings			
	Clearing and Grading			
	Roads and Parking			
	Sidewalks			
	Water and Sewer			
	Excavation and Backfill			
	Termite Treatment			
	Sub-Total Site Preparation Costs	\$	<u>0</u>	
(6)	Other (Specify)	\$	<u>0</u>	
(7)	Sub-Total Site Costs			\$ <u>0</u>

B. Construction Contract

(8)	Cost of Materials [Include]			
	General Requirements			
	Concrete/Masonry			
	Woods/Doors & Windows/Finishes			
	Thermal & Moisture Protection			
	Equipment/Specialty Items			
	Mechanical/Electrical			
	Sub-Total Cost of Materials	\$	<u>0</u>	
(9)	Cost of Labor	\$	<u>0</u>	
(10)	Other (Specify) \$			
(11)	Sub-Total Construction Contract			\$ <u>0</u>

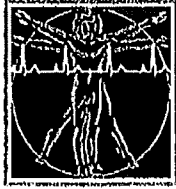
C. Miscellaneous Project Costs

(12)	Building Purchase	\$	<u>0</u>	
(13)	Fixed Equipment Purchase/Lease	\$	<u>0</u>	
(14)	Movable Equipment Purchase/Lease	\$	<u>211,961</u>	
(15)	Furniture	\$	<u>0</u>	
(16)	Landscaping	\$	<u>0</u>	
(17)	Consultant Fees			
	Architect/Engineering Fees	\$	<u>0</u>	
	Legal Fees	\$	<u>0</u>	
	Market Analysis	\$	<u>0</u>	
	Other (Specify)	\$	<u>0</u>	
	Total Consultant Fees	\$	<u>0</u>	
(18)	Financing Costs			
	(e.g. Bond, Loan, etc.)	\$	<u>0</u>	
(19)	Interest During Construction	\$	<u>0</u>	
(20)	Other (Specify)	\$	<u>0</u>	
(21)	Sub-Total Miscellaneous			\$ <u>211,961</u>

D. Total Capital Cost of Project (Sum A-C above) \$ 211,961

Exhibit 3

Quotation



COMPREHENSIVE CARE SERVICES, INC

31330 SCHOOLCRAFT RD., SUITE #200
LIVONIA, MI 48150

OFFICE: 734.525.9712 FAX: 734.525.9582

WWW.CCSPERFUSION.COM

COMPREHENSIVE CARE SERVICES

ADVANCED PERFUSION SYSTEM 1 & TLINK DATA MANAGEMENT SYSTEM HARDWARE PURCHASE PROPOSAL

For
CONE HEALTH

Quantity	Product No.	Description
1	801763	100/120V AC Platform APS w/QCU
1	816300	Central Control Monitor
1	802110	Air Detector Module
1	802111	Level Detector Module
1	131115	3' pole
1	145980	Crossbar Fitting
1	801188	EPGS System
1	814475	U.S. Hose Kit Air, O2, CO2
3	816570	System 1 4" Roller Pump
1	816572	System 1 Centrifugal Control Module
1	164267	Centrifugal Drive Motor
1	816620	Flexible Mounting Arm
1	164268	Delphin Manual Drive
1	802018	Flow Pod APS
1	6382	Centrifugal TOF Flow Sensor
1	801550	Flow Pod Bracket
1	5773	5773 Air Sensor 3/8 x 3/32
1	5791	5791 Air Sensor 1/4 x 1/32
1	802110	Air Detector Module
1	802112	Pressure Pod APS
2	802114	Temperature Pod APS
1	801558	Lamp, Short Neck APS
1	803479	Interface Module CDI 500
1	802113	Data Transfer Serial 232
1	143554	6 inch Adapter Cord
1	814871	TLink Data Management Software License
1	825184	TLink DMC Touchscreen Plus
1	814857	Touch Screen Mounting Bracket
1	814858	Extension Pole Mount Bracket

CCS OAKLAND, LLC CARDIOVASCULAR PERFUSION ASSOCIATES, LLC CCS CIRCULATORY SUPPORT, LLC CCS - PA, LLC
CCS BROWARD, LLC GENESSEE LIFE SUPPORT, LLC HEMA SOLUTIONS, LLC COMPREHENSIVE CARE OF FLORIDA, LLC

SPECIALIZING IN PERFUSION SERVICES, AUTOTRANSFUSION, THERAPEUTIC APHERESIS AND PRODUCTION OF AUTOLOGOUS TISSUE GLUE





COMPREHENSIVE CARE SERVICES, INC

31330 SCHOOLCRAFT RD., SUITE #200
LIVONIA, MI 48150
OFFICE: 734.525.9712 FAX: 734.525.9502
WWW.CCSPERFUSION.COM

1	814870	Touch Screen Stylus
1	814864	Mini-Keyboard
1	815681	4Port USB Extension Hub
1	815804	Barcode Laser Scanner
1	815805	Barcode Laser Scanner Holder
1	816096	50ft CAT5E Shielded Cable (RJ45-RJ45)
1	816098	TLink DMS Adpater (DB9F-RJ45)
1	816103	System 1/Other Adapter (DB9M-RJ45)
		Grand Total: \$211,961.00

Shipping: FOB Origin

Note: The Advanced Perfusion System 1 equipment listed above will be available for shipment from Terumo CVS post FDA Consent Decree restriction period.

Warranty

Please note that this equipment comes with a warranty covering all repairs, parts and labor for the first 12 months following delivery.

Accepted:

Cone Health

ITS: _____

DATE: _____

Comprehensive Care Services, Inc

Chet Czaplicka, BSN, RN, CCP
ITS: President

DATE: 1.1.2014

Director
1/10/14

