



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

Pat McCrory
Governor

Richard O. Brajer
Secretary DHHS

Mark Payne
Assistant Secretary for Audit and
Health Service Regulation

January 12, 2016

Elizabeth V. Kirkman
Assistant Vice President
CHS Management Company
2709 Water Ridge Parkway, Suite 200
Charlotte, North Carolina 28217

Exempt from Review – Replacement Equipment

Record #: 1827
Facility Name: Carolinas Medical Center (CMC)
FID #: 943070
Business Name: The Charlotte-Mecklenburg Hospital Authority
Business #: 1772
Project Description: Replace cardiac catheterization lab located in CMC's Cath Lab Room #06G113
County: Mecklenburg

Dear Ms. Kirkman:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of December 9, 2015 and information provided in your previous exemption request of September 9, 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 replace the existing Philips Integris Allura 9F Cardiac Imaging System, located in room #06G113 (Cath Lab #1) of CMC's main campus in Charlotte, with a comparable cardiac catheterization lab and relocate it to cardiac catheterization lab room #6044. The existing cardiac catheterization lab equipment to be replaced is a change from your previous exemption request of September 9, 2015 which would have replaced the Philips Allura XPER FD10 Single Plane Catheterization Lab System located in room #06G120. 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.



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

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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,



Gloria C. Hale
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



Carolinus HealthCare System



December 9, 2015

Ms. Martha Frisone, Assistant Section Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
N.C. Department of Health & Human Services
809 Ruggles Drive
Raleigh, NC 27603

RE: The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center –
Exemption Notice for Acquisition of Replacement Cardiac Catheterization Lab Equipment and
Relocation of Replacement Cardiac Catheterization Lab Equipment

Dear Ms. Frisone:

The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center (“CMC”), submitted an exemption request on September 9, 2015 (see Attachment A) and received approval on September 15, 2015 (see Attachment B) to acquire a Toshiba Infinix Cardio/Neuro Vascular Biplane Catheterization Lab System (“Replacement Equipment”). The Replacement Equipment will be relocated to Cardiac Catheterization Lab room 6044 (Pediatric Cath Lab #1) on the sixth level of CMC’s main campus.

The purpose of this letter is to let the Agency know that we have decided to replace and then relocate the existing cardiac catheterization equipment in room 06G113 (Cath Lab #1) to room 6044, rather than the existing cardiac catheterization equipment in room 06G120 (Cath Lab #3). All other items in the original exemption request remain the same including the new equipment, the location of the new equipment and the cost [The purchase price of the Replacement Cardiac Catheterization Equipment is \$1,541,553.58 (\$1,431,146.00 Cardiac Catheterization System + \$6,200.00 Freight + \$104,207.58 Tax). The projected total capital cost of the project is \$4,326,000 and includes the removal of the existing equipment and installation of the Replacement Equipment.] The existing equipment was purchased in 2004 (see Attachment C) and will be taken out of service and will not be re-sold or re-installed in North Carolina without appropriate certificate of need approval.

Based on the foregoing information, CMC hereby requests that the Agency provide a written response confirming the change in the proposed project. If the Agency needs additional information to assist in its consideration of this request, please let us know.

Thank you for your consideration of this notice.

Sincerely,

A handwritten signature in cursive script that reads "Elizabeth V. Kirkman".

Elizabeth V. Kirkman
Assistant Vice President
CHS Management Company

Attachments

cc: F. Del Murphy, Jr., CHS Management Company
W. Spencer Lilly, President, Carolinas Medical Center

Attachment A



Carolinus HealthCare System

September 9, 2015

Ms. Martha Frisone, Assistant Section Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
N.C. Department of Health & Human Services
809 Ruggles Drive
Raleigh, NC 27603

RE: The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinus Medical Center –
Exemption Notice for Acquisition of Replacement Cardiac Catheterization Lab Equipment and
Relocation of Replacement Cardiac Catheterization Lab Equipment

Dear Ms. Frisone:

The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinus Medical Center (“CMC”), seeks to acquire a Toshiba Infinix Cardio/Neuro Vascular Biplane Catheterization Lab System (“Replacement Equipment”). Please see Attachment A for a copy of CMC’s current hospital license. The Replacement Equipment will replace CMC’s current Philips Single Plane Catheterization Lab System (“Existing Equipment”). The Existing Equipment is currently housed and in use in Cardiac Catheterization Lab room 06G120 on the sixth level of CMC’s main campus (“Cath Lab #3”) located at 1000 Blythe Boulevard in Charlotte, NC 28203 (see Attachment B). The Replacement Equipment will be relocated to Cardiac Catheterization Lab room 6044 (labeled Cath Lab #1) on the sixth level of CMC’s main campus.

The purpose of this letter is to provide the Agency with notice and to request a determination that CMC’s purchase of the Replacement Equipment is exempt from Certificate of Need (“CON”) review under the replacement equipment exemption provisions contained in Session Law 2013-360, Section 12G.3(b) and Session Law 2013-363, Section 4.6 (which are codified at N.C. Gen. Stat. 131E-184(f)(1)-(3)).

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). Under the new provisions found at N.C. Gen. Stat. 131E-184(f)(1)-(3), the CON law provides:

- (f) The Department shall exempt from certificate of need review the purchase of any 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.

See Session Law 2013-360, Section 12G.3(b) and Session Law 2013-363, Section 4.6. The term "main campus" was defined in Session Law 2013-360, Section 13G.3(a) (codified N.C. Gen. Stat. 131E-176(14n)) as follows:

- (14n) "Main campus" means all of the following for the purposes of G.S. 131E-184(f) and (g) only:
 - a. The 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.
 - b. Other areas and structures that are not strictly contiguous to the main building but are located within 250 yards of the main building.

The Existing Equipment is currently located in room 06G120 on the sixth level of CMC's main campus ("Cath Lab #3") and the Replacement Equipment will be relocated to Cardiac Catheterization Lab room 6044 on the sixth level (see Attachment B). The main hospital building from which Carolinas Medical Center exercises financial and administrative control over Carolinas Medical Center services is located at 1000 Blythe Boulevard, Charlotte, NC 28203 (see Attachment B). Carolinas Medical Center's President's office is located on the second floor of the main hospital building.

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

A. Cost of the Replacement Equipment

The purchase price of the Replacement Cardiac Catheterization Equipment is \$1,541,553.58 (\$1,431,146.00 Cardiac Catheterization System + \$6,200.00 Freight + \$104,207.58 Tax). Quotes for the Cardiac Catheterization Lab System from Toshiba and supporting equipment are provided in Attachment C. The projected total capital cost of the project is \$4,326,000 and includes the removal of the existing equipment and installation of the Replacement Equipment. The total capital cost schedule and the certified cost estimate of the renovation required to install the new equipment are provided in Attachment D.

B. Equipment Being Replaced is Located on the Main Campus

The Existing Equipment is currently located in room 06G120 on the sixth floor of CMC's main campus ("Cath Lab #3") (see Attachment B). The Replacement Equipment will be located in room 6044 on the sixth level of CMC's main campus (see Attachment B).

C. Certificate of Need Issued for Equipment Being Replaced

This proposal also fits within the new exemption criterion in Section 131E-184(f)(2) because the Department issued an exemption request for the Existing Equipment (see Attachment E). The Existing Equipment was purchased in 2004.

D. 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.

CMC intends to use the Replacement Equipment for substantially the same Cardiac Catheterization procedures for which it currently uses the Existing Equipment. The Existing Equipment is a Philips Single Plane Catheterization Lab System that was installed new in 2004. This Existing Equipment has been used for Cardiac Catheterization procedures since installation.

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 Cardiac Catheterization procedures. (see Attachment F for the Equipment Brochure) The Replacement Equipment is therefore "comparable medical equipment" as defined in Subsection (c).

Furthermore, CMC does not intend to increase patient charges or per procedure operating expenses within the first 12 months after equipment acquisition. For further

equipment comparison, please refer to Attachment G, the Equipment Comparison Chart.

Subsection (d) of the regulation further provides:

- (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 10.0 percent increase in patient charges or per procedure operating expenses within the first twelve months after the replacement equipment is acquired.

The Replacement Equipment will meet all three of 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 Chart (Attachment G). Moreover, CMC represents the use of the Replacement Equipment will not result in the types of expense or charge increases described in Subsection (d)(3).

The Existing Equipment is currently in use and documentation provided in Attachment H indicates that 669 procedures were performed in the last 12 months.

E. Disposition of Equipment

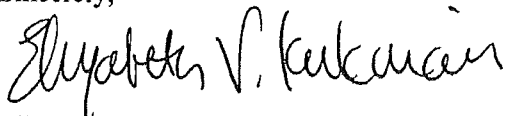
Please see Attachment I for a letter documenting the Existing Equipment will be taken out of service and will not be re-sold or re-installed in North Carolina without appropriate certificate of need approval.

CONCLUSION:

Based on the foregoing information, CMC hereby requests that the Agency provide a written response confirming that the acquisition of the Replacement Equipment described herein is exempt from CON review. If the Agency needs additional information to assist in its consideration of this request, please let us know.

Thank you for your consideration of this notice.

Sincerely,

A handwritten signature in black ink that reads "Elizabeth V. Kirkman". The signature is written in a cursive style with a large initial "E".

Elizabeth V. Kirkman
Assistant Vice President
CHS Management Company

Attachments

cc: F. Del Murphy, Jr., CHS Management Company
W. Spencer Lilly, President, Carolinas Medical Center

Attachment B



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

Pat McCrory
Governor

Richard O. Brajer
Secretary DHHS

Drexdal Pratt
Division Director

September 15, 2015

Elizabeth V. Kirkman
Assistant Vice President
CHS Management Company
2709 Water Ridge Parkway, Suite 200
Charlotte, North Carolina 28217

Exempt from Review – Replacement Equipment

Record #: 1719
Facility Name: Carolinas Medical Center (CMC)
FID #: 943070
Business Name: Charlotte-Mecklenburg Hospital Authority
Business #: 1772
Project Description: Replace cardiac catheterization lab located in CMC's Cath Lab Room #06G120
County: Mecklenburg

Dear Ms. Kirkman:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of September 9, 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 replace the existing Philips Allura XPER FD10 Single Plane Catheterization Lab System, located in Cath Lab Room #06G120 of CMC's main campus in Charlotte, with a comparable cardiac catheterization lab. 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.

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.



Office of the Director

<http://www.ncdhhs.gov/dhsr/>

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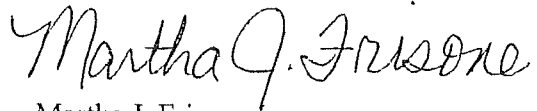
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Sincerely,



Gloria C. Hale
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

Attachment C



**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

November 5, 2004

*11/16/04
 Spoke to Mary about type*

Greg Bass, Director
 CHS Management Company
 Post Office Box 32861
 Charlotte, NC 28232-2861

RE: Exempt from Review/Carolinas Medical Center/Replace existing Philips Fluoroscopy System with a Philips Integris Allura 9F Cardiac Imaging System /Mecklenburg County

Dear Mr. Bass:

In response to your letters of July 28, 2004 and November 4, 2004, 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, a Philips Integris Allura 9F Cardiac Imaging System to replace the existing Philips Fluoroscopy System in Cardiac Cath Lab ~~33~~. This determination is based on your representations that the existing medical equipment 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,

Mary Edwards
 Mary Edwards
 Project Analyst

Lee B. Hoffman
 Lee B. Hoffman, Chief
 Certificate of Need Section

cc: Medical Facilities Planning Section, DFS

