

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

September 29, 2016

Douglas R. Lockett
2525 Court Drive
Gastonia, NC 28054

Exempt from Review – Replacement Equipment

Record #: 1999
Facility Name: CaroMont Regional Medical Center
FID #: 943184
Business Name: CaroMont Health, Inc.
Business #: 406
Project Description: Replace Linear Accelerator and renovate clinical support space
County: Gaston

Dear Mr. Lockett:

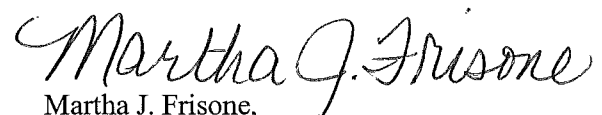
The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letters of June 14, 2016, July 26, 2016 and September 19, 2016, the above referenced proposal is exempt from certificate of need review in accordance with G.S 131E-184(a)(f). Therefore, you may proceed to acquire, without a certificate of need the Varian TrueBeam Linear Accelerator to replace the Varian 2100EX Linear Accelerator. 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.

Sincerely,


Gregory F. Yakaboski
Project Analyst


Martha J. Frisone,
Assistant Chief, 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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Douglas R. Lockett
September 29, 2016
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cc: Construction Section, DHSR
Paige Bennett, Assistant Chief, Healthcare Planning, DHSR
Acute and Home Care Licensure and Certification Section, DHSR

Yakaboski, Greg

From: David Legarth <dlegarth@nc.rr.com>
Sent: Monday, September 19, 2016 3:07 PM
To: Yakaboski, Greg
Subject: CRMC No Review Exhibit B
Attachments: CRMC Exhibit B.pdf

Hi Greg,

Attached is the campus map showing the location of the Cancer Center and the administrative and financial control of the facility.

Thank you.

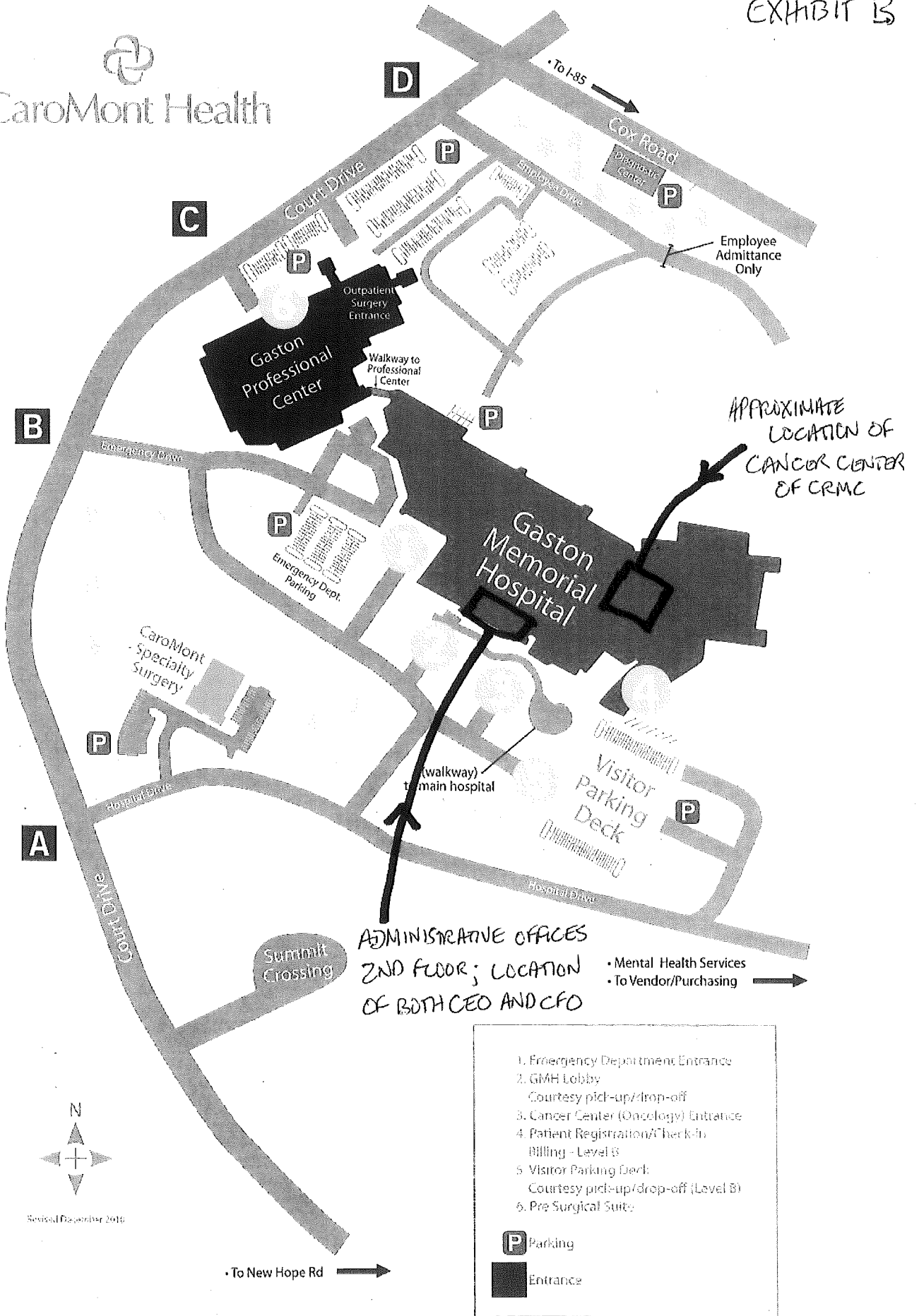
David Legarth
Senior Consultant



Mail Address:
PO Box 1936
Apex, NC 27502

FedEx/UPS Address:
108 Curley Maple Court
Apex, NC 27502

Phone:
919-244-7609





July 26, 2016



Martha Frisone, Assistant Chief
Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section
NC Department of Health and Human Services
2704 Mail Service Center
Raleigh, North Carolina 27699-2704

RE: Additional Information - Request for Exemption to CON Review for Replacement
Linear Accelerator at CaroMont Regional Medical Center / Gaston County

Dear Ms. Frisone:

Pursuant to NCGS 131E-176(22a), this letter is to notify the Agency that CaroMont Regional Medical Center will trade-in its Varian 2100EX linear accelerator to Varian Medical Systems as a term of its proposed purchase of a Varian TruBeam linear accelerator.

Varian Medical Systems will take possession of the Varian 2100EX linear accelerator and permanently remove the linear accelerator from North Carolina.

The Varian 2100EX linear accelerator will not operate in North Carolina without a health care facility first seeking the approval of the Agency.

If you require additional information concerning this request, please contact me at 704-834-2000.

Sincerely,

A handwritten signature in black ink, appearing to read "Kathleen Besson".

Kathleen Besson
EVP & Chief Operating Officer



June 14, 2016

Douglas R. Lockett, FACHE
President and Chief Executive Officer

Ms. Martha Frisone, Assistant Chief
Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section
NC Department of Health and Human Services
2704 Mail Service Center
Raleigh, North Carolina 27699-2704



RE: Request for Exemption to CON Review for Replacement Linear Accelerator at CaroMont Regional Medical Center / Gaston County

Dear Ms. Frisone:

CaroMont Regional Medical Center (CRMC) intends to replace an existing linear accelerator and make slight renovations within its existing health service facility at a total project cost of \$4,390,156 and requests a determination that such related capital expenditure is exempt from review because the related capital expenditure falls within the definition of NCGS § 131E-184(f).

Please refer to Exhibit A for the project capital costs.

Statement of Facts

CRMC owns and operates three linear accelerators at the Cancer Center within CRMC. Two linear accelerators are Varian 2100EXs and one is a Varian True Beam. This Request for Exemption to CON Review seeks to replace a linear accelerator and renovate clinical support space within the Cancer Center at CRMC.

Exemption from Review

Pursuant to NCGS § 131E-184(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(22a) 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."

Compliance

CRMC hereby certifies that:

- (1) The equipment being replaced is located on the main campus.**

The 2100EX linear accelerator is located in the Cancer Center of CRMC, which is the main building on the main campus. Please refer to Exhibit B.

- (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.**

The 2100EX linear accelerator to be replaced was purchased October 2004.

- (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."**

CRMC requests that the Division of Health Service Regulation make a determination that the capital expenditures related to the replacement of a linear accelerator and the slight renovation to existing space within CRMC is exempt from review because the related capital expenditures fall within the definition of NCGS § 131E-184(f).

Exemption from Review

Furthermore, 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.

10A NCAC 14C .0303(c) 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.

PROPOSED CAPITAL COSTS

Project name: Linear Accelerator and Clinical Support Space Renovation

Proponent: CaroMont Regional Medical Center

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	\$872,120
(9)	Other (Specify)	N/A
(10)	Sub-Total Construction Contract	\$872,120
Miscellaneous Project Costs		
(11)	Building purchase	N/A
(12)	Fixed equipment purchase/lease	\$3,518,036
(13)	PACS Interface	N/A
(14)	Furniture	N/A
(15)	A&E Fees	N/A
(16)	Consultant fees	N/A
(17)	Financing costs (e.g. bond, loan, etc.)	N/A
(18)	General Conditions	N/A
(19)	Other	N/A
(20)	Sub-Total Miscellaneous	\$3,518,036
(21)	TOTAL CAPITAL COST OF PROJECT	\$4,390,156

I assure that, to the best of my knowledge, the above capital costs for the proposed project are complete and correct and that it is my intent to carry out the proposed project as described.



 Douglas Lockett, President and CEO

6.14.2016

 Date

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	Linear Accelerator	Linear Accelerator
Manufacturer of Equipment	Varian	Varian
Tesla Rating for MRIs	N/A	N/A
Model Number	2100EX	TruBeam
Serial Number	2822	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	October 2004	2016
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	\$4,390,156
Total Cost of Equipment	N/A	\$3,518,036
Fair Market Value of Equipment	\$0	\$3,518,036
Net Purchase Price of Equipment	N/A	\$3,518,036
Locations Where Operated	CaroMont Regional MC	CaroMont Regional MC
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	Linear Accelerator Treatment	N/A
Type of Procedures New Equipment is Capable of Performing	N/A	Linear Accelerator Treatment