

DEPARTMENT OF HEALTH AND HUMAN SERVICES DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER GOVERNOR MANDY COHEN, MD, MPH SECRETARY

> MARK PAYNE DIRECTOR

November 8, 2017

Kenneth L. Burgess 130 South Franklin Street Rocky Mount, NC 27804

Exempt from Review - Replacement Equipment

Record #:

2432

Facility Name:

Mission Hospital

FID #:

943349

Project Description:

Replace and relocate existing CT scanner

County:

Buncombe

Dear Mr. Burgess:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of November 2, 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 of need the GE Healthcare CT scanner to replace the existing CT scanner and relocate the replacement CT scanner to Mission Hospital Cancer Center. 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 Construction, Radiation Protection, 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,

Julie Halatek Project Analyst

July Halatik

Martha J. Frisone

Chief, Healthcare Planning and Certificate of Need Section

cc:

Construction Section, DHSR

Radiation Protection Section, DHSR

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

Halatek, Julie F

From: Burgess, Kenneth L. <KBurgess@poynerspruill.com>

Sent: Monday, November 06, 2017 10:39 AM

To: Halatek, Julie F

Subject: [External] Mission CT Scanner Replacement/Relocation No Review/Exemption Letter:

Confirmation Regarding Scanner Being Replaced

Attachments: Mission CON Letter Siemens Removal.pdf

CAUTION: External email. Do not click links or open attachments unless verified. Send all suspicious email as an attachment to report.spam@nc.gov.

Hi Julie, attached and below please find confirmation from GE Healthcare, the entity which will be removing the existing CT Scanner at the Victoria Urological Clinic which is the subject of the No Review/Exemption Letter we filed late last week, that the existing scanner which is being replaced will not be resold or reinstalled in the state of North Carolina. Please let me know if this is sufficient for your purposes or if you need additional information. Thanks, Ken Burgess

From: Jonathan Bailey [mailto:Jonathan.Bailey@msj.org]

Sent: Friday, November 03, 2017 2:53 PM

To: Burgess, Kenneth L. <KBurgess@poynerspruill.com>

Cc: Rita Edwards <Rita.Edwards@msj.org>; Ann Young - General Counsel, Senior Vice President <Ann.Young@msj.org>

Subject: FW: CON Letter for Siemens Removal

Ken,

As we have discussed and is confirmed by GE, we will not reinstall or shall the CT scanner being removed by VA be resold in the state of North Carolina.

Thanks!

From: Donovan, John L. (GE Healthcare) [mailto:John.Donovan@med.ge.com]

Sent: Friday, November 03, 2017 2:45 PM

To: Jonathan Bailey < <u>Jonathan.Bailey@msj.org</u>> **Subject:** [EXTERNAL] CON Letter for Siemens Removal

Jonathon,

Good catching up with you today. Attached is the letter that you requested.

Please let me know if you have any questions.

Have a safe trip home!

John

GE Healthcare

John L. Donovan Client Executive



November 3, 2017

Mr. Jonathon Bailey Chief Program Development Officer Mission Health System, Inc 509 Biltmore Avenue Asheville, NC 28801



Dear Mr. Bailey:

This letter is to inform you that GE Healthcare will be removing the single slice Siemens CT scanner from Victoria Urology on trade as part of the purchase of the new Revolution EVO CT system. The Siemens system will be returned to GE Healthcare and will not be reinstalled in the state of NC.

Sincerely,

John Donovan Client Executive GE Healthcare 864-415-3886

Halatek, Julie F

From:

Halatek, Julie F

Sent:

Thursday, November 02, 2017 2:04 PM

To:

'Burgess, Kenneth L.'

Subject:

RE: [External] Notice of Exemption for Replacement/Relocation of Mission Health, Inc.

CT Scanner

Just need one final thing for the exemption. I need a statement to the effect that the CT scanner being replaced will be sold or otherwise disposed of outside of NC and not brought back for use in the state without a prior CON if one is needed.

From: Burgess, Kenneth L. [mailto:KBurgess@poynerspruill.com]

Sent: Thursday, November 02, 2017 1:55 PM

To: Halatek, Julie F

Subject: Re: [External] Notice of Exemption for Replacement/Relocation of Mission Health, Inc. CT Scanner

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I was there Monday and it's all Mission land. No public right of way. It's Mission-ville once you enter that part of campus. Thanks for jumping on this so quickly

Sent from my iPhone

On Nov 2, 2017, at 1:52 PM, Halatek, Julie F < <u>julie.halatek@dhhs.nc.gov</u>> wrote:

Ken, quick question. This may not be relevant at all - I'm just curious from looking at the map. Is there a public right-of-way between the two buildings? As in, does Mission own the two streets I see in the line drawing between the two buildings? I'm aware the "main campus" definition doesn't include anything about that - it's just a curiosity. Thanks.

From: Burgess, Kenneth L. [mailto:KBurgess@poynerspruill.com]

Sent: Thursday, November 02, 2017 9:53 AM

To: Frisone, Martha; Halatek, Julie F

Subject: [External] Notice of Exemption for Replacement/Relocation of Mission Health, Inc. CT Scanner

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Martha and Julie, attached please find an electronic copy of a Notice of Exemption we are filing on behalf of our client, Mission Health, Inc. for the replacement and relocation of a used CT Scanner from the Victoria Urological Clinic on the Mission main campus to the Cancer Center also located on the Mission Main campus. Hard copies of this correspondence are being mailed to each of you today. Please let me know once you review this information if you have any questions and/or need further information. Thanks, Ken Burgess



Poyner Spruill[™]

November 2, 2017

Partner
D: 919.783.2917
F: 252.972.7045
kburgess@poynerspruill.com

VIA EMAIL AND U.S. MAIL

Martha J. Frisone, Chief Julie Halatek, Project Analyst Healthcare Planning and Certificate of Need Section N.C. Department of Health and Human Services Division of Health Service Regulation 2701 Mail Service Center Raleigh, NC 27699-8139

RE: Exemption Request to Replace and Relocate CT Scanner to Mission Hospital Cancer Center

Dear Ms. Frisone and Ms. Halatek:

Our law firm represents Mission Health, Inc. ("Mission"), which owns and operates a CT scanner now located at Victoria Urology Associates (the "Victoria Clinic") on the Mission campus. Mission now desires to replace that CT scanner and relocate it to the Mission Hospital Cancer Center, also located on the Mission campus. This letter is to request that the N.C. Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section ("the CON Section") confirm that the replacement and relocation of the CT scanner on the Mission main campus is exempt from certificate of need ("CON") review within the meaning of N.C. Gen. Stat. §131E-184.

Background Facts

On or about September 1, 2012, Mission entered a Professional Services Agreement ("PSA") with the Victoria Urological Clinic, pursuant to which the physicians at that practice provide services to Mission and the Victoria Clinic is operated as an outpatient department of the hospital. Mission also acquired, and has validated that it holds title to, all of the assets of the Victoria Clinic. Those assets include a used CT scanner. As set forth in the memo attached as Exhibit 1 from Brian Moore, Executive Director of Public Policy and Regulatory Relations with Mission, there is no evidence that a CON was issued for the CT scanner, either in the Victoria Clinic's records, the records of the CON Section or in prior State Medical Facilities Plans. The CT Scanner was purchased new at a cost of \$292,250.00 and was installed on December 12, 2006. The CT Scanner currently has an estimated salvage value of less than fifty thousand dollars (\$50,000.00).

Mission wishes to replace the CT Scanner with a new CT Scanner and simultaneously relocate the scanner from the Victoria Clinic to the Cancer Center located on the main hospital campus.¹ The distance from the Victoria Clinic to the Cancer Center site is 590 feet, or approximately 197 yards. See campus map attached hereto as <u>Exhibit 2</u>.

¹ The Cancer Center was developed pursuant to a CON issued for Project I.D. No. B-7986-07, effective July 17, 2008. That project was completed and became operational in early 2012.

Martha J. Frisone Julie Halatek November 2, 2017 Page 2

Mission has obtained a purchase price quote for a new CT Scanner, comparable in function and clinical capacity to the existing used CT Scanner, from GE Healthcare in an amount of \$416,131.70. See *Exhibit* 3 hereto. This price includes some installation costs but also requires Mission to incur certain installation costs. The total estimated cost to remove the old CT scanner at the Victoria Clinic and make the new CT scanner operational in the Cancer Center is \$929,904.00. See capital cost sheet attached hereto as *Exhibit* 4, which is certified by Jonathan T. Bailey, Chief Program Development Officer for Mission Health and by R. Cullen Pitts, a North Carolina licensed architect.

Analysis

Based upon the above the facts we believe that the acquisition and relocation of the replacement CT scanner is covered by one of two statutory exemptions from the normal CON review requirements.

The CON Law precludes any person from offering or developing a "new institutional health service" without first obtaining a CON. The definition of "new institutional health service" includes, *inter alia*, the following:

- Incurring an obligation for a capital expenditure that exceeds \$2,000,000.00 to develop or expand
 a health service or health service facility, or which "relates" to the provision of a health service;
 and
- The acquisition by purchase, donation, lease, transfer or comparable arrangement of "major medical equipment, which is defined as a single unit or single system of components used to provide medical and health services which costs more than \$750,000.00, including the costs of the equipment and all studies, drawings, installation and any other activities essential to acquiring and making the equipment operational.

However, the CON Law contains two specific exemptions applicable to "replacement equipment," one of which applies to replacement equipment that costs less than \$2,000,000.00 and one of which applies to replacement equipment that costs \$2,000,000.00 or more. Either of these exemption categories, if applicable, would eliminate the need to obtain a CON before acquiring and installing the replacement equipment. They are described below.

Replacement Equipment Which Costs Less Than Two Million Dollars

N.C. Gen. Stat. §131E-184(a)(7) provides an express exemption from CON review for the acquisition and installation of "replacement equipment" costing less than \$2,000,000, provided that the CON Section receives prior written notice from the party proposing to acquire the equipment which explains why the proposed acquisition and installation qualifies under this exemption. The statute and accompanying regulations further define "replacement equipment" as follows:

Equipment that costs less than two million dollars (\$2,000,000.00) 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. In calculating the total cost of the replacement equipment, the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the replacement equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value or the cost of the equipment, whichever is greater.



Martha J. Frisone Julie Halatek November 2, 2017 Page 3

N.C. Gen. Stat. §131E 176(22a). Replacement equipment is "comparable" to the equipment being replaced if:

- 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
- 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. Admin. Code 14C .0303(d).

Based upon the above facts, the CT Scanner replacement and relocation would fall within the parameters of this exemption because:

- The equipment being replaced is part of the Mission Health system, and is located roughly 197
 yards from the site where the new CT Scanner will be placed, and the current scanner is situated
 at a location which is operated as a department of the hospital.
- 2. The total estimated cost of the project is \$929,904.00,² well within the \$2,000,000.00 maximum capital expenditure for this statutory exception.
- 3. The CT Scanner which will be replaced will be sold or disposed of and currently has an estimated salvage value of \$50,000.00.
- 4. The CT Scanner being replaced is more than three years old.
- 5. The new CT Scanner will have the same capabilities as the scanner being replaced, although it may have additional capabilities due to the advancement of CT Scanner technology, is functionally similar to the existing CT Scanner and will be used for the same diagnostic or treatment purposes as the equipment being replaced.
- The project will not increase patient charges or per procedure operating expenses more than 10% within 12 months of the replacement equipment being acquired. See memo from Mr. Bailey, <u>Exhibit</u> 5 hereto.

² In calculating construction costs, our clients relied upon prior Agency determinations that the construction costs "essential to acquiring and making operational the replacement equipment" should include only those costs directly related to removing the old equipment, installing the new equipment and making sure that equipment operates properly. In the case of a CT scanner, such cost should include upfit of the CT room related solely to the operation of the CT scanner (e.g., shielding, extra electrical connections), but need not include other construction costs associated with that room. Similarly, the Agency has previously determined that costs associated with the installation of equipment in the control room for the CT scanner should be included only to the extent that those costs would be different from construction related to general office space. Mission Hospitals, Inc. v. NC DHHS, N.C.App. , 696 SE2d 163 (2010).

Martha J. Frisone Julie Halatek November 2, 2017 Page 4

Replacement Equipment Which Costs More Than Two Million Dollars

The CON Law at N.C. Gen. Stat. §131E-184(f) provides an express exemption for replacement equipment that costs more than \$2,000,000.00. In determining the applicability of this exemption, the same definitions, cost components and other criteria which apply to the exemption for replacement equipment costing less than \$2,000,000.00 apply. In addition, there are two further statutory criteria which apply, as follows:

1. The equipment being replaced is located on the main campus.

The Department of Health and Human Services has previously issued a CON for the equipment being replaced, unless a CON was not required at the time the equipment was purchased by the licensed health service facility.

Should the CON Section find that the above facts do not demonstrate that the cost to replace and relocate the CT scanner are less than \$2,000,000.00, the project nevertheless fits within this exemption. The term "main campus" is defined as 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 or other areas and structures which are not strictly contiguous to the main building but are within 250 yards of the main building. N.C. Gen. Stat. §131E-176(14n). As shown in *Exhibit 2*, both the current CT scanner's location and the proposed location of the replacement CT scanner fit within these definitions. Further, and based on its acquisition cost in 2006, the current CT scanner was not a new institutional health service within the meaning of the CON Law, and no CON was required. N.C. Gen. Stat. §131E(7a), (9b), (14o), and (16)a, and p.

Conclusion

As described above, we believe the CT Scanner replacement project described above is exempt under one of the two replacement equipment exemptions in the CON Law and that no CON is required for the project. We respectfully request that you review the attached documentation and confirm that this is the case.

Please feel free to let me know if you have questions or need additional information regarding this project.

Sincerely.

Kenneth L. Burgess

Partner

Cc: Jonathan Bailey

Kenneth L Burgess



July 6, 2017

To whom it may concern,

I am writing to attest to research conducted in regards to Mission Hospital's acquisition of a medical office located at 100 Victoria Road, Asheville North Carolina on or about 9/01/2012. This office equipment included a used CT scanner. There is no evidence of any Certificate of Need, nor does any reference in previous medical facilities plan or CON records.

The unit has been identified as having a salvage value of less than \$50,000 and the building has not operated nor is licensed as an Outpatient Diagnostic Center.

12/1

Regard:

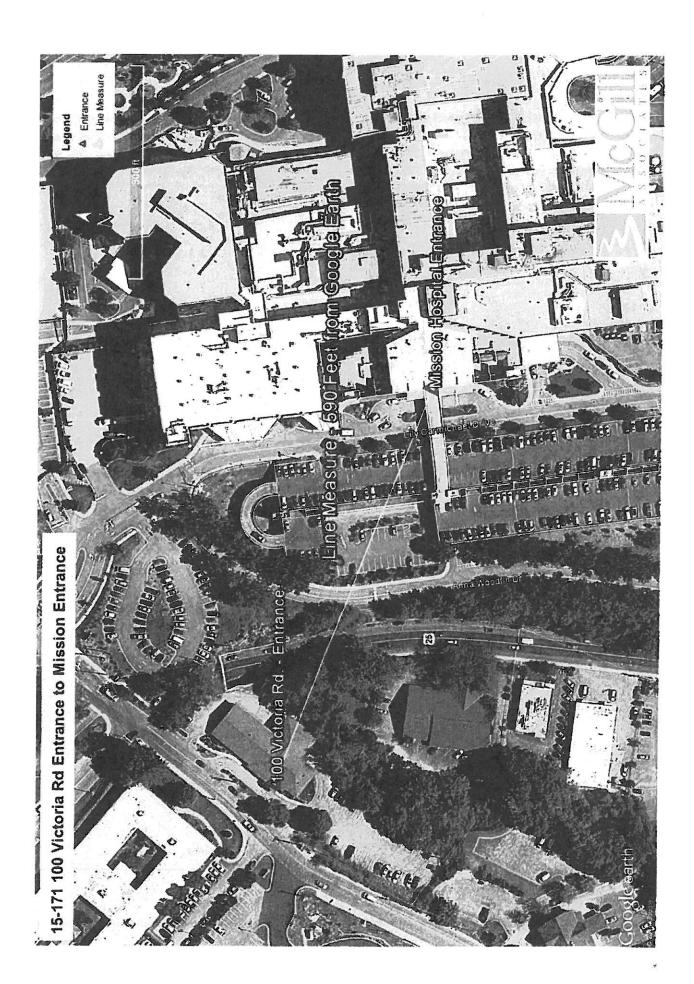
Brian Moore

Executive Director of Public Policy and Regulatory Relations

509 Biltmore Avenue

Asheville, NC 28801

Brian.moore@msj.org





Date: Quote #: 09-13-2017

Version #:

PR2-C83535

Mission Health System Inc 509 Biltmore Ave

Asheville NC 28801-4601

Attn: Rita Edwards

509 Biltmore Ave Asheville

NC 28801-4601

Customer Number:

87668

Quotation Expiration Date: 11-30-2017

This Agreement (as defined below) is by and between the Customer and the GE Healthcare business ("GE Healthcare"), each as identified herein. "Agreement" is defined as this Quotation and the terms and conditions set forth in either (i) the Governing Agreement identified below or (ii) if no Governing Agreement is identified, the following documents;

1) This Quotation that identifies the Product offerings purchased or licensed by Customer;

2) The following documents, as applicable, if attached to this Quotation: iii GE Healthcare Warrantylles); iiii GE Healthcare Additional Terms and Conditions; iiii) GE Healthcare Product Terms and Conditions; and fivi GE Healthcare General Terms and Conditions.

In the event of conflict among the foregoing items, the order of precedence is as listed above.

This Quotation is subject to withdrawal by GE Healthcare at any time before acceptance. Customer accepts by signing and returning this Quotation or by otherwise providing evidence of acceptance satisfactory to GE Healthcare. Upon acceptance, this Quotation and the related terms and conditions listed above for the Governing Agreement, if any shall constitute the complete and final agreement of the parties relating to the Products identified in this Quotation.

No agreement or understanding, oral or written, in any way purporting to modify this Agreement, whether contained in Customer's purchase order or shipping release forms, or elsewhere, shall be binding unless hereafter agreed to in writing by authorized representatives of both parties.

Governing Agreement:

Mission Master Relationship Agreement

Terms of Delivery:

FOB Destination

Billing Terms:

80% delivery / 20% Installation

Payment Terms:

NET 30

Total Quote Net Selling Price:

\$416,131.70

Purchase Order Number (if applicable)		Email: Kevin,Morris@ge,com Office: +1 803 608 2460 Mobile: 803-608-2460	
Print Name	Print Title	Imaging Account Manager	
Authorized Customer Signature	Date	Signature	Date
	Data	Kevin Morris	09-13-2017
CUSTOMER		GE HEALTHCARE	
Each party has caused this agree	ement to be executed b	by its duty authorized representative as of the date so	et forth below.
conditions and warranties, and (i	i) has not made any h	elved a complete copy of this Quotation, including t andwritten or electronic modifications. Manual char and an indication in the form of payment section below	iges or mark-ups on this
Third Party Lease (please identif	fy financing company)		
GE HFS Loan			
GE HFS Lease			
Cash/Third Party Loan			
If "GE HFS Loan" or "GE HFS Lease" is Services (GE HFS) to fund this arrang		e of signature, then you may NOT elect to seek financing w	vith GE Healthcare Financial
INDICATE FORM OF PAYMENT:			



Date: Quote #:

09-13-2017 PR2-C83535

Version #:

Total Quote Selling Price Trade-In and Other Credits

Total Quote Net Selling Price

\$416,131.70 \$0.00 \$416,131.70

To Accept this Quotation

Please sign and return this Quotation together with your Purchase Order To: **Anthony Morris** Office: +1 803 608 2460

Mobile: 803-608-2460 Email: Kevin.Morris@ge.com

Payment Instructions

Please Remit Payment for involces associated with this quotation to:

GE Healthcare P.O. Box 96483 Chicago, IL 60693

To Accept This Quotation

- Please sign the quote and any included attachments (where requested).
- · If requested, please indicate, your form of payment.
- If you include the purchase order, please make sure it references the following information
 - · The correct Quote number and version number above
 - The correct Remit To information as indicated in "Payment Instructions" above
 - The correct SHIP TO site name and address
 - The correct BILL TO site name and address
 - · The correct Total Quote Net Selling Price as indicated above

'Upon submission of a purchase order in response to this quotation, GE Healthcare requests the following to evidence agreement to contract terms. Signature page on quote filled out with signature and P.O. number.
Verbiage on the purchase order must state one of the following: (i) Per the terms of Quotation #; (ii) Per the terms of GPO#; (iii) Per the terms of MPA #; or (iv) Per the terms of SAA #, Include the applicable quote/agreement number with the reference on the purchase order. n addition, source of funds (choice of: Cash/Third Party Loan or GE HFS Lease or GE HFS Loan or Third Party Lease through), must be indicated, which may be done on the quote signature page (for signed quotes), on the purchase order (where quotes are not signed) or via a separate written source of funds statement (if provided by GE Healthcare)."

PROJECTED CAPITAL COST

Project Name:	Mission SECU - CT Suite				
Proponent:					
A. (1) (2) (3) (4) (5)	Site Costs Full purchase price of land Acres Price per Acre Clesing costs Site Inspection and Survey Legal fees and subsoil investigation. Site Preparation Costs Soil Borings Clearing-Earthwork Fine Grade For Slab Roads-Paving Concrete Sidewalks	\$	\$ \$ \$		
(6) (7)	Water and Sewer Footing Excavation Footing Backfill Termite Treatment Other (Specify) Sub-Total Site Preparation Costs Other (Specify) Sub-Total Site Costs	\$	\$	\$	
(9) (10) (10)	Construction Contract Cost of Materials General Requirements Concrete/Masonry Doors & Windows/Finishes Thermal & Moisture Protection Equipment/Specialty Items Mechanical/Ciectrical Other (Specify) Sub-Total Cost of Materials Cost of Labor Other — Test & Balance, Cleaning, PM	\$ \$ \$ \$ \$	\$ 214,779 \$ 143,186 \$ 7,000		
(11) C. (12) (13) (14) (15) (16) (17)	Sub-Total Construction Contract Miscellaneous Project Costs Building Purchase: Fixed Equipment Purchase/Lease Movable Equipment Purchase/Lease Furniture Landscaping Consultant Fees Architect and Engineering Fees Legal Fees	\$ 59,846	\$ 457,475 \$ 3,600	\$ 364,965	
(18) (19) (20) (21) D.	Market Analysis Other (Equipment Planning) Sub-Total Consultant Fees Financing Costs (e.g. Bond, Loan, etc.) Interest During Construction Other (contingency) Sub-Total Miscellaneous Total Capital Cost of Project	\$	\$ 8,778 \$ 68,624 \$ \$ \$ 35,340	\$ 564,939 \$ 929,904	
I certify that, to the best of my knowledge, the costs of the proposed project named above are complete and correct.					
(Signature of Licensed Architect or Engineer)					
Lassure that, to the best of my knowledge, the above costs for the proposed project are complete and correct and that it is my intent to carry out the proposed project as described. (Proponent - Signature of Officer) (Title of Officer) Effective: 5/16/06					



Memo

To:

FILE MEMO

From:

Jonathan Bailey, Chief Program Development Officer, Mission Health

CC:

Date:

June 12, 2017

Re:

Mission Cancer Center CT Scanner

To Whom It May Concern,

The replacement of the CT Scanner, currently located at Victoria Urological Associates, and relocation of that CT Scanner to the Mission Cancer Center will not have in immediate or near term impact to any charges that we are currently charging patients. Additionally, while there will be depreciation expenses, this replacement scanner will not require Mission to incur significant increased operating expenses. Technology advancements in it of themselves have certainly helped to provide clinical and diagnostic advantages over dated equipment, though this replacement scanner will not provide additional procedural capabilities beyond what is currently available in the existing CT scanner that is to be replaced.

Jonathan T. Bailey Chief Program Development Officer Mission Health (o) 828-213-3514 (c) 828-775-2049

509 Biltmore Ave Asheville, NC 28803