



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor

KODY H. KINSLEY • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

April 30, 2024

Iain Stauffer

istauffer@bakerdonelson.com

Exempt from Review – Replacement Equipment

Record #: 4438

Date of Request: April 16, 2024

Facility Name: Mission Hospital

FID #: 943349

Business Name: MH Mission Hospital, LLLP

Business #: 3045

Project Description: Replace existing linear accelerator located at the Mission Cancer Center on the hospital main campus

County: Buncombe

Dear Mr. Stauffer:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that the above referenced project is exempt from certificate of need review in accordance with G.S. 131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the Elekta Versa HD linear accelerator to replace the Elekta linear accelerator, Serial # 152469. 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.

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,

Ena Lightbourne, Project Analyst

Micheala Mitchell, Chief

cc: Acute and Home Care Licensure and Certification Section, DHSR
Radiation Protection Section, DHSR
Construction Section, DHSR

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603

MAILING ADDRESS: 809 Ruggles Drive, 2704 Mail Service Center, Raleigh, NC 27699-2704

<https://info.ncdhhs.gov/dhsr/> • TEL: 919-855-3873

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

IAIN MATTHEW STAUFFER, OF COUNSEL
Direct Dial: 984.844.7913
E-Mail Address: istauffer@bakerdonelson.com

April 16, 2024

VIA EMAIL

Micheala Mitchell, Esq., Chief - Micheala.mitchell@dhhs.nc.gov
Lisa Pittman, Assistant Chief - Lisa.Pittman@dhhs.nc.gov

Healthcare Planning and Certificate of Need Section
N.C. Department of Health and Human Services
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

Re: MH Mission Hospital, LLLP Notice of Exemption for Replacement of Linear
Accelerator; FDID #943349

Dear Micheala and Lisa:

Our law firm represents MH Mission Hospital, LLLP (“Mission”), which owns and operates a linear accelerator that currently is located at the Mission Cancer Center located on the Mission Hospital main campus at 21 Hospital Drive, Asheville, North Carolina. Mission now desires to replace the existing linear accelerator (“Linac”). I am writing 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 of the Linac on the Mission main campus is exempt from certificate of need (“CON”) review within the meaning of N.C. Gen. Stat. §131E-184(a)(7).

Mission proposes to replace its existing Elekta Linac with a new Elekta Versa HD Linac. See Exhibit 1 (Letter from Elekta, Inc.) and Exhibit 2 (statement of Mission’s Chief Operating Officer reflecting existing and replacement system descriptions). The existing Linac is currently located in the Mission Cancer Center at 21 Hospital Drive on the hospital’s main campus in Asheville, N.C. and the replacement Elekta Linac will also be located in Mission Cancer Center at 21 Hospital Drive.

4855-7584-0439v1
2957809-000061 04/16/2024

For the reasons set forth below, we believe that Mission's replacement of the existing Linac is exempt from CON review pursuant to N.C. Gen. Stat. §131E-184(a)(7).

Analysis

The CON Law precludes any person from offering or developing a "new institutional health service" without first obtaining a CON. N.C. Gen. Stat. § 131E-178(a). The definition of "new institutional health service" includes, inter alia, the following:

- 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 \$2,000,000.00, including the costs of the equipment and all studies, drawings, installation and any other activities essential to acquiring and making the equipment operational.

N.C. Gen. Stat. §§ 131E-176(16)(p) and (14o). However, the CON Law contains a specific exemption applicable to "replacement equipment" that costs less than \$3,000,000.00.

Statutory Exemption For Replacement Equipment Which Costs Less Than \$3,000,000.00

The CON Law at N.C. Gen. Stat. § 131E-184(a)(7) provides that 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 that the new institutional health service is for replacement equipment.

Replacement equipment is defined at N.C. Gen. Stat. § 131E-176(22a) as equipment which costs less than \$3,000,000.00 and which is "purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced."

Replacement equipment is "comparable" to the equipment being replaced if:

1. it is capable of providing the same health service as the equipment currently in use; and
2. the equipment to be replaced was acquired more than 12 months prior and was not refurbished or reconditioned when originally acquired.

10A N.C. Admin. Code 14C .0303(c).

Replacement Mission Hospital's Linac Is Exempt From CON Review Under These Authorities

The replacement of Mission's Linac falls within the parameters of this exemption because:

1. The equipment being replaced is currently located in the Mission Cancer Center at 21 Hospital Drive which is located on the hospital's main campus. The replacement Linac likewise will be located in the Cancer Center. See Exhibit 2 (statement of Mission's Chief Operating Officer). The Mission Cancer Center is licensed on the Mission Hospital license.
2. The equipment being replaced is currently in use at Mission. See Exhibit 2 (statement of Mission's Chief Operating Officer).
3. The total estimated cost of the project is \$2,682,421.00, placing the project within the terms of the statutory exception set forth at N.C. Gen. Stat. §131E-184(a). Of that amount, approximately \$2,065,176.00 will be expended on the Linac itself. The remaining costs consist of non-medical equipment, architect and engineering fees and construction required to upfit the room for the new Linac. See Exhibit 3 (Certified Total Capital Cost Worksheet).
4. The CON Section previously issued a CON for the equipment which is now in use and is being replaced. See Exhibit 4. See also, Exhibit 5 (2024 State Medical Facilities Plan ("SMFP") Table 15C-1 showing three (3) CON-authorized Linacs at the Mission Cancer Center).
5. The existing Linac will be dispositioned/recycled in accordance with applicable local, state and federal guidelines and the de-install agreement between Elekta and RS&A upon acquisition and installation of the replacement Linac. The existing Linac will be removed by and shipped to RS&A, Inc. See Exhibit 1 (letter from RS&A, Inc.).
6. The Linac being replaced was new when purchased by Mission and is more than 12 years old, having been purchased and installed in 2011. See Exhibits 2 (statement of Mission's Chief Operating Officer) and 4 (CON for existing Linac dated July 17, 2008).
7. The new Linac will have the same capabilities as the Linac being replaced, although it may have additional capabilities due to the advancement of Linac technology, is functionally similar to the existing Linac and will be used for the same diagnostic or treatment purposes as the equipment being replaced. See Exhibit 2 (statement of Mission's Chief Operating Officer).

Conclusion

For the reasons set forth above, we believe that the proposed replacement of Mission's existing Linac is exempt from CON review and that no CON is required for the project. We respectfully request that you review the attached documentation and confirm in writing that this is the case.

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

Micheala Mitchell
Lisa Pittman
April 16, 2024
Page 4

Best regards,

BAKER, DONELSON, BEARMAN, CALDWELL & BERKOWITZ, PC

A handwritten signature in cursive script that reads "Iain Stauffer". The signature is written in black ink and is positioned below the firm name.

Iain Matthew Stauffer, Of Counsel

Attachments



Oct 16th, 2023

Subject: Equipment Removal Letter
Reference: EL00239632

To whom it may concern,

Thank you for your consideration and trust in RS&A as a partner for your equipment project. This letter is to confirm the following equipment removal:

Elekta (SN 152469)

Located at 21 hospital Dr, Asheville, NC 28801

This piece of equipment will be shipped to:

RS&A Inc.
4957 Home Road
Winston-Salem, NC 27106

RS&A assures that this unit will be dispositioned / recycled in alignment with Local, State and Federal guidelines as well as the de-install agreement between Elekta / RS&A.

Thank you for this opportunity and please let us know if you have any questions.

Brian Dustin

Brian Dustin
Vice President, Operations
RS&A Inc.

Attachments:

- Associated picture







March 7, 2024

Re: Information/Items Needed for Mission Replacement Exemption letter to CON Section

To Whom It May Concern:

MH Mission Hospital, LLLP will be replacing an existing linear accelerator (“linac”) that is physically located at the Mission Cancer Center, 21 Hospital Drive on the Mission Hospital campus in Asheville, North Carolina. The linear accelerator to be replaced is currently in use and will be replaced with an Elekta Versa HD linear accelerator. The linear accelerator being replaced was purchased new when acquired more than 12 years ago and the replacement system will be a new unit. The replacement linear accelerator will have the same technology as the linear accelerator currently in use, although it may possess expanded capabilities due to technological advancements in linear accelerators. The new linear accelerator is functionally similar to the one being replaced and will be used for the same diagnostic or treatment purposes as the existing linear accelerator. The existing linear accelerator will be removed from the Mission Hospital campus and will not be used again at Mission Hospital.

Best Regards,

Scott Bracci
Chief Operating Officer
MH Mission Hospital, LLLP
509 Biltmore Avenue
Asheville, NC 28801

EXHIBIT

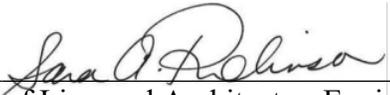
2

Projected Capital Cost Form

Building Purchase Price	\$0.00
Purchase Price of Land	\$0.00
Closing Costs	\$0.00
Site Preparation	\$0.00
Construction/Renovation Contract(s)	\$300,000.00
Landscaping	\$0.00
Architect / Engineering Fees	\$54,250.00
Medical Equipment (Clinical equip, Furnishings, signage, FFE)	\$2,065,176.00
Non-Medical Equipment	\$0.00
Furniture	\$0.00
Consultant Fees (specify)	\$0.00
Financing Costs	\$0.00
Interest during Construction	\$0.00
Other (Miscellaneous)	\$16,750.00
Other (Contingency, Sales Tax)	\$246,245.00
Total Capital Cost	\$2,682,421.00

CERTIFICATION BY A LICENSED ARCHITECT OR ENGINEER

I certify that, to the best of my knowledge, the projected capital cost for the proposed project is complete and correct.

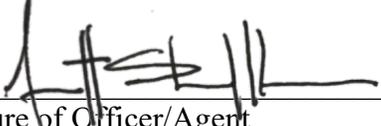


 Signature of Licensed Architect or Engineer

Date Signed: 02/21/2024

CERTIFICATION BY AN OFFICER OR AGENT FOR THE PROPONENT

I certify that, to the best of my knowledge, the projected total capital cost for the proposed project is complete and correct and that it is our intent to carry out the proposed project as described.



 Signature of Officer/Agent

Date Signed: 02/21/2024

Name **Garrett Shreffler**
 Title of Officer/Agent **Director, Facility Planning, Design & Construction**



STATE OF NORTH CAROLINA

Department of Health and Human Services
Division of Health Service Regulation

CERTIFICATE OF NEED

for

Project Identification Number # B-7986-07
FID# 943349

ISSUED TO: **Mission Hospitals, Inc.**
509 Biltmore Avenue
Asheville, NC 28801

Pursuant to N.C. Gen. Stat. § 131E-175, et. seq., the North Carolina Department of Health and Human Services hereby authorizes the person or persons named above (the "certificate holder") to develop the certificate of need project identified above. The certificate holder shall develop the project in a manner consistent with the representations in the project application and with the conditions contained herein and shall make good faith efforts to meet the timetable contained herein. The certificate holder shall not exceed the maximum capital expenditure amount specified herein during the development of this project, except as provided by N.C. Gen. Stat. § 131E-176(16)e. The certificate holder shall not transfer or assign this certificate to any other person except as provided in N.C. Gen. Stat. § 131E-189(c). This certificate is valid only for the scope, physical location, and person(s) described herein. The Department may withdraw this certificate pursuant to N.C. Gen. Stat. § 131E-189 for any of the reasons provided in that law.

SCOPE: Develop a six-level outpatient cancer center on the hospital campus to consolidate existing services, including PET-CT, radiation therapy, outpatient infusion, pediatric/adolescent oncology, the Cancer Registry, the Breast Program, laboratory and pharmacy, and replace one existing linear accelerator and one existing CT simulator/ Buncombe County

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: Mission Hospitals, Inc.
509 Biltmore Avenue
Asheville, NC 28801

MAXIMUM CAPITAL EXPENDITURE: \$53,204,741

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: May 15, 2009

This certificate is effective as of the 17th day of July, 2008

Lee B. Hoffman by CRD/AC
Chief, Certificate of Need Section
Division of Health Service Regulation

EXHIBIT

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CONDITIONS:

1. Mission Hospitals, Inc. shall materially comply with all representations made in its certificate of need application.
2. Mission Hospitals, Inc. shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application or that would otherwise require a certificate of need.
3. Mission Hospitals, Inc. shall dispose of the existing linear accelerator and CT simulator that are being replaced when the replacement equipment is fully operational.
4. Prior to issuance of the certificate of need, Mission Hospitals, Inc. shall submit to the Certificate of Need Section revised letters, documenting the availability of funds for the \$35,024,207 bond issue and the \$9,657,000 tax exempt lease.
5. Mission Hospitals, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.

A letter acknowledging acceptance of and agreeing to comply with all conditions stated in the conditional approval letter was received by the Certificate of Need Section on May 5, 2008.

TIMETABLE:

Approval of final drawings -----	October 1, 2008
Contract award -----	April 1, 2009
50% Completion of construction -----	February 1, 2010
75% Completion of construction -----	July 1, 2010
Completion of construction -----	December 1, 2010
Order Equipment -----	April 1, 2010
Operation of equipment/occupancy -----	March 1, 2011

Table 15C-1: Hospital and Free-Standing Linear Accelerators and Radiation Oncology Procedures

Facility Name	Service Area Number	County	Number of Linear Accelerators	Number of Procedures (ESTVs) 10/1/2021-9/30/2022	Average Number of Procedures per Unit
Harris Regional Hospital	1	Jackson	1	1,355	1,355
North Carolina Radiation Therapy Management Services - Franklin	1	Macon	1	1,984	1,984
Mission Hospital	2	Buncombe	3	15,170	5,057
North Carolina Radiation Therapy Management Services - Asheville	2	Buncombe	1	7,828	7,828
North Carolina Radiation Therapy Management Services - Asheville	2	Buncombe	1	0	0
North Carolina Radiation Therapy Management Services - Weaverville	2	Buncombe	1	2,915	2,915
North Carolina Radiation Therapy Management Services - Clyde	2	Haywood	1	4,308	4,308
North Carolina Radiation Therapy Management Services - Marion	2	McDowell	1	2,872	2,872
Watauga Medical Center	3	Watauga	1	2,336	2,336
Margaret R. Pardee Memorial Hospital	4	Henderson	1	6,194	6,194
North Carolina Radiation Therapy Management Services - Hendersonville	4	Henderson	1	3,536	3,536
North Carolina Radiation Therapy Management - Brevard	4	Transylvania	1	1,521	1,521
UNC Health Blue Ridge - Valdese Campus	5	Burke	2	5,506	2,753
Caldwell UNC Health Care	5	Caldwell	1	0	0
Catawba Valley Medical Center	5	Catawba	2	13,250	6,625
Frye Regional Medical Center - Main Campus	5	Catawba	1	2,737	2,737
Atrium Health Cleveland	6	Cleveland	1	6,561	6,561
CaroMont Regional Medical Center *	6	Gaston	3	21,210	7,070
North Carolina Radiation Therapy Management Services - Forest City	6	Rutherford	1	3,642	3,642
Atrium Health Carolinas Medical Center	7	Mecklenburg	3	19,496	6,499
Atrium Health Pineville	7	Mecklenburg	2	13,016	6,508
Atrium Health University City	7	Mecklenburg	1	7,918	7,918
Matthews Radiation Oncology Center	7	Mecklenburg	2	11,087	5,544
Novant Health Huntersville Medical Center	7	Mecklenburg	1	4,263	4,263
Novant Health Presbyterian Medical Center	7	Mecklenburg	2	12,699	6,350
Atrium Health Union	7	Union	1	8,279	8,279
Iredell Memorial Hospital, Inc.	8	Iredell	2	6,307	3,154
Lake Norman Radiation Oncology	8	Iredell	1	7,994	7,994
Novant Health Cancer Institute-Rowan	8	Rowan	1	6,041	6,041
Atrium Health Cabarrus	9	Cabarrus	3	12,954	4,318
Atrium Health Stanly	9	Stanly	1	3,661	3,661
Novant Health Forsyth Medical Center	10	Forsyth	5	10,631	2,126
Wake Forest Baptist Medical Center	10	Forsyth	4	23,199	5,800
Hugh Chatham Memorial Hospital	10	Surry	1	0	0

Table 15C-1: Hospital and Free-Standing Linear Accelerators and Radiation Oncology Procedures

Facility Name	Service Area Number	County	Number of Linear Accelerators	Number of Procedures (ESTVs) 10/1/2021-9/30/2022	Average Number of Procedures per Unit
Lexington Medical Center	11	Davidson	1	3,181	3,181
Cone Health	12	Guilford	4	30,468	7,617
High Point Medical Center	12	Guilford	2	9,977	4,988
UNC Rockingham Hospital	12	Rockingham	1	2,505	2,505
Randolph Health	13	Randolph	1	3,884	3,884
University of North Carolina Hospitals at Chapel Hill, DBA UNC Hospitals	14	Orange	6	39,067	6,511
Alamance Regional Medical Center	15	Alamance	2	9,630	4,815
Duke Regional Hospital	16	Durham	1	3,497	3,497
Duke University Hospital Main Campus	16	Durham	8	40,503	5,063
Maria Parham Health	16	Vance	1	6,203	6,203
FH Moore Regional Hospital	17	Moore	2	17,364	8,682
Scotland Memorial Hospital	17	Scotland	1	2,991	2,991
Cape Fear Valley Medical Center	18	Cumberland	5	19,399	3,880
Southeastern Regional Medical Center	18	Robeson	2	6,525	3,262
North Carolina Radiation Therapy Management Services - Clinton	18	Sampson	1	3,473	3,473
New Hanover Regional Medical Center **	19	New Hanover	5	34,506	6,901
Franklin County Cancer Center	20	Franklin	1	0	0
2023 Need Determination	20	Wake	1	0	0
Duke Raleigh Hospital	20	Wake	4	23,733	5,933
Rex Hospital	20	Wake	4	21,356	5,339
UNC Hospital Radiation Oncology -Holly Springs	20	Wake	1	0	0
UNC Rex Cancer Center of East Raleigh	20	Wake	1	4,240	4,240
Central Harnett Hospital	21	Harnett	1	0	0
Johnston Health Clayton Professional Plaza	22	Johnston	1	6,319	6,319
Smithfield Radiation Oncology	22	Johnston	1	5,239	5,239
Main Campus	23	Lenoir	1	7,653	7,653
North Carolina Radiation Therapy Management Services - Goldsboro	23	Wayne	1	6,017	6,017
Carteret Health Care	24	Carteret	2	6,980	3,490
CarolinaEast Medical Center	24	Craven	2	9,746	4,873
Onslow Radiation Oncology, LLC	25	Onslow	1	2,694	2,694
North Carolina Radiation Therapy Management Services - Roanoke Rapids	26	Halifax	1	2,484	2,484
Nash Hospitals Inc.	26	Nash	2	7,706	3,853
Wilson Radiation Oncology	26	Wilson	1	1,377	1,377
ECU Health Beaufort Hospital	27	Beaufort	1	4,354	4,354
Vidant Radiation Oncology	27	Hertford	1	2,026	2,026
Vidant Radiation Oncology	27	Pitt	3	14,375	4,792
Vidant Radiation Oncology	27	Pitt	1	6,604	6,604

Table 15C-1: Hospital and Free-Standing Linear Accelerators and Radiation Oncology Procedures

Facility Name	Service Area Number	County	Number of Linear Accelerators	Number of Procedures (ESTVs) 10/1/2021-9/30/2022	Average Number of Procedures per Unit
Outer Banks Health Hospital	28	Dare	1	3,029	3,029
Sentara Albemarle Medical Center	28	Pasquotank	1	5,584	5,584
Totals (73 Facilities)			132	625,148	4,736

* CaroMont Regional Medical Center has two linear accelerators in Gaston County and one linear accelerator in Lincoln County

** New Hanover Regional Medical Center has four linear accelerators in New Hanover County and one linear accelerator in Brunswick County.

From: [Stauffer, Iain](#)
To: [Mitchell, Micheala L](#); [Pittman, Lisa](#)
Cc: [Stancil, Tiffany C](#)
Subject: [External] MH Mission Hospital, LLLP Notice of Exemption for Replacement of Linear Accelerator; FDID #943349
Date: Tuesday, April 16, 2024 2:03:33 PM
Attachments: [4880-7473-1447 v.1 CORR - CON Exemption Request - Mission LINAC 4-16-2024.pdf](#)

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Good afternoon Micheala and Lisa. Attached please find a Notice of Exemption for Replacement of a Linear Accelerator, with attachments, on behalf of MH Mission Hospital, LLLP.

If there is anything else that you need, please do not hesitate to ask.

Thank you.

Iain

Iain Stauffer

Attorney

Baker, Donelson, Bearman, Caldwell & Berkowitz, PC
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Raleigh, NC 27607

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