



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director, Division of Health Service Regulation

VIA EMAIL ONLY

November 15, 2021

Kenneth Burgess
kburgess@bakerdonelson.com

Exempt from Review – Replacement Equipment

Record #: 3721
Date of Request: October 19, 2021
Facility Name: Mission Hospital
FID #: 943349
Business Name: MH Mission Hospital, LLLP
Business #: 3045
Project Description: Replace existing linear accelerator
County: Buncombe

Dear Mr. Burgess:

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(f). Therefore, you may proceed to acquire without a certificate of need the Elekta Versa HD linear accelerator to replace Elekta Infinity linear accelerator. 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: 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

KENNETH LEE BURGESS, SHAREHOLDER
Direct Dial: 615.726.5719
Direct Fax:
E-Mail Address: kburgess@bakerdonelson.com

October 19, 2021

Micheala Mitchell, Esq. Chief
Lisa Pittman, Assistant Chief
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

Via Email to: Micheala.mitchell@dhhs.nc.gov
Lisa.Pittman@dhhs.nc.gov

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 Infinity 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.

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 \$2,000,000.00¹, 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 more than \$2,000,000.00.

Statutory Exemption For Replacement Equipment Which Costs More Than \$2,000,000.00

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. Replacement equipment is defined at N.C. Gen. Stat. §131E-176 (22a) as equipment 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 has the same technology as the equipment currently in use, although it may possess expanded capabilities due to technological improvements;
2. it is functionally similar to 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.

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

¹ The previous capital cost threshold for "major medical equipment" of \$750,000.00 was increased effective October 1, 2021 by Session Law 2021-129.

In addition, where the total cost of the replacement equipment exceeds \$2,000,000.00, there are two further statutory criteria which apply, as follows:

1. The equipment being replaced is located on the main campus; and
2. 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.

The term “campus” is defined at N.C. Gen. Stat. § 131E-176(2c) as “the adjacent grounds and buildings, or grounds and buildings not separated by more than a public right-of-way, of a health service facility and related health care entities.”

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).

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 Room RLL218 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, in a neighboring room identified as RLL221, at 21 Hospital Drive on the hospital’s main campus. See Exhibit 2 (statement of Mission’s Chief Operating Officer). See also, Exhibit 3 (diagram of hospital campus showing location of Mission Hospital main building and the Mission Cancer Center). The Mission Cancer Center is licensed on the Mission Hospital license. The diagram at Exhibit 3 demonstrates that the Mission Cancer Center is located on grounds adjacent to the Mission Hospital main building separated by a single public right of way, Victoria Road. Further, with the completion of the Mission Hospital North Tower back in 2018, the Cancer Center is now well within 250 yards of the Mission Hospital main building. In July of 2019, Mission sought and obtained a determination from then-CON Section Chief, Martha Frisone, that the Mission Cancer Center is located on the Mission Hospital main campus for purposes of assessing CON Exemptions. See Exhibit 4 (email from Martha Frisone to Mission counsel, Ken Burgess).
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 \$3,646,431.00, placing the project within the terms of the statutory exception set forth at N.C. Gen. Stat. §131E-184(f). Of that amount, approximately \$2,281,979.66 will be expended on the Linac itself. The remaining costs consist of non-medical equipment, architect and engineering fees and construction required to upfit Room RLL221 for the new Linac. See Exhibit 5 (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 6. See also, Exhibit 7 (2021 State Medical Facilities Plan (“SMFP”) Table 17C-1 showing three (3) CON-authorized Linacs at the Mission Cancer Center).
5. The Linac which will be “sold or otherwise disposed of” upon acquisition and installation of the replacement Linac. The existing Linac will be removed by and returned to Elekta, Inc. See Exhibit 1 (letter from Elekta, Inc.).
6. The Linac being replaced was new when purchased by Mission and is more than three years old, having been purchased and installed in 2011. See Exhibits 2 (statement of Mission’s Chief Operating Officer) and 6 (CON for existing Linac dated 2011).
7. The new Linac will have the same capabilities as the scanner 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).
8. 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 Exhibit 2 (statement of Mission’s Chief Operating Officer).

Micheaela Mitchell, Esq., Chief
Lisa Pittman, Assistant Chief
Page 5


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.

Very truly yours,

BAKER, DONELSON, BEARMAN,
CALDWELL & BERKOWITZ, PC

A handwritten signature in blue ink that reads "Ken Burgess". The signature is written in a cursive, flowing style.

Kenneth Lee Burgess

KLB:jdm
Enclosure

EXHIBIT 1



July 7, 2021

Jason Desai, MS
Vice President of Operations
Mission Hospital
509 Biltmore Avenue, Asheville, NC 28801

Dear Mr. Desai,

This letter is to inform you that Mission Hospital is contracting with Elekta, Inc. to have a third party remove an existing linear accelerator from the Mission Hospital Cancer Center. Elekta will be replacing the removed linear accelerator with a new Elekta Versa HD linear accelerator.

The existing linear accelerator, which is being replaced, will be removed from the Mission Hospital campus and will not be reinstalled or reused in the state of North Carolina without the proper CON authorization.

Sincerely,

ELEKTA INC.

A handwritten signature in blue ink, appearing to read "Katrina Halbig", written over a circular stamp.

Katrina Halbig

Order Fulfillment Zone Director, Southeast

EXHIBIT 2



July 7, 2021

Re: *Information/Items Needed for Mission Cancer Center Replacement Exemption Letter to CON Section*

To Whom It May Concern:

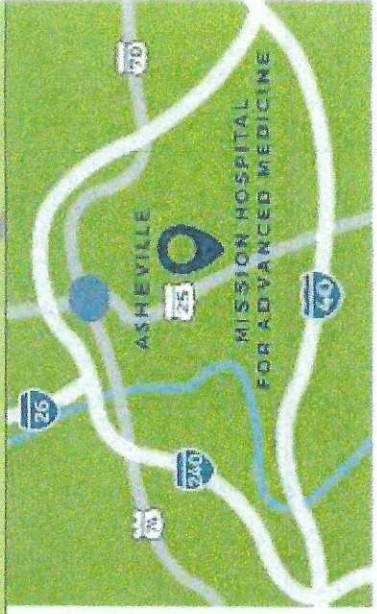
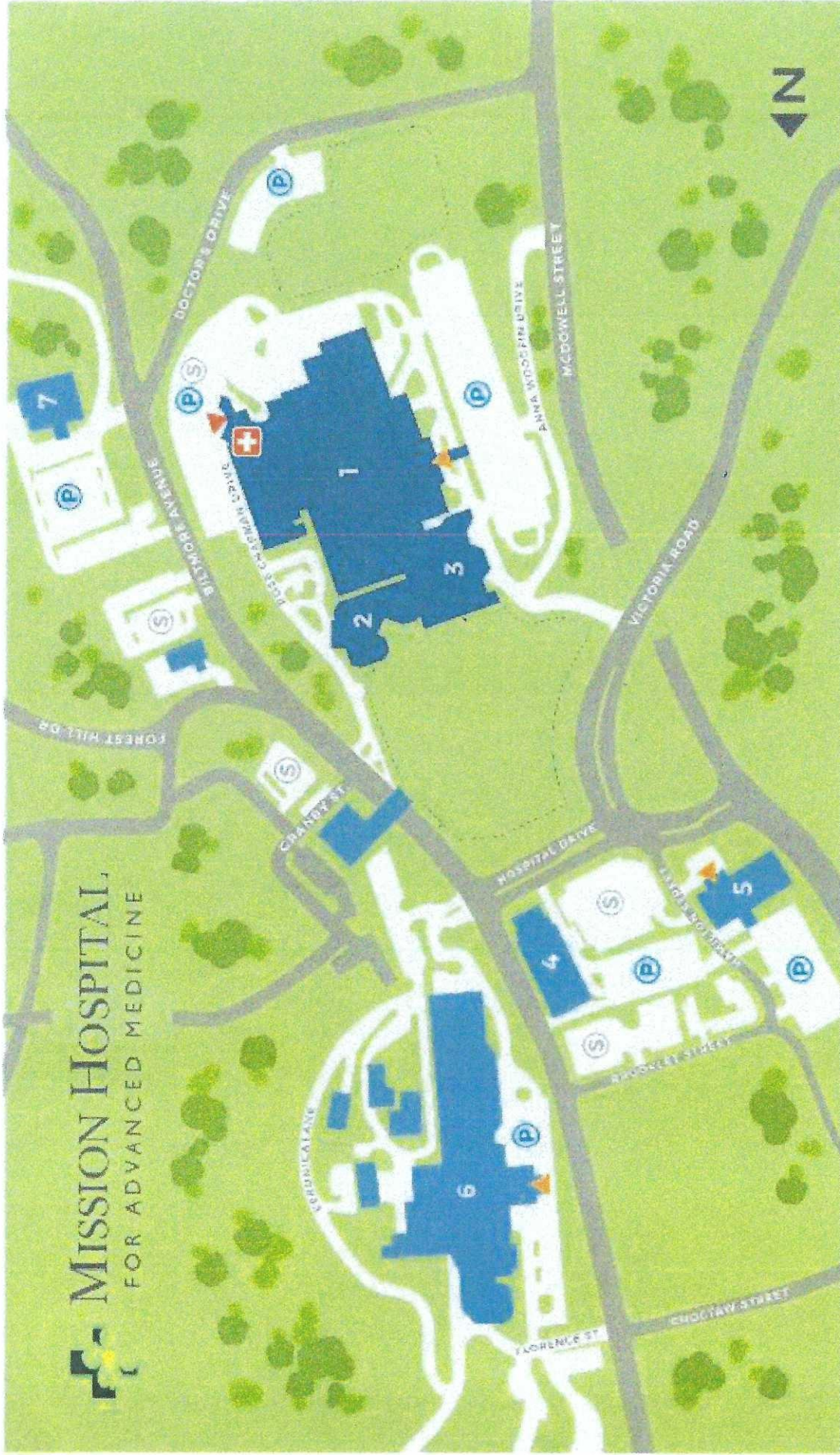
MH Mission Hospital, LLLP will be replacing an existing linear accelerator that is physically located at the Mission Cancer Center, 21 Hospital Drive on the Mission Hospital campus in Asheville, NC. The linear accelerator to be replaced is currently in use and will be replaced with an Elekta Versa HD linear accelerator. The replacement of this linear accelerator will not result in more than a 10% increase in patient charges or per procedure operating expense within the first 12 months after replacement of the equipment. The linear accelerator being replaced was purchased new when acquired 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 or in North Carolina with any CON Section approval that may be required.

Best Regards,

Joseph R. Rudisill
Chief Operating Officer
MH Mission Hospital, LLLP
509 Biltmore Avenue
Asheville, NC 28801
828-213-0185

EXHIBIT 3

MISSION HOSPITAL, FOR ADVANCED MEDICINE



LEGEND

- Main Hospital
- Mission Health Facility
- Main Entrance
- Visitor Parking
- Staff Parking
- Emergency Department

FACILITIES

- 1** Memorial Campus
- 2** Owen Heart Center
- 3** Outpatient Services
- 4** I Hospital Drive
- 5** SECU Cancer Center
- 6** St. Joseph Campus
- 7** Mission Imaging and Breast Center

MISSION HOSPITAL CAMPUS MAP & SURROUNDING PROPERTIES

03.23.2016

LEGEND

- MISSION PROPERTY OWNED
- POTENTIAL PROPERTY ACQUISITION
- FACILITY FOOTPRINT
- 250 YARD FACILITY OFFSET

SL#	ADDRESS	P.L.N.	ACRES	OWNER
1	362 McDowell St	9648475830	0.69	Little Pigs LLC
2	50 Doctors Dr - lot B	9648530663	3.04	MMH
2	50 Doctors Dr - lot A	9648427847	3.18	MMH
3	1 Doctors Dr	9648528949	0.99	CCP
4	275 McDowell St	9648432025	1.24	Lease to own by Mission Hospital
5	273 McDowell St	9648432263	0.45	CC Dickson
6	267 McDowell St	9648432363	0.39	MMH
7	257 McDowell St	9648432553	1.08	257 McDowell St Partnership
8	509 Billmore Ave	9648438750	27.78	MMH
9	534 Billmore Ave	9648535533	2.17	MMH
10	532 Billmore Ave	9648536757	2.57	MMH
11	528 Billmore Ave	9648534883	0.34	MMH
12	Forest Hill Dr	9648537806	0.93	MMH
13	Forest Hill Dr	9648533957	0.04	MMH
14	574 Billmore Ave	9648534935	0.67	MMH
15	520 Billmore Ave	9648533035	0.81	MMH
16	2 Forest Hill Dr	9648532242	0.30	MMH
17	500 Billmore Ave	9648530337	0.36	Habitat for Humanity
17	501 Billmore Ave	9648530364	0.17	Habitat for Humanity
17	506 Billmore Ave	9648531800	0.17	Habitat for Humanity
17	508 Billmore Ave	9648531225	0.29	Habitat for Humanity
18	496 Billmore Ave	9648485521	1.60	MMH
19	495 Billmore Ave	9648445476	1.46	MMH
20	86 Victoria Rd	9648433912	1.26	MMH
21	100 Victoria Rd	9648433538	1.33	Leased by Mission Hospital
22	93 Victoria Rd	9648337792	2.78	Huncombe County
23	91 Victoria Rd	9648339838	2.21	Asheville Property Investment LLC
24	75 Victoria Rd	9648441286	1.31	Aycock
25	Hospital Dr	9648443421	0.16	MMH
26	21 Hospital Dr	9648349733	3.05	MMH
27	15 Hospital Dr	9648441764	2.45	MMH
28	1 Hospital Dr	Multiple P.L.N.s	0	MMH
29	34 Granby St	9648449830	0.52	GMR Asheville, LLC
30	428 Billmore Ave	9648457138	11.99	MMH
31	435 Billmore Ave	9648452090	1.94	MMH
32	6 Brinkley St	9648440991	0	Leased by MMA
33	6 Brinkley St	9648440993	0.58	6 Brinkley Street Condo Owners
33	20 McDowell St	9648356287	2.14	MMH
34	39 Chocataw St	9648357556	0.18	2012 Rehoboth CSJ Trust
34	13 Hamilton St	9648357487	0.10	Timothy & Wendy Vort
34	15 Hamilton St	9648357492	0.10	Recardo Fernandez & Isabel Vine
34	23 Hamilton St	9648358325	0.20	Rosepat Properties, LLC
34	35 Hamilton St	9648358271	0.22	Rosepat Properties, LLC
34	41 Hamilton St	9648359104	0.11	Julia G Ray Living Trust
34	43 Hamilton St	9648359039	0.12	Laurel Mallet/Robert Whalman
34	Hamilton St	9648358248	0.10	Rosepat Properties, LLC
35	45 Hamilton St	9648359064	0.13	MMH
36	1 Doctors Pk	9648453227	0.63	AJA Holding Company
37	Doctors Pk	Various	Various	Various
39	373 Billmore Ave	9648452866	0.21	Hospice of Henderson County
39	5 Rockcliff Place	9648450601	1.02	Rockcliff Place Partners
40	30 Chocataw St	9648358776	3.40	30 Chocataw Complex Condo Owners
41	5 Frederick St	9648357991	0.31	MMH
42	345 Billmore Ave	9648403002	4.32	MMH
43	356 Billmore Ave	9648464095	2.78	Huncombe County
44	324 Billmore Ave	9648464336	0.78	DJR Enterprises
45	319 Billmore Ave	9648460425	4.13	Duke Energy
46	Billmore Ave	9658463028	1.35	Duke Energy



Burgess, Kenneth L.

From: Jonathon.Yeatman@HCAHealthcare.com
Sent: Tuesday, July 09, 2019 9:36 AM
To: Burgess, Kenneth L.; Garrett.Shreffler@HCAHealthcare.com;
Angela.Fletcher@HCAHealthcare.com
Subject: Re:Cancer Center Multidisciplinary Clinic - CON Exception - Assignments below - Due 7/11
Attachments: 20160323-Site Slide_UPDATED.PDF

The attached map was prepared by the architecture firm Freeman White. It shows a 250 yard line from the boundaries of the main hospital (including the new tower). The cancer center is building #26.

From: Burgess, Kenneth L. [mailto:KBurgess@poynerspruill.com]
Sent: Tuesday, July 09, 2019 7:45 AM
To: Shreffler Garrett <Garrett.Shreffler@HCAHealthcare.com>; Fletcher Angela <Angela.Fletcher@HCAHealthcare.com>; Yeatman Jonathon <Jonathon.Yeatman@HCAHealthcare.com>
Subject: {EXTERNAL} RE: Cancer Center Multidisciplinary Clinic - CON Exception - Assignments below - Due 7/11

That is very good news—thank you! What we've done in the past that has been accepted by the CON Section is just to create a picture/document that shows the 2 sites or the 2 buildings with a red arrow and the yardage/distance indicated on or near the arrow. I'm sure there are other ways but anything we can submit that demonstrates the "within 250 yards" is fine. It doesn't have to be official because in the Exemption Notice we'll be filing, we'll be certifying to the accuracy of the information we're submitting. Is that sort of diagram something you guys can whip up? If not, if you can get the "unofficial" distance, I'm sure we can create something here. I just remember getting something like I've described in prior cases. Thanks, Ken

From: Garrett.Shreffler@HCAHealthcare.com [mailto:Garrett.Shreffler@HCAHealthcare.com]
Sent: Tuesday, July 09, 2019 6:22 AM
To: Angela.Fletcher@HCAHealthcare.com; Burgess, Kenneth L. <KBurgess@poynerspruill.com>; Jonathon.Yeatman@HCAHealthcare.com
Subject: Re:Cancer Center Multidisciplinary Clinic - CON Exception - Assignments below - Due 7/11

Ken,

With the new North Tower addition, the Cancer Center is now well within the 250 yard threshold distance. If needed, Facilities can provide an unofficial measurement or a surveyor can be engaged if a formal certification of distance is required.

Hospital Drive is a public right of way.

Garrett Shreffler, CHFM
P 828.213.9445 | M 828.777.0753

From: Fletcher Angela
Sent: Monday, July 08, 2019 3:44 PM
To: Burgess, Kenneth L. <KBurgess@poynerspruill.com>; Yeatman Jonathon <Jonathon.Yeatman@HCAHealthcare.com>; Shreffler Garrett <Garrett.Shreffler@HCAHealthcare.com>
Subject: RE: Cancer Center Multidisciplinary Clinic - CON Exception - Assignments below - Due 7/11



September 11, 2009

Lee B. Hoffman, Chief
Certificate of Need Section
Division of Health Service Regulation
North Carolina Department of Health
and Human Services
2704 Mail Service Center
Raleigh, North Carolina 27699-2704

RE: Mission Hospital Letter of Non Review: Relocation of an OR from the St. Joseph's building to a current GYN procedure room in the Memorial building

Dear Ms. Hoffman:

Mission Hospital ("Mission") submits this letter as prior written notice that it plans to relocate an OR currently located in the St. Joseph's building to a current GYN procedure room in the Memorial building. The Memorial building and the St. Joseph's building are located on the same campus as defined within the meaning of N.C.G.S. 131E-176 (2c) "adjacent grounds and buildings not separated by more than one public right-of-way" and therefore not subject to CON review. In an email correspondence Lee Hoffman noted, "Because St. Joseph and Mission are a single licensed hospital that are located on a single campus (i.e. grounds that are adjacent and not separated by more than one public right of way) operating rooms may be moved between buildings on this campus that are licensed as part of Mission Hospital without a CON if the cost of the project is less than \$2 million."

Construction for this project is due to begin October, 2009 and will be completed November 30, 2009. Upon completion of this project, the space once occupied by OR 5 in the St. Joseph's building will be used to expand the existing sterile core. Expansion of the sterile core will provide a more centrally located area for all sterile supplies. Currently, surgical supplies in the St. Joseph's building are located in two separate areas and need to be combined. In addition, relocating an OR from the St. Joseph's building to the Memorial building will result in improved efficiencies associated with redundant staffing and costs within Mission's surgical services. Having an additional OR in the Women's services department will provide space where emergent and urgent surgeries for pregnant patients, elective C-Sections and elective GYN cases can be preformed all in one area. This will also provide a more family oriented area for delivering mothers and their personal support. Having an additional OR room in Women's Services will allow GYN/OB cases to be performed closer to Labor and Delivery keeping surgeons within close proximity to other laboring patients. In addition, supplies are currently located in three different areas in the Memorial building to accommodate Women's surgical services which are, at times, performed on a separate floor. If Women's surgical services are in the same area staffing will be more consistent thus saving on excesses of staffing three different areas. See attached floor plans of the current location of OR 5 in the St. Joseph's building along with the floor plan of the new OR location in Women's Services at the Memorial building. The

procedure room in the Memorial building will not be relocated. The procedure room will be upgraded to an OR once OR 5 has been relocated.

Relocating the OR from St. Joseph's building to the Memorial building will not increase the total number of licensed OR's at Mission Hospital. The proposed changes would not involve the acquisition of any major medical equipment or equipment otherwise covered under the CON Act. Please see the table on the next page for a breakout of the original and proposed OR's in the St. Joseph's and Memorial buildings.

Pre New OBGYN 3rd OR and Decommissioning of SJOR 5

Type of Operating Room	Memorial Hospital	St. Joseph's Hospital	Asheville Surgery Center	Total
Dedicated Open Heart Surgery	6	0	0	6
Other Dedicated Inpatient Surgery*	15	2	0	17
Dedicated Ambulatory Surgery	0	4	9	13
Shared-Inpatient/Ambulatory Surgery	2	9	0	11
Total Operating Rooms	23	15	9	(47)

Post New OBGYN 3rd OR and Decommissioning of SJOR 5

Type of Operating Room	Memorial Hospital	St. Joseph's Hospital	Asheville Surgery Center	Total
Dedicated Open Heart Surgery	6	0	0	6
Other Dedicated Inpatient Surgery*	15	2	0	17
Dedicated Ambulatory Surgery	0	4	9	13
Shared-Inpatient/Ambulatory Surgery	3	8	0	11
Total Operating Rooms	24	14	9	47

Mission seeks confirmation that the replacement of the GYN procedure room does not constitute a new institutional health service subject to CON review within the meaning of NCGS 131E-176 (16)(b). The North Carolina law defining those services which require a CON contains no provisions applicable to the proposed project. The definition of "new institutional health services" requiring a CON which potentially could apply to the proposed project is "The obligation by any person of a capital expenditure exceeding two million dollars (\$2,000,000) to develop or expand a health service or a health service facility. This project will cost \$332,000 to complete including construction, equipment, and contingency. These costs are only for the upgrade of the procedure room to an OR. The procedure room located in the Memorial building will not be relocated. There will be no additional costs associated with expansion of the sterile core in the St. Joseph's building. The OR is located currently located in the same area as the sterile core. See the attached drawings of the current location of OR 5 in the St. Joseph's building. A projected capital cost verification form signed by the architect, Steven Bowers of Bowers, Ellis and Watson Architects, PA, is attached.

We look forward to receiving your letter confirming that Mission's relocation of an existing OR from the St. Joseph's building to the Memorial Building on the same campus. All components are exempt from certificate of need review pursuant to N.C. Gen. Stat. § NCGS 131E-176 (16)(b). Please contact me at (828) 213-3509 if there is any additional information I can provide to facilitate your review of this request.

Sincerely,



Brian Moore
Director of Strategic Planning



North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section
2704 Mail Service Center ■ Raleigh, North Carolina 27699-2704

Beverly Eaves Perdue, Governor
Lanier M. Cansler, Secretary

www.ncdhhs.gov/dhsr

Lee Hoffman, Section Chief
Phone: 919-855-3873
Fax: 919-733-8139

September 30, 2009

Brian Moore
Director of Strategic Planning
Mission Hospitals
509 Biltmore Avenue
Asheville, NC
28801

RE: No Review/ Mission Hospitals/ Relocation of one OR from the St. Joseph Building to a Procedure Room in the Memorial Building/ Buncombe County
FID #943349


Dear Mr. Moore:

The Certificate of Need (CON) Section received your letter of September 11, 2009 regarding the above referenced proposal. Based on the CON law in effect on the date of this response to your request, the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Certificate of Need Section. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

In addition, you should contact the Construction Section, DHSR to determine if they have any requirements for development of the proposed project. Please contact the CON Section if you have any questions. Also, in all future correspondence you should reference the Facility I.D.# (FID) if the facility is licensed.

Sincerely,


Paula Quirin,
Project Analyst


Lee B. Hoffman, Chief
Certificate of Need Section

cc: Construction Section, DHSR



EXHIBIT 4

Burgess, Kenneth L.

From: Frisone, Martha <martha.frisone@dhhs.nc.gov>
Sent: Tuesday, July 09, 2019 10:55 AM
To: Burgess, Kenneth L.
Cc: Faenza, Julie M; Pittman, Lisa; Hale, Gloria; Wilson, Fatimah
Subject: RE: [External] MH Mission Hospital Question

After reviewing the map, the Cancer Center is located on the main campus.

Martha J. Frisone

Chief

Division of Health Service Regulation, Healthcare Planning and Certificate of Need
NC Department of Health and Human Services

Office: 919-855-3879
martha.frisone@dhhs.nc.gov

809 Ruggles, Edgerton
2704 Mail Service Center
Raleigh, NC 27699-2704

[Twitter](#) | [Facebook](#) | [YouTube](#) | [LinkedIn](#)

From: Burgess, Kenneth L. <KBurgess@poynerspruill.com>
Sent: Monday, July 08, 2019 3:44 PM
To: Frisone, Martha <martha.frisone@dhhs.nc.gov>
Subject: [External] MH Mission Hospital Question

CAUTION:

Martha, I'm working with Mission Hospital on a project that I think qualifies under the 131E-184(g) exemption for renovation on the same site of all or part of a health service facility and I'm hoping you can take a look at the attached main campus map and give me your reading of the following – the Cancer Center, which is where the renovation will occur, is building 5 on the diagram. The main hospital is building 1. The two are separated by a greenway and Victoria Road which you cross twice but it's the same road based on my recent trip to Mission. I'm obtaining precise distance measurements but it looks like it's probably more than 250 yards away from the main hospital building but I know that in the past, the Agency has viewed the St. Joe's building, which is building 6 on the map, as "main campus" and it's about equidistant from the main hospital building and also separated by one road (Biltmore Avenue). Those buildings are clearly all part of the big main Mission campus but I want to ensure they qualify technically in the eyes of the Agency. Please advise if you need more information. Thanks, Ken Burgess

This message constitutes a confidential attorney-client communication. If you have received this communication in error, do not read it. It is not intended for transmission to, or receipt by, any unauthorized persons. Please delete it from your system without copying it, and notify the sender by reply email or by calling 919-783-6400, so that our address record can be corrected. Thank you.

Burgess, Kenneth L.

From: Burgess, Kenneth L.
Sent: Monday, July 08, 2019 3:44 PM
To: 'Frisone, Martha'
Subject: MH Mission Hospital Question
Attachments: Mission Main Campus Map.pdf

Martha, I'm working with Mission Hospital on a project that I think qualifies under the 131E-184(g) exemption for renovation on the same site of all or part of a health service facility and I'm hoping you can take a look at the attached main campus map and give me your reading of the following – the Cancer Center, which is where the renovation will occur, is building 5 on the diagram. The main hospital is building 1. The two are separated by a greenway and Victoria Road which you cross twice but it's the same road based on my recent trip to Mission. I'm obtaining precise distance measurements but it looks like it's probably more than 250 yards away from the main hospital building but I know that in the past, the Agency has viewed the St. Joe's building, which is building 6 on the map, as "main campus" and it's about equidistant from the main hospital building and also separated by one road (Biltmore Avenue). Those buildings are clearly all part of the big main Mission campus but I want to ensure they qualify technically in the eyes of the Agency. Please advise if you need more information. Thanks, Ken Burgess


EXHIBIT 5

**Projected Capital Cost Form
Mission Hospital Linear Accelerator Replacement**

Building Purchase Price	\$0.00
Purchase Price of Land	\$0.00
Closing Costs	\$0.00
Site Preparation	\$0.00
Construction/Renovation Contract(s)	\$844,263.00
Landscaping	\$0.00
Architect / Engineering Fees	\$106,500.00
Medical Equipment	\$2,281,979.66
Non-Medical Equipment	\$303,269.24
Furniture	\$0.00
Consultant Fees (specify)	\$0.00
Financing Costs	\$0.00
Interest during Construction	\$0.00
Other (Contingency)	\$110,419.10
Total Capital Cost	\$3,646,431.00

CERTIFICATION BY A LICENSED ARCHITECT OR ENGINEER

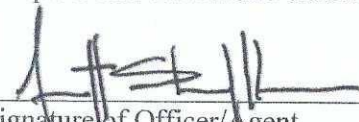
I certify that, to the best of my knowledge, the projected capital cost for the proposed project is complete and correct.


Signature of Licensed Architect or Engineer

Date Signed: 10/05/2021

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: 10/05/2021

Director, Facility Planning, Design & Construction
Title of Officer/Agent

EXHIBIT 6

STATE OF NORTH CAROLINA

*Department of Health and Human Services
Division of Health Service Regulation*

CERTIFICATE OF NEED

for

Project Identification Number #B-8542-10

FID #943349

**ISSUED TO: Mission Hospital, 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: Mission Hospital, Inc. shall acquire a replacement linear accelerator for a total of three linear accelerators/ Buncombe County

CONDITIONS: See Reverse Side

**PHYSICAL LOCATION: Mission Hospital Regional Cancer Center
60 Hamilton Street
Asheville, NC 28801**

MAXIMUM CAPITAL EXPENDITURE: \$2,159,280

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: March 15, 2011

This certificate is effective as of the 23rd day of November, 2010



Chief, Certificate of Need Section
Division of Health Service Regulation

CONDITIONS:

1. Mission Hospital, Inc. shall materially comply with all representations made in the certificate of need application and supplemental documents. In those instances where representations conflict, Mission Hospital, Inc. shall materially comply with the last-made representation.
2. Mission Hospital, Inc. shall acquire no more than one linear accelerator to replace the existing Siemens Primus® linear accelerator for a total of no more than three linear accelerators upon project completion.
3. Mission Hospital, Inc. shall dispose of the existing Siemens Primus® linear accelerator by removing it from North Carolina.
4. Mission Hospital, 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.
5. Mission Hospital, 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.

TIMETABLE:

Contract Award	_____	April 1, 2010
50% Completion of Construction	_____	November 15, 2010
Completion of Construction	_____	August 31, 2011
Occupancy/Offering of Service(s)	_____	January 1, 2012

From: [Mitchell, Micheala L](#)
To: [Waller, Martha K](#)
Cc: [Lightbourne, Ena](#)
Subject: FW: [External] MH Mission Hospital, LLLP: Notice of Exemption For Replacement of Linear Accelerator
Date: Tuesday, October 19, 2021 4:04:58 PM
Attachments: [Scan.pdf](#)

For you Martha. Thanks,

Micheala Mitchell, JD
[NC Department of Health and Human Services](#)
[Division of Health Service Regulation](#)
Section Chief, Healthcare Planning and CON Section
809 Ruggles Drive, Edgerton Building
2704 Mail Service Center
Raleigh, NC 27699-2704
Office: 919 855 3879
Micheala.Mitchell@dhhs.nc.gov

Don't wait to vaccinate. Find a COVID-19 vaccine location near you at [MySpot.nc.gov](https://www.myspot.nc.gov).
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From: Burgess, Ken <kburgess@bakerdonelson.com>
Sent: Tuesday, October 19, 2021 4:00 PM
To: Mitchell, Micheala L <Micheala.Mitchell@dhhs.nc.gov>; Pittman, Lisa <lisa.pittman@dhhs.nc.gov>; Lightbourne, Ena <ena.lightbourne@dhhs.nc.gov>
Subject: [External] MH Mission Hospital, LLLP: Notice of Exemption For Replacement of Linear Accelerator

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to [Report Spam](#).

Micheala, Lisa and Ena, attached please find a Notice of Exemption regarding the replacement of a linear accelerator which I'm filing on behalf of our client MH Mission Hospital, LLLP, along with supporting attachments. Please let me know if you need additional information, or have questions, regarding this Exemption Notice. Thank you, Ken Burgess

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