



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

July 9, 2020

Matthew A. Fisher

MFisher@poynerspruill.com

Exempt from Review – Replacement Equipment

Record #: 3308
Facility Name: Charlotte Radiology Breast Center
FID #: 021188
Business Name: Charlotte Radiology, P.A.
Business #: 468
Project Description: Replace existing breast MRI scanner
County: Mecklenburg

Dear Mr. Fisher:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of June 22, 2020, 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 Siemens Magnetom Vida MRI scanner and additional equipment to replace the Siemens Magnetom Symphony MRI scanner. 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,

Julie M. Faenza
Project Analyst

Martha J. Frisone
Chief

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

June 22, 2020

Matthew A. Fisher
Partner
D: (919) 783-2924
F: (919) 783-1975
mfisher@poynerspruill.com

VIA E-MAIL ONLY

Martha Frisone, Chief
Julie Faenza, Project Analyst
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: *Charlotte Radiology, PA's Notice of Exemption for Replacement of Breast MRI Scanner*

Dear Martha and Julie:

Our client, Charlotte Radiology, PA (“Charlotte Radiology”), owns and operates a Breast MRI scanner currently located at Charlotte Radiology Breast Center (“CRBC”), a diagnostic center located at 1025 Morehead Medical Drive, Charlotte, NC, 28204. Charlotte Radiology now desires to replace that MRI scanner at the same site. I am writing to provide advance written notice to the N.C. Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section (the “Agency” or the “CON Section”) of our client’s planned acquisition of replacement equipment and to request that the CON Section provide written confirmation that the replacement of the Breast MRI scanner at CRBC is exempt from certificate of need (“CON”) review within the meaning of N.C. Gen. Stat. §131E-184(a)(7).

The existing Breast MRI scanner is a Siemens Magentom Symphony MRI scanner, which was acquired by Charlotte Radiology and installed at CRBC pursuant to a CON issued for Project I.D. # F-6725-02. See Exhibit A (CON issued to Charlotte Radiology on 24 September 2003). In 2005, following a Declaratory Ruling issued by DHSR Director Robert Fitzgerald, Charlotte Radiology relocated the MRI to its present location. See Exhibit D (19 May 2005 Declaratory Ruling). Charlotte Radiology now proposes to replace the existing MRI scanner with a Siemens Magnetom Vida MRI scanner.

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,” costing more than \$750,000.00. N.C. Gen. Stat. § 131E-176(16)p.
- The acquisition by purchase, donation, lease, transfer or comparable arrangement of an MRI scanner, regardless of cost. N.C. Gen. Stat. § 131E-176(16)f1.7.

Ms. Frisone • Ms. Faenza
 June 22, 2020
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As discussed below, the costs associated with the acquisition and installation of the replacement Breast MRI scanner will exceed \$750,000. Yet, 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 \$2,000,000.00, 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.

N.C. Gen. Stat. §131E-176(22a). 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; 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.*

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

The replacement of the Breast MRI scanner at CRBC falls within the parameters of this exemption.

1. The equipment being replaced is currently in use at CRBC. See Exhibit B (letter from Jerome Carter, Charlotte Radiology Director of Operations).
2. The total estimated cost to acquire and install the MRI scanner is less than \$2,000,000, placing the project well within the terms of the statutory exception set forth at N.C. Gen. Stat. §131E-184(a)(7). This estimated project cost is **exclusive of equipment** and related installation costs required to make the replacement MRI scanner operational, and is based on the following attached quotations:¹

¹ Portions of the attached quotations are not included to protect confidentiality and because they are not material to the CON Section’s determination.

Ms. Frisone • Ms. Faenza
 June 22, 2020
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1	Construction	\$	400,000.00
2	Architect Fees	\$	43,200.00
3	Breast MRI coils	\$	124,000.00
4	Medrad Injector	\$	29,815.00
5	RF Shielding	\$	85,000.00
7	Physicist Fee	\$	1,000.00
	Total:	\$	693,015.00

3. Due to the confidential nature of the pricing by the vendor for the replacement MRI scanner, no quote is attached. In the alternative, per your specific instructions, the Affidavit of Cheryl Marks attests—under oath—to the overall cost of this project. See Exhibit C. This affidavit shows that, when added to the costs enumerated above, the cost of the new Breast MRI scanner will result in a total project cost of less than \$2,000,000.
4. The MRI scanner which will be replaced will be disposed of upon acquisition and installation of the replacement scanner. The existing scanner will be removed by and returned to Siemens Medical Solutions USA, Inc. See Exhibit C.
5. The MRI scanner being replaced is more than three years old. See Exhibit A. The existing scanner was purchased new in when acquired, and the replacement scanner will be a new unit, as well. See Exhibit B.
6. The new MRI scanner will have the same capabilities as the scanner being replaced, although it may have additional capabilities due to the advancement of MRI scanner technology, is functionally similar to the existing MRI scanner and will be used for the same diagnostic or treatment purposes as the equipment being replaced. Charlotte Radiology will not acquire any other major medical equipment or develop any other new institutional health services described in N.C. Gen. Stat. §131E-176 (16) as part of this project. See Exhibit B and C.
7. 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 B.


CONCLUSION

As described above, we believe the proposed replacement of CRBC’s existing Breast MRI scanner 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 that this is the case.

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

Ms. Frisone • Ms. Faenza
June 22, 2020
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Very truly yours,

A handwritten signature in blue ink, appearing to read "Matthew A. Fisher". The signature is fluid and cursive, with a large initial "M" and "F".

Matthew A. Fisher
Partner

Attachments

cc w/enc: Cheryl Marks • Jerome Carter (via e-mail)

Ms. Frisone • Ms. Faenza
June 22, 2020
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INDEX OF EXHIBITS

- A. CON issued to CIS on January 25, 2006 for Project I.D. # F-7167-04
- B. Letter from Jerome Carter, Charlotte Radiology Director of Operations
- C. Affidavit of Cheryl Marks
- D. February 29, 2008 Declaratory Ruling
- E. FMK Architects, P.A. Proposed AIA Standard Form of Agreement
- F. Jenison Construction, Inc. Cost Estimate

STATE OF NORTH CAROLINA
Department of Health and Human Services
Division of Facility Services

CERTIFICATE OF NEED
for
Project Identification Number F-6725-02
FID#021188

ISSUED TO: Charlotte Radiology, PA
d/b/a Charlotte Radiology Breast Center
1701 East Boulevard
Charlotte, NC 28203-5823

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: Charlotte Radiology, PA d/b/a Charlotte Radiology Breast Center/Acquire a dedicated breast magnetic resonance scanner (MRI) and establish a new diagnostic center/Mecklenburg County

CONDITIONS: See Reverse Side

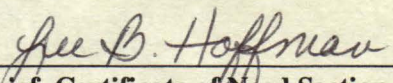
PHYSICAL LOCATION: Charlotte Radiology Breast Center
6836 Morrison Boulevard
Charlotte, NC 28211

MAXIMUM CAPITAL EXPENDITURE: \$1,273,565

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: January 2, 2004

This certificate is effective as of the 24th day of September, 2003.



Chief, Certificate of Need Section
Division of Facility Services

CONDITIONS

1. Charlotte Radiology, PA d/b/a Charlotte Radiology Breast Clinic shall materially comply with all representations made in the certificate of need application and supplemental documents provided to the Agency on June 11 and August 7, 2003. In those instances in which any of these representations conflict, Charlotte Radiology, PA d/b/a Charlotte Radiology Breast Center shall materially comply with the last-made representations.
2. Charlotte Radiology, PA d/b/a Charlotte Radiology Breast Clinic 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. The facility's charges for the first three years of operation following completion of its project shall be limited to the following:

Procedure	ICD-9 Code	Year One	Year Two	Year Three
Unilateral	76093	\$1,483	\$1,483	\$1,483
Bilateral	76094	\$1,613	\$1,613	\$1,613

TIMETABLE

Obtaining funds necessary to undertake project	November 1, 2003
Completion of final drawings and specifications	December 7, 2003
Contract award	February 21, 2004
25% completion of construction	March 15, 2004
50% completion of construction	April 1, 2004
75% completion of construction	April 21, 2004
Completion of construction	May 14, 2004
Offering of service	June 1, 2004

December 5 2005

2006

2007

2008

700 E. Morehead St.
Suite 300
Charlotte, NC 28202

P 704.334.7800
F 704.334.7818



June 8, 2020

Re: Information/Items Needed for Breast MRI Scanner Replacement Exemption Letter to CON Section

To Whom It May Concern:

Charlotte Radiology, PA will be replacing our existing MRI scanner that is physically located at Charlotte Radiology Breast Center, 1025 Morehead Medical Drive, Charlotte, NC, 28204. The scanner to be replaced is currently in use. The replacement of this scanner will not result in more than a 10% increase in patient charges or per procedure operating expense within the first twelve months after replacement. The scanner being replaced was purchased new when acquired and the replacement scanner will be a new unit. All new functionality associated with the new MRI scanner will be due to advancement of technology. The existing equipment will be traded in as part of the purchase of the new equipment.

Best Regards,

A handwritten signature in black ink that reads "Jerome S. Carter". The signature is written in a cursive style with a long horizontal flourish extending to the right.

Jerome Carter
Director of Operations
Charlotte Radiology, PA

Lindsay I. Muns, CEO
Robert L. Mittl Jr., M.D., President


AFFIDAVIT OF CHERYL MARKS

Cheryl Marks, being first duly sworn, deposes and says as follows:

1. I am the Vice President of Operations for Charlotte Radiology, PA, and having reached the age of majority am competent to make this Affidavit which I do on my own knowledge.
2. As part of my duties as Vice President of Operations, I am responsible for the oversight of all outpatient operations across Charlotte Radiology, which includes our Breast Services division.
3. I am personally familiar with proposed project to replace the Breast MRI scanner currently located at Charlotte Radiology Breast Center ("CRBC"), a diagnostic center located at 1025 Morehead Medical Drive, Charlotte, NC, 28204.
4. Under pain of perjury I certify that the total costs of the CRBC Breast MRI Scanner Replacement project will not total in excess of TWO MILLION AND 00/100 DOLLARS (\$ 2,000,000.00).
5. Furthermore, Charlotte Radiology will not acquire any other major medical equipment or develop any other new institutional health services described in N.C. Gen. Stat. §131E-176 (16) as part of this project.

FURTHER AFFIANT SAYETH NAUGHT.

This the 8th day of June, 2020.

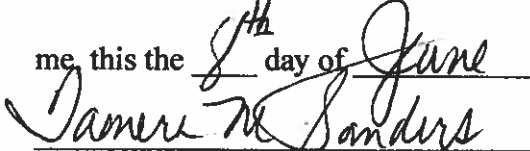


CHERYL MARKS
Vice President of Operations
Charlotte Radiology, PA

STATE OF NORTH CAROLINA
COUNTY OF MECKLENBURG

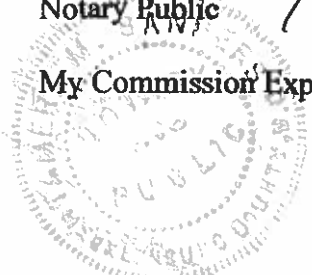
Sworn to and subscribed before

me, this the 8th day of June, 2020.



Notary Public

My Commission Expires: 6/22/2022



BODE, CALL & STROUPE, L.L.P.

ATTORNEYS AT LAW

3105 GLENWOOD AVENUE, SUITE 300
RALEIGH, NORTH CAROLINA 27612

(919) 881-0338

TELECOPIER (919) 881-9548

JOHN V. HUNTER III

RETIRED

DAVID P. GREEN

(1945 - 1985)

MAILING ADDRESS

POST OFFICE BOX 6338
RALEIGH, NORTH CAROLINA
27628-6338

JOHN T. BODE
W. DAVIDSON CALL
ROBERT V. BODE
ODES L. STROUPE, JR.
V. LANE WHARTON, JR.
S. TODD HEMPHILL
DIANA EVANS RICKETTS
JOHN S. BYRD II
MATTHEW A. FISHER

May 20, 2005

Mr. Mark Jensen
Administrator
Charlotte Radiology, P.A.
1701 East Boulevard
Charlotte, NC 28203

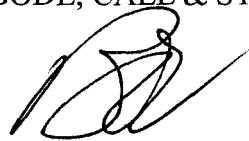
Re: Declaratory Ruling for Charlotte Radiology, P.A. d/b/a Charlotte Radiology Breast
Center - Project I.D. #F-6725-02, Mecklenburg County

Dear Mark:

I am pleased to enclose the original executed Declaratory Ruling issued by the State in the
above matter. You have permission to proceed as requested. Please call me with any questions.
My regards to Chris.

Very truly yours,

BODE, CALL & STROUPE, L.L.P.



Robert V. Bode

RVB:jgp

Enclosure

F:\Charlotte Rad\Breast MRI\Nensen ltr 05-20-05.wpd

NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF FACILITY SERVICES
RALEIGH, NORTH CAROLINA

IN RE: REQUEST FOR A DECLARATORY)
RULING BY CHARLOTTE RADIOLOGY, P.A.)
d/b/a CHARLOTTE BREAST RADIOLOGY)
CENTER)
)

DECLARATORY RULING

I, Robert J. Fitzgerald, as Director of the Division of Facility Services (the "Agency"), do hereby issue this declaratory ruling to Charlotte Radiology, P.A. d/b/a Charlotte Breast Radiology Center, pursuant to N.C. Gen. Stat. §150B-4 and 10 N.C.A.C. 3B.0310 under the authority delegated to me by the Secretary of the Department of Health and Human Services. This declaratory ruling will interpret whether CRBC, by proposing to change site location and selecting a new vendor for the dedicated breast MRI scanner for which it received a Certificate of Need ("CON") in 2003, remains in material compliance with its CON within the meaning of N.C. Gen. Stat. §131E-181(b).

For the reasons set out herein, the proposed change in site location does not materially alter the project as proposed in CRBC's CON application, and CRBC may proceed to develop the proposed project at the Morehead Medical Plaza location without fear of the Agency withdrawing its CON.

For the reasons set out herein, the proposed change in the vendor/manufacture of the MRI equipment does not materially alter the project as proposed in CRBC's CON application, and CRBC may proceed to acquire the proposed MRI scanner from Siemens instead of Aurora without fear of the Agency withdrawing its CON.

This ruling will be binding on this Agency so long as the material facts stated herein are accurate. This ruling applies only to this request. Except as provided by N.C. Gen. Stat. §150B-4, the Agency reserves the right to change the conclusions that are contained in this ruling. Mr. Robert V. Bode, of the law firm Bode, Call & Stroupe, L.L.P., has requested this ruling on behalf of CRBC, and has provided the facts set out below:

STATEMENT OF FACTS

CRBC submitted a certificate of need application on or about November 15, 2002 to acquire a fixed dedicated breast MRI scanner in Mecklenburg County. The review was non-competitive. On March 26, 2003, the CON Section notified CRBC that its application was disapproved. Following the filing of a petition for contested case hearing, the parties involved entered into a settlement agreement.

As a condition of the settlement agreement, CRBC was required to materially comply with all representations made in the certificate of need application and the supplemental documents provided to the Agency on June 11, 2003 and August 7, 2003. The supplemental documents from June 11, 2003 primarily dealt with the cost of providing the service to the proposed patient population. The August 7, 2003 documents addressed certain issues involving financial issues related to the office space and equipment leases. In the August 7, 2003 documents, CRBC also addressed proposed utilization and the pro formas for the project.

CRBC seeks to utilize office space that is closer to the hospital and roughly four miles from the initial site. CRBC has selected a new equipment vendor due to quality and financial concerns involving the initial vendor, Aurora. The proposed changes will not materially alter the intent of the proposed project to provide dedicated breast MRI services in Mecklenburg County.

ANALYSIS

The CON law requires a review of a proposed change of site if it represents a material change in the physical location of the project [N.C. Gen. Stat. §131E-181(a)]. In its application, CRBC proposed to utilize one of its existing mammography facilities as the site for the project. CRBC now proposes to utilize space at Morehead Medical Plaza, a medical office building, which was built by Carolinas Medical Center. The new site is four miles from CRBC's original site in the CON application. Morehead Medical Plaza will also house two major obstetrics/gynecology practices as well as Carolinas Medical Center's Women's Institute. These services are in line with the proposed project to provide dedicated breast MRI scans.


The CON law also requires a review of a proposed change in defined scope of the project if it represents a material change for the project. In its application, CRBC proposed to lease an Aurora 0.6T MRI scanner to provide fixed dedicated breast MRI scans. Since the time the application was filed in 2002, the 0.6T MRI scanners are now outdated and are being replaced by 1.5T scanners. CRBC has also learned that Aurora may be experiencing quality and financial difficulties, which raises concerns about the vendor's future viability.

CONCLUSION

For all of the foregoing reasons, assuming the statement of facts in the request to be true, I conclude that the proposed change in site location to Morehead Medical Plaza from Morrison Boulevard in Charlotte will not violate N.C. Gen. Stat. §131E-181(a) because it will not constitute a material change in the terms of the CON related to location and will not constitute a failure to satisfy a condition of the CON in violation of N.C. Gen. Stat. §131E-189(b). I also conclude that the proposed change in the equipment vendor will not violate N.C. Gen. Stat. §131E-181(a) because it will not constitute a material change in the terms of the CON related to the defined scope of the project and will not constitute a failure to satisfy a condition of the CON in violation of N.C. Gen. Stat. §131E-189(b).

This ruling is not intended, and should not be interpreted, to authorize any increase in the approved capital expenditure for this project, a change in the conditions placed on the certificate of need, or any other change in the approved project.

This the 19th day of May, 2005.


Robert J. Fitzgerald
Director, Division of Facility Services

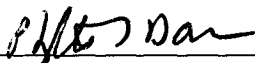
CERTIFICATE OF SERVICE

I certify that a copy of the foregoing Declaratory Ruling has been served upon the nonagency party by certified mail, return receipt requested, by depositing the copy in an official depository of the United States Postal Service in first-class, postage pre-paid envelope addressed as follows:

CERTIFIED MAIL

Robert V. Bode
Bode, Call & Stroupe, L.L.P.
Attorneys at Law
3105 Glenwood Avenue, Suite 300
Raleigh, North Carolina 27612

This the 19th day of May, 2005.



Phyllis T. Daw
Chief Operating Officer

November 06, 2019



Mr. Jerome Carter
Charlotte Radiology
700 East Morehead Street
Suite 300
Charlotte, NC 28203

Re: MMP Breast Center - MR Upgrade & Renovation
Architectural-Engineering Services Proposal

Dear Jerome,

Thank you for giving FMK Architects the opportunity to work with Charlotte Radiology (CR) on this project. We are confident that our services, experience and professional quality will be a benefit to both the project and Charlotte Radiology.

This proposal is intended to address our specific role and services for the project through completion of construction. The scope of work for FMK Architects and our sub-consultants is related to the Architectural and Engineering Services for the room renovation but does not include any design services related to providing, nor installation of the new magnetic resonance magnet equipment or controls.

Should you have any questions or concerns related to this agreement, please do not hesitate to contact me for clarification.

Sincerely,
FMK Architects, PA

A handwritten signature in black ink, appearing to read "Neil C. Dixon".

Neil C. Dixon, AIA
Principal

SCOPE OF SERVICES:

FMK Architects (FMKA) along with sub-contracted engineering consultants (Architect) will provide design services to Charlotte Radiology (Client) for the replacement and upgrade of the magnetic resonance magnet and room renovation in the Morehead Medical Plaza I building in Charlotte, North Carolina.

The Basic Design Services are described as follows:

1. Schematic Design (SD):

The Architect will perform the following tasks associated with Schematic Design:

- Review of program requirements with Client for full understanding of a necessary components for the room.
- Preparation of schematic floor plans for review and approval by the Client. The Architect has included up to three (3) design and review cycles in the Schematic Design process. Additional revisions and redesign direction by the Client will be considered Additional Services and will be billed on an hourly basis.
- Preparation of engineering systems narrative to accurately describe scope of HVAC, electrical and plumbing systems work required for the project.
- Collaborate with the Client's selected General Contractor to assemble estimates of probable construction cost to establish a project baseline budget. The Client will be responsible for review and approval of the budget which will establish the point of comparison for subsequent design phases of the project.

At the conclusion of the Schematic Design phase, the Architect shall prepare a summary package for the Client's review and approval prior to proceeding to the Construction Documents phase.

2. Construction Documents (CD):

Based on the approved Schematic Design package, The Architect will prepare Construction Documents with the following information as required to describe the project scope for project bid, permit submittal and construction:

- Architectural floor plans, elevations, sections, details and schedules
- Mechanical floor plans, details, and schedules
- Electrical floor plans, details, and schedules
- Specifications

Construction Documents will be prepared with the understanding that the Client will be using the documents to negotiate a construction contract with the selected General Contractor for the scope of work.

3. Permits / Project Coordination:

The Architect will assist the Client with the following permit submittals and project review services:

- Submission of building design information and Owner-provided equipment information to PDC Facilities, Inc. for shielding calculations and design. It is understood that PDC will handle documentation and submission of all required information to the State of North Carolina regulatory agencies, as required.
- Assist the Client with submittal of the design documents to Healthcare Realty Services (the Landlord) for review and approval.
- Assist the Client with submittal of the Project documents to Mecklenburg County for the purpose of obtaining an approved building permit.
- Based on past experience with the building permit submittal and review process, the Architect anticipates up to two (2) rounds of review at the County. Should additional rounds of revisions be required through no fault of the Architect, these services can be provided as an Additional Service.

4. Construction Pricing / Budget Monitoring:

Detailed cost estimating is not provided by the Architect. The Architect will work with the Owner's General Contractor, who will provide all construction cost monitoring during the design process. Therefore, the Architect will not be responsible for the cost to revise the drawing set after completion of the Construction Documents. To facilitate this process, the Architect will provide the Client document review sets at the end of the SD phase, and a final construction set at the completion of the CD phase.

5. Construction Phase Services

The Architect will provide construction phase services to include preconstruction meetings, regular Owner-Architect-Contractor meetings, site visits and construction observation, recommendations regarding defective work, document clarifications and interpretations, review of contractor applications for payment, change order review and recommendations, shop drawing review, and project closeout including punchlist review and certificate of substantial completion.

As part of the Construction Phase services, the Architect has assumed an Eight (8) week construction schedule and the Scope of Services includes up to four (4) meetings / site visits for the FMKA representative(s). In addition, the PME consulting engineer has included up to two (2) site visits to observe the progress of the work. Requests for site visits in excess of these amounts will be considered Additional Services.

6. Record Documents

FMKA will provide record documentation in PDF format to Charlotte Radiology, including all noted field adjustments by the GC on their as-built set of drawings.

7. Meetings

FMKA will attend meetings as required by the project and initiate coordination meetings as needed to organize and support the design process. Design team meetings between FMKA and its sub-consultants are included in the Architect's scope of services.

The Architect has assumed a total of up to three (3) coordination meetings with the Client prior to completion of the Construction Documents. Additional meetings will be considered Additional Services.

8. Conditions and Clarifications

CLARIFICATIONS:

- The Architect has included professional design services for the renovation design only.
- The project will *not* require a Certificate of Need (CON) submittal to the NC Department of Health Services Regulation (DHSR), nor will it fall under their regulatory purview. Should Charlotte Radiology determine that this is not the case, and a CON submittal and regulatory review be required, these services can be provided for an additional fee.
- The mechanical engineering services do not include verification of capacity of the existing chilled water loop for adequacy to serve the new equipment. It is understood the Owner has already had that done and the capacity is indeed adequate.
- The Architect shall prepare the construction documents based on the approved schematic design package. Design changes after SD approval which alter the Client's direction to the Architect will be considered a change in service and revisions to work completed will be provided as an hourly Additional Service.
- The scope reflects the design process with one set of construction documents for the project. Breakdown of the project into multiple permit or construction phases are considered Additional Services.
- The Architect has included basic finish material selections and will coordinate with the Client to provide adequate opportunity to review and approve the selections. Material and color selections will be specified within the Construction Documents.
- The Client shall provide the Architect all existing site-specific information as it relates to the Project building.
- It is assumed that the existing slab on grade and service troughs will be adequate for the new equipment and no structural engineering work will be required.

EXCLUSIONS:

- All site / civil engineering.
- Structural engineering
- Plumbing Engineering
- The design of voice/data, security, UPS or other specialty systems potentially required by the Client

11/06/19

MMP Breast Center - MR Upgrade & Renovation

A/E Proposal

Page 5

- Signage or Environment Graphics consultants or services.
- LEED Certification
- Building System Commissioning.
- Extended Value Engineering or cost cutting revisions that occur after the Client has reviewed each phase of the Project.
- Regulatory approvals by any agency outside of Mecklenburg County
- Testing and certification of x-ray shielding systems, and submission to regulatory agencies of said certifications as required
- Selections of equipment or artwork and installation management of same.
- Professional fees do not include any amount for surveys, testing, permit review and application fees, or project specific business license fees. Fees paid by the Architect on behalf of the Client and the Project will be considered a reimbursable expense.

9. Professional Fees, Expenses and Billing

FMKA Architects proposes a lump sum professional fee of **\$43,200.00** for the Architect's full Scope of Services described above.

- Professional fees are provided as a lump sum amount and will be billed monthly based on the percentage complete of each phase.
- Hourly billings for Client requested and approved Additional Services will be included on the monthly invoices based on actual services performed and tracked by the consultants. Tasks identified as hourly shall be billed at our current hourly rates.
- Expenses incurred by The Architect, solely in the interest of the project, shall be reimbursable and billed at 1.10 times direct cost. Reimbursable costs shall include, travel / mileage, shipping and mailing costs, courier services, printing and photographic reproductions, project specific fees, etc.
- Invoices are issued by the Architect between the 20th - 25th of each month. Invoices are due thirty days from the invoice date. Payments not received within thirty (30) days of the invoice date will be subject to a service charge in the amount of one and one-half percent (1.5%) per month which will be charged to the outstanding invoice, retroactive to the date the invoice is due.

10. Additional Services, Hourly Rates

Any work required in addition to that outlined under Scope of Services will be billed on an hourly basis according to the Architect's established hourly rates or may be negotiated as a lump sum fee for a defined scope of work. Additional services shall be provided only when authorized in writing by the Client, and they shall be paid for by the Client as hereinafter provided.

FMKA's hourly rates are as follows and are current through December 31, 2019 at which time they will be revised to reflect our current billing rates.

Principal	\$225.00/hour
Project Architect	\$150.00/hour
Project Manager	\$ 120.00/hour
Intern Architect	\$ 100.00/hour
Administrative Support	\$ 65.00/hour

11. Agreement

This agreement represents in total the contract between the Client and Architect.

A. Ownership and Use of Documents:

All documents produced by FMKA under this Agreement ("Documents") are instruments of service. The drawing and information thereon shall remain the property of FMKA. The Client shall have a nonexclusive license to use, copy and reproduce the Document in connection with the construction, repair, maintenance and occupancy of the project. Such license shall not be transferable except with the written consent of FMKA. FMKA shall not be responsible for changes made in the Documents by anyone other than FMKA or for the Client's use of the Documents without the participation of FMKA as provided in this Agreement. The Client shall indemnify and defend FMKA against all claims and liability arising out of such changes or such use. The agreement shall be governed by the interpreted, construed and enforced laws of the State of North Carolina.

B. Professional Liability:

The Architect maintains professional liability insurance for protection against negligent acts, errors and omissions. In recognition of the relative risks and benefits of the Project to the Client and the Architect, the risks have been allocated such that the Client agrees, to the fullest extent of the law, notwithstanding any other provisions of this Agreement or the existence of applicable insurance coverage, that the total liability, in the aggregate, of the Architect and the Architect's officers, directors, employees, agents, and subconsultants to the Client or to anyone claiming by, through or under the Client, for any and all claims, losses, costs or damages whatsoever arising out of, resulting from or in any way related to the services under this Agreement from any cause or causes, including but not limited to, the negligence, professional errors or omissions, strict liability or breach of contract or any warranty, express or implied, of the Architect or the Architect's officers, directors, employees, agents and subconsultants, shall not exceed twice the total compensation received by the Architect under this agreement or \$100,000, whichever is greater. Higher limits of liability may be negotiated for additional fee. Under no circumstances shall the Architect be liable for extra costs or other consequences due to changed conditions or for costs related to the failure of contractors to perform work in accordance with the plans and specifications. This section is intended solely to limit the remedies available

to the Client or those claiming by or through the Client, and nothing in this section shall require the Client to indemnify the Architect.

The services of the Architect in connection with the Project shall not subject the Architect's individual employees, officers or directors to any personal legal exposure associated with this project.

Thank you again for this opportunity and we look forward to working with you on this project. Please feel free to call me should you have any questions regarding this proposal.

Sincerely,

FMKA Architects



Neil C. Dixon, AIA
Principal

Accepted By

Date

Price Breakdown

Charlotte Radiology MMP	\$	380,838
MRI Replacement		
	ITEM	TOTAL
1 General Conditions		46,775
Demolition		18,541
2 Temp Access		5,119
3 Concrete infill		5,904
4 Masonry		-
5 Metals		-
Rigging		-
6 Carpentry		-
Rough Carpentry		8,238
Finish Carpentry		8,678
7 Thermal and Moisture Protect		-
Roof penetrations		-
8 Doors, Glass & Glazing		-
Doors, Frames & Hardware		1,411
Glass & Glazing		7,875
9 Finishes		-
Drywall		18,680
Acoustical Ceilings		24,617
Paint		5,618
Flooring		3,743
10 Specialties		-
Shielding		-
Access flooring		-
Coat Hooks		-
Fire Extinguishers & Cabinets		-
15 Mechanical		-
Sprinklers		3,841
Plumbing		-
HVAC		115,500
16 Electrical		65,415
		339,955
Bldrs Rsk Insurance		-
Permit		6,261
Subtotal		346,216
Fee		34,622
Total		380,838



From: [Frisone, Martha](#)
To: [Waller, Martha K](#)
Subject: FW: [External] Exemption Request : Charlotte Radiology Breast MRI scanner Replacement
Date: Thursday, June 25, 2020 1:02:40 PM
Attachments: [image002.png](#)
[image003.png](#)
[image004.png](#)
[image005.png](#)
[CORR - CON Section - EXEMPTION - 2020-06-22.pdf](#)

Martha J. Frisone

Chief

[Division of Health Service Regulation](#), Healthcare Planning and Certificate of Need
[NC Department of Health and Human Services](#)

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Office: 919-855-3879

martha.frisone@dhhs.nc.gov

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

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From: Fisher, Matthew A. <MFisher@poynerspruill.com>

Sent: Thursday, June 25, 2020 1:00 PM

To: Frisone, Martha <martha.frisone@dhhs.nc.gov>; Faenza, Julie M <Julie.Faenza@dhhs.nc.gov>

Subject: [External] Exemption Request : Charlotte Radiology Breast MRI scanner Replacement

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Ms. Frisone and Ms. Faenza:

Attached please find an exemption request submitted pursuant N.C. Gen. Stat. §131E-184(a)(7) on behalf of Charlotte Radiology, PA seeking a determination that the replacement of its existing breast MRI scanner is exempt from CON review.

Kindly review the attached letter and advise whether the Agency concurs that this project is exempt from CON review.

In the meantime, should you have any questions or concerns don't hesitate to contact me at any time.

Best Regards,

Matt Fisher

Matthew A. Fisher | Partner

Poyner Spruill^{LLP}

ATTORNEYS AT LAW

301 Fayetteville Street, Suite 1900, Raleigh, NC 27601

PO Box 1801, Raleigh NC 27602-1801

D: 919.783.2924 | **M:** 919.413.7697 (*Please Use Mobile at Present Due to Coronavirus Response*)

mfisher@poynerspruill.com | www.poynerspruill.com



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Maintaining a safe work environment, while continuing to serve our clients is our highest priority. We have taken steps to ensure that our attorneys and staff are equipped with the proper technology that will allow them to seamlessly serve our clients. Thank you for your patience and understanding during this time of uncertainty.

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Faenza, Julie M

From: Faenza, Julie M
Sent: Friday, June 26, 2020 9:45 AM
To: Fisher, Matthew A.
Subject: RE: [External] Exemption Request : Charlotte Radiology Breast MRI scanner Replacement

No need to discuss further. I was familiar with the idea that the document showing the components of the pricing was confidential at times – I had just never encountered a situation where the price itself was confidential, and that's what I wanted to clarify. Thanks for the explanation!

Julie M. Faenza, Esq.

Project Analyst, Certificate of Need

[Division of Health Service Regulation](#), [Healthcare Planning and Certificate of Need Section](#)
[NC Department of Health and Human Services](#)

Office: 919-855-3873

Julie.Faenza@dhhs.nc.gov

Pronouns: She/her/hers

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From: Fisher, Matthew A. <MFisher@poynerspruill.com>
Sent: Friday, June 26, 2020 9:44 AM
To: Faenza, Julie M <Julie.Faenza@dhhs.nc.gov>
Subject: RE: [External] Exemption Request : Charlotte Radiology Breast MRI scanner Replacement

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Julie:

The reason it is not included is due to the confidential pricing relationship my client has with the vendor. The vendor considers its pricing a trade secret and Charlotte Radiology could be subject to civil liabilities if it publicly disclosed that information.

I spoke with Martha about this a few months ago and she said it was fine to not include the price so long as I provided something to demonstrate we were under the threshold. Thus, she suggested the inclusion of the affidavit which is attached to the exemption request certifying under oath that when the cost of actual MRI unit is added to the other capital costs, the total capital costs are still below \$2 million.

I'm happy to call if you feel we need to discuss.

Best Regards,

Matt Fisher

Matthew A. Fisher | Partner

Poyner Spruill^{LLP}

ATTORNEYS AT LAW

D: 919.783.2924 | M: 919.413.7697 (Please Use Mobile at Present Due to Coronavirus Response)

mfisher@poynerspruill.com

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From: Faenza, Julie M <Julie.Faenza@dhhs.nc.gov>

Sent: Friday, June 26, 2020 9:36 AM

To: Fisher, Matthew A. <MFisher@poynerspruill.com>

Subject: RE: [External] Exemption Request : Charlotte Radiology Breast MRI scanner Replacement

Thanks, Matt! I have one last question. The cost of the entire MRI machine does not seem to be included in the price breakdown. I understand that the quote document may be proprietary, but is there a reason the cost of the new MRI is not also included in the table showing the breakdown?

Julie M. Faenza, Esq.

Project Analyst, Certificate of Need

[Division of Health Service Regulation](#), [Healthcare Planning and Certificate of Need Section](#)
[NC Department of Health and Human Services](#)

Office: 919-855-3873

Julie.Faenza@dhhs.nc.gov

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From: Fisher, Matthew A. <MFisher@poynerspruill.com>

Sent: Friday, June 26, 2020 9:10 AM

To: Faenza, Julie M <Julie.Faenza@dhhs.nc.gov>

Subject: RE: [External] Exemption Request : Charlotte Radiology Breast MRI scanner Replacement

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Julie:

The answer to your questions are set forth below in **Blue**:

1. What types of procedures does Charlotte Radiology intend to use this replacement MRI scanner for?
 - The replacement MRI will only be used for breast procedures like the existing unit.
2. Is the entire MRI scanner being replaced, or is this an upgrade of parts of the scanner?
 - Due to the fact there is not currently a reliable manufacturer who sells dedicated Breast MRI units in the United States, this replacement will be the purchase of an entirely new full-body MRI with Breast coils added. That said, it will only be used for breast procedures.

Should you have any additional questions, feel free to contact me at any time.

Best Regards,

Matt Fisher

Matthew A. Fisher | Partner

Poyner Spruill^{LLP}

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D: 919.783.2924 | M: 919.413.7697 (Please Use Mobile at Present Due to Coronavirus Response)

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From: Faenza, Julie M <Julie.Faenza@dhhs.nc.gov>

Sent: Thursday, June 25, 2020 3:55 PM

To: Fisher, Matthew A. <MFisher@poynerspruill.com>

Subject: RE: [External] Exemption Request : Charlotte Radiology Breast MRI scanner Replacement

Matt, I have two questions for you to clarify some information:

1. What types of procedures does Charlotte Radiology intend to use this replacement MRI scanner for?
2. Is the entire MRI scanner being replaced, or is this an upgrade of parts of the scanner?

Thanks!

Julie M. Faenza, Esq.

Project Analyst, Certificate of Need

[Division of Health Service Regulation](#), [Healthcare Planning and Certificate of Need Section](#)
[NC Department of Health and Human Services](#)

Office: 919-855-3873

Julie.Faenza@dhhs.nc.gov

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From: Fisher, Matthew A. <MFisher@poynerspruill.com>

Sent: Thursday, June 25, 2020 1:00 PM

To: Frisone, Martha <martha.frisone@dhhs.nc.gov>; Faenza, Julie M <Julie.Faenza@dhhs.nc.gov>

Subject: [External] Exemption Request : Charlotte Radiology Breast MRI scanner Replacement

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Ms. Frisone and Ms. Faenza:

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Kindly review the attached letter and advise whether the Agency concurs that this project is exempt from CON review.

In the meantime, should you have any questions or concerns don't hesitate to contact me at any time.

Best Regards,

Matt Fisher

Matthew A. Fisher | Partner

Poyner Spruill^{LLP}

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