

TO THE NORTH CAROLINA STATE HEALTH COORDINATING COUNCIL

**PETITION REGARDING EXISTING AND APPROVED SPECIALIZED BREAST MRI
SCANNERS, EXCLUDED FROM PLANNING INVENTORY**
2022 State Medical Facilities Plan

March 3, 2021

Via Email: DHSR.SMFP.Petitions-Comments@dhhs.nc.gov

1. Name, address, email address and phone number of Petitioners:

Andrea M. Gymer Vice President, Operational Planning and Innovation Novant Health, Inc. 2085 Frontis Plaza Boulevard Winston-Salem, North Carolina 27103 amgymer@novanthealth.org 336.341.0408	Christopher L. Murphy Vice President, Development MedQuest Associates, Inc. 3480 Preston Ridge Road, Suite 600 Alpharetta, GA 30005 cmurphy@medquestmail.com 336.254.9944
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2. Statement of the requested change, citing the policy or planning methodology in the SMFP for which the change is proposed.

Petitioners Novant Health, Inc. (“Novant”) and MedQuest Associates, Inc. (“MedQuest”) (collectively, “Petitioners”) propose that the two dedicated breast MRI Scanners (“Breast MRI Scanners”) now shown in Table 17E-2 of the 2021 State Medical Facilities Plan (“SMFP”) be included in Table 17E-1 of the 2022 SMFP. If this Petition is approved, these Breast MRI Scanners would be included in the fixed MRI inventory in North Carolina. Since this Petition has a statewide impact, and since the Breast MRI Scanner Petitioners own was part of a statewide need determination, Petitioners are submitting their Petition in the Spring petitioning cycle. *See* 2021 SMFP, Chapter 2 at p. 7.¹

¹ Petitioners acknowledge that there are other types of specialized MRI scanners in Table 17E-2. These include cardiovascular, pediatric, radiation oncology and intraoperative MRI scanners (“Other Specialized MRI Scanners”). The three cardiovascular MRI scanners listed in Table 17E-2 were approved pursuant to SMFP Policy AC-3. Except for operating rooms, assets approved under Policy AC-3 are not considered in calculating need determinations in the SMFP. *See* 2021 SMFP, Chapter 4 at p. 19. Petitioners believe that that the Other Specialized Scanners are sufficiently different from the Breast MRI Scanners that it is unlikely that the Other Specialized Scanners would be used for anything other than their current highly-specialized uses. The differences include their highly-specialized functions as well as their locations within health service facilities (*e.g.*, operating rooms, a children’s hospital, and radiation oncology areas). Therefore, this Petition is limited to the Breast MRI Scanners and draws upon Petitioners’ first-hand experience with its Breast MRI Scanner.

Chapter 17 of the SMFP contains two tables identifying the existing and approved MRI scanners in North Carolina. The first table, Table 17E-1, identifies all fixed and mobile MRI scanners that are able to be used for general clinical purposes. Table 17E-1 is often referred to as the “MRI Inventory.” See 2021 SMFP, Chapter 17 at pages 347-364. The second table, Table 17E-2, is entitled “Existing and Approved Specialized MRI Scanners, Excluded from Inventory” (the “Specialized MRI Scanners”). See 2021 SMFP, Chapter 17 at p. 365. The ten Specialized MRI Scanners in Table 17E-2 are *not* part of the MRI Inventory. As the 2021 SMFP states, the SMFP inventory excludes “MRI scanners awarded based on need determinations for a dedicated purpose or demonstration project (Table 17E-2).” See 2021 SMFP, Chapter 17 at p. 344 (Assumptions of the Methodology no. 4). Thus, for planning purposes, the two Breast MRI Scanners are not factored into the standard methodology utilized by the State in calculating the need for additional fixed MRI scanners in a given service area. An MRI service area is the same as an Acute Care Bed Service area as defined by Chapter 5 and shown in Figure 5.1 of the SMFP. See 2021 SMFP, Chapter 17 at p. 344; Chapter 5 at p. 36. For example, Forsyth County, where one of the Breast MRI Scanners is located, is its own service area for purposes of calculating MRI need, as is Mecklenburg County, where the other Breast MRI Scanner is located. As the note below Table 17E-2 states, “[t]hese scanners shall be used only for the purposes indicated above. They shall not be used for general clinical purposes.” 2021 SMFP, Chapter 17 at p. 365.

Novant owns one of the Specialized MRI Scanners—one of the two Breast MRI Scanners— shown in Table 17E-2. For the reasons explained in this Petition, Petitioners seek to move the Breast MRI Scanners² from Table 17E-2 to Table 17E-1, where they will be counted in the MRI Inventory. If approved, this Petition would be the first step in a two-step process so that Petitioners can replace their Breast MRI Scanner with a general purpose MRI scanner *and use it* for general clinical purposes. Step One, the subject of this Petition, is to place the Breast MRI Scanners in the MRI Inventory. Step Two can only be taken if the Breast MRI Scanners are moved into the MRI Inventory.³

² The other Breast MRI Scanner is owned by Charlotte Radiology, PA d/b/a Charlotte Radiology Breast Center (“CRBC”). CRBC received its CON pursuant to Project I.D. No. F-006725-02, a non-competitive CON review. See 2021 SMFP, Chapter 17 at p. 365. CRBC’s Breast MRI Scanner resulted from an adjusted need determination in the 2002 SMFP for Health Service Areas III and V, and MRI Service Area 17 (Anson, Mecklenburg and Union Counties). See 2002 SMFP, Chapter 8 at p. 131. Petitioners do not own or manage CRBC. Recognizing that it may be practically impossible to include one of the Breast MRI Scanners in the MRI Inventory, but not the other Breast MRI Scanner, Petitioners seek to move both Breast MRI Scanners from Table 17E-2 to Table 17E-1. Even if both Breast MRI Scanners are moved to Table 17E-1 in the 2022 SMFP, however, CRBC would be free to continue to use its Breast MRI Scanner for breast imaging only. See also Exhibit A, a July 9, 2020 replacement equipment exemption request providing further details about the CRBC scanner.

³ To be clear, this Petition does not seek permission to replace Petitioners’ Breast MRI Scanner (Step Two). Petitioners are providing the information about Step Two for context. Depending on the capital costs, Step Two will be accomplished either by a Notice of Exemption or a certificate of need application. See N.C. Gen. Stat. §§ 131E-184(a)(7) (replacement equipment exemption) and 131E-176(16)b. (requiring an application where the capital costs to develop or expand a health service or a health service facility exceed \$2 million). Based on presently-known information, Petitioners believe a CON application will be required. The Breast MRI Scanners must first be placed into the MRI Inventory before they can be replaced *and used* for general clinical purposes. See 2021 SMFP, Chapter 17 at p. 365.

Novant is a North Carolina nonprofit corporation that owns and operates a health system. It operates and manages twelve hospital licenses (sixteen facilities) in the State of North Carolina with over 580 locations, including hundreds of outpatient facilities and physician clinics across North Carolina, South Carolina and Virginia. As of February 1, 2021, New Hanover Regional Medical Center joined Novant. Novant's network also consists of rehabilitation programs, surgery and diagnostic centers and imaging facilities.

MedQuest is a subsidiary of Novant. MedQuest provides management services for a number of Novant's imaging facilities. MedQuest provides daily operational support for health systems in partnerships throughout North Carolina and other states. It owns, operates and/or manages a network of approximately fifty (50) freestanding imaging centers, as well as a fleet of mobile imaging equipment including MRI scanners, mammography and ultrasound.

3. Reasons for the proposed change, including:

As technology and patient needs evolve, health planning must also continually evolve so that expensive resources are used to benefit the greatest number of patients. Health planning decisions that were made fifteen years ago may not continue to make sense today. As this Petition illustrates, over the course of the last fifteen years, MRI technology has advanced considerably. Although it was once believed that a dedicated MRI scanner specifically for breast imaging delivered superior imaging, that is no longer the case. In fact, there is no longer a reliable manufacturer of dedicated breast MRI scanners in the United States, so replacing these machines necessarily entails purchasing a general purpose, full body MRI scanner and equipping it with breast coils. *See, e.g.,* Exhibit A, July 9, 2020 Replacement Equipment Exemption Request for Charlotte Radiology Breast Center. Petitioners seek to have the Breast MRI Scanners included in the 2022 MRI Inventory so that Petitioners can seek approval to replace their own non-functional and outmoded Breast MRI Scanner with a new, general purpose fixed MRI scanner that can be utilized to provide not only breast imaging, but also all types of MRI scans. At the present time, Petitioners may replace their Breast MRI Scanner with a general purpose MRI scanner, but can only use the replacement for breast imaging, in order to be consistent with the restrictions placed on Specialized MRI Scanners. *See* 2021 SMFP, Chapter 17 at p. 365; *see also* Exhibit A.

Background on Petitioners' Breast MRI Scanner

The 2006 SMFP included a statewide adjusted need determination for one dedicated and specialized breast MRI scanner (the "Adjusted Need Determination"). *See* 2006 SMFP, Chapter 9 at p. 134. The Adjusted Need Determination was not a demonstration project. On November 26, 2006, The Breast Clinic MRI, LLC ("The Breast Clinic"), a subsidiary of Novant, was awarded a certificate of need ("CON") to acquire a fixed, dedicated breast MRI scanner to be located in Forsyth County, North Carolina, identified as Project I.D. No. G-7601-06. *See* Exhibit B attached hereto. The Breast Clinic was the only applicant for this specialized scanner. The Breast MRI Scanner is not included in the MRI Inventory for planning purposes. *See* 2021 SMFP, Chapter 17 at p. 365. One of the conditions on the CON is that the applicant "shall not use the dedicated breast MRI scanner for non-breast related general diagnostic purposes." *See* Exhibit B.

In 2007, Novant purchased a 1.5 Tesla (“1.5T”) Aurora Breast MRI Scanner (the “Aurora”), where it was used in outpatient settings.⁴ At the time, the Aurora was considered to be state-of-the-art technology, offering a specialized tool to complement other imaging modalities such as mammography and ultrasound. Declaration of James Sancrant, Jr. D.O. at 5 (“Dr. Sancrant Declaration”); Declaration of Christopher L. Murphy at 8 (“Murphy Declaration”). Specialized, dedicated MRI scanners were among the newest modalities utilized in diagnostic imaging. *See, e.g.*, 2006 SMFP, Chapter 9 at p. 134 (containing a statewide adjusted need determination for a demonstration project for a fixed extremity MRI scanner). In the mid-2000s, lower cost imaging modalities such as 3D mammography and automated breast ultrasound (“ABUS”) were not available. At that time, breast MRI imaging was also not utilized for screening, but rather in the course of treatment and diagnosis of certain patients experiencing problems or requiring additional testing or pre-surgical scans. *See* Declaration of Lee Ann Naylor, M.D. at 12 (“Dr. Naylor Declaration”); Murphy Declaration at 14.

In the early to mid-2000s, the technology offered by a dedicated breast MRI scanner, designed specifically to scan both breasts and the surrounding chest cavity, tissues and lymph nodes, was believed to provide higher quality, more accurate images. In addition, such specialized equipment was designed to provide more efficient scanning for patients and facilities. At that time, the design of the specialized coil system for general purpose MRI scanners was much less user-friendly than it is today. Changing coils and making necessary adjustments between patients on earlier model, general purpose machines decreased accessibility of services because each scan took longer to complete. *See* Dr. Sancrant Declaration at 7. Moreover, it was believed that the specialized MRI scanner technology would continue to advance as time went on. *See* Dr. Sancrant Declaration at 8.

Many of Petitioners’ beliefs and expectations for the dedicated breast MRI scanner did not hold true. Murphy Declaration at 9. Utilization of the Aurora was never robust and steadily declined over time. *See* Table 1 on p. 7. In addition, the Aurora technology did not advance and was soon outmoded by general purpose MRI scanners whose manufacturers continued to invest in research, development and technology. As Dr. Sancrant describes it, the Aurora became “stuck in time.” *See* Dr. Sancrant Declaration at 8. Today’s general purpose MRI scanners with specialized breast coils produce images of far better quality than the Aurora produced. Other less expensive technology, such as mammography and breast ultrasound, also continued to evolve, providing a cost-effective option for patients and payors.

By 2015, after eight years of use, the Aurora had reached the end of its useful life. On December 18, 2015, the Certificate of Need Section (“CON Section”) issued a replacement equipment exemption request for the Aurora. At the time, Novant intended to replace the Aurora with a Siemens Aera 1.5T general purpose MRI scanner with a specialized breast coil. Because of the condition on the CON, the replacement approval also restricted the use of the replacement MRI scanner to breast scans only. *See* Exhibit C, attached hereto; Murphy Declaration at 10.

Separately and unrelated to the Aurora replacement, in early 2016, Novant acquired a 3.0 Tesla (“3T”) general purpose MRI scanner with bilateral breast coils to be used at one of its outpatient centers, Novant Health Imaging-Maplewood (“Maplewood”). Most of Novant’s breast imaging

⁴ The Breast MRI Scanner was first used at Salem MRI and later at the Breast Clinic.

studies in the Winston-Salem market are now done at Maplewood. *See* Dr. Naylor Declaration at 10. This newer technology produced superior images. The Aurora was quickly phased out and used sparingly, only for appropriate patient studies. *See* Dr. Naylor Declaration at 9. Having seen the superior images produced by the 3T machine at Maplewood, Petitioners realized that their 2015 plan to replace the Aurora with a 1.5T scanner was no longer the best choice for patients.

On May 13, 2017, before Novant could replace it, the Aurora was severely damaged in a flood, rendering the machine unusable. *See* Murphy Declaration at 11. The machine has been in storage and has not served any patients since 2017. Novant has determined that the Aurora is simply no longer viable given its age, water damage, limited functionality compared to current technology and the uncertainties surrounding technical support and repairs. *See* Murphy Declaration at 12. While the CON Section has authorized replacing the Aurora, the replacement machine can only be used for breast imaging and not for other types of scans. *See also* Exhibit A, July 9, 2020 replacement equipment exemption issued to CRBC.

a. A statement of the adverse effects on the providers or consumers of health services that are likely to ensue if the change is not made.

Including the Breast MRI Scanners in the State inventory will not adversely affect providers or consumers, as demonstrated below. The ultimate replacement of the Aurora with a general purpose scanner, including bilateral breast coils, that will be used for all types of imaging, including breast imaging, will not adversely affect providers or consumers of health services, but rather will enhance value, accessibility and quality of services for all patients. This is precisely what the State health planning process seeks to promote. *See* 2021 SMFP, Chapter 1, at pages 2-3. Replacing the Aurora will require a substantial capital investment. A 3T scanner will likely cost approximately \$2 million. *See* Murphy Declaration at 14. With construction, total costs for the replacement will likely to exceed \$2 million. Petitioners respectfully submit it does not make economic sense, nor is it in the best interest of patient care, access and affordability, to limit the use of a replacement scanner to only one particular type of scan.

While breast MRI imaging is still a critical tool in the treatment of patients, Petitioners' experience is that there is not a need for a machine that can only be used for breast imaging. Rather, there is a need for a general purpose machine that is capable of providing breast images as well as other scans. *See* Murphy Declaration at 18. Two major factors influence this decision. First, the number of breast MRI scans compared to the total number of MRI scans is relatively small. *See* Tables 1 and 2 on pages 7 and 8. Second, reimbursement has changed. Reimbursement for breast MRI imaging by payors was nearly twice its current rate when the Aurora was acquired. Because payors are now steering patients to lower cost modalities (such as ultrasound) for breast imaging and requiring preauthorization before covering breast MRI scans, the ability to utilize this replacement scanner for many different types of scans will offset the differential in reimbursement and allow Petitioners to continue providing advanced technology to their patients. *See* Murphy Declaration at 17.

On the other hand, not granting this Petition would have an adverse effect on providers and consumers. This is a machine that Petitioners invested significant resources in purchasing and making operational and which, through no fault of Petitioners, is no longer viable. However,

Petitioners cannot replace the machine and utilize it for any purpose other than breast imaging, unless the scanner is included in the MRI Inventory. Petitioners respectfully submit that utilizing a replacement scanner for breast imaging only is not a reasonable option and does not best serve the community.

Future Replacement of the Aurora

Petitioners intend to replace the Aurora with a GE 3T Pioneer MRI scanner with bilateral breast coils as well as coils that can be utilized for other types of scans. *See* Murphy Declaration at 13-14. This replacement scanner is estimated to cost \$2 million. *See* Murphy Declaration at 14. Construction costs will likely drive the total cost of replacement over \$2 million, which will require a CON application. N.C. Gen. Stat. § 131E-176(16)b. Without approval to include the Aurora in the fixed MRI inventory, Petitioners could undergo a costly regulatory process and spend more than \$2 million for the replacement, but may only use the replacement for a single, limited service and not take advantage of the full potential of the machine. This does not enhance services to patients and is inconsistent with the basic principles of safety, quality, access and value governing development of the SMFP and the purpose of the CON Law. *See* 2021 SMFP at pp. 2-4; N.C. Gen. Stat. § 131E-175.

Unlike at the time when the Aurora was acquired, the use of MRI imaging as a screening tool to diagnose patients with dense breast tissue and those determined to be at high risk for developing breast cancer, has risen exponentially. *See* Dr. Naylor Declaration at 12. MRI as a screening tool for certain patients has become, in more recent years, an official recommendation of the American Cancer Society and the American College of Radiology. Patients are evaluated for these risk factors at The Breast Center and are scanned sometimes yearly and sometimes at other intervals, depending upon the level of risk. *See* Dr. Naylor Declaration at 12.

Additionally, Petitioners have led the charge in offering abbreviated breast MRI imaging (shorter, more cost effective studies) in recent years as a way to effectively expand MR imaging to patients who do not require a traditional, full MRI breast scans, but who need additional modalities to complement other diagnostic techniques. As such, Petitioners expect that the need for breast MRI services will continue to increase. *See* Dr. Sancrant Declaration at 9. However, Petitioners do not expect breast MRI to become so prevalent that it would make sense to limit the use of an MRI scanner to only breast imaging. In fact, payors continue to steer patients to lower modalities such as 3D mammography, ultrasound and stereotactic biopsy where medically appropriate. *See* Murphy Declaration at 17. As such, a 3T general purpose scanner with specialized breast coils will provide breast patients with the highest quality images available at this time, while providing Petitioners with the flexibility to serve non-breast patients. *See* Murphy Declaration at 17.

Under these circumstances, it does not make economic sense or serve the best interests of patients to spend approximately \$2 million on a general purpose MRI scanner that can only be used for a limited subset of patient needs. *See* Murphy Declaration at 14. If approved, Petitioners intend to locate the replacement MRI scanner at one of their outpatient centers in Winston-Salem, Novant Health Imaging-Piedmont (“Piedmont”), which serves a high volume of patients and where utilization would be supported.

Historical Utilization

As shown below, utilization of the Aurora never met the expectations Novant had for the machine when it first acquired the scanner in November 2007.⁵

Table 1: Novant Health – Dedicated Aurora Breast MRI Scanner Historical MRI Volume							
Time Period	10/1/09- 9/30/10	10/1/10- 9/30/11	10/1/11- 9/30/12	10/1/12- 9/30/13	10/1/13- 9/30/14	10/1/14- 9/30/15	10/1/15- 9/30/16
Unweighted MRI Volume	221	705	686	611	521	501	145
Contrast Scans	209	674	647	587	514	501	136
Weighted MRI Total	305	975	945	846	727	701	199

While utilization of the Aurora peaked in CY 2010-2011, it dropped rapidly thereafter. Even at its peak, the volume of breast MRI scans was below 1,000 weighted scans, far insufficient to justify dedicating an MRI scanner to performing solely breast scans. This is less than 1/4 of the total number of weighted procedures each year that the SMFP defines as the State’s planning threshold.⁶

By comparison, breast imaging represents only a small percentage of the total utilization of MRI imaging at Petitioners’ Forsyth County facilities:

⁵ Data is no longer available for the time period of November 2007 through September 2009. Petitioners believe, however, that the Aurora’s utilization between November 2007 to September 2009 was consistent with the data shown on Table 1.

⁶ The SMFP defines fixed MRI capacity as utilization for at least 66 hours per week, 52 weeks per year. The planning threshold for Forsyth County is 70% of that number, which equates to 4,805 weighted procedures per year. *See* 2021 SMFP, Chapter 17, MRI Scanner Assumptions and Application of the Methodology at pp. 344-345.

Table 2: Unweighted MRI Volume by Facility Type at Novant facilities in Forsyth County					
	CY 2016	CY 2017	CY 2018	CY 2019	CY 2020
Acute Care Sites	12470	13625	13915	14746	13411
Breast MRI Procedures	0	29	72	57	41
Breast MRI as % of Total	0	0.21%	0.52%	0.39%	0.31%
Acute Care includes: NHForsyth Medical Center, NHClemmons, NHKernersville					
Outpatient Sites	21055	22499	23241	22059	19899
Breast MRI Procedures	840	1021	1000	898	802
Breast MRI as % of Total	4.00%	4.50%	4.30%	4.07%	4.04%
Outpatient includes: Maplewood, Piedmont Imaging and NHI Kernersville					

This data does not support acquiring a new, general purpose MRI scanner that can only be used for breast MRI scans.

Current Technology

In contrast to the Aurora, which became “stuck in time,” the technology for general purpose MRI scanners has advanced tremendously. *See* Dr. Sancrant Declaration at 8. Unlike fifteen years ago, dedicated specialized MRI scanners are no longer the standard or preference of providers. Rather, general purpose machines with specialized coils, such as breast coils, are highly favored. Not only can a greater variety of scans be performed on a general purpose machine, but a larger population of patients can be served, including patients with non-breast imaging needs. In addition, the improved technology allows specialized coils such as breast coils, to be interchanged more efficiently between patients, thus resolving a major concern that led to the development of specialized breast MRI scanners two decades ago. *See* Dr. Sancrant Declaration at 7.

b. A statement of alternatives to the proposed change that were considered and found not feasible.

Petitioners considered not filing this Petition and maintaining the status quo. Maintaining the status quo would mean that the Breast MRI Scanners would continue to be excluded from the MRI Inventory for planning purposes. Maintaining the status quo leads to two potential options:

- (1) Do not replace the Aurora but leave it in storage where it does not provide services to patients;
- (2) Replace the Aurora with a general purpose fixed MRI scanner, limited to providing breast MRI scans only.

Neither of these alternatives results in the needed provision or expansion of imaging services to patients.

4. Evidence that the proposed change would not result in unnecessary duplication of health resources in the area.

This Petition, which seeks to add the two Breast MRI Scanners to the MRI inventory, will not cause unnecessary duplication of MRI resources. The Breast MRI Scanners are existing, CON-approved machines. If allowed to replace their Breast MRI Scanner with a general purpose MRI scanner, Petitioners would continue to use the replacement for breast imaging as well as other imaging needs, so that the technology can benefit the greatest number of patients. Based on their current estimate that capital costs will exceed \$2 million, Petitioners will be required to file a CON application to replace the Aurora. N.C. Gen. Stat. § 131E-176(16)b. Petitioners will therefore be required to demonstrate that the proposal is consistent with Criterion (6), which requires applicants to demonstrate that the proposal will not result in the unnecessary duplication of services. N.C. Gen. Stat. § 131E-183(a)(6). Thus, the CON Section retains the authority to evaluate whether services are unnecessarily duplicated.

There is one placeholder CON in the 2021 SMFP in Forsyth County for a fixed MRI scanner awarded to Wake Forest Baptist Imaging- Kernersville in response to a 2019 need determination (Project I.D. No. G-11798-19). That project is not yet developed. There is no need determination for any additional fixed MRI scanners in Forsyth County in the 2021 SMFP. *See* 2021 SMFP, Table 17E-3 at p. 366. Based upon the most recent data, Petitioners do not project that there will be a need determination for an additional fixed MRI in Forsyth County in the 2022 or 2023 SMFPs, even without counting the Breast MRI Scanner in the State inventory. Thus, including the Aurora in the inventory for Forsyth County will not unnecessarily duplicate or negatively impact the need methodology or suppress a need for a new fixed MRI scanner.

Similarly, there are two placeholder CONs for undeveloped projects in the 2021 SMFP in Mecklenburg County for fixed MRI scanners. One of these was awarded to Atrium Health Kenilworth Diagnostic Center for 2019 project and the other for the 2020 SMFP Need Determination. *See* 2021 SMFP, Table 17E-1 at p. 356-357. Even with these undeveloped scanners, Mecklenburg County generated sufficient need for an additional fixed MRI scanner in the 2021 SMFP. *See* 2021 SMFP, Table 17E-3 at p. 366. While reporting data has not yet been made available for other entities, it has been Petitioners' experience that fixed MRI utilization decreased during the COVID-19 pandemic. Even if such temporary decrease in utilization impacts a need determination in the 2022 SMFP, historically, Mecklenburg County generates a need for an additional fixed MRI nearly every year. *See, e.g.,* 2016-2021 SMFPs.⁷ Petitioners do not expect that the requested change in inventory will have any negative impact on the need methodology or suppress a need for a new fixed MRI scanner in Mecklenburg County.

Accordingly, this Petition will not result in the unnecessary duplication of health resources.

5. Evidence that the requested change is consistent with the three Basic Principles governing the development of the North Carolina State Medical Facilities Plan: safety and quality, access, and value.

⁷ Except for 2018, in each year of that time period, there was a need generated for an MRI scanner in Mecklenburg County.

This Petition is grounded in the Basic Principles of the SMFP and the desire to better serve patients with safe, effective, and remarkable care.

a. Safety and Quality

The purpose of this Petition is to ensure the highest standards of safe, quality MRI imaging services are available to meet patients’ needs. There is no question that the Aurora needs to be replaced; the question is whether it continues to make sense to restrict the replacement machine to images of one part of the body. Petitioners respectfully submit that it does not, and that the replacement machine should be used to provide safe, high quality imaging to a broader group of patients.

b. Access

Currently, the Aurora is in storage and is not utilized to provide any MRI services. Replacement, relocation and use of a general purpose MRI for a range of imaging studies will improve equitable access to imaging services for all patients, including low income and diverse patients. Novant provides services to all persons, regardless of their ability to pay. In addition to its Uninsured Discount Policy, Novant’s robust charity care policy allows a patient with a household income up to 300% of the Federal Poverty Level to easily seek charity care for needed medical services. Based upon the 2021 Federal Poverty Level, this means that an uninsured family of four with an annual income of \$79,500 or less will receive a write-off of all charges from services received in the Novant system.⁸ *See* Murphy Declaration at 16. Limiting the types of scans performed on the replacement scanner, however, will limit the population that can benefit from Novant’s charity care policy.

c. Value

Replacement of the Aurora with a general purpose MRI to be located at Piedmont, an Independent Diagnostic Testing Facility (“IDTF”), offers a lower cost option for imaging patients requiring advanced imaging studies such as MRI, in addition to convenient physical access. *See* Murphy Declaration at 15. Under present circumstances, the only scans a replacement for the Aurora can perform are breast imaging studies, thereby eliminating the vast majority of MRI studies.

The proposal will also ultimately promote competition for imaging services by providing patients with another choice for their imaging services. This in turn will promote value and decrease costs for citizens, consistent with the guiding purposes of the CON Law. *See* N.C. Gen. Stat. § 131E-175(3).

Precedent from Other Specialized MRI Scanners

There is recent precedent that supports this Petition. In 2017, the Technology and Equipment Committee of the SHCC approved a request by Triangle Orthopaedic Associates, P.A. (“TOA”) to include its specialized dedicated multi-positional fixed MRI scanner (Project I.D. No. J—008107-08) in the inventory with all other fixed MRI scanners. Until that time, the multi-positional

⁸ *See* <https://aspe.hhs.gov/poverty-guidelines>. The 2021 Federal Poverty Level for a family of four is \$26,500. Novant’s charity care policy of 300% of the Federal Poverty Level equates to \$79,500 annually.

fixed MRI scanner CON included a condition that the scanner is not later replaced with a general purpose scanner. TOA's multi-positional scanner, and another multi-positional scanner owned by Carolina Neurosurgery & Spine Associates, P.A. ("CNSA") (Project I.D. No. F-008106-08) in Mecklenburg County were both moved into the MRI inventory effective with the 2018 SMFP.⁹ Following inclusion of the multi-positional fixed MRI scanner in the Inventory, TOA was approved to replace its scanner with a general purpose MRI scanner by letter of exemption from the CON Section dated October 3, 2017. *See* Exhibit D, attached hereto.

Similarly, in 2019, the Bone & Joint Surgery Clinic ("Bone & Joint") appealed to the Technology and Equipment Committee to include its fixed extremity MRI scanner (Project I.D. No. J-007605-06) in the inventory. Bone & Joint had replaced its specialized extremity MRI scanner with a general purpose scanner; however, because the scanner was not yet in the inventory of fixed MRI equipment, the replacement scanner was limited to performing only extremity scans. Bone & Joint's request was approved, and the scanner was included in the inventory effective with the 2020 SMFP. Bone & Joint then filed a CON Application (Project I.D. No. J-11757-19) and received approval to expand the procedures it could perform on its scanner.¹⁰

As demonstrated by the above examples, the SHCC has approved the inclusion of dedicated specialized MRI scanners in the inventory of fixed MRI equipment in the recent past. Doing so has expanded the availability of general purpose fixed MRI services to patients in Durham, Mecklenburg and Wake Counties, respectively, and has not unnecessarily duplicated existing services or artificially suppressed future need.

Conclusion

Petitioners respectfully request that the SHCC include the Breast MRI Scanners in Table 17E-1, the MRI Inventory, in the 2022 SMFP.

⁹ Inclusion of the CNSA multi-positional scanner in the inventory did not affect MRI need determinations for Mecklenburg County in the 2019-2021 SMFPs.

¹⁰ It does not matter that these examples involved demonstration project while the Breast MRI Scanners are not demonstration projects. The point is that highly-specialized scanners have been moved into the MRI Inventory without disrupting the need methodology or the planning process.



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

EXHIBIT A

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
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VIA E-MAIL ONLY

Martha Frisone, Chief
Julie Faenza, Project Analyst
Healthcare Planning and Certificate of Need Section
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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

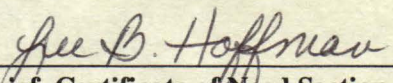
PHYSICAL LOCATION: Charlotte Radiology Breast Center
6836 Morrison Boulevard
Charlotte, NC 28211

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, flowing style.

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.

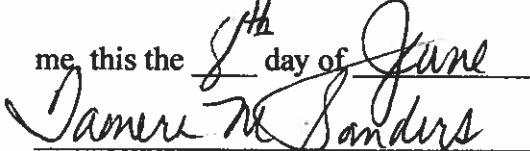


CHERYL MARKS
Vice President of Operations
Charlotte Radiology, PA

STATE OF NORTH CAROLINA
COUNTY OF MECKLENBURG

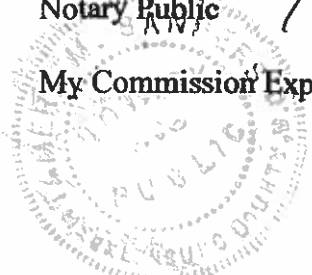
Sworn to and subscribed before

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

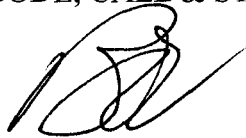
Re: Declaratory Ruling for Charlotte Radiology, P.A. d/b/a Charlotte Radiology Breast
Center - Project I.D. #F-6725-02, Mecklenburg County

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/manufacturer 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

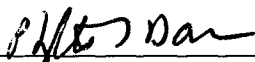
CERTIFICATE OF SERVICE

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



Due to the increasing risks posed by the spread of COVID-19, we have made the decision to have all attorneys and staff work remotely. This decision comes after much planning and close monitoring of media and local government coverage of the virus.

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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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.

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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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

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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}

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

CERTIFICATE OF NEED

for
 Project Identification Number G-7601-06
 FID#060617

ISSUED TO: The Breast Clinic MRI, LLC
 1900 South Hawthorne Rd., Bldg. 7, Suite 718
 Winston-Salem, NC 27103

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: Acquire a dedicated breast Magnetic Resonance Imaging (MRI) scanner/Forsyth County

CONDITIONS: See Reverse Side

PHYSICAL LOCATION: The Breast Clinic
 2025 Frontis Plaza Blvd.
 Winston-Salem, NC 27103

MAXIMUM CAPITAL EXPENDITURE: \$2,003,999

TIMETABLE: See Reverse Side

FIRST PROGRESS REPORT DUE: May 1, 2007

This certificate is effective as of the 27th day of November, 2006.

Lee B. Hoffman by CRAC
 Chief, Certificate of Need Section
 Division of Facility Services

CONDITIONS
G-7601-06

1. The Breast Clinic MRI, LLC shall materially comply with all representations made in the certificate of need application.
2. The Breast Clinic MRI, LLC shall not use the dedicated breast MRI scanner for non-breast related general diagnostic purposes.
3. The Breast Clinic MRI, LLC 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.
4. The Breast Clinic MRI, LLC shall obtain accreditation from the Joint Commission for the Accreditation of Healthcare Organizations within two years following operation of the dedicated breast MRI scanner.
5. The Breast Clinic MRI, LLC 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 and compliance with all conditions stated in the conditional approval letter was received by the Certificate of Need Section on November 27, 2006.

TIMETABLE

Completion of final drawings and specifications _____	March 1, 2007
Contract Award _____	April 1, 2007
25% completion of construction _____	May 15, 2007
50% completion of construction _____	July 1, 2007
75% completion of construction _____	August 15, 2007
Completion of construction _____	October 1, 2007
Order Equipment _____	June 1, 2007
Operation of Equipment _____	January 1, 2008



North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Richard O. Brajer
Secretary DHHS

Drexdal Pratt
Division Director

VIA EMAIL ONLY

December 18, 2015

Tiffany Brooks
MedQuest Associates, Manager, Certificate of Need

Exempt from Review – Replacement Equipment

Record #: 1821
Facility Name: Novant Health Breast Clinic
FID #: 060617
Business Name: Foundation Health Systems, Corp., an affiliate of Novant Health, Inc.
Business #: 767
Project Description: Replace an existing dedicated breast MRI scanner
County: Forsyth

Dear Ms. Brooks:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter emailed on December 16, 2015, the above referenced proposal 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 Siemens Aera 1.5 T MRI scanner, with special breast coil. This determination is based on your representations that the replacement unit will be used for breast scans only and the unit being replaced will be removed from North Carolina and will not be used again in the State without first obtaining a certificate of need.

Moreover, you need to contact the Agency's Construction and Acute and Home Care Licensure and Certification Sections to determine if they have any requirements for development of the proposed project.

It should be noted that the Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this office and a



Healthcare Planning and Certificate of Need Section

www.ncdhhs.gov

Telephone: 919-855-3873 • Fax: 919-715-4413

Location: Edgerton Building • 809 Ruggles Drive • Raleigh, NC 27603

Mailing Address: 2704 Mail Service Center • Raleigh, NC 27699-2704

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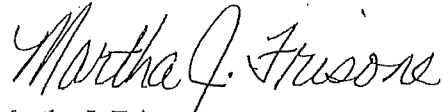


separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,



Celia C. Inman
Project Analyst



Martha J. Frisone,
Assistant Chief, Certificate of Need

cc: Kelli Fisk, Program Assistant, Healthcare Planning
Denise Gunter
Per Normark



DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

October 3, 2017

George Sheasley
120 Williams Penn Plaza
Durham, NC 27704

Exempt from Review – Replacement Equipment

Record #: 2398
Facility Name: EmergeOrtho (formerly Triangle Orthopaedic Associates)
FID #: 040412
Business Name: EmergeOrtho
Business #: 1888
Project Description: Replace existing magnetic resonance imaging (MRI) scanner
County: Durham

Dear Mr. Sheasley:

The Healthcare Planning and Certificate of Need Section, Division of Health Service Regulation (Agency), determined that based on your letter of September 15, 2017, the above referenced proposal is exempt from certificate of need review in accordance with N.C. Gen. Stat. §131E-184(a)(7). Therefore, you may proceed to acquire without a certificate of need the Siemens 1.5T MRI scanner to replace the existing Fonar 0.6T MRI scanner located in the Southpoint Professional Center, NC Highway 54 in Durham. This determination is based on your representations that the existing unit will be sold or otherwise disposed of and will not be used again in the State without first obtaining a certificate of need if one is required.

Moreover, you need to contact the Agency's Construction and Radiation Protection Sections to determine if they have any requirements for development of the proposed project.

It should be noted that the Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this office and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Bernetta Thorne-Williams
Project Analyst

Martha J. Frisone
Chief, Healthcare Planning and
Certificate of Need Section

cc: Construction Section, DHSR
Radiation Protection Section, DHSR
Sharetta Blackwell, Program Assistant, Healthcare Planning, DHSR

HEALTHCARE PLANNING AND CERTIFICATE OF NEED SECTION
WWW.NCDHHS.GOV

TELEPHONE 919-855-3873

LOCATION: EDGERTON BUILDING • 809 RUGGLES DRIVE • RALEIGH, NC 27603

MAILING ADDRESS: 2704 MAIL SERVICE CENTER • RALEIGH, NC 27699-2704

AN EQUAL OPPORTUNITY/ AFFIRMATIVE ACTION EMPLOYER



Record # 2348
Business # 1888
FID # 040412
120 William Penn Plaz.
Durham, NC
27704



September 7, 2017

Ms. Martha Frisone
Chief, Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, NC 27603



RE: Imaging Equipment Replacement at EmmergeOrtho/Durham County
CON Project # J-8107-08

Dear Ms. Frisone:

EmmergeOrtho (EO), formerly Triangle Orthopaedic Associates, intends to replace its existing Fonar multi-position fixed MRI scanner located in our Southpoint Professional Center clinic on N.C. Highway 54 in Durham. Pursuant to NCAC 14C .0303(a), EO requests confirmation that this replacement lies within the definition of NCGS 131E-176(22a) and the regulations set out in NCGS 131E-184(a)(7) and NCAC 14C .0303, as exempt from review.

EO began using its upright MRI scanner in 2009, and intends to replace it with a refurbished Siemens Aera 1.5T fixed MRI scanner. Via this letter, EO affirms that it will sell the Fonar upright MRI scanner to a third-party, for removal of the Fonar scanner from North Carolina. EO will continue to maintain an inventory of one (1) fixed MRI scanner at its Southpoint Professional Center.

Pursuant to NCGS 131E-184(a)(7) *"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, when notice includes an explanation of why the new institutional health service is required, for any of the following: ... (7) To provide replacement equipment."*

NCGS 131E-176(22a) defines "replacement equipment" as *"equipment that costs less than \$2,000,000 and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced"*.

Applicable Regulations

NCAC 14C .0303 defines "comparable medical equipment" as equipment that is functionally similar and which is used for the same diagnostic or treatment purposes. Replacement equipment is comparable if:

- (1) it has the same basic 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 12 months after replacement equipment is acquired.

Compliance

EO hereby certifies that:

1. The total project cost for the MRI scanner replacement is \$1,176,000, as shown in Attachment A. Please refer to Attachment B for the Siemens equipment quote. EO will locate the replacement MRI scanner in the existing MRI equipment room at the Southpoint clinic. EO's General Contractor confirms that relatively modest space renovations are required to accommodate the replacement MRI scanner. The cost to remove the existing MRI scanner from EO will be borne by the third-party buyer, and Siemens is including delivery and installation costs in the sale price of the refurbished Area scanner. During the equipment replacement process, EO will temporarily contract for a mobile MRI scanner to serve the Southpoint clinic.
2. The replacement MRI scanner will be installed at EO for the sole purpose of replacing comparable equipment currently in use, which will be relocated out of state. A comparison of the existing and replacement equipment is provided in Attachment C.
3. The replacement MRI scanner is functionally similar to the existing equipment and will be used for the same diagnostic procedures as the equipment currently in use. The replacement equipment is a full-featured MRI scanner, with features that do not change the basic technology or result in the provision of a new health service or type of procedure.

4. No increase in charges will occur within the first twelve months after the replacement MRI scanner is acquired.
5. The average cost per procedure will not increase by more than 10% as a result of the replacement.

As per the Proposed 2018 State Medical Facilities Plan, the State Health Coordinating Council has ended the multi-position MRI scanner demonstration project, and has added EO's Fonar Upright MRI scanner to the standard MRI inventory for Durham County. EO requests that the Division of Health Service Regulation confirm that replacement of the fixed upright MRI scanner as proposed herein does not constitute a new institutional health service and is exempt from certificate of need review.

Please contact me at 919.281.1804 regarding any questions concerning this request.

Sincerely,



George Sheasley
Chief Financial Officer

Attachments: A - Proposed Capital Cost
B - Vendor Equipment Quote
C - Equipment Comparison

Attachment A: Proposed Capital Cost

Attachment A

PROPOSED CAPITAL COST

Project name: MRI Scanner Replacement
 Proponent: EmergeOrtho

A. Site Costs	
(1) Full purchase price of land # Acres ____ Price per acre _____	
(2) Closing costs and legal fees	
(3) Site inspection and survey	
(4) Site preparation costs	
(5) Other	
(6) Subtotal Site Costs	\$0
B. Construction Contract(s)	
(7) Cost of construction contract(s)	\$75,000
(8) Other	\$0
(9) Subtotal construction contract(s)	\$75,000
C. Miscellaneous Project Costs	
(10) Building purchase	
(11) Equipment & furniture not included above	\$975,000
(12) Consultant fees	
Architect & engineering fees	\$5,000
Certificate of need preparation	
Legal fees	
Market analysis	
Other	
Subtotal consultant fees	\$5,000
(13) Financing costs	
Bond	
HUD	
Commercial loan	
Other (specify)	
Subtotal financing costs	\$0
(14) Interest during construction	\$0
(15) Other (sales tax)	\$71,000
(15) Other (mobile MRI scanner rental)	\$50,000
(16) Subtotal miscellaneous project costs	\$126,000
Total Capital Cost of Project	\$1,176,000

Attachment B: Vendor Equipment Quote

Subject:

FW: Attention George. Nationwide Imaging Follow Up. Fonar.

2010 SIEMENS AERA 1.5T TIM PLUS DOT MRI
SYNGO MR E11, VE11A
XJ-GRADIENTS, 33 MTM, SR 125
48 RF CHANNELS
TIM 204 X 48
OR 98 MAGNET
SUMMITOMO COLDHEAD AND COMPRESSOR
TIM APPLICATION SUITE
ANGIO SUITE
CARDIAC SUITE
NEURO SUITE
BODY SUITE
ONCO SUITE
ORTHO SUITE
QUIET SUITE
BREAST SUITE
SCIENTIFIC SUITE
SYNGO GENERAL
3D USAGE
3D MPR
3D SSD
3D MIP
3D SSD
ARGUS VIEWER
WORKLIST
PHOENIX ZIP
CISS AND DESS
TIM CT FAST VIEW
I PAT EXTENSIONS
MOTION CORRECTION
IMAGE FILTER
MPPS
INLINE 3D DISTORTION CORRECTION
3D DISTORTION CORRECTION
MDDW
MORPHE QUALITY CONTROL
INLINE DIFFUSION
BLADE
TGSE
DOT ENGINE BASIC

BRAIN DOT ENGINE
AUTO ALIGN HEAD
SPECTROSCOPY SVS
FLOW QUANTIFICATION
SPECTROSCOPY 2D CSI
MR SPECTROSCOPY EVALUATION
COMPOSING
INLINE PERFUSION
INLINE COMPOSING
DIFFUSION TENSOR IMAGING
TIM PLANNING SUITE
SWI
TWIST
NATIVE
2D ASL
SPECTROSCOPY 3D CSI
IMAGE MANAGEMENT
NEURO PERFUSION LOCAL A/F
FAST DICOM
Q-SPACE
TQSE
FLOW QUANT
SPEC POST PROC
PAT ADVANCED
DYNAMIC 3D
ARTERIAL SPIN LABELLING
STEREOTATIC TSE
48 CHANNEL
MR ARGUS MAIN
CAP 3D FLY MODE
MR ARGUS FLOW ANALYSIS
MR SPEC POST PROCESS
SYNGO GENERAL
FILM VFS
CAP3D MAIN
CAP 3D VOI MODE
CAP 3D FILTER SSD
CAP 3D FILTER MIP
CAP 3D FILTER VRT
CAP 3D EDITOR
CAP 3D FUSION BASE
CAP 3D FUSION LM
CAP 3D FUSION AUTO
CAP 3D FUSION LAYOUT
CAP 3D FUSION CLIP VIEW
CAP 3D ROTATING OMIP
DICOM SR VEIWER
DIFFUSION TENSOR
REMOTTE DESKTOP
CAP 3D MULTI MONITOR

CAP 3D BONE REMOVAL
GEN MAIN
IVT ADVANCED RENDERING
3D DIFFUSION TRACTS
SYNGO VIA READY
COILS:
HEAD NECK 20
SPINE 32 CH
BODY 18CH
HAND/WRIST
FOOT /ANKLE
SHOULDER LARGE SHOULDER SMALL
TIM COIL INTERFACE
FLEX COIL INTERFACE
4 CH FLEX LARGE
4CH FLEX SMALL
4CH BREAST
15 CH KNEE
PHANTOMS

PRICE: \$975,000.00

THIS PRICE INCLUDES DELIVERY, INSTALLATION AND A 1 YEAR SERVICE AGREEMENT

Attachment C: Equipment Comparison

Attachment C

EQUIPMENT COMPARISON

	EXISTING EQUIPMENT	REPLACEMENT EQUIPMENT
Type of Equipment (List Each Component)	MRI Scanner	MRI Scanner
Manufacturer of Equipment	Fonar	Siemens
Tesla Rating of MRIs	0.6T	1.5T
Model Number	Upright	Aera
Serial Number	1412	
Provider's Method of Identifying Equipment	MRI #1	MRI #1
Specify if Mobile or Fixed	Fixed	Fixed
Mobile Trailer Serial Number/VIN#	NA	NA
Mobile Trailer Serial Number/VIN#	NA	NA
Date of Acquisition of Each Component	2008	Target Fall 2017
Does Provider Hold Title to Equipment or Have a Capital Lease?	Title	
Specify if Equipment Was/Is New or Used When Acquired	New	Refurbished
Total Capital Cost of Project (Including Construction, etc.)		\$1,176,000
Total Cost of Equipment		\$975,000
Fair Market Value of Equipment	\$100,000	
Net Purchase Price of Equipment	\$2,381,107	\$975,000
Locations Where Operated	Durham, NC	Durham, NC
Number Day in Use/To be Used in NC per Year	365	365
Percent of Change in Patient Charges (by Procedure)	NA	No increase
%Change in per Procedure Operating Expenses (by Procedure)	NA	No increase
Type of Procedures Currently Performed on Existing Equipment	High Resolution Imaging	NA
Type of Procedures New Equipment is Capable of Performing	NA	High Res.Imaging

TO THE NORTH CAROLINA STATE HEALTH COORDINATING COUNCIL

Declaration of James Sancrant, Jr., D.O. in Support of

**PETITION BY NOVANT HEALTH, INC. and MEDQUEST ASSOCIATES, INC.,
REGARDING EXISTING AND APPROVED SPECIALIZED BREAST MRI SCANNERS,
EXCLUDED FROM PLANNING INVENTORY
2022 State Medical Facilities Plan**

Pursuant to 28 U.S.C. § 1746, James Sancrant, Jr., D.O. declares as follows:

1. My name is James Sancrant, Jr., D.O. I am a resident of the State of North Carolina. The facts stated in this Declaration are true of my own personal knowledge, and if called to testify, I would so testify. I am over the age of eighteen and do not suffer from any disability that impacts this Declaration or my ability to testify truthfully.

2. I am a partner with Triad Radiology Associates (“Triad Radiology”) where I have worked since 2006. I most recently served as the Chair for Clinical Operations, Chairman of the Executive Committee and Director of Computed Tomography for Triad Radiology for approximately ten years.

3. I attended Ohio University where I earned both my Bachelor’s degree and my Doctor of Osteopathic Medicine degree. I completed my internship at Ohio University and my residency and fellowship in radiology at Wake Forest School of Medicine. I am board certified by the American Board of Radiology in Diagnostic Radiology and specialize in breast cancer imaging/image-guided biopsies and musculoskeletal imaging. I am also a member of the American College of Radiology, the Radiological Society of North America and the American Roentgen Ray Society.

4. As a partner at Triad Radiology, I provide professional radiological image readings and image guided interventions for the Novant Greater Winston-Salem Market, including Novant Health Imaging Piedmont and The Breast Center, as well as for numerous other providers and facilities across the State.

5. Magnetic Resonance Imaging (“MRI”) is a vital tool utilized to diagnose and treat a number of cancers and other conditions and injuries. In particular, it provides an important complement to other breast imaging modalities including mammography and ultrasound. This option has proven particularly important in certain populations of women, such as those with dense breast tissue, where limitations on mammography imaging can miss 50% to 65% of malignancies. MRI uses a magnetic field and computer-generated radio waves to create detailed imaging of the tissues and organs in the body. Many MRI scans also utilize contrast, a type of dye

that enhances the visibility of certain tumors and soft tissues as well as assessing changes and identifying malignancies.

6. Through my work with Triad Radiology, I am familiar with the Novant dedicated Aurora breast MRI scanner (the “Aurora Breast MRI Scanner”) previously operated at The Breast Center. The Aurora Breast MRI Scanner has not been operational since mid-2017 when it was damaged in a flood. Prior to that time, the functionality of the Aurora Breast MRI was already substantially limited by the age of the machine (10 years) and its outdated technology.

7. Before the flood at The Breast Center, I was one of the radiologists reading images produced by the Aurora Breast MRI Scanner. In the mid-2000s when the Aurora Breast MRI was acquired, specialized MRI scanners were considered by many to be efficient, state-of-the-art technology. The interchangeability of specialized coils on general purpose MRI scanners was limited and often time consuming, so dedicated MRI scanners were believed to provide a better alternative. The technology offered by a dedicated breast MRI scanner at the time also was believed to be superior because it was specifically designed to scan both breasts, the surrounding chest cavity, tissues and lymph nodes and its images were believed to be more accurate and of higher quality than general purpose scanners available at the time.

8. While it served a useful purpose at the time, the Aurora MRI Breast Scanner did not meet all expectations. Unfortunately, the technology of the dedicated breast MRI scanner never progressed beyond its initial stages and remained stuck in time, unlike the technology for general purpose MRI scanners, which has continued to progress over the years. In my professional opinion, the images produced by general purpose MRI scanners with bilateral breast coils are far superior to the images produced by the Aurora Breast MRI Scanner. General purpose MRI scanners can perform all of the functions that the Aurora Breast MRI Scanner performed with higher quality, superior images.

9. In my practice, I review a large number of breast MRI images and I believe the frequency of MRI utilization in diagnostic care and treatment, will continue to be high. In recent years, abbreviated breast MRI scans have become an integral complement to other imaging modalities. Triad Radiology has partnered with Novant Health Imaging Maplewood to provide this new supplemental breast cancer screening option for certain patients. We use a general purpose MRI scanner to perform these scans. Abbreviated breast MRI scans utilize intravenous contrast and produce digital images that essentially remove the normal dense breast tissue from the image, creating multiple 2-dimensional and one 3-dimensional images of the breasts, essentially allowing the radiologist reading the image to “see thru” the dense breast tissue. They are a less costly, less time-consuming option that is appropriate for patients with certain dense breast tissue. Abbreviated breast MRI scans take approximately ten minutes to complete, compared with approximately forty minutes required for a standard scan, and produce fewer images than a standard scan. I believe the demand for abbreviated breast MRI imaging will continue to increase. However, the demand is not likely to increase to the point where a dedicated breast MRI scanner is needed. Therefore, the ability to use an MRI scanner for all types

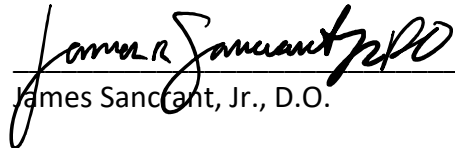
of scans, not just breast scans, is important, so that advanced technology is well utilized and benefits a range of patients.

10. The current preferred technology for breast imaging is a general purpose MRI scanner with specialized bilateral breast coils. Not only does this type of equipment support advanced breast imaging, but it allows providers to scan a larger population of individuals with varying imaging needs, not just breast scans. It also provides the clearest images. As technology advances and more options are made available to patients, I believe utilization of this important diagnostic and treatment tool will also increase. It is my understanding that Novant intends to replace the Aurora Breast MRI Scanner with a 3.0 Tesla general purpose MRI scanner, if approval is received from the State. The 3.0 Tesla technology is the best on the market and in my opinion, offers patients high quality care. As a physician, I believe that it is in the best interest of patient care to deploy the 3.0 Tesla technology for the benefit of all patients, not just a subset of patients.

11. I respectfully urge the State Health Coordinating Council to grant Novant's petition so that it will be able to replace the Aurora Breast MRI Scanner and use the replacement to provide all types of MRI scans.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on February 25, 2021.


James Sancrant, Jr., D.O.

TO THE NORTH CAROLINA STATE HEALTH COORDINATING COUNCIL

Declaration of Christopher L. Murphy in Support of

**PETITION BY NOVANT HEALTH, INC. and MEDQUEST ASSOCIATES, INC.,
REGARDING EXISTING AND APPROVED SPECIALIZED BREAST MRI SCANNERS,
EXCLUDED FROM PLANNING INVENTORY
2022 State Medical Facilities Plan**

Pursuant to 28 U.S.C. § 1746, Christopher L. Murphy declares as follows:

1. My name is Christopher L. Murphy. I am a resident of the State of North Carolina. The facts stated in this Declaration are true of my own personal knowledge, and if called to testify, I would so testify. I am over the age of eighteen and do not suffer from any disability that impacts this Declaration or my ability to testify truthfully.

2. I have served as Vice President of Development for MedQuest Associates, Inc. ("MedQuest") since 2017. I have worked for MedQuest in various capacities for over fifteen years. Prior to joining MedQuest, I worked at Universal Health Services, Inc. ("UHS") for more than nine years, including as the Director of Corporate Health Services.

3. I hold an MBA in Business with a focus in Health Care Administration from Nova Southeastern University and a BBA in Marketing Management from Northwood University-Florida.

4. Novant Health, Inc. ("Novant") is the ultimate parent company of MedQuest, Piedmont Imaging, LLC and Novant Health Breast Center, f/k/a The Breast Clinic MRI, LLC. Novant acquired MedQuest in November 2007. Among other activities, MedQuest manages Novant's imaging services, including arrangements with third party vendors to supply imaging services to Novant. Imaging services include modalities such as magnetic resonance imaging ("MRI"), computed tomography ("CT"), positron emission tomography ("PET")/CT, X-ray, ultrasound and bone density.

5. In my current role at MedQuest, I am responsible for managing operations and expansions of the facilities we own and/or manage in North Carolina and other states. In this capacity, I am well versed in the needs of our patients, facilities and healthcare partners, as well as imaging technology, such as technology in MRI scanners. I work closely with our affiliates and partners such as Novant to ensure we are providing the highest quality care and state of the art equipment available to meet the imaging needs of our patients.

6. I also interface regularly with the radiology teams who are responsible for providing the imaging readings and image-guided treatments at our facilities. I am also familiar with the North Carolina State Medical Facilities Plan (“SMFP”) and the Certificate of Need (“CON”) planning process.

The Aurora Breast MRI Scanner

7. One of the MRI scanners owned by Novant is a 1.5 Tesla specialized, dedicated breast MRI scanner manufactured by Aurora Imaging Technology, Inc. (the “Aurora Breast MRI Scanner”). This MRI scanner was acquired in 2007 after Novant Health Breast Center f/k/a The Breast Clinic MRI, LLC, was awarded a CON (Project I.D. No. G-007601-06) in response to an adjusted need determination for one dedicated, specialized breast MRI scanner. A condition on the CON states that The Breast Clinic “shall not use the dedicated breast MRI scanner for non-breast related general diagnostic purposes.” The Aurora Breast MRI Scanner is not in the inventory of MRI scanners in the SMFP (Table 17E-1). Rather, the Aurora Breast MRI Scanner appears in Table 17E-2, titled “Existing and Approved Specialized MRI Scanners, Excluded from Inventory.”

8. When the Aurora Breast MRI Scanner was acquired nearly fourteen (14) years ago, the technology was considered to be state-of-the-art. It was believed, at that time, that a specialized scanner, utilized only for breast imaging services, would provide the most efficient, cost effective, quality scans and services to meet the needs of our patients in Forsyth County and surrounding areas. At that time, lower cost, advanced modalities such as 3D mammography or automated breast ultrasound (“ABUS”) were not available. The Aurora Breast MRI Scanner was first installed at Salem MRI and was later relocated to The Breast Center in mid-2010. Substantial efforts and investment in the Aurora Breast MRI Scanner have been made to maximize its utilization.

9. Unfortunately, Novant’s expectations for the Aurora Breast MRI Scanner were not fully realized. Utilization of the Aurora Breast MRI Scanner never exceeded 975 weighted scans annually. In its last Calendar Year of operation, the Aurora Breast MRI Scanner performed only 199 breast MRI scans.

10. The Aurora Breast MRI Scanner was utilized for 8 years, only for breast imaging, at which time it was determined that the scanner had reached the end of its useful life. Novant received approval from the Certificate of Need Section (“CON Section”) to replace the scanner with a Siemens 1.5 Tesla general use scanner with a specialized breast coil in 2015. However, replacing the Aurora Breast MRI Scanner with a general use scanner was conditioned upon utilizing the scanner only for breast images.

11. Before a replacement scanner could be acquired and implemented, a flood at The Breast Center on May 13, 2017 substantially damaged the Aurora Breast MRI Scanner and

rendered the machine unusable. A water supply line on the floor above the Aurora Breast MRI Scanner leaked, and flooding in The Breast Center reached up to two inches deep in some areas. The Aurora Breast MRI Scanner had to be ramped down in order to lower its magnetic field so that the radio frequency shield enclosing the examination room could be inspected safely. Inspection revealed water damage to the radio frequency shield. The Aurora Breast MRI Scanner had to be completely disassembled to remove damaged floor panels and allow access to dry the slab and perimeter walls to prevent mold.

12. As I was informed by Aurora, the company stopped manufacturing MRI scanners in 2014 when it filed for bankruptcy and operates only as a service company. MedQuest is concerned that replacement parts are likely unavailable due to the uncertain status of the manufacturer. Even if repair of the Aurora Breast MRI Scanner were possible, however, there is no guarantee that the machine, now fourteen years old and out of service for nearly four years, could continue to operate safely and efficiently given the level of damage and unavailability of technical and operational support from the manufacturer. Thus, the Aurora Breast MRI Scanner has not been used since the flood.

The Replacement Scanner

13. The technology in the Aurora Breast MRI Scanner is now obsolete. The image quality on a new, general purpose MRI scanner with bilateral breast coils is far better than the image quality on the Aurora. While we have permission to replace the Aurora Breast MRI Scanner with a new, general purpose MRI scanner, we can only use the replacement scanner for breast MRI scans. The need for breast imaging services is not sufficient to support utilizing an MRI scanner for a single purpose— breast imaging. We understand that because the Aurora Breast MRI Scanner is not in the SMFP inventory, it cannot be replaced *and used* as a general purpose MRI scanner until it is placed in the SMFP inventory in Table 17E-1.

14. While breast MRI imaging has become a critical step in the continuum of care for some patients, including in the screening of patients for malignancies and other breast disease, because the demand for breast MRI scans is significantly smaller compared to the total demand for MRI scans, we believe that the most efficient next step that will benefit the greatest number of patients is to replace the Aurora Breast MRI Scanner with a general purpose GE 3.0 Tesla Pioneer MRI scanner (the “3.0T Replacement Scanner”) with bilateral breast coils and other coils that can be used to provide a variety of scans to many different patients. The 3.0T Replacement Scanner is expected to cost approximately \$2 million dollars. The 3.0T Replacement Scanner offers the most advanced, cutting edge technology with enhanced imaging capabilities. The table will have built in coil technology for spine and body imaging scans. Coils are moving from heavy plastic and electronic accessories to resemble blankets, which make them easier to utilize and change out as needed. Thus, the new 3.0T Replacement Scanner will offer the latest technology for breast and other imaging, for the benefit of many different patient needs.

15. The 3.0T Replacement Scanner would be placed at Novant Health Imaging Piedmont (“NHI Piedmont”), an outpatient imaging facility that offers a convenient, affordable,

outpatient setting to the community. As an Independent Diagnostic Testing Facility (“IDTF”), NHI Piedmont offers a low cost option for patients requiring advanced imaging studies such as MRI. NHI Piedmont is the busiest outpatient imaging facility in Forsyth County and has been for many years. As reported in the 2021 State Medical Facilities Plan, NHI Piedmont performed 12,388 weighted MRI scans in 2019 and also utilized mobile MRI services one to two days per week to meet demand.


16. The 3.0T Replacement Scanner would be accessible to all patients, regardless of their ability to pay. Novant’s generous charity care policy applies to this facility, whose physical location within the City of Winston-Salem will enhance access for minority patients and those patients with lower incomes. It would be available for breast scans as well as other scans and procedures thereby increasing accessibility for a broader range of patients.

17. In the mid-2000s when the Aurora Breast MRI Scanner was first acquired, payor reimbursement for breast MRI imaging was nearly double what it is today. The trend today is for payors to first steer patients to lower cost modalities, such as ultrasound, and require preauthorization for breast MRI scans. We still believe that breast MRI is a critical tool in the diagnosis and treatment of breast cancer, and we are committed to providing this service. However, because reimbursement for breast MRI is comparatively low, being able to utilize a replacement scanner for many other types of scans that are in demand will help offset this differential in reimbursement and allow Novant and MedQuest to continue providing the most technologically advanced options to all patients in our system. Moreover, patients requiring scans of the breast and other areas of the body, would benefit by the use of general scanner to provide all such services.

18. While breast MRI imaging is a growing modality used in breast screening and an important tool in the fight against breast cancer and other disease, there is not enough demand in this market for an MRI scanner that is only available for breast imaging, and we do not believe it is a prudent use of capital or in the best interests of patient care to limit the use of critical technology to one specific category of scans. For these reasons, we respectfully ask the SHCC to include the Aurora Breast MRI Scanner in the inventory of general use MRI scanners so that we can begin the process of replacing the Aurora Breast MRI Scanner and using the replacement scanner to perform high quality breast imaging as well as many other types of scans.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on February 24, 2021.



Christopher L. Murphy

TO THE NORTH CAROLINA STATE HEALTH COORDINATING COUNCIL**Declaration of Dr. Lee Ann Naylor in Support of****PETITION BY NOVANT HEALTH, INC., MEDQUEST ASSOCIATES, INC.,
PIEDMONT IMAGING, LLC, d/b/a NOVANT HEALTH IMAGING PIEDMONT, AND
NOVANT HEALTH BREAST CENTER
TO INCLUDE AN EXISTING AND APPROVED SPECIALIZED, DEDICATED BREAST MRI SCANNER
IN THE FIXED MRI EQUIPMENT INVENTORY
IN THE 2022 SMFP**

Pursuant to 28 U.S.C. § 1746, Lee Ann Naylor, M.D. declares as follows:

1. My name is Lee Ann Naylor, M.D. I am a resident of the State of North Carolina. The facts stated in this Declaration are true of my own personal knowledge, and if called to testify, I would so testify. I am over the age of eighteen and do not suffer from any disability that impacts this Declaration or my ability to testify truthfully.
2. I am a partner with Triad Radiology Associates ("Triad Radiology") where I have worked since 1996. I currently serve as the Director of Breast Imaging at Triad Radiology and am the Medical Director of the Novant Health Breast Center ("The Breast Center") in Winston-Salem.
3. I graduated from Clemson University in 1979 with a Bachelor of Science degree. I earned my Doctor of Medicine degree from the Medical University of South Carolina in 1983. I completed my residency training in Diagnostic Radiology at Wake Forest University Baptist Medical Center in 1987. I am board certified by the American Board of Radiology (Diagnostic Radiology) and I specialize in breast imaging. I am also a member of the American College of Radiology and the Radiological Society of North America.
4. In my work for Triad Radiology, I provide professional radiological image readings and image guided interventions for the Novant Greater Winston-Salem Market, including The Breast Center and Novant Health Imaging Piedmont. I also provide these services to other medical facilities and imaging centers across North Carolina.
5. As Medical Director of The Breast Center, I oversee the clinical services and operations provided, which includes Screening and Diagnostic Mammography, 3D Tomosynthesis/3D Mammography, Breast MRI, Ultrasound, Breast Biopsy and other

procedures and Bone Density. We also support mobile mammography services that travel to area churches, community centers, medical offices and businesses to ensure the availability of mammography services to those patients who may otherwise not have access to these screening exams.

6. Breast MRI scans complement other imaging modalities and detect cancer in a different way than traditional mammography or ultrasound scans. Breast MRI scans can detect cancer based upon tumor-related biological changes that cause alterations in blood vessel and inflammation from biochemicals created by tumor cells.

The Aurora Breast MRI Scanner

7. I am familiar with the Novant dedicated breast MRI scanner manufactured by Aurora (the "Aurora Breast MRI Scanner") that was first acquired by Novant in 2007. At the time, the scanner was a valuable asset. It was not utilized for breast cancer screening but rather in a limited capacity for patients with diagnosed cancers, surgical planning or other specific diagnostic examination and treatment.

8. However, over time, the limitations and shortcomings of the Aurora Breast MR Scanner became clear. It was difficult to obtain servicing and parts for the Aurora Breast MRI Scanner. While the technology for general purpose MRI scanners continued to improve, the Aurora Breast MRI Scanner technology did not improve and advance over the years. Instead, the best technology available to our breast imaging patients was the general purpose MRI scanners with bilateral breast coils.

9. In early 2016, Novant Health Imaging Maplewood ("Maplewood") acquired a general purpose 3.0 Tesla MRI Scanner with breast coils. This newer, more technologically advanced general purpose MRI scanner provided superior image quality and as a result, the Aurora Breast MRI Scanner was able to be phased out and used only sparingly for appropriate studies after early 2016. In May 2017, it was damaged irreparably in a flood and has been unusable ever since.

10. Currently, most of the breast MRI scans in the Novant Greater Winston-Salem market are done on a 3.0 Tesla general purpose MRI scanner located at Maplewood. This machine utilizes specialized bilateral breast coils and provides very clear, detailed, state-of-the-art images. The 3.0 Tesla MRI Scanner at Maplewood is used for many different types of scans, not just breast scans. It is my understanding that Novant intends, if its petition and subsequent request to the Certificate of Need Section are approved, to replace the Aurora Breast MRI Scanner with a similar 3.0 Tesla Scanner with bilateral breast coils, much like what is offered at Maplewood. This type of machine is considered to be the highest standard of care for breast and other general MRI imaging.

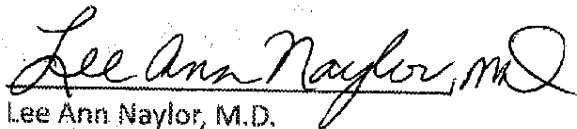
The Current Status of Breast MRI Imaging

11. As part of The Breast Center's commitment to early detection and evaluation, the Breast Center began operating a High-Risk Clinic to evaluate patients' lifetime risk of developing breast cancer based upon a number of factors, including personal history and family history. These evaluations are used to make recommendations for the most appropriate screening modalities necessary to fit each patient's individual needs and risks. These evaluations did not exist in 2007 when Novant first acquired the Aurora Breast MRI Scanner.
12. Breast MRI, in combination with mammography and other imaging modalities, is now recommended as a screening tool for those women deemed to have a higher-than-average risk of developing breast cancer over their lifetime. The specific recommendations for the frequency of MRI screening depend upon a woman's specific lifetime risk. The American Cancer Society currently recommends yearly MRI and mammography screening for patients with a greater than 20% lifetime risk. Again, such recommendations did not exist in 2007 when Novant first acquired the Aurora Breast MRI and screening MRI procedures were not typically utilized.
13. In addition, in recent years Triad Radiology and Novant Health Imaging Maplewood have partnered to implement the use of abbreviated breast MRI scans to complement the imaging services available to those patients who need it. This service provides a lower cost option to patients that requires less time but provides a valuable screening tool for those whose needs qualify for this service.
14. Due to the combination of the above factors, breast MRI imaging is on the rise; however, the only real option to provide this service is through a general purpose MRI scanner with bilateral breast coils. This is the preferred technology for such scans as it provides the latest, most advanced technology and highest quality images. Furthermore, while utilization of breast MRI imaging is increasing, I do not believe that the demand will rise to the level of requiring an MRI scanner dedicated *solely* to breast imaging. Rather, the best option to meet this demand is a general purpose MRI scanner that can be utilized both for breast imaging and for any other MRI service needed. This would allow the MRI scanner to provide the highest quality breast imaging service while at the same time benefitting all patients, not just a particular subset of patients.
15. In sum, I respectfully request that the State Health Coordinating Council approve Novant's petition so that it can ultimately seek to replace the Aurora Breast MRI Scanner

with a new, general purpose MRI scanner that can be utilized to provide MRI scans of all types to its patients.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on February 18, 2021.


Lee Ann Naylor, M.D.