

TO THE NORTH CAROLINA STATE HEALTH COORDINATING COUNCIL
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

July 28, 2021

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

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

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Overview

This Petition seeks one change to the Proposed 2022 State Medical Facilities Plan (“SMFP”): to include a single, existing dedicated breast-only MRI scanner in Table 17E-1’s inventory of magnetic resonance imaging scanners (“MRIs”) in the State Medical Facilities Plan (“SMFP”).

This Petition will be the first step in a two-step process to provide greater access to outpatient MRI services to all residents of Forsyth County by replacing a technologically-obsolete piece of equipment designed only to conduct breast imaging studies with new state-of-the-art technology that will make a variety of scans available to all patients, not just one type of scan for a limited group of patients. Step One, which is the only subject of this Petition, involves moving a single dedicated breast MRI Scanner from Table 17E-2 of the SMFP to Table 17E-1’s inventory of MRI scanners. Step Two of this process would involve the replacement and relocation of that dedicated breast MRI Scanner so that it can be used to provide a range of MRI scans. Petitioners acknowledge that Step Two can only be taken if this Petition is granted.¹

¹ To be clear, the only dedicated breast MRI Scanner that is the subject of this Petition is the dedicated breast MRI Scanner owned by Novant. This Petition is not asking for permission to replace the dedicated breast MRI scanner or relocate the scanner (Step Two). Depending on the capital costs, Step 2 will be accomplished either by a Notice of Exemption Acquisition and Material Compliance Determination or a

Novant

Novant Health, Inc. (“Novant”) is a North Carolina nonprofit corporation that owns and operates a major 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 joined Novant. Novant’s network also consists of rehabilitation programs, surgery and diagnostic centers and imaging facilities.

Novant first began operating in 1891 as Twin City Hospital, located in Winston-Salem, North Carolina. Over the next nearly 130-year history, the Novant system continued to grow and expand. On July 1, 1997, Novant Health was formed through the merger of Carolina Medicorp of Winston-Salem and Presbyterian Health Services of Charlotte. Novant’s mission is to improve the health of our communities, one person at a time. Novant is steadfastly committed to community engagement and improving health in its communities, as demonstrated by the many key initiatives it leads including, for example:

- Mobile mammography services that ensure women have access to high quality breast health screening even if they are unable to travel to imaging facilities;
- Novant Health Cares, providing volunteer opportunities for team members;
- Wellness Webinars featuring community experts;
- No cost Remarkable You health screenings that provide blood pressure, body mass index, cholesterol, triglycerides and prediabetes screenings;
- The One Charlotte Health Alliance serving the most at-risk members of the Charlotte community;
- Free community classes on a broad range of topics, including breast health, cancer, diabetes, weight management, nutrition, vascular health, and stroke prevention;
- Providing children at low income schools with needed immunizations;
- Partnering with 12 local African-American churches through “Project Care” to help community members at high risk of chronic diseases with exercise classes, wellness coaching, and nutritional demonstrations;
- “Gateway to Success”, a diabetes prevention program, which is a collaboration with the Gateway YWCA of Winston-Salem, Wake Forest Baptist, and the United Way;
- Supporting local Chambers of Commerce and Social Service Agencies such as the United Way and the Arts Council of Winston-Salem and Forsyth County;
- Providing free community clinics;
- Providing more than 15,000 COVID-19 tests in Forsyth County;
- Administering some 416,534 COVID-19 vaccinations in multiple clinics across the State;
- Opening screening and respiratory assessment centers designed to test and treat patients experiencing moderate to severe respiratory symptoms associated with COVID-19;
- Supporting Colleges and Universities including programs that prepare students for careers in healthcare or that improve community health such as the Winston-Salem State University-Rams Health on Wheels mobile clinic;

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).

- Assisting local employers improve the health of their employees by making smart health-related decisions at work and home;
- Offering on-site employee screenings, health risk assessments, on-site clinics, lifestyle modification programs such as smoking cessation, stress management and weight loss; and
- Providing employer’s occupational medicine services like pre-employment physicals, primary care connection and executive health programs.

Novant addresses the comprehensive needs of its communities by first assessing those specific needs through a strategic community benefit review and then implementing community-specific plans. Among the myriad services offered, Novant provides many types of screening and diagnostic imaging services and procedures at its medical centers and at eighteen (18) outpatient clinics throughout its service area. Novant operates ten (10) fixed MRI scanners in Forsyth County, both hospital-based and at outpatient clinics. *See* Proposed 2022 SMFP, Table 17E-1, pp. 346-63. Novant provides prompt imaging reports and flexible scheduling to meet patient needs and ensure equitable access to advanced testing and interventional treatment.

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.² *See* Declaration of Christopher L. Murphy (“Murphy Declaration”) at 16.

MedQuest

MedQuest Associates, Inc. (“MedQuest”) is a subsidiary of Novant. MedQuest provides management services for a number of Novant imaging facilities, including Piedmont Imaging, LLC d/b/a Novant Health Imaging Piedmont (“NHI Piedmont”). 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.

NHI Piedmont

NHI Piedmont is an outpatient imaging facility centrally located at 185 Kimel Park Drive in Winston-Salem. This highly-utilized facility is located in the population center of Forsyth County.³ NHI Piedmont offers an array of general imaging services including MRIs, diagnostic X-ray, computed tomography, ultrasound, breast ultrasound, mammography, DEXA, myelograms,

² *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.

³ The 2019 population estimate for Forsyth County is 382,295. *See* <https://www.census.gov/quickfacts/fact/table/forsythcountynorthcarolina.winstonsalemcitynorthcarolina/PST045219>.

Of this number, 247,945 residents are in the City of Winston-Salem. *See* <https://www.census.gov/quickfacts/fact/table/winstonsalemcitynorthcarolina.forsythcountynorthcarolina,NC/PST045219>.

and fluoroscopy. NHI Piedmont currently operates two fixed 1.5 Tesla MRI scanners and has been Forsyth County's busiest outpatient imaging facility for many years. As reported in the 2021 SMFP, Table 17E-1, p. 352, NHI Piedmont's two fixed MRI scanners provided a total of 12,388 weighted MRI scans in FFY 2019 and a total of 10,676 weighted MRI scans in FFY 2020, as reported in the Proposed 2022 SMFP, Table 17E-1, p. 351. This utilization represents a decrease of only 1,712 scans despite the COVID-19 pandemic and all of the associated delays, closings, cancellations and restraints placed on capacity. Both existing fixed MRI scanners at NHI Piedmont continue to operate well above the planning threshold of 4,805 scans annually. NHI Piedmont also utilized one to two days of mobile MRI service weekly throughout 2019 in order to accommodate the high demand.

The Breast Center

Novant is the ultimate parent company of Novant Health Breast Center (the "The Breast Center") (f/k/a The Breast Clinic MRI, LLC). The Breast Center is located at 2025 Frontis Plaza Boulevard, Winston-Salem and offers numerous diagnostic imaging and other women's health services including: breast MRI, ultrasound, breast biopsy, screening and diagnostic mammography, 3D tomosynthesis/3D mammography, bone density and other special breast procedures. The Breast Center focuses solely on breast health and related services.

Collectively, Novant, MedQuest, NHI Piedmont, and The Breast Center are referred to as the "Petitioners."

2. Statement of the requested adjustment, citing the provision or need determination within the Proposed SMFP for which the adjustment is proposed.

There are two specialized, dedicated breast MRI scanners in the State. One is owned by Novant and was formerly located at The Breast Center. This scanner was manufactured by Aurora Imaging Technology, Inc. ("Aurora") (hereinafter, the "Aurora Breast MRI Scanner"). The other dedicated breast MRI Scanner is owned by the Charlotte Radiology Breast Center and located in Mecklenburg County; it is not the subject of this Petition.⁴ See Proposed 2022 SMFP, Chapter 17E (Table 17E-2) at p. 364.

Currently, the SMFP inventory excludes "MRI scanners awarded based on need determinations for a dedicated purpose or demonstration project (Table 17E-2)." See Proposed 2022 SMFP, Chapter 17E at p. 345 (Assumptions of the Methodology no. 4). Thus, for planning purposes, the two dedicated breast MRI scanners operating in the State 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 Proposed 2022 SMFP at p. 38. Forsyth County is its own service area for purposes of the calculation of MRI need.

⁴ Because the present Petition deals only with the Aurora Breast MRI Scanner, the Charlotte Radiology breast MRI Scanner will not be affected. If the Petition is approved as proposed, the Charlotte Radiology breast MRI Scanner will continue to be included in Table 17E-2 of the SMFP and therefore excluded from the inventory of fixed MRI Scanners in Mecklenburg County.

Here, Petitioners propose only to include Novant’s Aurora Breast MRI Scanner listed in Table 17E-2 in the 2022 SMFP inventory such that this breast MRI scanner and its utilization will be factored into the methodology for the future calculation of need for additional fixed MRI scanners in Forsyth County. If this Petition is approved and the Aurora Breast MRI Scanner is included in the inventory, Petitioners will then proceed to Step 2, which will propose to replace the Aurora Breast MRI Scanner with a general purpose MRI scanner to be placed at NHI-Piedmont that can be used for a range of imaging studies, not just breast imaging studies. Petitioners do not propose to include any additional need determinations in the 2022 SMFP for fixed MRI scanners.

3. Reasons for the proposed change, including:

Petitioners seek to have the Aurora Breast MRI Scanner included in the inventory so that in the near future, they can seek approval from the CON Section to replace the non-functional and outmoded Aurora 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 the Aurora Breast MRI Scanner with a general purpose MRI scanner, but can only use the replacement for breast imaging. This is not an efficient use of healthcare resources and Petitioners do not believe it best serves the needs of Forsyth County.

Background of the Novant Aurora Breast MRI Scanner

In response to a petition to the State Health Coordinating Council (“SHCC”) submitted by Novant, the 2006 SMFP included an adjusted need determination for one dedicated and specialized breast MRI scanner (the “Adjusted Need Determination”). This was a statewide adjusted need determination but Novant was the only applicant for the breast MRI scanner. The Adjusted Need Determination was not a demonstration project by name; however, the purpose and use was akin to the demonstration projects approved by the State in that the highly specialized need determination was for a limited and specific purpose—a dedicated, breast only MRI scanner. This analogous designation is evidenced by the fact that both the dedicated special use MRI and demonstration project MRIs are categorized by the State in the same part of the SMFP—Table 17E-2—and are treated the same way for planning purposes (*e.g.*, they are not included in the inventory for MRI planning purposes).

In response to the Adjusted Need Determination, on November 26, 2006, The Breast Clinic MRI, LLC (“The Breast Clinic”) 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 A* attached hereto. The Breast Clinic was the only applicant for this specialized scanner. Because of this special designation, the breast MRI scanner is not included in the State MRI scanner inventory for planning purposes, but rather is included in Table 17E-2 along with other specialized MRI scanners and demonstration projects. *See Proposed 2022 SMFP, Table 17E-1.* One of the conditions on the CON is that Novant Health Breast Center “shall not use the dedicated breast MRI scanner for non-breast related general diagnostic purposes.” Exhibit A.

In 2007, The Breast Clinic purchased a 1.5 Tesla Aurora Breast MRI Scanner. The Aurora Breast MRI Scanner was first installed at Salem MRI and then in mid-2010, was relocated to The Breast

Clinic (now called The Breast Center) and used only for breast MRI scans, per the condition in its CON. Novant invested substantial capital and made considerable efforts to maximize utilization of the Aurora Breast MRI Scanner.

At the time, the Aurora Breast MRI Scanner was considered 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”); Murphy Declaration at 8. Specialized, dedicated MRI scanners were among the newest modalities utilized in diagnostic imaging. In the mid-2000s, given high breast cancer incidence rates in North Carolina, the need for a dedicated breast MRI scanner and its value in fighting and lowering breast cancer mortality rates and increasing early detection and treatment, were clear. This unique project was intended to meet those demands and provide treatment, diagnoses and care with a specific, dedicated modality. Moreover, lower cost imaging modalities such as 3D mammography and automated breast ultrasound (“ABUS”) were not available. Breast MRI imaging was also not utilized for screening at the time, 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.

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. Petitioners believed it was an important and worthy investment to make so that patients received the best possible care and treatment available on the market. At that time, the design of the specialized coil system for general purpose scanners was also 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* 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. For all these reasons, Petitioners pursued a specialized breast MRI scanner.

Unfortunately, many of Petitioners’ beliefs and expectations for the dedicated breast MRI scanner did not hold true. Murphy Declaration at 9. Utilization of the Aurora Breast MRI Scanner was never robust and steadily declined over time. 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 Breast MRI Scanner 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 Breast MRI Scanner had reached the end of its useful life. On December 18, 2015, the Certificate of Need Section (“CON Section”) approved a replacement equipment exemption request for the Aurora Breast MRI Scanner. Novant intended to replace the Aurora Breast MRI Scanner with a Siemens Aera 1.5 Tesla 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 B*, attached hereto; Murphy Declaration at 10.

In early 2016, Novant Health Imaging Maplewood (“Maplewood”) acquired a 3.0 Tesla general purpose MRI scanner with bilateral breast coils. This newer technology produced superior images and the use of the Aurora Breast MRI Scanner was quickly phased out and used sparingly, only for appropriate patient studies. *See* Dr. Naylor Declaration at 9.⁵ On May 13, 2017, before Novant could replace the Aurora Breast MRI Scanner, the Aurora Breast MRI Scanner was severely damaged in a flood. *See* Murphy Declaration at 11 (“Murphy Declaration”). During the overnight hours, a water supply line on the floor above the Aurora Breast MRI Scanner leaked, flooding The Breast Center with water reaching up to two inches in depth in some areas. The Aurora Breast MRI Scanner was ramped down, dropping its magnetic field to allow for the safe inspection of the radio frequency shield enclosing the examination room. Upon inspection, water damage to the radio frequency shield was found, which required a complete disassembly of the Aurora Breast MRI Scanner to remove damaged floor panels and to allow access to dry the slab and perimeter walls to prevent mold. Murphy Declaration at 11.

The flood rendered the Aurora Breast MRI Scanner unusable. The machine has been in storage and has not served any patients since 2017. Breast MRI imaging services, using a general purpose MRI scanner with special coils, are primarily performed at Maplewood.⁶ Novant has determined that the Aurora Breast MRI Scanner is simply no longer viable given its age, water damage, limited functionality compared to current technology and the uncertainties surrounding technical support and repairs.⁷ As such, the only viable replacement technology for the dedicated breast MRI project that initially started more than 15 years ago, is a general purpose scanner. However, while the CON Section has approved the replacement of the Aurora Breast MRI Scanner, the replacement machine can only be used for breast imaging and not for patients who need other types of scans. Petitioners respectfully submit that costly and limited healthcare resources should be used where they can have the greatest impact to improve health. For this reason, Petitioners request that the Aurora Breast MRI Scanner be included in the MRI inventory in Table 17E-1 of the 2022 SMFP, so that Petitioners can proceed to Step 2, the replacement of the Aurora Breast MRI Scanner with a scanner that will be used for a variety of scans, including breast MRI scans. This will further both the spirit and the stated goals of the CON Law to ensure the availability of cost-effective resources to promote the health and welfare of citizens of North Carolina. *See* N.C. Gen. Stat. § 131E-175.

⁵ The majority of Novant’s breast MRI scans in Forsyth County are done at Maplewood on the 3.0 Tesla general purpose MRI scanner with specialized breast coils. *See* Dr. Naylor Declaration at 10.

⁶ A small number of breast MRI scans are performed at Novant Health Kernersville Medical Center and at Novant Health Forsyth Medical Center-Clemmons.

⁷ It is uncertain whether replacement parts and repairs for this outdated scanner are even available given the instability of the manufacturer, Aurora (one of the reasons the Aurora Breast MRI Scanner was decommissioned in the first place). *See* Murphy Declaration at 12. Upon information and belief of Petitioners, Aurora stopped manufacturing MRI scanners in 2014 when it filed for bankruptcy. It serves only as a service company and there is no guarantee that the machine could be safely repaired given the age, level of damage and unavailability of technical and operational support from the manufacturer. *See* Murphy Declaration at 12.

a. A statement of the adverse effects on the population of the affected area that are likely to ensue if the change is not made.

Including Novant's existing, specialized, dedicated breast MRI scanner in the State inventory will not adversely affect providers or the population in the affected area, as demonstrated below. Rather, being able to operationalize a previously approved resource and utilize that resource to provide a greater variety of services to an entire population, greatly benefits the community it is intended to serve. The ultimate replacement of the Aurora Breast MRI Scanner 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 in its service area, but rather will enhance accessibility and quality of services for all patients. While the Aurora Breast MRI Scanner fulfilled its original purpose, it is no longer the best type of technology for patients. Replacing the scanner will require a substantial capital investment, estimated to be approximately \$2 million. *See* Murphy Declaration at 14. 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 the replacement scanner to only one particular type of scan.

While breast MRI imaging is still a critical tool in the treatment of patients, Petitioners have determined that there is not a need within the Novant system for a machine that can only be used for breast imaging. Rather, there is a need within the Novant system for a general purpose machine that is capable of providing breast images as well as other services. *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 in Forsyth County is relatively small. Second, reimbursement has changed. Reimbursement for breast MRI imaging by payors was nearly twice its current rate when the Aurora Breast MRI Scanner 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 the relevant population. The Aurora Breast MRI Scanner is, and has been, dormant and unusable for years. 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, Novant cannot replace the machine and utilize it for any purpose other than breast imaging, without first gaining approve to include the scanner in the fixed MRI inventory. Utilizing a replacement general purpose scanner for breast imaging only is not a reasonable option and does not best serve the community as described herein. Thus, this existing and crucial healthcare resource is going unused and essentially being wasted.

Future Replacement of the Aurora Breast MRI Scanner

Petitioners intend to ultimately seek authorization from the CON Section to replace the Aurora Breast MRI Scanner with a GE 3.0 Tesla 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. Without

approval to include the Aurora Breast MRI Scanner in the fixed MRI inventory, Petitioners could spend \$2 million for the MRI equipment, but may only use it for a single, limited service and not take advantage of the full potential of the machine. This does not enhance services to the community and is antithetical to the basic principles of safety, quality, access and value governing development of the SMFP and the purpose of the CON Law. *See Proposed 2022 SMFP at pp. 2-4; N.C. Gen. Stat. § 131E-175.*

To be clear, Petitioners will not abandon their commitment to providing quality breast imaging studies for patients. Quite the opposite. Petitioners recognize the importance of women's health services and ensuring access to the most advanced imaging services. The Breast Center specializes in breast health, primarily for women. Breast MRI imaging plays a pivotal role in the detection and diagnosis of breast cancer, but with technological advancements, breast imaging does not need to be performed exclusively on dedicated breast scanners. *See Dr. Naylor Declaration at 11, 14.*

Breast MRI imaging is an important complement to other imaging modalities, particularly mammography, which can miss anywhere from 50% to 65% of malignancies in certain populations of women, like those with dense breast tissue. *See Dr. Sancrant Declaration at 5; Dr. Naylor Declaration at 12.* Unlike at the time when the Aurora Breast MRI Scanner 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 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, in recent years, abbreviated breast MRI scans have become an important instrument used by physicians and radiologists in diagnosing and treating certain breast cancers and diseases. Abbreviated breast MRI scans are appropriate for certain populations of women, such as women with dense breast tissue, under certain circumstances. The studies are short and very cost effective for patients and are expected to continue to play an important role in imaging diagnostics. *See Dr. Sancrant Declaration at 9.* Novant has invested substantial resources in The Breast Center to focus only on those issues affecting women's breast health. It is committed to providing the highest quality technology to support this mission.

Petitioners have led the charge in offering abbreviated breast MRI imaging in recent years to effectively expand MR imaging to patients who do not require a traditional, full MRI breast scan, 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 high Tesla general purpose scanner with specialized breast coils will provide patients with the highest quality images available at this time, while providing Petitioners with the flexibility and discretion to serve other non-breast patients. This is true for breast patients as well those who may have

complications that require additional scans of other areas of the body. *See* Murphy Declaration at 17.

Under these circumstances, it does not make economic sense for Petitioners to further invest in a dedicated breast machine, or to spend approximately \$2 million on a general purpose MRI scanner that can only be used for one type of scan. *See* Murphy Declaration at 14. Instead, Petitioners intend to acquire a general purpose fixed MRI scanner to replace the Aurora Breast MRI Scanner once it is included in the State’s inventory. Petitioners intend to locate the replacement MRI scanner at NHI-Piedmont, which serves a high volume of patients and where utilization would be supported. Petitioners would commit to obtaining bilateral breast coils to ensure high quality breast MRI imaging services are available to patients, but the machine would also be able to serve a larger population because it would not be solely limited to providing breast MRI scans.

Moreover, the intended relocation of the existing MRI to NHI Piedmont is an intentional step designed to ensure needed, lower cost MRI services remain available to the population center of Forsyth County, which is also an underrepresented area of Forsyth County, as addressed in greater detail.

Historical Utilization

Utilization of the Aurora Breast MRI Scanner never met the expectations Novant had for the machine when it first acquired the scanner in November 2007. Historical utilization of the dedicated Aurora Breast MRI Scanner was as follows:⁸

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

As shown above, utilization of the Aurora Breast MRI Scanner peaked in the 2010-2011 time frame; however, utilization then dropped rapidly thereafter. Even at its peak, the volume of breast MRI scans was well below 1,000 scans, far insufficient to justify dedicating an MRI machine to

⁸ Data is no longer available for the Aurora Breast MRI Scanner for the time period of November 2007 through September 2009, however, Petitioners believe the experience with utilization of the Aurora Breast MRI Scanner during that time period is accurately reflected in the table below.

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.⁹

However, in recent years, utilization of MRI imaging at Novant facilities in Forsyth County (both for breast and other procedures) has continued to remain high, even during the 2020 COVID-19 pandemic. Breast imaging, however, represents only a small percentage of the total utilization of MRI imaging:

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 diagnostics.

The consistent underutilization of the Aurora Breast MRI Scanner and small percentage of breast MRI scans compared to the total number of scans buttresses the need to include the machine in the inventory so that Petitioners can seek to replace the machine with a state-of-the-art, general purpose MRI scanner that can be well utilized for the benefit of all patients.

Current Technology

In contrast to the Aurora Breast MRI Scanner, which became “stuck in time,” the technology for general purpose MRI scanners has advanced tremendously. *See* Dr. Sancrant Declaration at 8. Unlike some fifteen years ago, dedicated specialized MRI scanners are no longer the standard of care 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 machines nearly two decades ago. *See* Dr. Sancrant Declaration at 7.

⁹ 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* Daft 2022 SMFP, MRI Scanner Assumptions of the Methodology at pp. 343-345.

Because current general purpose MRI technology has outpaced specialized MRI technology, the best utilization of healthcare resources is to replace this outdated machine with a multi-functional, general purpose scanner that can serve *all* patients. *See* Dr. Sancrant Declaration at 10. A general purpose MRI scanner with bilateral breast coils is the preferred standard of care by radiologists specializing in breast imaging. *See* Dr. Sancrant Declaration at 10.

Future Utilization

NHI Piedmont is the most highly utilized outpatient imaging facility in Forsyth County. Utilizing Petitioners’ internal data, NHI Piedmont performed some 12,847 weighted scans in Calendar Year 2018, 12,747 weighted scans in Calendar Year 2019 and 11,305 weighted scans in Calendar Year 2020:

Piedmont Imaging - MRI Volume					
	CY 2016	CY 2017	CY 2018	CY 2019	CY 2020
Unweighted MRI volume	11310	11604	11255	11687	10350
With Contrast Scans	2897	3485	3979	2650	2388
Weighted Total MRI Volume	12469	12998	12847	12747	11305
Weighted Volume/Fixed MRI Scanner	6235	6499	6424	6374	5653

While there was some decrease in utilization in 2020 due to COVID-19 with many patients delaying care because of the pandemic, utilization at NHI Piedmont still exceeds the planning threshold in the 2021 and Proposed 2022 SMFPs.¹⁰ As services and behaviors continue to normalize, Petitioners expect this volume to increase. Currently, a significant number of the MRI scans done at NHI Piedmont are neurological scans. NHI-Piedmont is also located in the most populated area of Forsyth County—Winston-Salem. Approximately 65% of the population of Forsyth County lives in Winston-Salem.¹¹ When utilization fully returns to pre-COVID-19 levels, additional imaging capacity will be needed to keep up with demand. Thus, Petitioners expect scan volumes at NHI Piedmont to continue to increase with the robust neurological imaging demand, large population and increased abbreviated and screening breast MRI imaging.

This data supports Petitioners’ request and the need to replace the dedicated breast MRI scanner with a general purpose scanner that can alleviate capacity constraints at NHI Piedmont and serve a greater population of patients, including neuro patients. While there is no need for a dedicated, breast only MRI scanner in this market, there is a need for an additional general purpose MRI scanner.

¹⁰ *See* 2021 SMFP at p. 345; Draft 2022 SMFP at p. 351. The SMFP planning threshold for Forsyth County is 70% of that number, which equates to 4,805 weighted procedures per year. *See* Draft 2022 SMFP, MRI Scanner Assumptions of the Methodology at pp. 343-345.

¹¹ *See* <https://www.census.gov/quickfacts/fact/table/winstonsalemcitynorthcarolina,forsythcountynorthcarolina,NC/PST045219>.

Other Considerations

Replacing the Aurora Breast MRI Scanner with a new general purpose scanner that can be used to perform all different types of scans, and placing that scanner at NHI Piedmont, will also better serve our at-risk population. Winston-Salem has the highest percentage of residents with no health coverage in Forsyth County. It is the most racially diverse of all populations in Forsyth County and more than 60% of Forsyth County residents over age 65 live in Winston-Salem. There remains a need for quality, accessible healthcare services, including imaging services, for this population, which can be filled with the intended replacement MRI scanner at NHI-Piedmont, thus enhancing access to low income and minority patients. This location will also enhance access and affordability because it will be placed as an affordable Independent Diagnostic Testing Facility (“IDTF”), offering a low-cost option for its patients. *See* Murphy Declaration at 15-16.

For all of these reasons, Novant has made the determination that it would not be economically feasible or in the best interest of patient care to make a substantial capital investment attempting to replace the Aurora Breast MRI Scanner with a new machine that could only be used for one type of imaging study. The demand for breast imaging studies does not support a need for an MRI scanner that performs nothing but breast images. Rather, patients would most benefit from a general purpose MRI scanner with bilateral breast coils and other coils that can provide both breast imaging and a variety of other imaging studies. A new machine with the most up-to-date technology and advancements will increase operational efficiencies and offer better quality, higher resolution images to aid in the fight against cancer and by providing the highest level of diagnostics.

b. A statement of alternatives to the proposed adjustment 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 Aurora Breast MRI Scanner would continue to be excluded from the fixed MRI scanner inventory for planning purposes.

If the status quo is maintained and the breast MRI scanner continues to be excluded from the fixed MRI inventory, Petitioners have two potential options available to them:

- (1) leave the existing Aurora Breast MRI Scanner in storage, unused and not providing services of any kind to patients;
- (2) replace the Aurora Breast MRI Scanner 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. After careful review and analysis, Petitioners determined that none of these alternatives is feasible and none provides a meaningful alternative that benefits patients. Rather, the proposal in this Petition considers the needs of patients and how best to serve those patients.

4. Evidence that health service development permitted by the proposed adjustment would not result in unnecessary duplication of health resources in the area.

If approved, this proposal will not result in the unnecessary duplication of MRI services. Because the Novant system, specifically NHI Piedmont, can support adequate utilization of a general purpose MRI replacement as described herein, including the Novant dedicated breast MRI scanner in the inventory will not duplicate existing MRI resources.

There is one placeholder CON in the Proposed 2022 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 Proposed 2022 SMFP. *See* Proposed 2022 SMFP, Table 17E-3 at p. 365. 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 Aurora Breast MRI Scanner in the State inventory. Thus, including the Aurora Breast MRI Scanner in the inventory will not create unnecessarily duplication or negatively impact the need methodology or suppress a need for a new fixed MRI scanner.

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 in the inventory with all other fixed MRI scanners. Until that time, the multi-positional fixed MRI scanner CON included a condition that the scanner not be later replaced with a general purpose scanner. 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 C*, attached hereto.

Similarly, in 2019, the Bone and Joint Surgery Clinic (“Bone and Joint”) appealed to the Technology and Equipment Committee to include its extremity fixed MRI scanner in the inventory. Bone and Joint had replaced its dedicated, 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 and Joint’s request was approved, and the scanner was included in the inventory. Bone and 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.

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 and Wake Counties, respectively, and has not unnecessarily duplicated existing services or artificially suppressed future need. Rather, it has expanded patient and provider choice and allowed equipment to be utilized for any necessary diagnostic imaging purpose, thus fulfilling the basic principles of the SMFP: safety and quality, access, and value. *See* Proposed 2022 SMFP at 2-4.

While the TOA and Bone and Joint projects were both originally approved as demonstration projects, the precedent is equally applicable here. In both of the above-referenced cases, the equipment acquired by the original demonstration projects ran the course of their useful lives. Because those specialized scanners and projects were no longer deemed viable or necessary, the SHCC included them in the MRI inventory in Table 17E-1, thus allowing TOA and Bone and Joint the opportunity to demonstrate a need for replacement equipment with general purpose scanners that can be utilized for all types of scans. Because the purposes of the demonstration projects and the dedicated breast MRI Scanner are so analogous, the treatment of their replacements should be as well. Moreover, there is no provision in the CON Law or regulations that prohibits the same treatment for specialty projects like the Aurora Breast MRI Scanner. Thus, this proposed Petition should be granted in the same way similar demonstration project MRI scanners were allowed to be included in the inventory in Table 17E-1.

5. Evidence that the requested adjustment is consistent with the three Basic Principles governing the development of the SMFP: safety and quality, access, and value.

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

a. Safety and Quality

Petitioners are committed to providing exceptional quality care to all patients within the Novant system. Safety and quality are Petitioners' top priorities when it comes to patient care. Since 2009, Novant has operated a system-wide quality program called "First Do NO Harm: Leadership Methods in a Safe Culture" that utilizes proven management techniques and education to improve patient safety. Imaging services are no exception. Petitioners are held to rigorous training and accreditation standards, as are facilities like NHI-Piedmont.

The impetus behind filing this petition is to ensure the highest standards of safe, quality MRI imaging services are available to meet our patients' needs. Including the Aurora Breast MRI Scanner in the State inventory so that Petitioners can seek to replace an outmoded, non-functional machine with new, versatile, state-of-the-art equipment that can be used for a variety of imaging studies, will improve safety and quality for patients.

b. Access

Currently, the Aurora Breast MRI Scanner 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 at NHI-Piedmont will improve equitable access to imaging services for all patients, including low income and diverse patients in Forsyth County. Novant provides services to all persons, regardless of their ability to pay. Novant provides discounts to uninsured patients and its charity care policy allows a patient with a household income up to 300% of the Federal Poverty Level to easily seek financial forgiveness for needed medical services. This charity care will be available to patients utilizing the replacement MRI scanner. *See* Murphy Declaration at 16. Limiting the types of scans

performed on the replacement scanner, however, will also limit the population that can benefit from Novant's charity care policy.

The physical location of the replacement, general purpose scanner also enhances access to patients by offering a convenient, non-hospital location.

c. Value

Replacement of the Aurora Breast MRI Scanner with a general purpose MRI to be located at NHI-Piedmont, a non-hospital-based outpatient imaging facility, will add value to the community and patients utilizing these services. This 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).

Moreover, NHI-Piedmont has existing space within its facility to place a new, general purpose MRI scanner. While some renovation and/or construction may be required to upfit the appropriate space, a new facility will not need to be constructed and existing common areas such as waiting areas, dressing rooms and equipment control space can be used to also accommodate a new MRI scanner at NHI-Piedmont.

Conclusion

Petitioners respectfully request that the SHCC include the Novant existing and approved specialized, dedicated breast MRI scanner in the fixed MRI equipment inventory in the 2022 SMFP.

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

An Equal Opportunity/ Affirmative Action Employer

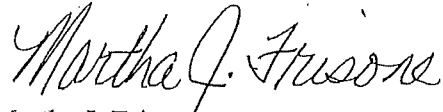


separate determination. If you have any questions concerning this matter, please feel free to contact this office.

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 Christopher L. Murphy 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, 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 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 eight 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 sufficiently strong 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. As the Draft 2022 SMFP reflects, utilization of fixed MRI services at NHI Piedmont decreased only slightly in 2020, despite the COVID-19 pandemic, to 10,676 weighted scans, still well above the State's planning threshold.

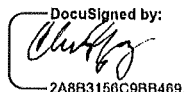
16. The 3.0T Replacement Scanner would be accessible to all patients, regardless of their ability to pay. Novant's generous charity care policy applies to this facility, whose physical location within the City of Winston-Salem will enhance access for minority patients and those patients with lower incomes. 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 from a 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 July 14, 2021.

DocuSigned by:

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Christopher L. Murphy

TO THE NORTH CAROLINA STATE HEALTH COORDINATING COUNCIL

Declaration of James Sancrant, Jr., D.O. 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, 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 July 7, 2021.



James Sancrant, Jr., D.O.

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 needs.

8. However, over time, the limitations and shortcomings of the Aurora Breast MRI 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.

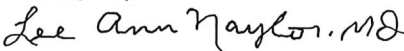
13. In addition, in recent years Triad Radiology and Novant Health Imaging Maplewood have partnered to implement the use of abbreviated breast MRI scans to complement the imaging services available to those patients who need it. This service provides a lower cost option to patients that requires less 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 July 7, 2021.

DocuSigned by:

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Lee Ann Naylor, M.D.