

Petition to the State Health Coordinating Council
Proposal to Revise SMFP Policy TE-3: Plan Exemption for Fixed Magnetic Resonance Imaging Scanners
for the 2023 State Medical Facilities Plan
March 2, 2022

Petitioner: WakeMed
3000 New Bern Avenue
Raleigh, NC 27610

Contact: Thomas Gough, Executive Vice President & Chief Operating Officer
919-350-1960
tgough@wakemed.org

Statement of Requested Adjustment

WakeMed respectfully requests that the State Health Coordinating Council approve revision of Policy TE-3 in the 2023 State Medical Facilities Plan. Specially, the revised Policy TE-3 would be worded as follows:

Policy TE-3: Plan Exemption for Fixed Magnetic Resonance Imaging Scanners
Qualified applicants may apply for a fixed magnetic resonance imaging scanner (MRI).

To qualify, the health service facility proposing to acquire the fixed MRI scanner shall demonstrate in its certificate of need application that it is a licensed North Carolina acute care hospital with, on the same campus, emergency care coverage 24 hours a day, seven days a week, inpatient and outpatient surgical services, and that does not currently have an existing or approved fixed MRI scanner as reflected in the inventory in the applicable State Medical Facilities Plan.

The applicant shall demonstrate that the proposed fixed MRI scanner will perform at least 850 weighted MRI procedures during the third full operating year.

The performance standards in 10A NCAC 14C.2703 would not be applicable.

~~The fixed MRI scanner must be located on the hospital's "main campus" as defined in G.S. 131E-176 (14n)a., but it may operate the fixed MRI as part of the hospital, a diagnostic center, or an independent diagnostic testing facility (IDTF).~~

In addition to deletion of the last sentence, which limits qualified applicants to facilities that meet the definition of "main campus", WakeMed proposes new language that would require a qualified acute care hospital to provide inpatient and outpatient surgical services, in addition to 24/7 emergency services, on the same campus. WakeMed believes the new language more accurately reflects the intent of the original Policy, and the definition of a health service facility based on patient access and the combination of services provided, rather than administrative licensure status.

Background of Petitioner

Acute Care Hospitals

WakeMed currently operates three acute care hospitals, all located in Wake County:

Table 1: WakeMed Acute Care Hospitals

Hospital License No.	Facility	No. Licensed Acute Care Beds	Year Opened
H0199	WakeMed (d/b/a WakeMed Raleigh Campus)	567	1961
	WakeMed North Hospital	61	2015
	<i>Subtotal WakeMed</i>	<i>628</i>	
H0276	WakeMed Cary Hospital	208	1991
	<i>Total WakeMed System</i>	<i>836</i>	

WakeMed Raleigh Campus is a tertiary medical center offering specialized services such as Level I trauma, Level IV neonatal, cardiovascular, orthopaedics, and neurosciences. WakeMed Cary Hospital is a community hospital providing Level III trauma, Level III neonatal, cardiovascular, obstetric, orthopaedics, and general surgical services. WakeMed North Hospital is one of North Carolina’s newest acute care hospitals, having opened its inpatient beds in 2015. It provides general medical/surgical, obstetric, orthopaedics, and Level III neonatal services. WakeMed North shares the Medicare provider number with, and is licensed as part of, WakeMed Raleigh Campus, meaning the two facilities share administrative, financial, and medical staffs.

MRI Services

WakeMed operates 2 fixed MRI scanners at its Raleigh Campus and 1 fixed MRI scanner at Cary Hospital. WakeMed North is currently served by a mobile MRI scanner, owned by WakeMed, and on-site six days a week. As required by 10A NCAC 14C .2701(11), WakeMed’s mobile MRI scanner also serves a second host site, at Central Regional Hospital in Butner (Granville County) one day per week. Because Central Regional Hospital is a State-owned facility, the MRI volume provided at this host site is not included in WakeMed’s mobile MRI utilization in the SMFP.

Reasons for the Requested Change

History of Policy TE-3

In 2016, Cape Fear Valley Health System filed a Spring petition proposing to develop Policy TE-3, to allow acute care hospitals without fixed MRI scanners a means to acquire this technology without a need determination in the annual SMFP. The petition was denied by the State Health Coordinating Council. As a substitute, Agency staff, including representatives from the Certificate of Need and Healthcare Planning Sections, crafted alternate language that was eventually approved and adopted as Policy TE-3 in the 2017 SMFP. The last sentence in the Policy, which limits its application to hospitals that are considered a “main campus” under G.S. 131E176(14n)a, has an unintended consequence: it restricts community hospitals that operate under the license of a larger facility from acquiring a fixed MRI

scanner. The SHCC meeting minutes at which the substitution was approved do not discuss the reasoning behind the “main campus” wording. However, it is reasonable to perceive a desire to limit the number of qualified locations to full-service inpatient acute care hospitals.

Because WakeMed North is on the WakeMed Raleigh Campus license, it does not meet the definition of a “main campus”, per G.S. 131E-176-(14n)a, which states:

The site of the main building from which a licensed health service facility provides clinical patient services and exercises financial and administrative control over the entire facility, including the building and grounds adjacent to that main building.

The “main campus” provision in Policy TE-3 prevents WakeMed from using this policy to obtain a CON to acquire a fixed MRI scanner at WakeMed North Hospital. Though WakeMed would convert its mobile scanner to fixed, there are no CON Administrative Rules or SMFP Policies that permit a mobile MRI scanner to be converted to fixed.

WakeMed also cannot compete for a fixed MRI generated by the Standard Methodology, because of the low volume of MRI procedures performed on the mobile scanner. The performance standard in 10A NCAC 14C.2703(a)(8) require applicants to demonstrate 3,328 weighted procedures in the prior 12 months. Mobile MRI is contraindicated for certain patients, including critically ill patients who require constant monitoring, ventilator-assisted patients, and patients requiring constant oxygen or suction. The space constraints that are inherent in mobile scanners provide insufficient room for a crash cart – other imaging modalities must be utilized for patients at risk for code blue. During the COVID-19 pandemic, this limitation necessitated that WakeMed North transfer 100 percent of its patients requiring oxygen or ventilator support to WakeMed Raleigh Campus for an MRI procedure, when WakeMed North was otherwise able to care for them. In addition, it is not optimal for patients, some of whom are very ill, to be moved outside the hospital to access the mobile MRI – this is a particular issue during times of inclement weather, including rain, extreme heat and cold. Likewise, transfer of patients between facilities for a standard imaging procedure is expensive, inconvenient to patients, and could be avoided.

WakeMed North is a current example. Other similar community hospitals are currently under development across the state.

Fixed MRI is a Standard of Care in Acute Care Hospitals

Magnetic resonance imaging is now an accepted and essential diagnostic imaging modality used in acute care hospitals and other clinical settings for medical diagnosis. It is particularly desirable because the procedures do not expose the body to harmful radiation. Approximately 12,000 scanners are currently in use in the United States. Other benefits of an MRI scan relate to its accuracy in detecting structural abnormalities in the body. MRI provides valuable information on bone and joint structures, internal body systems, and can better differentiate abnormalities in soft tissue than computed tomography (CT). Because MRI does not use ionizing radiation, it is often preferred to CT when either modality could provide similar information to clinicians.

The development of Policy TE-3 and its inclusion in the annual SMFP is an acknowledgement that fixed MRI is a necessary diagnostic tool that should be available at any North Carolina acute care hospital that provides on-site emergency and surgical services.

Satellite Hospitals Licensed Under a Main Campus

WakeMed North Hospital is one of very few acute care hospitals in the state that is not considered a “main campus” and which also does not currently have a fixed MRI scanner. Although WakeMed North Hospital does not meet the textual definition of “main campus”, it functions as such from a clinical perspective. A review of the 2021 Hospital License Renewal Applications on file at DHSR indicates that 11 acute care hospitals operated under the license of a larger facility, yet nearly all of these satellite facilities offer fixed MRI services, whether that scanner was grandfathered, relocated within the same health system, or obtained through an SMFP need determination. Please see the following table.

Table 2: Acute Care Hospitals Sharing a Common License

Hospital License No.	Main Campus	Satellite Facility Under Common License No.	No. Licensed Acute Care Beds at Satellite	Satellite Facility Has Fixed MRI Scanner?
H0024	Atrium Health Cleveland	Atrium Health Kings Mountain	47	Yes
H0071	Carolinas Medical Center-Main	Carolinas Medical Center-Mercy	196	Yes
H0159	Cone Health-Moses Cone Memorial Hospital	Cone Health-Wesley Long Hospital	175	Yes
H0224	Harnett Health-Betsy Johnson Hospital	Harnett Health-Central Harnett Hospital	50	Yes
H0151	Johnston Health	Johnston Health-Clayton	50	Yes
H0267	Maria Parham Health	Maria Parham Franklin	70	Yes
H0209	Novant Health Forsyth Medical Center	Novant Health Clemmons Medical Center	36	Yes
		Novant Health Kernersville Medical Center	50	Yes
H0010	Novant Health Presbyterian Medical Center	Novant Health Charlotte Orthopaedic Hospital	48	Yes
H0162	UNC Health Blue Ridge ¹	UNC Health Blue Ridge-Valdese	131	Yes
H0157	UNC Hospitals-Chapel Hill	UNC Hospitals-Hillsborough	83	Yes
H0199	WakeMed	WakeMed North Hospital	61	No

Source: 2021 Hospital License Renewal Applications

New Acute Care Hospitals Approved for Development

North Carolina’s population continues to grow, and new acute care hospitals have been approved in recent years to serve growing suburban communities in Durham, Wake, Mecklenburg, New Hanover and Union Counties. These facilities may be licensed under larger hospital campuses, will operate 24/7 emergency departments and surgical services, and will require fixed MRI technology to serve their

¹ Formerly Carolinas HealthCare System Blue Ridge.

patients. See below for facilities that are either currently under development or that recently received conditional approval.

Table 3: New Acute Care Hospitals Approved Since 2018

CON Project No.	County	Facility	Proposed No. Licensed Beds	Projected Opening Year
F-11618-18	Union	Atrium Health Union West	40	<i>Opened Feb. 2022</i>
F-11625-18	Mecklenburg	Novant Health Ballantyne Medical Center	36	2023
O-11947-20	New Hanover	Novant Health New Hanover Regional Medical Center-Scotts Hill	66	2024
F-11993-20	Mecklenburg	Novant Health Steele Creek Medical Center	32	2025
F-12010-20	Mecklenburg	Atrium Health Lake Norman	30	2024
J-12029-21	Wake	Duke Health Green Level Hospital	40	2026
J-12065-21	Durham	UNC Hospitals-RTP	40	2026 ²
F-12084-21	Mecklenburg	Atrium Health Steele Creek	26	2024

Source: Healthcare Planning and CON Section, Certificates Issued, accessed at:

<https://info.ncdhhs.gov/dhsr/coneed/certificatesissued.html>

MRI Methodology Work Group

In preparation for the 2023 SMFP, an MRI Methodology Work Group was convened in late 2021, charged with evaluating the current MRI need methodology and recommending modifications accordingly. However, the Work Group's scope was narrowly focused on the need methodology for fixed MRI, and did not include addressing SMFP policies related to MRI.

Impact If Petition Not Approved

Adverse Effects on Population

Denial of this Petition will substantially delay and possibly prevent acute care hospitals that operate satellite locations under a common license from using Policy TE-3 to acquire a fixed MRI scanner, until and unless those satellite facilities are designated as a "main campus". Patients who require MRI procedures that cannot be performed on a mobile scanner, or who present when a mobile scanner is not available, will continue to require transfer to other facilities, risking delayed diagnosis and patient care.

Alternatives to This Petition

WakeMed considered several alternatives to this Petition, which are described below.

1. Maintain Status Quo

Status quo assumes acute care hospitals that provide emergency and surgical services on site, but which are not considered to be "main campuses", will either utilize mobile MRI scanners

² Project was conditionally approved; Agency decision was under appeal at the time this Petition was filed.

and/or transfer patients who require the capabilities of a fixed MRI to another facility. This is not an effective alternative for WakeMed, because as WakeMed North Hospital's patient utilization and acuity level grows, its need to provide MRI services in a fixed unit will continue to increase. The current Policy TE-3 does not allow WakeMed North to apply for CON approval to acquire a fixed MRI. Further, there is currently no provision that allows a provider of mobile MRI to convert to a fixed scanner.

2. Make WakeMed North Hospital a "Main Campus"

As shown in Table 2 above, it is not uncommon for a community hospital to be licensed as part of a larger acute care facility. This is particularly true for newer facilities and hospitals with adjacent campuses. WakeMed North opened inpatient beds in 2015 as a satellite of WakeMed under Hospital License No. H0199. Doing so has allowed WakeMed to share the administrative costs for WakeMed North with the larger entity and minimize duplication of support services. However, WakeMed North's license status and administrative arrangement do not alleviate its need for fixed MRI services. Today, WakeMed North could readily generate the Policy TE-3 procedure volume threshold.

3. Relocate an Existing Fixed MRI Scanner to WakeMed North

WakeMed system currently operates 2 fixed MRI scanners at WakeMed Raleigh, and 1 fixed MRI at WakeMed Cary. It would not be reasonable to relocate WakeMed Cary's only fixed MRI to another location. WakeMed Raleigh is a tertiary hospital with a Level I Trauma Center. In FY 2021, WakeMed Raleigh's fixed scanners performed 14,284.6 weighted MRI scans, approximately 104 percent of standard capacity³. Relocating one scanner to another location would result in excessive waits and delays in diagnosis that would compromise patient care. The MRI volume at Raleigh Campus could not be accommodated with one scanner. MRI scans on tertiary inpatients take longer than those performed on outpatients, as reflected in the need methodology's weighting system. The same will be true for other tertiary hospitals that develop satellite acute care campuses to respond to North Carolina's growing population. For these reasons, this alternative was not deemed to be a reasonable solution.

4. Propose New SMFP Policy to Allow Conversion of Mobile MRI to Fixed MRI

Another alternative would be to develop a new SMFP policy that would allow facilities with a mobile MRI scanner to convert their equipment to a fixed scanner. The concept of such a policy is not without precedent. The 2022 SMFP contains Policy TE-1: Conversion of Fixed PET Scanners to Mobile PET Scanners. The net number of PET scanners in the state has not changed since this Policy was adopted in 2015. The Policy only provided for a better distribution of the assets.

Prior to 2004, the SMFP methodology was designed to allow hospitals build MRI volume on a mobile scanner and then apply for a fixed scanner. At that time, the SHCC understood that volumes on mobile units would always be lower than the potential volume of a fixed scanners at the same location. WakeMed notes that the volume on WakeMed's mobile MRI is higher than

³ Defined in 10A NCAC 14C.2701(2) as 6,864 weighted MRI procedures per unit.

the minimum threshold required for a new fixed MRI in a county that has no fixed MRI units. A policy that permits conversion at a defined threshold could provide an orderly trajectory for other facilities that build reasonable MRI activity on mobile units.

WakeMed believes that the most effective and reasonable alternative is to propose minor revisions to existing Policy TE-3, to remove the “main campus” provision and to add language requiring that acute care hospitals seeking to employ the Policy provide inpatient and outpatient surgery in addition to emergency services.

No Evidence of Unnecessary Duplication

Prior Use of Policy TE-3

Approval of the proposed change in wording to Policy TE-3 would not result in an unnecessary duplication of fixed MRI services statewide. There are few instances where a hospital not currently defined as a “main campus” would utilize the revised Policy. According to the Healthcare Planning and Certificate of Need Section’s monthly CON Application Logs, Policy TE-3 has been used on only three occasions since its introduction in the SMFP:

- G-11284-17: FirstHealth Moore Regional Hospital – Hoke Campus
- G-11537-18: Davie Medical Center
- N-11445-18: Cape Fear Valley Hoke Hospital

The effect of approving this policy change would not result in a proliferation of new fixed MRI scanners across the state. As with the current Policy TE-3, a hospital seeking to acquire a fixed MRI using the revised Policy TE-3 would be required to obtain certificate of need approval to demonstrate need.

Fixed MRI Scanners at North Carolina Hospitals

A review of the 2022 SMFP and DHSR’s list of Licensed Facilities shows that 17 of the state’s acute care hospitals do not have a fixed MRI scanner. Two of those facilities are closed. Please see the table below.

Table 4: Status at North Carolina Acute Care Hospitals Without a Fixed MRI Scanner
Excludes LTACHs, Rehabilitation Hospitals and Facilities Under Common License Listed in Table 2

Hospital License No.	MRI Service Area	Facility	No. of Licensed Acute Care Beds	Critical Access Hospital?
H0274	Alexander	Alexander Hospital [CLOSED]	25	✓
H0108	Alleghany	Alleghany Memorial Hospital	41	✓
H0082	Anson	Atrium Health Anson	15	
H0037	Avery	Charles A. Cannon, Jr. Memorial Hospital	30	✓
H0268	Bertie	Vidant Bertie Hospital	6	✓
H0154	Bladen	Cape Fear Valley-Bladen County Hospital	48	✓
H0007	Chatham	Chatham Hospital	25	✓
H0166	Duplin	Vidant Duplin Hospital	56	
H0075	Durham	North Carolina Specialty Hospital	18	
H0229	Forsyth	Novant Health Medical Park Hospital	22	
H0078	Martin	Martin General Hospital	49	

**Table 4: Status at North Carolina Acute Care Hospitals Without a Fixed MRI Scanner
Excludes LTACHs, Rehabilitation Hospitals and Facilities Under Common License Listed in Table 2**

Hospital License No.	MRI Service Area	Facility	No. of Licensed Acute Care Beds	Critical Access Hospital?
H0003	Montgomery	FirstHealth Montgomery Memorial Hospital	37	
H0115	Pender	Pender Memorial Hospital	43	✓
H0079	Polk	St. Luke's Hospital	25	✓
H0165	Stokes	LifeBrite Community Hospital of Stokes	53	✓
H0006	Washington	Washington Regional Medical Center	25	✓
H0155	Yadkin	Yadkin Valley Community Hospital [CLOSED]	22	✓

Sources: N.C. Division of Health Service Regulation Licensed Facilities, accessed at <https://info.ncdhs.gov/dhsr/reports.htm>, and 2022 SMFP, Table 17E-1 and Appendix F.

Even if all 15 hospitals were to seek CON approval under the proposed revised Policy TE-3, the state would have improved access without a major impact on use of the rest of the statewide fixed MRI inventory.

Consistency with Basic Principles of the SMFP

This Petition is consistent with the Basic Principles described in Chapter 1 of the State Medical Facilities Plan.

Safety and Quality

An excerpt from this Principle states:

The SHCC recognizes that while safety, clinical outcomes and satisfaction may be conceptually separable, they are often interconnected in practice. The North Carolina State Medical Facilities Plan should maximize all three elements.

Providing appropriate care in the appropriate setting works to ensure quality care for patients. It is of utmost importance that acute care hospitals, regardless of their licensure status, have adequate diagnostic tools to ensure provision of safe, high quality patient care. Given that patient satisfaction is considered a component of this Principle, all healthcare providers should strive to provide the highest level of care to maximize customer experience. For an acute care hospital, this standard of care includes fixed MRI scanners.

An acute care hospital that is not licensed as a main campus, but which operates a 24/7 emergency department and provides inpatient and outpatient surgical services, should be permitted to offer its community full service. Nothing in State or Federal policy indicates that such a hospital has a lesser need for fixed MRI than facilities that are main campuses.

Access

This Principle states, in part:

Access barriers of time and distance are especially critical to rural and small communities. However, urban populations can experience similar access barriers.

The proposed revised Policy TE-3 will improve access to patients who require MRI services at satellite acute care hospitals, regardless of whether these facilities are located in rural or urban settings. The current Policy TE-3 effectively creates a “two-tier system”, of acute care hospitals that are defined as main campuses, and satellite facilities licensed under a main campus and which may offer equivalent services.

Patients at WakeMed North Hospital who currently cannot be accommodated by the mobile MRI scanner, either because of limited capabilities or because the scanner is providing services at another host site, must be transferred to another facility. This is expensive, and not optimal for patients who need these facilities and who depend on their local hospital to have full-service emergency departments and inpatient/outpatient surgical services. Any North Carolina community hospital that serves a rapidly growing service area, such as WakeMed North, should have fixed MRI technology to serve all patients who seek its services.

Value

The proposed changes to Policy TE-3 will have minimal impact on the inventory of fixed MRI scanners. The cost of providing mobile MRI services is expensive for an acute care hospital and its patients. Likewise, transfer of patients who require a fixed MRI procedure represents a poor use of healthcare resources. The development of fixed MRI services is a more effective alternative than continuing to rely on mobile technology which that by its mobile nature cannot care for the higher acuity patients, such as those on ventilators and those at risk of coding, which became apparent during the COVID-19 pandemic.

Summary

The proposed revision of Policy TE-3 represents a logical modification to a policy that was put in place to ensure that community hospitals can provide fixed MRI services to their patient populations. As was the case with the original Policy, the proposed revision of Policy TE-3 will not result in a proliferation of new fixed MRI scanners in North Carolina. The Policy will continue to allow community hospitals to develop this service to care for the populations they serve. The State has decided that these hospitals should exist. Therefore, it should permit them to offer standard diagnostic imaging care. The revised language clarifies the definition of a qualified applicant, and does not obviate that a hospital choosing to use this Policy obtain certificate of need approval.

For these reasons, WakeMed believes the SHCC should approve this Petition.