

**Technology and Equipment Committee
Agency Report
Petition for
Change in Policy TE-2 to Allow Intraoperative Magnetic
Resonance Imaging Scanning Use for Outpatients
in the
Proposed 2025 State Medical Facilities Plan**

Petitioner:

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Contact:

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Request:

Atrium Health requests that the State Health Coordinating Council (SHCC) consider a minor revision in language included in Policy TE-2 to allow the use of intraoperative MRI (iMRI) scanners for selected outpatients in the *North Carolina 2025 State Medical Facilities Plan (SMFP)* or “Plan”).

Background Information:

Chapter Two of the *2024 SMFP* provides that “[a]nyone who finds that the North Carolina State Medical Facilities Plan policies or methodologies, or the results of their application, are inappropriate may petition for changes or revisions. Such petitions are of two general types: those requesting changes in basic policies and methodologies, and those requesting adjustments to the need projections.” The annual planning process and timeline allow for submission of petitions for changes to policies and methodologies in the spring. The Petition requests a policy change.

The SHCC, in response to a 2015 petition from Atrium Health, approved Policy TE-2, beginning with the 2016 SMFP. It states:

Policy TE-2: Intraoperative Magnetic Resonance Imaging Scanners

The applicant proposing to acquire an intraoperative Magnetic Resonance Imaging Scanner (iMRI) to be used in an operating room suite shall demonstrate in its certificate of need application that it is a licensed acute care hospital which:

1. performed at least 500 inpatient neurosurgical cases during the 12 months immediately preceding the submission of the application; and

2. has at least two neurosurgeons that perform intracranial surgeries currently on its Active Medical Staff; and
3. is located in a metropolitan statistical area as defined by the US Census Bureau with at least 350,000 residents.

The iMRI scanner shall not be used for outpatients and may not be replaced with a conventional MRI scanner.

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

Intraoperative procedures and inpatient procedures performed on the iMRI shall be reported separately on the Hospital License Renewal Application.

These scanners shall not be counted in the inventory of fixed MRI scanners; the procedures performed on the iMRI will not be used in calculating the need methodology and will be reported in a separate table in Chapter 17 [sic].

The Petitioner requests that the first paragraph following the enumerated list of conditions be revised as follows:

The iMRI scanner shall not be used for outpatients unless the patient has a simultaneous surgical procedure, interventional procedure or treatment. The iMRI ~~and~~ may not be replaced with a conventional MRI scanner.

Currently, only Carolinas Medical Center (Atrium Health) has a scanner approved as an iMRI. Table 1 shows the number of procedures performed annually for the past five reporting years. Duke University Medical Center also has an MRI in an operating room (OR); it functions as an iMRI. In addition, the University of North Carolina Medical Center (UNC) has approval for an AC-3 MRI in an OR, but it is not yet operational.¹

Table 1: iMRI procedures at Carolinas Medical Center, 2019-2023

Year	Number of Procedures	
	Carolinas Medical Center	Duke University Medical Center
2019	90	71
2020	509	96
2021	917	101
2022	641	114
2023	744	121

¹ Note that the surgical procedures performed in the ORs with MRIs (AC-3 or iMRI) are included in the methodology, but the MRI scans are not.

Analysis/Implications:

Historically, iMRI has primarily been the domain of neurosurgery. However, it is also used in other magnetic resonance-guided procedures that may or may not be surgical (i.e., may not involve at least one incision).

It is useful to distinguish between interventional MRI and intraoperative MRI. What the SMFP terms *intraoperative* MRI is also frequently referred to using the broader term, *interventional* MRI. In fact, the abbreviation, “iMRI” is often spelled out as “interventional MRI.” It appears to be more common for non-surgical iMRI procedures to be referred to as “interventional” and to be performed by radiologists rather than surgeons. (Interventional MRI is the term often used to describe procedures performed by interventional radiologists.) Regardless, Policy TE-2 refers to inpatient procedures performed in an OR, but it does not actually require that they be surgical procedures.

The Petition mentions the transurethral ultrasound ablation (TULSA) procedure as an example of the type of outpatient procedure that could be performed if the policy is changed. The U.S. Food and Drug Administration approved TULSA in 2020.² Although the TULSA procedure is a growing use for iMRI, it seems that other types of outpatient procedures that may be most commonly described as interventional MRI could also be performed in an OR (e.g., biopsies, ablation) and that many of these procedures may not be considered surgery.

With these things in mind, the Petitioner requests a language change to Policy TE-2 that encompasses non-surgical procedures. However, the Petitioner does not recommend approval of MRIs for intraoperative/interventional procedures performed in settings other than ORs.

Going beyond the request in the Petition, the Agency investigated other aspects of Policy TE-2. As mentioned above, iMRI normally has been associated with neurosurgery, and Policy TE-2 was originally approved on that basis. However, it does not limit use of the iMRI to neurosurgery. With the expansion of iMRI into other specialties, the SHCC may wish to consider whether it is useful to include neurosurgery-related restrictions in the policy. Policy TE-2 also limits iMRIs to hospitals and to metropolitan statistical areas (MSA) with at least 350,000 population.

In 2021, the 2022 Hospital License Renewal Applications (LRA) showed that 14 NC facilities had at least 500 inpatient neurosurgery cases. The LRA does not include the number of neurosurgeons on staff. Nine MSAs have at least 350,000 population. Based on the conditions in the current Policy TE-2, Table 2 shows the facilities eligible to apply for an iMRI, provided they also have at least two neurosurgeons on staff.

² <https://tulsaprocedure.com/tulsa-procedure/about-tulsa-procedure/tulsa-procedure-benefits-risks/>

Table 2: Facilities Eligible to Apply for iMRI Scanners under Current Policy TE-2

Metropolitan statistical area (MSA)	MRI Service Areas	2022 Population	Number of Inpatient Neurosurgical Procedures, 2022	Eligible Hospitals
Charlotte–Concord–Gastonia (NC-SC)	Mecklenburg, Cabarrus, Gaston	2,756,069	2,392	Carolinas Medical Center
			884	Novant Health Presbyterian Medical Center
			502	Atrium Health Cabarrus
Raleigh–Cary	Wake	1,484,338	506	UNC Rex Health Care
			807	WakeMed
Winston-Salem	Forsyth, Guilford	688,471	1,708	Atrium Health Wake Forest Baptist
			1,155	Cone Health
			747	Novant Health Forsyth Medical Center
Durham–Chapel Hill	Durham/Vance/Warren, Orange	602,407	2,124	Duke University Medical Center
			1,412	UNC Hospitals
Wilmington	New Hanover	453,722	867	Novant Health New Hanover Regional Hospital
Asheville	Buncombe	413,463	1,285	Mission Hospital

Source: "2020 Population and Housing State Data". United States Census Bureau, Population Division. May 18, 2023 (Archived from the original on June 29, 2022); Healthcare Planning, 2023 Hospital License Renewal Applications (procedures at main campus only).

If both the neurosurgery and staffing requirements were removed, hospitals in three additional MSAs would also be eligible: Fayetteville (390,486 population); Hickory-Lenoir-Morganton (368,347); and the Virginia Beach-Chesapeake-Norfolk, VA-NC (1,787,188) (see Table 3).³ Table 3 displays all facilities that would become eligible under the proposed changes to Policy TE-2. However, since a hospital may still require a substantial neurosurgery program to be able to support an iMRI, removing all but the population restriction is not likely to lead to a proliferation of iMRI scanners.

³ Most of the population in the Virginia Beach-Chesapeake-Norfolk, VA-NC is in Virginia. It includes Gates, Camden, Currituck, Pasquotank, and Perquimans counties in NC and the largest city in NC is Elizabeth City.

Table 3: Additional Hospitals Eligible to Apply for iMRI Scanners under Proposed Policy TE-2

Metropolitan statistical area (MSA)	MRI Service Areas	Number of Inpatient Neurosurgical Procedures, 2022	Hospitals
Charlotte–Concord–Gastonia, NC-SC	Mecklenburg, Cabarrus, Gaston	*	Atrium Health Lake Norman
		247	Atrium Health Pineville
		0	Atrium Health University City
		*	Novant Health Ballantyne Medical Center
		0	Novant Health Huntersville Medical Center
		0	Novant Health Matthews Medical Center
		0	Novant Health Mint Hill Medical Center
		*	Novant Health Steele Creek Medical Center
		*	Atrium Health Harrisburg
		166	CaroMont Regional Medical Center
Raleigh–Cary	Wake	*	CaroMont Regional Medical Center - Belmont
		*	Duke Green Level Hospital
		345	Duke Raleigh Hospital
		17	WakeMed Cary Hospital
Winston-Salem	Forsyth, Guilford	*	WakeMed Garner Hospital
		0	Novant Health Medical Park Hospital
Durham–Chapel Hill	Durham/Vance/Warren, Orange	0	High Point Regional Health
		0	Duke Regional Hospital
Fayetteville	Cumberland	0	North Carolina Specialty Hospital
		442	Cape Fear Valley Medical Center
Hickory-Lenoir-Morganton	Alexander, Burke, Caldwell, Catawba	0	UNC Health Blue Ridge
		5	Caldwell UNC Health Care
		0	Catawba Valley Medical Center
		165	Frye Regional Medical Center
Virginia Beach-Chesapeake-Norfolk (VA-NC)	Camden, Currituck, Gates, Pasquotank, Perquimans	0	Sentara Albemarle Medical Center

* New facility. No surgical procedures in 2022.

Source: "2020 Population and Housing State Data". United States Census Bureau, Population Division. May 18, 2023 (Archived from the original on June 29, 2022); Healthcare Planning, 2023 Hospital License Renewal Applications (procedures at main campus only).

The Agency does not recommend changing the population-based limitation in the policy, nor does it recommend expanding eligibility beyond hospitals. Large metropolitan areas and hospitals are probably best positioned to support an OR suite with an iMRI. To illustrate, Carolinas Medical Center is the largest hospital in the state, and it only performed an average of about 700 procedures in the four full years since the iMRI became operational, which is far fewer than the standard MRI capacity.

Agency Recommendation:

The Agency recognizes the importance of responding to advancements in health care. The request in this Petition offers a reasonable way to expand the use of a resource to better meet the needs of patients. Upon review, the Agency recommends further changes toward this same goal.

Given available information submitted by the March 20, 2024 deadline, and in consideration of factors discussed above, the agency recommends approval of the request in this Petition, and incorporated additional edits to Policy TE-2, as follows:

Policy TE-2: Intraoperative Magnetic Resonance Imaging Scanners

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- ~~1. performed at least 500 inpatient neurosurgical cases during the 12 months immediately preceding the submission of the application; and~~
- ~~2. has at least two neurosurgeons that perform intracranial surgeries currently on its Active Medical Staff; and~~

is located in a metropolitan statistical area as defined by the US Census Bureau with at least 350,000 residents.

The iMRI scanner shall not be used for outpatients unless the patient has a simultaneous surgical procedure, interventional procedure or treatment. ~~The iMRI~~ and may not be replaced with a conventional MRI scanner.

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

Intraoperative procedures and inpatient procedures performed on the iMRI shall be reported separately on the Hospital License Renewal Application.

These scanners shall not be counted in the inventory of fixed MRI scanners; the procedures performed on the iMRI will not be used in calculating the need methodology and will be reported in a separate table in Chapter ~~47~~ 15.