COMMENTS REGARDING PROPOSED CHANGES TO POLICY TE-3

FILED BY DUKE UNIVERSITY HEALTH SYSTEM, INC.

Duke University Health System, Inc. ("DUHS") presents these in connection with the proposed revisions to Policy TE-3 included in the 2023 State Medical Facilities Plan. The proposed change to the Policy is not needed at this time and will limit access to critical patient care. DUHS urges the SHCC to continue to include the existing Policy TE-3 going forward without the proposed changes. Both the 2022 and draft 2023 policies are set forth in the Appendix to these Comments.

Background

Policy TE-3 was added to the State Medical Facilities Plan in 2017, and has remained in effect since that time (with one minor update to clarify that the MRI acquired pursuant to the policy can be placed in an IDTF on the hospital's campus or within the hospital). This Policy appropriately recognizes that MRI is an important resource for emergency acute care treatment. Patients presenting in a hospital emergency department who require MRI imaging to diagnose or rule out emergent conditions by definition need to be evaluated quickly; these patients cannot simply have the necessary imaging scheduled at a later time to another facility. Requiring patients to be transferred to another facility solely because they need emergent MRI imaging can cause unnecessary delays and complications in care.

Accordingly, the existing Policy TE-3 provides an avenue for "licensed North Carolina acute care hospital with emergency care coverage 24 hours a day, seven days a week and that does not currently have an existing or approved fixed MRI scanner" to apply for an MRI scanner absent any need in the SMFP. Nothing in the original Policy TE-3 reflects a geographic restriction for such hospitals; the emergency needs of hospital patients are not dependent on what county they are in, or what services may exist elsewhere.

MRI imaging continues to be an important tool for diagnosis of many conditions requiring emergency acute care, including spinal cord compression, carotid artery dissection, cerebral ischemia (TIA and stroke), and many others. See Freshta M. Sahak & Michael D. Burg, "MRI for Emergency Clinicians: Indications, Cautions, and Helpful Hints Sure to 'Resonate' with Your Practice," Emergency Medicine, December 2018 (see https://www.researchgate.net/publication/329844434_MRI_for_Emergency_Clinicians). As set forth in that article, "MRI utilization by [emergency physicians] will continue to increase as the factors governing its use evolves. These factors include: decreasing scan times; wider availability; possible cost reductions; new and changing indications; more research; and the always-present pressure on EPs to care for a broader spectrum of evermore challenging patients."

The effect of the existing policy creates additional flexibility and ability for hospital providers to meet critical patient care needs in the following ways:

1) A hospital that operates an emergency hospital but does not have an MRI may apply for a CON for an MRI scanner without a need for additional MRI capacity to be demonstrated in the service area. This creates more flexibility for hospitals to develop this critical service.
2) An eligible hospital does not have to compete with other applicants, including outpatient diagnostic centers, for any need determinations that do arise. Due to typical CON comparative factors such as average revenue or cost per scan, it can be difficult for a hospital to prevail in a competitive review with outpatient providers with lower costs but who do not serve emergent patients.
3) An eligible hospital may demonstrate the need with a different performance threshold (850 weighted procedures per year) than might apply to a provider applying in response to a need determination. This different standard reflects that even if a hospital does not project a high number of patients needing scans at the hospital, there may nonetheless be a compelling need based on the emergent needs of patients who cannot be treated elsewhere.

2023 change to Policy TE-3

The 2023 Draft SMFP includes proposed revisions to this policy. WakeMed filed a petition in spring 2022 to extend the applicability of this policy to hospital campuses with an emergency department, even if on the same license as a hospital with an MRI. It identified its own WakeMed North campus, which operates 61 acute care beds and a 24/7 emergency department, as an example of a facility that sees and treats emergency patients who may need time-sensitive MRI imaging.

Duke University Health System filed comments supporting the petition, but proposing that the change be initially limited to hospital campuses of a certain size if the SHCC wanted to expand the policy gradually. There were other comments both in favor and opposed to WakeMed's proposed expansion, but no commenter urged limiting the scope of the policy. Instead of simply recommending approval or disapproval of the petition, or adopting the limited expansion of the policy as proposed by Duke, however, the Agency recommended new restrictions on eligibility for applicants for this policy. Under the new proposal, eligibility is limited to hospital applicants in counties "for which the inventory in the SMFP does not reflect an existing or approved fixed MRI scanner in the five years immediately preceding the filing of the CON application for the proposed scanner."

The Agency recommendation purports to "broaden" the scope of the policy by expanding it to new hospital campuses on another hospital's license. This is not the effect of the language. By state law, with very few exceptions, all hospital campuses on the same license must be in the same county. See NCGS 131E-77(e1). Therefore, any second hospital campus that would seek to take advantage of this policy will necessarily be in the same county as the main licensed facility. That main facility will typically already have an MRI, as it is unlikely that the second campus will apply for an MRI before the main campus. Therefore, any expansion to second

campuses is illusory. At the same time, the revised policy is greatly narrowed by limiting it to counties without an MRI in the inventory in the past five years.

The Agency recommendation itself recognizes the value of the existing policy (2022 Agency report, pp 2-3, emphasis added):

> In addition, eight new hospitals are under development, four of which are slated to be campuses an existing hospital. The remaining four are proposed to be separately licensed. As such, they could take advantage of the current Policy TE-3. The four that are proposed as satellite campuses would have to obtain an MRI scanner via a relocation from the main hospital, wait for a need determination generated from the methodology, or contract with a third-party provider to acquire MRI services. *As an acute care and emergency facility, these locations need MRI services onsite 24/7 to provide standard of care for patients. In these instances, mobile MRI services are generally insufficient because they do not usually operate 24/7 and cannot serve the same location every day.*

The report does not identify the four satellite campuses that would theoretically benefit from this change to the policy, but DUHS believes that they would all be in counties for which the inventory already shows an existing or approved MRI, and therefore would in fact be excluded from the revised policy.

These new geographic restrictions on the scope of the policy are not reasonably related to the clinical needs of patients across the state or to the standard of care. Just because an MRI may exist elsewhere in the county does not ensure emergency access to such services, and certainly does not provide them at the hospital emergency department where patients need urgent care. Even if a need determination does arise for which the hospital could apply – no guarantee, especially if the inventory already reflects an existing or approved scanner – hospital applicants may face an uphill battle in a competitive review with outpatient providers with lower average costs and charges. This may leave hospitals without a feasible path to develop on-site MRI imaging. In the meantime, patients presenting at emergency departments at hospitals in urban or suburban areas have the same urgent need for access to imaging, including MRI, as hospitals in rural areas. The opportunity for hospitals to meet these needs should be the same as well.

Adverse effect on providers and consumers from revised Policy

The Agency itself identified the potential harm to providers and patients if hospitals with emergency departments do not have an avenue to develop onsite MRI imaging to meet the emergent needs of patients. Simply because an existing or approved MRI has appeared in the inventory in recent years does not mitigate that adverse effect.

Alternatives considered

The various alternatives to the draft revisions include:

- Retaining existing (2022) Policy TE-3
- Implementing WakeMed's proposed expansion of Policy TE-3 to include separate campuses with acute care beds and an emergency department on another hospital's license
- Implementing DUHS's proposed variation on WakeMed's petition that satellite campuses must be of a certain size to be eligible for the policy, in the event the SHCC was concerned about the potential proliferation of MRI scanners at "micro" satellites.

None of these alternatives would have the effect of limiting access to emergency imaging, which is created by the proposed change that appears in the draft SMFP. Any of these alternatives would be preferable to ensure patient care.

Evidence that the existing Policy would not result in unnecessary duplication of health resources in the area

As set forth in the Agency Report, there are only eight hospitals or campuses under development that might be eligible for the development of an MRI under Policy TE-3 in the near future. There may be a small number of existing satellite campuses, such as WakeMed North, which would seek to make use of the policy if expanded to such campuses. At these hospitals, providing access to emergency services, including imaging, would not unnecessarily duplicate imaging services at another location that would require a patient transfer.

Evidence that the existing Policy is consistent with the Basic Principles of Safety and Quality, Access, and Value:

As set forth above, Policy TE-3 in its existing (2022) form, or expanded as proposed by WakeMed, is consistent with ensuring access to emergency services that are safe and consistent with the standard of care.

Conclusion

For all the foregoing reasons, DUHS urges the SHCC to retain the existing Policy TE-3 without the proposed revisions, or to accept the expansion to hospital campuses on the same license with inpatient beds and a 24/7 emergency department.

APPENDIX

Existing Policy TE-3 from 2022 State Medical Facilities Plan

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 emergency care coverage 24 hours a day, seven days a week 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 scanner as part of the hospital, a diagnostic center, or an independent diagnostic testing facility (IDTF).

Proposed TE-3 from 2023 Draft State Medical Facilities Plan

Policy TE-3: Plan Exemption for Fixed Magnetic Resonance Imaging Scanners

The applicant proposing to acquire a fixed magnetic resonance imaging (MRI) scanner shall demonstrate in its certificate of need (CON) application that it is a licensed North Carolina acute care hospital:

1. that has licensed acute care beds;
2. that provides emergency care coverage 24 hours a day, seven days a week; and
3. for which the inventory in the SMFP does not reflect an existing or approved fixed MRI scanner in the five years immediately preceding the filing of the CON application for the proposed scanner.

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 either:

1. on the main campus of the hospital as defined in G.S. 131E-176(14n); or

2. at another acute care hospital on a campus that operates under the hospital's license.

The proposed scanner may operate as part of the hospital, a diagnostic center, or an independent diagnostic testing facility (IDTF) location that does not currently provide fixed MRI services.