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PETITION

TO: State Health Coordinating Council
North Carolina Division of Health Service Regulation
Healthcare Planning
DHSR.SMFP.Petitions-Comments@dhhs.nc.gov

FROM: On behalf of Alliance Healthcare Services, Inc.:

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Attorneys for Alliance Healthcare Services, Inc.

DATE: July 29, 2020

RE: Petition to Remove Proposed Policy TE-4 from the Proposed 2021 State Medical Facilities Plan

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The undersigned, on behalf of Alliance Healthcare Services, Inc. ("Alliance" or "Petitioner"), respectfully submit this petition to request that the State Health Coordinating Council ("SHCC") take formal action to remove Proposed Policy TE-4 from the Proposed 2021 State Medical Facilities Plan ("SMFP" or "State Plan").

STATEMENT OF THE REQUESTED ADJUSTMENT

Because Proposed Policy TE-4 would adversely affect health care providers and consumers alike, Petitioner respectfully asks the SHCC to take formal action to remove it from the State Plan.

Proposed Policy TE-4 was introduced by planning staff without any of the specific showings and evidence typically included in a petition—it was first revealed ***after*** the comment period, effectively precluding any public input.

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If included in the 2021 SMFP, this Policy would allow providers with vendor service agreements to apply for CON approvals for their own MRIs, either mobile or fixed, when there is no need determination identified in the Service Area. It would obviate some of the very reasons for the CON Law: namely, to control health care costs by restricting duplicative services and to determine whether new capital expenditures meet a community need.

Need Determinations in North Carolina are validly based on an examination of the inventory and utilization of MRI scanners across a Service Area – Proposed Policy TE-4 disregards the data to permit non-competitive CON proposals based on only the utilization of a single scanner without consideration of the capacity in the relevant area. This is an issue that is larger than a single provider; this is a question of sound health planning.

As explained below, Proposed Policy TE-4 is untenable, the product of flawed procedure, and would work to the detriment of North Carolina's health planning process, patients, and health care providers.[1]

REASONS FOR THE PROPOSED ADJUSTMENT

Proposed Policy TE-4 is problematic for numerous reasons:

- Proposed Policy TE-4 was first revealed after the comment period, precluding any public input on its terms.
- Proposed Policy TE-4 would improperly—and for no clear reason—undermine the Standard Methodology for MRI need determinations.
- Proposed Policy TE-4 would result in MRI scanner proliferation in markets with no need.
- Proposed Policy TE-4 would eliminate competition from the CON process.
- Proposed Policy TE-4 is riddled with undefined terms and ambiguous standards.
- Proposed Policy TE-4 would cause numerous unintended consequences.
- Proposed Policy TE-4 cannot now be rewritten.

1. Proposed Policy TE-4 was first revealed after the comment period, precluding any public input on its terms.

Statement of the adverse effects on the population of the affected area that are likely to ensue if the adjustment is not made:

[1] Presentations in opposition to Proposed Policy TE-4 were offered on behalf of Alliance at each of the six summer public hearings throughout the course of July 2020, the written versions of which are incorporated herein by reference.

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Without the adjustment to remove Proposed Policy TE-4, North Carolina citizens will be adversely affected because a policy will be included in the State Plan without the benefit of public input and public deliberation, likely leading to numerous unintended consequences and potentially decreasing access to affordable, quality MRI services.

A. The Agency Report Recommended Denial of the Only Two Timely-Filed Petitions and the Report fails to support Proposed Policy TE-4.

The Agency Report recommended denying the only two petitions filed in advance of the March 4 deadline, one by Carolina Neurosurgery & Spine Associates ("CNSA") and another by Raleigh Radiology. Novant Health and Alliance both filed comments opposing these petitions, each pointing out that the Standard Methodology was working effectively to identify need determinations, including MRI needs in Mecklenburg and Wake Counties. Moreover, complaints over particular contracts or a desire to avoid competitive CON Reviews are hardly grounds for a new statewide MRI policy.

The Agency Report acknowledged that it has no role in vendor/provider contract matters and it recognized that, if new scanners were authorized, vendors would be free to continue to serve new locations. The Agency expressed concern over both expanding the State inventory of MRI scanners and precluding future MRI need determinations.

Yet, in its final sentence, with no accompanying analysis, the Agency Report appended a new Proposed Policy TE-4. The Agency Report did not address the merits or the mechanics of Proposed Policy TE-4 at all. It did not discuss any of the showings required in a petition.[2] Instead, after rejecting the CNSA and Raleigh Radiology Petitions and reciting support for the Standard Methodology, the Agency Report simply appends Policy TE-4 **without any further discussion whatsoever**. From the start, the fundamental information typically considered for a statewide policy change was wholly lacking.

[2] The State Plan requires a petition to explain:

- the adverse effects on the providers or consumers of health care services that are likely to ensue if the change is not made;
- the alternatives to the proposed change that were considered and found not feasible; and
- the evidence that the proposed change would not result in unnecessary duplication of health resources in the area.

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B. Proposed Policy TE-4 was revealed after the comment deadline.

The Agency Report proposed Policy TE-4 for the first time after the close of the comment period, effectively precluding any public comment on its terms.

The SMFP indicates that proposals with statewide effect "need to be considered in the first four months of the calendar year." *Id.* The State Plan's comment process implicitly recognizes that input from the health care industry is not only helpful but critical to sound health planning. The terminology in a statewide policy is critically important: commenters can spot problems, such as undefined terms, and can flag issues, such as when the policy sets different standards than the CON regulations. The framework contemplates petitions by March 4 and comments by March 18, followed by a Committee vote. *See id.*, pp. 7-8, 12.

Because Proposed Policy TE-4 was not revealed on the Agency website until on or about April 8, 2020, well after the March 18 close of the comment period, there was no opportunity for public input on Proposed Policy TE-4, undermining the framework intended to ensure a thorough review.

The Technology and Equipment Committee meeting in April was not a "public hearing," meaning the public could not speak on Proposed Policy TE-4 absent a Committee member requesting input. No such requests were made during the meeting.

Moreover, the Committee did not discuss Proposed Policy TE-4 at its April meeting. Without deliberating or soliciting public input, the Committee voted to recommend Proposed Policy TE-4 on the strength of only three Committee member votes: Dr. Ullrich (Charlotte Radiology), Dr. Perry (North Carolina Eye, Ear, Nose & Throat), and Harnett County Commissioner McKoy. Four other Committee members recused themselves from the vote.

Following the April Committee vote, Alliance requested that the Committee entertain comments and take a new vote on Proposed Policy TE-4 at the Committee's May meeting. *See* Exhibit A. By doing so, Alliance afforded the Agency an opportunity to remedy the obvious "cart-before-the-horse" problem it had caused by taking a vote to recommend Proposed Policy TE-4 without first receiving comments.

But, by email message dated May 6, 2020, the Agency refused this request and indicated the Alliance Comments would not be posted—and the Committee members would not receive a link to the Alliance Comments—until July 2020. *Id.*

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Having decided to "hold" the Alliance Comments until July 2020, the Agency ensured the SHCC vote in June would occur **before** Alliance could offer remarks through the summer public hearings. And it ensured such vote would proceed without any public input with respect to Proposed Policy TE-4. Predictably, based on the Committee's recommendation, the SHCC—without deliberation or discussion—voted to include Policy TE-4 in the Proposed Plan.

In contrast to the Agency's approach to Proposed Policy TE-4, the Agency extended the comment deadline for proposed changes to the psychiatric and substance use disorder methodologies. Prior to the Long Term and Behavioral Health Committee's May meeting, the Agency sent an email to the Interested Parties listserv announcing that comments would be accepted through May 6, 2020 to allow for input on material circulated after the original deadline for comments had passed. The email indicated that any such comments would be considered at the May Committee meeting. Thus, interested parties could comment on proposed methodology changes even **after** the close of the comment period. No such concession was afforded to interested parties prior to the Technology and Equipment Committee's May meeting, though the Agency was clearly capable of doing so.

By refusing to consider the Alliance Comments at the May Committee meeting, the Agency allowed a Committee vote to stand when it was obviously tainted by a failure to allow comments. Allowing a recommendation to stand in such circumstances defeats the purpose of the Committee process in the first instance. If the Committee votes to recommend proposed policies and does so without any industry/public input and with no meaningful discussion, the utility of convening such a deliberative body is defeated.

The Agency's decision to prevent public comment precluded input by Alliance, a healthcare provider who has delivered outstanding quality healthcare in this State for more than 30 years, and which has assisted countless hospitals and other healthcare providers in securing their own CON approvals.

Put simply, Proposed Policy TE-4 has not followed the intended path. It would be a dangerous precedent to allow a policy to find its way into the State Plan in such a way.

Our State's health planning process exists for good reason, and the process through which Policy TE-4 has arisen is a departure from the appropriate course of healthcare planning in North Carolina. If there truly is an issue requiring a statewide policy change, industry participants should be able to weigh in. Then, the Committee should engage in meaningful public deliberation before voting to recommend the policy to the full SHCC. Anything less is procedurally deficient and risks adverse unintended consequences for health care providers and consumers.

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The SHCC must act on Petitions by its last meeting. That said, the health planning process does not work well or fairly if new statewide Policy terms are revealed late in the year when comment opportunities have expired. The notion of now bifurcating Proposed Policy TE-4 or adding terms and provisions is unworkable because no public hearings or comment periods remain within the planning year schedule. When a proposed policy demands ongoing discussion, deliberation and changes, the SHCC in years past has appropriately relied on Work Groups or Special Committees to allow for important industry input.[3] Having failed to follow that path, Proposed Policy TE-4 should not be included in the 2021 Plan.

2. **Proposed Policy TE-4 would improperly—and for no clear reason—undermine the Standard Methodology for MRI need determinations.**

Statement of the adverse effects on the population of the affected area that are likely to ensue if the adjustment is not made:

Without the adjustment to remove Proposed Policy TE-4, a policy of statewide effect will be included in the State Plan allowing providers to circumvent the Standard Methodology for MRI need determinations, which will likely suppress competition for MRIs and disincentivize providers from offering affordable, quality MRI services to North Carolinians.

Proposed Policy TE-4 is fundamentally problematic because it would subvert the Standard Methodology and allow additional magnets into Service Areas with no MRI need.

The Agency Report introducing Proposed Policy TE-4 professes support for "the standard methodology and current policies for MRI equipment." Yet, Proposed Policy TE-4, if adopted, would represent a fundamental break from that very methodology and the current planning policies.

Under the Standard Methodology, a need determination for an additional MRI is identified only when the expected scan volume exceeds the existing MRI capacity in the Service Area. This is logical: if there is adequate MRI capacity in the Service Area to accommodate the anticipated scan volume, there is no need for more capacity. On the other hand, if there is not enough MRI capacity in a Service Area, the Standard Methodology will identify a need determination, and providers will be free to apply and, if necessary, compete to meet the need.

[3] This form of Policy has simply not been the subject of years of consideration as commenters have suggested. In fact, Proposed Policy TE-4 was first revealed in April 2020.

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In contrast, Proposed Policy TE-4 would allow CON Applications to be filed for fixed or mobile MRIs where the Standard Methodology shows no need for additional magnets. And Proposed Policy TE-4 would ignore all MRI data other than for the applicant's own scanners. The Proposed Policy would allow any provider with a contract with a vendor for mobile MRI services to file a CON Application based on its own scan volume. In effect, the proposed policy would allow "qualified applicants" to dispense with the Standard Methodology altogether.

Importantly, while Proposed Policy TE-4 is titled "substitution" of scanners, it would not require vendors to remove their scanners from the Service Area once a provider secured CON approval under the policy. To the contrary, MRI vendors would maintain the lawful right to operate their scanners in that Service Area, and it is doubtful they would cease doing so merely because one customer secured an MRI CON. As noted in the Agency Report, vendors would simply contract with other providers. Thus, Policy TE-4 would add scanners to the inventory, likely suppressing future need determinations and preventing other providers from filing CON applications for their own scanners. In effect, TE-4 would work an end-run around the Standard Methodology.

Proposed Policy TE-4 runs counter to North Carolina's health planning fundamentals by creating an opportunity to apply for a CON for a new MRI without reference to ***any*** information relied on in the Standard Methodology, including:

- the MRI inventory;
- the MRI procedures performed by type;
- the procedures per MRI; or
- the planning thresholds for additional MRIs for the Service Area.

While the Proposed Policy states an applicant must make projections consistent with the Performance Standards, those Standards only require projections for the scanners which the applicant or related entity owns in the Service Area. In other words, once a TE-4 "qualified applicant" shows the requisite volume on its contract scanner, to secure a CON for a new scanner, it will never have to make any showings on the historical or projected volumes for any MRIs others own and operate in the Service Area. Consequently, a Service Area could have multiple underutilized MRIs and Proposed Policy TE-4 would still allow a new scanner to be acquired and located in that Service Area.

By effectively ignoring the Standard Methodology, including all information on scanner inventories and procedure volumes, Proposed Policy TE-4 creates an opportunity to apply for a fixed MRI ***based on one year of data for one scanner in the service area.*** There is no compelling reason to allow providers contracting with an

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MRI vendor to dispense with the Standard Methodology. This is simply not sound health care planning.

Certain policies allow providers to deviate from the Standard Methodology, but only to solve discrete health planning problems. There is no such problem to be solved here. A petition for an adjusted need determination can already be used to address special or unique circumstances on a case-by-case basis. If deviation from the Standard Methodology is warranted, providers compete to meet the need. Proposed Policy TE-4 would create a blanket opportunity to apply without any competitive review.

Proposed Policy TE-4, without justification, creates a wholesale exception to the Standard Methodology that swallows the rule. For that reason, it should be set aside.

3. **Proposed Policy TE-4 would result in the proliferation of MRIs in markets where they are not needed.**

Statement of the adverse effects on the population of the affected area that are likely to ensue if the adjustment is not made:

Without an adjustment to remove Proposed Policy TE-4, North Carolinians will be adversely affected by a policy of statewide effect that allows for the introduction of MRIs not needed in the first place, which will likely exacerbate the underutilization of existing scanners and potentially increase costs for patients.

Proposed Policy TE-4 is titled "Substitution of Vendor Owned MRI Scanner for Provider Owned MRI Scanner," suggesting it would allow a provider to replace its contracted scanner for a scanner it would own, with no incremental increase in MRIs in the State inventory. Not so.

The fundamental problem with Proposed Policy TE-4 is that there will be no true "substitution" of one MRI scanner for another, nor will one scanner be a "replacement" for the other.

The acquisition of "replacement equipment" is exempt from CON Review presumably because it does not add to the equipment inventory in the State. The entity that wants to replace its equipment does not have to act in response to a need determination for new scanner capacity in its Service Area and the CON Section does not need to review and evaluate a CON application proposing to acquire the equipment precisely because all it will do is serve as a "replacement" for existing equipment.

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If, on the other hand, the acquisition of an MRI is not a "replacement," it is an acquisition that requires a CON under North Carolina law. The acquisition of an MRI in North Carolina requires a CON, regardless of cost.

The CON Law definition of "replacement equipment" is very specific. That definition requires the entity proposing the replacement to represent that the existing equipment "will be sold or otherwise disposed of when replaced."

Here, the existing equipment is the vendor-owned MRI provided via contract. The vendor owns that equipment and it most certainly will not be "sold or otherwise disposed of" if a provider were CON approved to acquire a new scanner under Proposed Policy TE-4.

Inasmuch as the provider does not own the existing scanner, it certainly cannot represent anything about the future sale or disposal of the equipment. Thus, it cannot propose anything that would meet the legal or dictionary definition of a replacement or, for that matter, substitution.

Ultimately, the CON approvals resulting from Proposed Policy TE-4 would not merely substitute or replace one MRI with another. To the contrary, if a provider were to use Policy TE-4 to acquire a scanner, the contracted scanner serving that community would remain in the State inventory and continue to operate. Thus, where there was one scanner, the contracted scanner, there would then be two scanners: the contracted scanner and the newly approved provider-owned scanner. Fundamentally, because the policy could only be used where the Standard Methodology shows no need, the policy would allow new scanners in the very Service Areas without need for such scanners.

A statewide policy allowing providers using contracted MRIs to—in name only—"substitute" scanners would cause an influx of duplicative magnets throughout the State. Proposed Policy TE-4 could potentially introduce not just a few, but numerous new scanners on top of those already operated on a contract basis throughout North Carolina. The resulting MRI proliferation in Service Areas without an MRI need would contravene the CON Law and undermine the health planning process.

4. Proposed Policy TE-4 would eliminate competition from the CON process.

Statement of the adverse effects on the population of the affected area that are likely to ensue if the adjustment is not made:

Without the adjustment to remove Proposed Policy TE-4, North Carolinians will be adversely affected by a policy of statewide effect that allows providers to secure either

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mobile or fixed MRIs without competition, likely resulting in increased costs for patients and a decline in the quality of services offered.

Proposed Policy TE-4 is not simply superfluous,[4] which would be reason enough to set it aside. A substantially greater concern is that Policy TE-4 removes competition from the CON process and could well be more widely used than anticipated.

With an adjusted need determination, anyone can apply to meet the identified need. This is an intentional feature in the health planning process—when multiple applicants apply, the CON Section can undertake a Comparative Analysis and use various factors to choose the most effective alternative.

This competition incentivizes applicants to make robust commitments to provide charity care, keep patient costs low, and ensure their services comport with high quality standards. For instance, in 2016, Raleigh Radiology's CON proposal was found to be non-conforming and a less effective alternative for a new MRI in Wake County. When it recently applied again, it received an initial Agency approval. When a provider knows it is playing a zero-sum game, it knows it must go the extra mile to ensure its proposal is compelling. This process works to benefit North Carolinians.

In contrast, because Proposed Policy TE-4 defines a "qualified applicant" as a party to a contract with an unrelated person for an MRI, **every CON Review under Proposed Policy TE-4 will be non-competitive**. The CON Section will have no mechanism to perform a Comparative Analysis to evaluate competing CON proposals and no way to base its decision on a comparison of costs, charity care access, or any other important comparative factors.

And Policy TE-4 would treat similarly situated providers differently. While providers without vendor contracts would need to wait for an SMFP need per the Standard Methodology or seek an adjusted need determination to apply in a competitive review, those with vendor contracts would be free to apply for their own magnets without fear of competition. There is no reason to insulate providers with vendor contracts from competition, while requiring others to compete.

The SHCC is charged with planning for new health care services and capabilities; the CON Section makes decisions on CON approvals. Here, Proposed Policy TE-4 blurs those lines by having the SHCC define who can secure CON approvals. Policy TE-4 parses out which entities can be awarded CON approvals: only those who contract for MRI services are "qualified" CON applicants. Policy TE-4 not only invades the CON

[4] Proposed Policy TE-4 is superfluous because the petition for adjusted need determination process already allows providers to argue that special circumstances warrant a special need being placed in the Plan.

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Section's province, it offers no valid reason to declare contracting parties as preferred CON applicants.

Because the SMFP has no mobile MRI need methodology, a provider must file an adjusted need petition and compete with any other applicants who file a CON Application to secure a mobile magnet. Proposed Policy TE-4 would simply eliminate competition from the equation altogether. If a provider qualified under TE-4, it would have a clear path to a mobile MRI CON. And this would likely suppress future need determinations for fixed magnets, thereby reducing or eliminating any possibility for new providers to apply for new MRIs.

And there would be no limit on the times a provider could invoke Proposed Policy TE-4. Providers could continue to claim "qualified applicant" status and apply for additional magnets as many times as they would like, all the while suppressing future need determinations. Some providers might use the proposed policy for anti-competitive reasons, intentionally proliferating MRI volume in their health systems to ensure the Standard Methodology did not identify any opportunity for competing providers to apply for MRIs.

Proposed Policy TE-4 would provide no real benefit for patients or providers because it would simply allow providers with contract MRI service to apply for new MRIs. Providers can already petition and participate in competitive reviews. Proposed Policy TE-4 would accomplish nothing other than side-stepping the petition process and eliminating competition from the MRI calculus.

5. **Proposed Policy TE-4 is riddled with undefined terms and ambiguous standards.**

Statement of the adverse effects on the population of the affected area that are likely to ensue if the adjustment is not made:

Without the adjustment to remove Proposed Policy TE-4, North Carolinians will be adversely affected by a policy of statewide effect that is not well drafted and likely to lead to litigation, thereby delaying timely access to services by patients and potentially increasing costs for MRI services.

Setting aside the broader health planning issues with Proposed Policy TE-4, the Policy is also unworkable because of its multiple undefined terms and standards. For example, a "qualified applicant" must be a "provider," a term not defined in the policy nor in the CON Law. *See* N.C. Gen. Stat. § 131E-176 ("Definitions").

"Provider" and "vendor" are key terms in the Proposed Policy but are simply not defined in either the CON Law or in regulations. Given this ambiguity, it is possible

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a vendor could qualify as a "provider"—especially to the extent it staffs the scanner—and utilize Policy TE-4 to secure its own CON. Is this the intent of Policy TE-4?

Also, the provider must contract with an "unrelated person," another term not defined in the Policy nor in the CON Law. This is a significant problem given the various connections among those who provide and use MRI services. To give just one example, Novant Health, Inc. receives MRI services on a scanner owned by Presbyterian Mobile Imaging, LLC. Apparently, these are two separate legal entities, but are they "unrelated persons?" How does one tell? Is it a shared parent test? A percentage ownership test? How much ownership could be held and still have the persons considered unrelated: 5%? 10%? Where does one draw the line?

Other terms are defined in the CON Law or elsewhere, such as "person" and "related entities," but the terms selected for use in Policy TE-4 are either undefined altogether or an inexplicable variation on terms with existing definitions.

Per the Policy, an applicant must show "[t]he contracted scanner . . . is not moved to other host sites." This requirement has no time parameter: not moved for how long? And there is no meaningful way for a provider receiving service on a grandfathered scanner to "vouch" for whether or when the vendor will move the contract scanner to serve other sites. Grandfathered scanners may lawfully move at any time. What would happen if the vendor moved its contract scanner during the CON Review? Would that render the pending CON application pursuant to Policy TE-4 unapprovable? At best, this ambiguity creates confusion; at worst, it invites litigation.

The Policy also speaks about scanners that "should be treated as a fixed." What defines whether scanners should be treated as fixed? If there is no governing threshold or standard, how will this be applied? And for that matter, treated as fixed for what purpose, exactly?

Per the Policy, the provider must be "unable to apply pursuant to a need determination." Presumably, it was intended that TE-4 could be invoked only where there is no need determination in the Plan (an issue in and of itself), but the current language is susceptible of multiple interpretations. For example, a provider may claim it is "unable to apply" where it cannot identify a CON consultant to prepare its application. A provider might also claim it is "unable to apply" where it missed a CON filing deadline earlier in the year. And, insofar as a provider is free to petition the SHCC to include an adjusted need determination in the Plan, could a provider ever claim it was "unable to apply" without first filing such a petition? Must every provider file such a petition before invoking Policy TE-4?

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Policy TE-4 also uses standards that differ from the duly adopted CON regulations. The Policy sets a volume threshold for all the applicant's scanners in the Service Area combined. But the CON regulation sets a volume threshold for each applicant scanner in the Service Area. Thus, the policy imposes two distinctly different standards. Query whether the Policy can legally do away with a validly enacted regulation?

The wording and word choices in Policy TE-4 were never sufficiently perfected and are likely to create problems and ambiguities giving rise to legal issues. Definitions are lacking. Indeed, considering the vague policy terms, **it is unclear how SHCC members can even be expected to determine if they have Executive Order 46 interests at stake with this Policy, and determine whether to recuse themselves from voting on the Policy**.[5] *See* Executive Order 46 ("WHEREAS, it is important that the [SHCC] exercise its advisory authority in a transparent manner so that the Governor and citizens have full knowledge of the professional and economic interests [that] members of the [SHCC] represent").

In sum, this Policy appears to have been hastily constructed. Proposed Policy TE-4 would create a host of obvious legal problems by setting different standards without explaining whether or how the duly adopted regulations will apply. It would also create troubling possibilities for potential use and misuse which could have long term negative effects by proliferating scanners in areas without need.

6. **Proposed Policy TE-4 would cause a number of unintended consequences.**

Statement of the adverse effects on the population of the affected area that are likely to ensue if the adjustment is not made:

Without the adjustment to remove Proposed Policy TE-4, North Carolinians will be adversely affected by a policy of statewide effect that has not been adequately studied or deliberated, which may compromise patient access to scanners, increase health care costs, and result in decreased quality of health care services.

[5] Based on the MRI inventory and the SHCC member disclosure forms, there are at least 10 healthcare organizations with fixed MRI, mobile MRI and/or contracted MRI services that also have some type of business, financial, or employment relationship with SHCC members, including the following:

- Charlotte Radiology / Carolinas Imaging Services
- Duke University Health System
- EmergeOrtho
- Greensboro Imaging
- Novant Health
- OrthoCarolina
- Sentara Medical Center
- UNC Rex Healthcare
- Vidant Health
- Wake Radiology

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The Agency Report introducing Policy TE-4 appears to suggest that few providers could apply using Policy TE-4. Not so.

The Agency Report fails to consider that a litany of providers, including numerous hospitals across the State, could use TE-4 simply by contracting with a vendor for one day of mobile MRI service. Hospitals that do not currently contract for MRI services could easily do so and easily meet Proposed Policy TE-4's volume threshold of 3,328 weighted MRI procedures across all their service sites. With that, they could declare themselves qualified under Policy TE-4 to acquire their own mobile MRIs in non-competitive reviews, even though they are in counties with no MRI need determinations. These providers could keep their fixed scanners in place, but also secure CON approval for mobile scanners to serve their hospitals as well as other sites.

Surely, the Agency did not intend to allow providers to flood North Carolina with new mobile scanners throughout Counties across the State, even absent need determinations, and not require them to compete to do so. Yet, as Proposed Policy TE-4 is drafted, it would be simple for multiple providers to do just that. Instead of considering the propriety of authorizing new mobile MRI providers pursuant to a petition for an adjusted need determination, Policy TE-4 would create a "free pass" for non-competitive MRI CON Applications.

Proposed Policy TE-4 is a serious threat to the appropriate delivery of mobile MRI services because it could allow numerous hospitals and practices to take on endeavors far outside their business models without proper infrastructure in place. Far from being simple, operating a mobile MRI requires specialized expertise well beyond the purview of many providers. Scanner and coach operations pose logistical challenges that many providers are not prepared for.

For example, as to scanner operation, there are many differences between operating a unit that moves between multiple locations versus operating a fixed scanner. Mobile scanners require multiple configurations to be built into the system, unlike fixed or parked systems. If not correctly configured, incorrect information can be embedded on patients' images, which could adversely affect patient care. Moreover, mobile MRIs require specialized staff, which must be trained to address medical emergencies without the same support typically available with in-house scanners. Networking, setup, and troubleshooting pose additional challenges in the mobile environment that require experience to handle. Staff must be trained on common networking issues with a system that moves to different locations because moving components and connections can fail. Configuration changes must be managed to maintain network security. Further, while claustrophobia is of major concern in the

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MRI industry, this issue is especially pronounced in the mobile setting. Navigating this issue in the mobile environment is more complicated than with fixed scanners.

Coach operation also poses challenges beyond the expertise of most providers. The patient lift poses an injury risk for patients and staff; specialized lift-failure training is required for safety in a mobile setting. Also, troubleshooting of critical systems on a coach are key challenges in mobile MRI operations. Without teams specifically trained to handle mobile MRI errors—which may require resetting HVAC systems, testing or resetting scanner chiller systems, and replacing network cabling or connections—patient care is at risk of compromise.

From a logistics standpoint, operating a mobile MRI requires expertise most providers simply do not have. Access to a fleet of drivers able to adapt to constant variations in patient scheduling is critical, and most providers simply are not staffed for or accustomed to managing this aspect of a mobile MRI program. This logistical hurdle will likely impact scanner utilization for inexperienced mobile providers and may ultimately affect scan quality and patient access to MRI services.

Allowing an influx of mobile MRI applicants would pose a very real threat to the delivery of quality services to North Carolinians. Proposed Policy TE-4 is ill-conceived because it opens the door for inexperienced applicants to apply in areas with no need and in reviews guaranteed to be non-competitive.

Proposed Policy TE-4 could allow for the award of MRIs in higher numbers than the total of scanners allocated over the last several State Plan years combined. The Agency Report identified 12 potential TE-4 "qualified applicants," suggesting that that many providers could be approved in the next year, notwithstanding the fact that only 11 need determinations for MRIs have appeared in the past four State Plans combined.

Despite the many underutilized mobile MRIs throughout the State, the Policy sets no limit on how many additional MRIs could be approved. Whether it would be two scanners per year or ten per year, adding these additional MRIs would delay the Standard Methodology from identifying legitimate need determinations open to all CON applicants. Any potential benefit of Policy TE-4 is far outweighed by the overall detriment caused for numerous potential CON applicants for many years.

And it can hardly be ignored that this Policy would adversely affect vendors like Alliance without solving any real health planning issue. Alliance is not the sole MRI provider in North Carolina. Alliance is one of 18 different mobile MRI providers statewide, including InSight Imaging, Kings Medical, and others who lawfully operate CON-approved and grandfathered MRIs.

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Prior to CON regulation, Alliance had the foresight and resources to obtain MRIs through a series of mergers and acquisitions. Alliance later applied for CON approvals to acquire additional MRI and PET scanners. Alliance successfully grew its business both before and after CON regulation, consistently reporting all data in accordance with applicable requirements.

Over the years, Alliance has enabled many hospital and physician group customers to grow MRI volumes to qualify for their own MRI CON approvals. Alliance did not appeal the recent CON approval of Raleigh Radiology in Wake County. In high growth markets, multiple customers seek contracts for MRI service. Alliance responds to establish contracts and add host sites and has successfully implemented multiple joint ventures with its customers.

Alliance is the primary resource for many hospitals in North Carolina should they have an emergency need for temporary MRI or CT scanners. And, in 2020, Alliance has been the first and only company to request authorization to provide a temporary mobile MRI for service to COVID-19 patients in North Carolina.

Contrary to the portrayal of Alliance as a company with an unfair competitive advantage, Alliance is a company that has invested in resources and human capital and has expanded its customer relationships with excellent service and high customer satisfaction.

Now, Proposed Policy TE-4 abandons the Standard Methodology in favor of a "free pass" allowing any provider with a vendor service to acquire its own equipment in a Service Area without an MRI need. The Proposed Policy is a wholly unjustified abandonment of health planning process fundamentals and may well have the unintended consequence of limiting the extent to which Alliance is able to offer safety-net MRI services at a reasonable price.

If the SHCC was genuinely concerned about the lack of adequate competition for a specific healthcare service, it should also be examining mobile cardiac catheterization and dialysis centers. Only one provider offers grandfathered mobile cardiac catheterization equipment in North Carolina. Only two companies own and operate most dialysis stations in North Carolina. Yet, the Agency is not proposing a policy to throw open these services and remove them from the usual need determination process. Nor should it.

Policy TE-4 would invite excess MRI capacity and, for no clear reason, undermine the MRI Standard Methodology.

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7. It is too late to rewrite or amend Proposed Policy TE-4.

Statement of the adverse effects on the population of the affected area that are likely to ensue if the adjustment is not made:

Without the adjustment to remove Proposed Policy TE-4, North Carolinians will be adversely affected by a policy of statewide effect, which several commenters have conceded needs work and one SHCC member has indicated was merely a mechanism to "start a dialogue" on MRI issues.

In an apparent recognition of the flaws in Proposed Policy TE-4, it has been suggested the policy was introduced to "start a dialogue" on MRI issues, and several commenters have called the Policy "a good start." There has even been a suggestion that Policy TE-4 should be amended to focus on fixed MRI with a companion Policy TE-5 to address mobile MRI.

However, the deadline for proposing policies of statewide effect was March 4, 2020. The time to rewrite Proposed Policy TE-4, propose amendments, or introduce a companion policy has long since passed. Chapter 2 of the State Plan makes clear that such proposals must be considered in the first four months of the health planning year. If the Policy were amended or rewritten at this juncture, the same problem would persist: the public would have no opportunity to comment on the *revised* version, leading to many of the same problems with the Policy in its current iteration.

Good people work hard each year to develop the State Plan using a process that is well-defined and worthy of compliance. There are obvious and serious defects in Proposed Policy TE-4 both on a fundamental level and in terms of the mechanics of the Policy itself. For this reason, the policy should be removed from the Proposed 2021 SMFP.

EVIDENCE THAT HEALTH SERVICE DEVELOPMENT PERMITTED BY THE PROPOSED ADJUSTMENT WOULD NOT RESULT IN UNNECESSARY DUPLICATION OF HEALTH RESOURCES IN THE AREA

Alliance seeks the proposed adjustment **because** failure to do so will result in the unnecessary duplication of MRI services across the State. *See also Number 3 under "Reasons for the Proposed Adjustment," supra at pp. 8-9, incorporated by reference.* Proposed Policy TE-4 is in direct conflict with the Standard Methodology for MRIs as stated in Table 17E-3 ("It is determined that there is no need anywhere else in the State and no other reviews are scheduled."). The Standard Methodology sets the limit

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on the number of additional MRIs that can be approved. N.C. Gen. Stat. § 131E-183(a)(1).

EVIDENCE THAT THE REQUESTED ADJUSTMENT IS CONSISTENT WITH THE THREE BASIC PRINCIPLES GOVERNING DEVELOPMENT OF THE NORTH CAROLINA SMFP: SAFETY AND QUALITY, ACCESS AND VALUE

Whether intentional or not, Proposed Policy TE-4 would eliminate competitive reviews that allow the CON Section to evaluate proposals on safety and quality, access and value. The request for an adjustment to remove Proposed Policy TE-4 from the Sate Plan will advance the Basic Principles by avoiding a departure from the Standard Methodology and an abandonment of the competitive CON Review process which allows for meaningful comparisons focused on safety and quality, access and value.

With no competitive reviews, the CON Section would be unable to compare competing proposals to ensure CON approvals are issued to applicants who will provide equitable access to services for Medicare, Medicaid, charity care, and low-income persons. There has been no discussion of imposing minimum standards for payor percentages for Policy TE-4 applicants.

The Proposed Policy would also fail to promote quality of care and safety because there are no minimum standards for staff training or MRI safety training, nor any time limits on new MRI providers obtaining accreditation. No information or discussion has been provided regarding MRI interpretation and physician supervision.

And the Proposed Policy would fail to promote value/cost-effectiveness because the CON Section would be unable to conduct an analysis to compare applicants on costs and charges. There has been no discussion of imposing standards for costs and charges for Proposed Policy TE-4 applicants.

Indeed, because Proposed Policy TE-4 was presented without the requisite Petition, the Agency has engaged in no discussion whatsoever of how it would impact safety and quality, access, and value.

ALTERNATIVES TO THE PROPOSED CHANGE THAT WERE CONSIDERED, BUT REJECTED AS NOT FEASIBLE

Alliance considered not filing a petition to remove Proposed Policy TE-4 from the State Plan, but rejected this alternative as not feasible because doing so would risk allowing a procedurally deficient, bad health planning policy to impact the delivery

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of MRI services across the State without a full airing of the issues implicated by such a drastic change.

Further, Alliance considered allowing the SHCC to consider the merits of Proposed Policy TE-4 based on the record established by the Technology and Equipment Committee; however, it rejected this alternative as not feasible because there was no public input or public deliberation of the Policy at the Committee level.

Moreover, Alliance attempted to engage in productive dialogue regarding Proposed Policy TE-4 during the Committee meetings earlier in the year, but it was foreclosed from participating and has thus been relegated to participating in the summer petition process.

Finally, Alliance considered limiting its input only to speaking at the public hearings; however, it rejected this alternative as not feasible because it would not require the SHCC to formally address its concerns with Proposed Policy TE-4 as underscored during the July public hearings and summer petition process.

CONCLUSION

Alliance is willing and able to discuss the policies that govern MRIs in North Carolina. However, for the foregoing reasons, the SHCC should take formal action to vote to exclude Policy TE-4 from the 2021 State Medical Facilities Plan because it is exceedingly problematic and unnecessary.

Respectfully submitted, this the 29th day of July, 2020.

WILLIAMS MULLEN

/s/ Joy Heath
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Attorneys for Alliance Healthcare Services, Inc.

Shackelford, Anderson

From: Frisone, Martha <martha.frisone@dhhs.nc.gov>
Sent: Wednesday, May 6, 2020 2:49 PM
To: Shackelford, Anderson; Heath, Joy
Cc: Craddock, Amy D; Michael, Trenesse M; Burgon, Bethany; Ullrich, Christopher (chris.ullrich@att.net); Lyndon Jordan MD (LJordan@WakeRad.com)
Subject: Comments on Proposed Policy TE-4

Thank you for your comments. Policy TE-4 will be included in the proposed 2021 SMFP if the full SHCC votes at its June 10, 2020 meeting to include it in the Proposed 2021 SMFP. The deadline for comments on the Proposed 2021 SMFP is not until 5:00 p.m. on August 12, 2020. You may also make oral comments at the six public hearings held in July 2020. See Chapter 2 in the 2020 SMFP.

Consistent with past practice, the Agency will post your comments online at the end of July. The committee members receive an email with a link to the posting as soon as they are posted. Proposed Policy TE-4 will be an agenda item at the September 9, 2020 T&E Committee meeting if it was included in the Proposed 2021 SMFP. Committee votes are recommendations to the full SHCC.

Martha J. Frisone
Chief
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From: Shackelford, Anderson <ashackelford@williamsmullen.com>
Sent: Wednesday, May 6, 2020 1:26 PM
To: Craddock, Amy D <amy.craddock@dhhs.nc.gov>
Cc: Heath, Joy <jheath@williamsmullen.com>; Frisone, Martha <martha.frisone@dhhs.nc.gov>
Subject: RE: [External] SHCC/Committee Procedures [IWOV-IWOVRIC.FID1554264]

Dr. Craddock,

On behalf of our client, Alliance Healthcare Services, Inc., we ask that the Technology and Equipment Committee present and address the following Comments in opposition to Proposed Policy TE-4.

Specifically, we ask that the Committee Chair, Lyndon Jordan, III, M.D. read aloud the following Comments at the May 20, 2020 Committee meeting and invite discussion by the Committee.

EXHIBIT A

A Committee Member who recuses himself or herself from voting is not prohibited from deliberating on the matter unless the Chair otherwise determines.

Following discussion, the Commenters request that the Committee entertain a Motion and vote to recommend disapproval of Proposed Policy TE-4.

Best,
Joy and Anderson

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From: Shackelford, Anderson
Sent: Wednesday, April 15, 2020 2:21 PM
To: Craddock, Amy D <amy.craddock@dhhs.nc.gov>
Cc: Heath, Joy <jheath@williamsmullen.com>; Frisone, Martha <martha.frisone@dhhs.nc.gov>
Subject: RE: [External] SHCC/Committee Procedures [IWOV-IWOVRIC.FID1795534]

Thank you, Dr. Craddock.

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From: Craddock, Amy D <amy.craddock@dhhs.nc.gov>
Sent: Wednesday, April 15, 2020 1:33 PM
To: Shackelford, Anderson <ashackelford@williamsmullen.com>
Cc: Heath, Joy <jheath@williamsmullen.com>; Frisone, Martha <martha.frisone@dhhs.nc.gov>
Subject: RE: [External] SHCC/Committee Procedures [IWOV-IWOVRIC.FID1795534]

Executive Orders 46 and 122 govern. A quorum is 51% of the members. These documents are in the Appendix to the 2020 SMFP.

In terms of voting, we follow Roberts Rules. A motion carries when a majority of the members present and voting vote "aye." As I understand it, as long as there is a possibility of a positive vote, it does not matter how many members vote or recuse (or abstain). That is, votes from 3 people can carry a motion if 2 vote "aye."

As you know, committee votes are recommendations to the full SHCC, and SHCC votes are recommendations to the Governor. The SHCC is free to vote on the committee recommendations as a bloc or to ask for specific items to be extracted for discussion.

Amy Craddock, PhD
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From: Shackelford, Anderson <ashackelford@williamsmullen.com>
Sent: Wednesday, April 15, 2020 11:46 AM
To: Craddock, Amy D <amy.craddock@dhhs.nc.gov>
Cc: Heath, Joy <jheath@williamsmullen.com>
Subject: [External] SHCC/Committee Procedures [IWOV-IWOVRIC.FID1795534]

Hi Dr. Craddock,

I hope you are safe and well during these uncertain times. Are you able to direct me to the procedural requirements (i.e., voting requirements, quorum, etc.) that govern the SHCC and its committees? I have not seen them posted anywhere, and am interested in reviewing them.

Thanks,
Anderson

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