ALLIANCE HEALTHCARE SERVICES, INC.'s WRITTEN COMMENTS OPPOSING PROPOSED POLICY TE-4

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Through its counsel, Alliance Healthcare Services, Inc. ("Alliance") respectfully submits its comments in accordance with the August 12 deadline established by the 2020 State Medical Facilities Plan ("SMFP" or "Plan").

Alliance asks the State Health Coordinating Council ("SHCC") to act on Alliance's prior-filed Petition and remove Proposed Policy TE-4 from the 2021 Plan.

I. Proposed Policy TE-4 is not similar to or consistent with other TE Policies.

Proposed Policy TE-4 is unlike policies previously adopted by the SHCC.

A. Policy TE-1

Proposed Policy TE-4 is ***fundamentally different*** than Policy TE-1.

Policy TE-1 allows an applicant with its own existing or approved fixed PET scanner to apply for a CON to "convert" the applicant's own existing or approved fixed PET scanner to a mobile PET scanner if certain conditions are met. Thus, a new mobile scanner approved under Policy TE-1 takes the place of the applicant's existing or approved fixed PET scanner. In contrast, scanners approved under Proposed Policy TE-4 will exist in addition to the scanners already in service.

- A new Policy TE-4 scanner will add to the existing inventory of scanners in North Carolina.
- A new Policy TE-1 scanner does not add to the existing inventory of scanners in North Carolina.
- A new Policy TE-4 scanner can serve unlimited host sites, including ones not owned by an Applicant entity.
- A new Policy TE-1 scanner is limited to serving host sites owned by an Applicant entity.
- Policy TE-4 imposes no limit on the CON Application filing opportunities.
- Policy TE-1 limits CON Applications to one each calendar year.

B. Policy TE-2

Proposed Policy TE-4 is in no way "similar" to or "consistent" with Policy TE-2.

Policy TE-2 provides an opportunity to file for CON approval for an "intraoperative" MRI scanner ("iMRI") to be used solely within an operating room suite. An iMRI approved under Policy TE-2 is not a typical MRI scanner but is a unique piece of

equipment. Policy TE-2 provides that any iMRI approved under the Policy would not be used for any outpatients. Moreover, Policy TE-2 specifies that an iMRI secured under the Policy could never be replaced with a "conventional MRI scanner."

The fixed and mobile MRI scanners potentially approvable under Proposed Policy TE-4 are "conventional" MRI scanners to be used in the ordinary way in which MRI technology is used. Proposed Policy TE-4 scanners will be fully available to outpatients.

Unlike Proposed Policy TE-4, applicants invoking Policy TE-2 must satisfy special requirements relating to the number of "inpatient neurosurgical cases" performed and the number of neurosurgeons performing "intracranial surgeries." Intracranial neurosurgery refers to surgery on the brain or spine "within the skull." These surgeries are necessary to treat brain disorders and diseases that are life-threatening or able to cause permanent brain damage. Obviously, Policy TE-2 addresses a limited, special set of circumstances. Not so with Proposed Policy TE-4.

Unlike the new scanners potentially approved under Proposed Policy TE-4, Policy TE-2 scanners are not counted in the inventory of fixed MRI scanners. Considering the unique character of the iMRI scanner and the different terms of the Policies, there is little upon which to compare Policy TE-2 and Proposed Policy TE-4.

C. Policy TE-3

Proposed Policy TE-4 is different from, and not "essentially a natural progression of" Policy TE-3.

Policy TE-3 allows a licensed acute care hospital *without any existing or approved fixed MRI scanner* to apply for a CON to acquire an MRI to be located on its main campus. The only hospitals qualifying to apply per Policy TE-3 are those offering 24/7 emergency care without a fixed MRI.

The discussion of statewide Policy TE-3 included mention of having each "hospital at the ready to respond to disasters" and prepared for "any emergency, no matter how small or large." Policy TE-3 was described as a Policy that would allow hospitals "to serve the emergency needs of their communities."

Unlike Policy TE-3, Proposed Policy TE-4 has not been described as allowing for disaster preparedness or emergency response readiness. Instead, Proposed Policy TE-4 could be used to add new MRI capacity in counties that already have, within their borders, numerous MRI scanners, both fixed and mobile.

Unlike Policy TE-3, Proposed Policy TE-4 is not a remedy for hospitals lacking fixed MRI scanners but rather a blanket policy allowing any "provider" (an undefined term potentially including all types of health care facilities and potentially even vendors)

to seek CON approvals regardless of the extent to which Service Area patients already have access to MRI capacity through either fixed and/or mobile equipment.

The breadth of potential "qualified applicants" under Policy TE-3 is much more easily discernable as compared to Proposed Policy TE-4. A licensed hospital offering 24/7 emergency care can only apply per Policy TE-3 if it lacks a fixed MRI – defining who can apply is as simple as comparing the list of hospitals with the MRI inventory. Commenters have noted that relatively few Applications have been submitted under Policies TE-1, TE-2 and TE-3 because, as defined, the Policies narrowed the field of Applicants.

Not so with Proposed Policy TE-4. Proposed Policy TE-4 leaves considerable uncertainty over the number of "qualified applicants" who now *or in the future* could invoke TE-4 to seek CON approvals. An "unintended consequence" of Proposed Policy TE-4 is that a "provider" could secure temporary "vendor" service as a way of qualifying to proceed under the Policy. Proposed Policy TE-4 does <u>not</u> apply only to a defined limited universe of hospitals but creates the potential for multiple present and future applications to add MRI capacity – to hospitals, physician offices or newly established free-standing centers.

II. Proposed Policy TE-4 applicants can be approved without addressing the Basic Principles of Safety and Quality, Access, and Value.

Remarkably, as explained below, Proposed Policy TE-4 allows applicants to completely by-pass the Basic Principles of Safety and Quality, Access and Value.

A Policy of General Applicability, Policy GEN-3, must be satisfied by any CON applicant applying to meet a Need Determination. Applicants must demonstrate how their projects will "promote safety and quality … while promoting equitable access and maximizing healthcare value for resources expended." The CON Section evaluates conformity with Policy GEN-3 under Criterion One of the CON Law. *See* N.C. Gen. Stat. § 131E-183(a)(1). Per Policy GEN-3, applicants must "document" plans for providing access and show how its projected volumes incorporate the concepts defined in the Basic Principles.

Yet, because a Policy TE-4 applicant will not be applying to acquire a MRI scanner for which a need determination was identified in the Plan, the applicant will not have to meet Policy GEN-3 or make any of the showings described above!

A. <u>Safety & Quality</u>

In a typical CON Review, applicants must demonstrate conformity with Policy GEN-3 and address the concepts of Safety and Quality in the delivery of health care services. However, under Proposed Policy TE-4, potential applicants such as Raleigh Radiology and others will not be subject to any scrutiny under Policy GEN-3. Surely,

this is a problem of fundamental importance which should cry out for rejection of Proposed Policy TE-4.

In 2019, quality events at Raleigh Radiology were widely reported. To be clear, these events related to Raleigh Radiology's *unaccredited* mammography unit, which is not a unit furnished by Alliance; see https://www.fda.gov/radiation-emitting-products/reports-mqsa/mammography-facility-adverse-event-and-action-report-february-11-2020-raleigh-radiology-blue-ridge.

- On August 27, 2019, the American College of Radiology (ACR) notified Raleigh Radiology Blue Ridge it was required to participate in an Additional Mammography Review (AMR) based on the facility conducting mammography on an unaccredited unit.

- On October 23, 2019, the ACR notified the Food and Drug Administration (FDA) and Raleigh Radiology that the AMR revealed serious deficiencies with clinical image quality and that Raleigh Radiology failed to meet the ACR's clinical image evaluation criteria.

- Based on the failed AMR results, on November 5, 2019, the ACR revoked Raleigh Radiology's application for accreditation.

- After evaluating the reasons for the accreditation revocation, on November 6, 2019, the FDA declared Raleigh Radiology's MQSA certificate to be no longer in effect until such time as the Raleigh Radiology accreditation was reinstated and Raleigh Radiology complied with all FDA requirements.

- Based on the serious image quality deficiencies noted during the AMR, the FDA declared the mammography performed at Raleigh Radiology was a serious risk to human health, and therefore required Raleigh Radiology to perform a Patient and Referring Healthcare Provider Notification (PPN) to alert all at-risk patients and their providers of the mammography quality problems at Raleigh Radiology.

The concepts embodied in the Basic Principles, made applicable to CON Reviews per Policy GEN-3, are of fundamental importance to the CON process and to the citizens of our State. SHCC Members should be especially wary of Proposed Policy TE-4 as it will permit applicants to avoid scrutiny under the Policy GEN-3 Basic Principles.

B. Access & Value

Access and Value are among the Basic Principles that, absent Proposed Policy TE-4, an applicant must address to secure CON approval. By invoking Proposed Policy TE-4, applicants avoid Policy GEN-3's requirements to demonstrate equitable access and healthcare value.

Two physician group petitioners suggested scanner ownership would be, for them, financially advantageous as compared to existing contract arrangements. Yet, applicants seeking a CON under Policy TE-4 will never have to make the showings on access and value required by Policy GEN-3!

Providers proposing acquisition of their own MRI scanners will typically incur millions in operating expenses annually. Acquiring an MRI usually involves a multi-million-dollar capital expenditure which is typically made via a loan necessitating the payment of interest to repay the obligation. Moving from a contract MRI to an installed unit may involve hundreds of thousands of dollars in facility renovation costs. The cost of acquiring, owning, maintaining, staffing and trouble-shooting a fixed or mobile MRI scanner is not insubstantial.

Yet, because Proposed Policy TE-4 absolves applicants of any duty to address access and value under Policy GEN-3, applicants can avoid documenting generalized claims about money savings. A TE-4 applicant will be under no obligation to "document . . . plans for providing access to services for patients with limited financial resources," nor will a TE-4 applicant be required to "demonstrate how its projected volumes . . . address[] the needs of all residents in the proposed service area." All other CON applicants must address Policy GEN-3 and explain how their projects will maximize healthcare value for resources expended but not those applying under Policy TE-4.

A TE-4 applicant can pursue a CON without explaining whether purported cost-savings will promote equitable access for patients in the form of lower charges or will, instead, inure solely to the benefit of the MRI owner in the former of bumped-up profits of operation. Proposed Policy TE-4 is a dangerous departure from the intent of the planning process and the CON Law because TE-4 applicants will not be subject to Policy GEN-3.

III. Proposed Policy TE-4 is directed at a problem that doesn't exist.

Proposed Policy TE-4 is fashioned as a statewide policy. Yet, despite multiple opportunities, commenters cannot claim that North Carolina has some unaddressed statewide MRI "access problem" – rather, apart from a handful of appropriately-identified areas of need, the State is well-served and many of its MRI scanners are not fully utilized.

Not a single petitioner elected to pursue an Adjusted Need petition to present any unique circumstances at its existing MRI sites. Alliance operates in various locations across the State, reporting high patient and customer satisfaction. Since the onset of COVID-19, MRI utilization has fallen sharply and is likely to remain depressed into

the future. No facts support a need for a statewide Policy change to allow new MRI scanners into our State.

Nor can any provider claim there is any lack of "process" for seeking an MRI CON in North Carolina. To the contrary, anyone can apply for a 2021 MRI CON per a validly identified Need. Applicants can apply when a special Adjusted Need is found or if the Standard Methodology identifies a Need Determination. When an Application is filed, it can be approved if it is found conforming and the most effective alternative.

The planning process, combined with the CON process, ensures North Carolina's Counties are served by appropriate levels of health care resources and the most effective health care alternatives. Proposed Policy TE-4 is not only problematic but wholly unnecessary because the system is working as intended.

A. 2015-2016

Proposed Policy TE-4 does not address a "problem" the Agency failed to solve in 2015. If 2015-16 history is even germane to the present discussion, SHCC Members should at least work from an accurate recounting of past events.

For 2016, the Standard Methodology did not identify a Wake County Need Determination but one was included based on Raleigh Radiology's Adjusted Need petition. Three (3) fixed MRI CON applications were submitted to the Certificate of Need Section ("the CON Section") in response to the Adjusted Need.

The "problem" for Raleigh Radiology was with Raleigh Radiology's CON application, not with the planning process. The CON Section simply found Raleigh Radiology's CON application "not conforming" and "not approvable."

According to the CON Section, Raleigh Radiology's projected payor mix was questionable, and it did not adequately demonstrate medically underserved groups would have adequate access to the proposed MRI. Considering there were, at that time, 15 other fixed MRIs and several mobile MRI sites operating in Wake County, the CON Section found it "not reasonable" to project that over 40% of additional MRI scans for Medicare recipients would be performed at Raleigh Radiology Cary.

The CON Section also found Raleigh Radiology's projected capital costs questionable because of a discrepancy between Raleigh Radiology's projected costs and the quotes it obtained and its failure to include any state taxes. The CON Section found Raleigh Radiology did not adequately demonstrate it proposed a cost-effective alternative.

In protracted litigation, Raleigh Radiology argued over the CON Section's 2016 decision but, in 2019, Raleigh Radiology lost its case. The North Carolina Court of Appeals upheld the CON Section decision disapproving Raleigh Radiology. *Raleigh Radiology LLC v. N.C. Dep't of Health & Human Servs.*, 833 S.E.2d 15, 21 (2019).

Notwithstanding the outcome, Raleigh Radiology plainly had a fair chance to compete for an MRI CON approval. Any Raleigh Radiology issues over the 2015-2016 CON Review have nothing to do with Alliance nor any "problem" in the health planning process.

B. 2019-2020

In 2019, in response to a Need Determination per the Standard Methodology, Raleigh Radiology applied and was approved for an MRI CON.[1] As Raleigh Radiology did in 2016, other applicants challenged the CON Section decision. (Alliance did not apply and is not a party to this ongoing CON contested case).

The important take-away is that providers, including Raleigh Radiology have and can use the existing CON process without Policy TE-4.

IV. The SMFP Chapter 2 planning process is of critical importance.

Alliance is concerned that, while North Carolina's CON Law remains in full force and effect, the Plan's MRI Chapter could be functionally set aside through a proposed policy recommended on only three (3) votes with no advance industry/public input. It should come as no surprise that Alliance has expended time and resources to address SHCC members over the summer.

But Alliance's participation was only allowed after the Committee already recommended Proposed Policy TE-4 and after the full SHCC already voted to include it in the Proposed Plan. Alliance's participation this summer does not change the fact that a statewide policy could be submitted to the Governor without the intended public deliberation. The SHCC expressly noted at each summer public hearing that the Proposed Plan would not be debated. As announced, the summer public hearings are not the time for the deliberation on proposed policies which is intended to occur at the Committee level **before** policies are presented to the full SHCC.

By relegating Alliance to the summer process, the Agency has postured Proposed Policy TE-4 for inclusion in the Plan, when the opposite ought to be true. The Agency has inexplicably adopted the practice of presenting policy to the SHCC as if it were thoroughly vetted, when this couldn't be further from the truth. Deliberation should occur **before** statewide policies are considered for inclusion in the Proposed Plan, not **after**. The opportunity to comment over the summer does not remedy this deficiency.

[1] Raleigh Radiology also proposed a Knightdale MRI but conceded this was not the most effective alternative for Wake County; the CON Section found its Knightdale proposal unapprovable.

A. 11th-Hour Policy Re-Write

Revising Proposed Policy TE-4 now would only make the procedural problems with the Policy worse because no one can comment on a revised Policy arising from a Fall Committee or SHCC meeting. If the Committee or the SHCC acts to put forth some new Policy TE-4 version this Fall, no one will be able to see it and comment on it because there is no further opportunity for public comment after August 12. The problem will, from this point, be spiraling further out of control.[2]

Raleigh Radiology complains that no TE-4 Applications would be allowed in Counties with a Need Determination, but unlimited Applications could be filed in Counties without a Need Determination. Yes, this is among several highly problematic aspects of Proposed Policy TE-4. Yet, instead of rejecting the flawed Policy as Alliance would urge, Raleigh Radiology wants to allow unlimited MRI Applications **in all Counties**. Obviously, this confounds, not solves, the problem.

Raleigh Radiology contends Proposed Policy TE-4 is salvageable with what it has characterized as "minor" edits. But the edits proposed by Raleigh Radiology are a far cry from minor. As is evident with a cursory glance at Raleigh Radiology's redline of Proposed Policy TE-4, Raleigh Radiology is advocating for a wholesale policy re-write at this late date in the planning process. Raleigh Radiology proposes:

- Changing the Proposed Policy's title;
- Writing a new "Qualified Applicant" definition; and
- Transforming the Proposed Policy's conditions by dropping several original requirements and adding new ones.

However, even if the SHCC were to rewrite Proposed Policy TE-4 based in part on Raleigh Radiology's wishes, few, if any, of Alliance's critical concerns would be addressed.

Even with Raleigh Radiology's suggested edits, the Proposed Policy would remain fundamentally problematic as it would still add unneeded MRI capacity and reduce the likelihood of future need determinations. Raleigh Radiology acknowledges as much, stating "[a]ny MRI scanner approved under Policy TE-4 would be counted in the standard methodology."

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[2] Raleigh Radiology asserted in its public hearing remarks on July 21 that it has "listened to Alliance's attorneys many assertions that the language of TE4 [sic] cannot be altered [and that Raleigh Radiology counsel] has assured us that the opinion of the Alliance lawyers is wrong." Raleigh Radiology stated that its "attorney's full analysis will be presented at a later date." As of the date of this filing, Raleigh Radiology has failed to make such an analysis available.

And Raleigh Radiology's version of Proposed Policy TE-4 continues to treat similarly situated providers differently. Why is it fair to allow providers with a contract service to invoke Proposed Policy TE-4 and dispense with the Standard Methodology, while relegating those without a contract service to waiting for an organic need determination? Why should TE-4 applicants be insulated from competition, while others are subjected to it? There is no rational reason for distinguishing between providers with a contract service and those without one, and this dichotomy raises constitutional/equal protection concerns.

1. Suggested Title Change

Interestingly, in its redline, Raleigh Radiology proposes renaming Proposed Policy TE-4 "Exemption for Existing Contracted MRI Services in Fixed Locations." Such a change would trade one misnomer for another.[3] Under the CON Law, an "exemption" refers to a "new institutional health service" which is "exempt from [CON] review." N.C. Gen. Stat. § 131E-184(a). But under Proposed Policy TE-4 (both the current version and redline versions), the acquisition of an MRI is not exempt. To the contrary, a TE-4 applicant would have to apply. It just wouldn't do so in response to a valid Need Determination nor would it participate in a competitive Review, like all other MRI applicants must.

Such a proposed title change is quite telling. The goal becomes obvious: to be "exempt" from applying only in response to a legitimately identified Need and exempt from competing for a CON. But in addition to constitutional/equal protection implications, allowing Applications without a Need Determination and insulating certain applicants from competition directly contravenes the CON Law. Our General Assembly has chosen to CON-regulate MRI scanners. *See* N.C. Gen. Stat. §§ 131E-176(16)f1.(7); -178(a). Implicit in this regulation is that – absent a compelling health planning/policy reason – providers compete to meet identified needs. *See id.* at § 131E-183(a)(1) ("The proposed project shall be consistent with applicable policies and need determinations . . . which constitutes a determinative limitation on the provision of any health service . . . that may be approved.").

While the SHCC is authorized to develop the State Plan, there is a real legal question around creating "qualified applicants" who can apply without need or competition. Indeed, the entire notion of defining a "qualified applicant" intrudes upon the province of the CON Section, the arm of the state agency charged with administering the CON Law. **The General Assembly has already decided that acquisition of MRIs requires a CON. If the SHCC creates "qualified" applicants who can apply in the absence of need and without competition, it may be acting beyond its statutory**

[3] The current version of Proposed Policy TE-4 is entitled "Substitution of Vendor Owned MRI Scanner for Provider Owned MRI Scanner." However, "substitution" is a misnomer because the total inventory of scanners will increase when a TE-4 CON is awarded; there is no true substitution of one scanner for another.

authority. Health policy ought to apply to everyone, absent compelling circumstances. Such circumstances are absent from the equation here.

2. **New Definitions/Conditions**

Even with the suggested redline edits, the Proposed Policy terms are still hopelessly vague: What is an "MRI provider?" Would an MRI manufacturer qualify? What about vendors? The problem with key undefined terms persists.

Further, how does one determine, specifically, that "[t]he acquisition and operation of the facility's own MRI scanner will allow the facility to reduce the cost of providing the MRI service at that facility?" What showings must a TE-4 applicant make to satisfy this condition?

Insofar as an applicant would be solely responsible for staffing, maintenance, repairs, construction/installation costs, etc., is it plausible for a provider to demonstrate reduced costs? As a practical matter, how would the CON Section confirm the veracity of an applicant's representation that acquisition/operation of its own scanner will allow it to reduce the cost of providing MRI service? There are no Application form questions to address this topic. And, the requirement creates a classic "fox guarding the henhouse" problem, as the CON Section will likely have to take the applicant at its word because it has no basis to disagree with the representation.

But even assuming acquiring one's own scanner results in reduced costs, does this truly inure to the public's benefit? There is nothing in Proposed Policy TE-4 in original or redline version to suggest that cost savings must be passed along to patients in the form of reduced charges. Nor is there any suggestion that CON approval will be conditioned on patient charges being capped for a given time period. This begs the question: Is the Proposed Policy intended solely for the Raleigh Radiologies of the world to improve their bottom lines, without regard to patient charges, quality, or access? For whose benefit is Proposed Policy TE-4 intended, exactly?[4]

Moreover, in the current version of Proposed Policy TE-4, a "qualified applicant" is one "unable to apply pursuant to a need determination."[5] **But in Raleigh Radiology's redline version, the "unable to apply" verbiage has been stricken**. This underscores Raleigh Radiology's true motivations in supporting Proposed Policy TE-4: it seeks an avenue to apply even where there is a need determination identified by the Standard Methodology, so it won't have to compete for a CON approval. Raleigh Radiology is posturing to have multiple bites at the MRI apple in 2021, allowing it to apply

[4] Notably, in its most recent CON Application, Raleigh Radiology revealed its plan to earn **$1.16 million *in profit*** on its MRI in the first year of operation.

[5] However, a putative TE-4 applicant may very well conjure up various reasons it is "unable to apply," even where there is a need determination.

pursuant to the 2021 need determination, and then apply pursuant to Proposed Policy TE-4 – perhaps more than once.

Proposed Policy TE-4 is problematic and made even more so by Raleigh Radiology's proposed edits. The issues with the Policy -- and whether it is even needed at all -- should be ironed out by a work group or special committee, with appropriate and careful deliberation.

Raleigh Radiology itself asks the SHCC to throw out the Mobile MRI provisions in Proposed Policy TE-4, citing numerous issues with those terms of the Policy. As should be abundantly clear at this point, this Proposed Policy is far from a consensus solution to any MRI issues in North Carolina and far from ready to be a part of any State Plan.

3. Unintended Consequences

Raleigh Radiology suggests only one County, Wake, could have qualified applicants under TE-4 in 2021. This assertion is flatly incorrect. Under either the current or redline version of Proposed Policy TE-4, there could be qualified applicants for fixed MRIs in multiple counties in 2021, potentially including at least Wake, Guilford and Johnston Counties. And in Wake County, there would appear to be four qualified applicants, not three as Raleigh Radiology contends. Even in a County the size of Wake County, such an influx of new scanners would constitute a wholesale departure from the one-MRI Need limitation validly included in the Plan statewide.

Under Proposed Policy TE-4, a variety of applicants would qualify to apply for a mobile scanner and an even greater number of providers could become qualified to use TE-4 to seek a mobile scanner merely by contracting for service with a mobile vendor. As drafted, Proposed Policy TE-4 could unintentionally invite numerous CON approvals in areas already well-served or even oversupplied by existing MRI capacity.

B. Proposed Policy TE-4 is problematic and unnecessary.

Proposed Policy TE-4 completely ignores MRI utilization data for every scanner in the Service Area other than of the TE-4 applicant. Ignoring such data directly contravenes the Standard Methodology, North Carolina Administrative Code

provisions, and the CON Law itself. And it does so without addressing any health planning issue.[6]

Proposed Policy TE-4 is fundamentally unnecessary and certainly not needed to combat the highly dubious claim that the Standard Methodology somehow forces residents to seek MRI scans "out of county." It is difficult to believe that with numerous mobile MRI scanners and well over a dozen different MRI locations throughout Wake County there would ever be a situation in which a patient was literally unable to schedule an MRI scan without traveling outside the County. Alliance knows of nothing to support this incredible claim. Any such circumstance would be quite peculiar and anecdotal.

Proposed Policy TE-4 has been spearheaded by only two physician groups. Alliance is not alone in its concerns over Proposed Policy TE-4. In addition to Alliance, Novant Health also opposed the Petitions filed earlier this year and has more recently opposed Proposed Policy TE-4 by filing its own petition to remove it from the Proposed 2021 Plan.

Proposed Policy TE-4 is not needed to address a so-called Alliance "virtual monopoly" on contract MRI mobile units and equipment upgrades. For instance, the Plan shows Raleigh Radiology uses not only Alliance MRI equipment, but also MRI scanners furnished by Foundation Health Mobile Imaging and Pinnacle Health Services. Others both own and contract for MRI equipment.

Alliance scanners operate in North Carolina lawfully, not per any "loophole." These and other distractor arguments have been voiced before. *See,* *https://info.ncdhhs.gov/dhsr/mfp/pets/2019/tec/0816_mri_wake_ahs.pdf*. SHCC Members are urged to retain a focus on the true issues respecting Proposed Policy TE-4.

The notion that Proposed Policy TE-4 does not guarantee a CON to any applicant glosses over the key defect in Policy TE-4: a TE-4 applicant will never have to compete for CON approval as contemplated by the CON Law, and there would be no comparative analysis in which the CON Section could weigh competing proposals to determine which one is best for the public. The lack of competition would work to the detriment of patients and North Carolina's health delivery system.

[6] A reference to "trends" in utilization does not suggest the Standard Methodology examines multiple years of data but rather that utilization changes are accounted for from year-to-year to identify need determinations. For example, in 2018, a county without high utilization across its inventory will not identify a need determination. With utilization growth, in 2019, the Standard Methodology can identify a need determination in that county. (Such was the case in Wake County.) Thus, while a particular State Plan does not examine data "trends," each State Plan does account for data updates from the previous year's Plan.

The ability to comment against non-competitive TE-4 applications is no substitute for competition. The CON Section makes its own decisions about whether to agree with commenters. While an Applicant in a competitive review is allowed to take up its issues with a Judge, under the current state of the law, a Judge is highly unlikely to hear from a mere non-applicant commenter.

And, because every TE-4 Review will be non-competitive, notwithstanding concerns raised by commenters, the CON Section can steer around any issues with the Applicant one-on-one during the Review. Or the Applicant can file a contested case and settle with the CON Section on negotiated terms. Thus, the TE-4 applicant will be in position to secure a CON without any meaningful chance for the concerns of commenters to be addressed by a Judge.

Conclusion

The issues with Proposed Policy TE-4 are not Alliance issues; rather, they are important questions over the future of sound health planning in North Carolina. The comments of Policy opponents, including Alliance and Novant Health, are not "rhetoric" but legitimate concerns over the terms of Proposed Policy TE-4 and adherence to the framework of Chapter 2 of the Plan.

Proposed Policy TE-4 is unnecessary and problematic and should not be a part of the 2021 Plan. Thank you for your consideration and your vote to remove Policy TE-4.