

WILLIAMS MULLEN

Direct Dial: 919.981.4001

jheath@williamsmullen.com

ashackelford@williamsmullen.com

Lauren Fussell's Comments in Opposition to Proposed Policy TE-4 Offered at July 10, 2020 Public Hearing

Good Afternoon. My name is Lauren Fussell, an attorney with Williams Mullen. I understand SHCC members will vote later this summer on whether to include Proposed Policy TE-4 in the State Plan and I've been asked to address briefly some of the more obvious legal issues with the Policy.

The Proposed Policy uses multiple undefined terms and standards. A "qualified applicant" must be a "provider," a term not defined in the Policy nor in the CON Law Definitions. *See* N.C. Gen. Stat. § 131E-176, "Definitions." Query whether 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?

Per the Policy, the provider must contract with "an unrelated person," another term not defined in the Policy or in the CON Law – a significant problem given the various connections among those who provide and use MRI services. Novant Health, Inc. receives MRI services on a scanner owned by Presbyterian Mobile Imaging, LLC – evidently, two separate legal entities – but are they "unrelated" persons? How do we know? Is it a shared parent test? Or, a percentage ownership test: 5%?, 10%? Where does one draw the line?

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? Is there really any meaningful way for a provider receiving weekly service on a grandfathered scanner to "vouch" for whether or when the vendor will move the contract scanner to serve other sites? Can't a grandfathered scanner lawfully move at any time? What happens if the vendor moves the contract scanner during the CON Review? Is the application then unapprovable? At best, this ambiguity creates confusion; at worst, it invites litigation.

The Policy speaks about scanners that "should be treated as a fixed." What defines which scanners should be treated as fixed? If there's 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 this suggests TE-4 could be invoked when there is no need determination in the Plan, but is a provider "unable to apply" if it cannot identify a CON consultant to prepare its application? Could a provider miss a CON filing deadline early in the year and then later in the year claim to then be "unable to apply?" Query how a provider could ever say it is "unable to apply" unless it first

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petitions to seek a Need Determination? Is every provider obligated to bring forward a petition before invoking Policy TE-4?

Policy TE-4 uses standards different than 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 of the applicant's scanners in the service area. Two distinctly different standards. Query whether the Policy can legally do away with a validly enacted regulation?

Proposed Policy TE-4 creates a host of obvious legal problems by setting different standards without explaining whether or how the duly adopted Regulations will apply.

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. 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.

In sum, this Policy appears to have been hastily constructed. It creates troubling possibilities for potential use and misuse which could have long term negative effects by proliferating scanners in areas without need.

From a legal perspective, this is a draft Policy that needs to be set aside in 2020. Thank you.