

**Technology and Equipment Committee
Agency Report
Petitions for Removal of Policy TE-4 from the
2021 State Medical Facilities Plan**

Petitioners:

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Request:

Novant Health, Inc. (Novant) requests the new Proposed Policy TE-4 in the Proposed 2021 State Medical Facilities Plan (SMFP) not be included in the 2021 SMFP.

Williams Mullen, on behalf of Alliance Healthcare Services, Inc. (Williams Mullen/Alliance), requests the State Health Coordinating Council (SHCC) take formal action to remove proposed Policy TE-4 from the 2021 SMFP.

Background Information:

Chapter Two of the SMFP allows for “[a]nyone who finds that the North Carolina State Medical Facilities Plan policies or methodologies, or the results of their application, are inappropriate may petition for changes or revisions. Such petitions are of two general types: those requesting changes in basic policies and methodologies, and those requesting adjustments to the need projections.” The SMFP annual planning process and timeline allow for submission of petitions for changes to policies and methodologies in the spring and petitions requesting adjustments to need projections in the summer. In addition, the Agency may bring recommendations to the SHCC and its committees pertaining to policies, methodologies and need determinations. Most commonly, such recommendations are based on the results of interested parties’ meetings, workgroups, or staff analysis.

Spring petitions are due at 5:00 p.m. on the same date as the first SHCC meeting of the year. The first meeting of the SHCC in 2020 was on March 4, 2020. Immediately following this meeting, the SHCC holds a public hearing on matters relating to policies and methodologies. A two-week

comment period follows this public hearing. During this time, anyone may comment on petitions or other matters.

The relevant committee of the SHCC reviews petitions, comments, and Agency recommendations regarding new or adjusted policies and/or methodologies at the relevant committee's first meeting of the year. The first meeting of the Technology and Equipment Committee in 2020 was on April 15, 2020. The relevant committee forwards its recommendation to the SHCC for consideration at the SHCC's second meeting of the year. The second meeting of the SHCC in 2020 was on June 10, 2020. If the SHCC decides to include a new or adjusted policy or methodology in the Proposed SMFP, there is a comment opportunity during the month of July that allows the public to express any concerns with the decision. The planning process described in the SMFP does not include a public comment opportunity between the March public hearing/comment period and the July public hearing/comment period.

Policy TE-4 was developed as a result of two spring petitions that each called for a new policy regarding vendor-owned MRI scanners: the petition from Carolina Neurosurgery & Spine Associates pertained to mobile MRIs submitted on March 4, 2020 and the petition from Raleigh Radiology pertained to fixed MRIs submitted on March 4, 2020 (Spring Petitions).

It is extremely unusual for the Agency to recommend approval of a petition that proposes a new or adjusted policy or methodology without suggesting modifications to the proposed policy or methodology as presented in a petition. In some cases, such petitions call for actions that are outside the scope of the SHCC (e.g., a policy to increase Medicaid reimbursements). In other cases, the language does not conform to the requirements of the CON Law or rules. It is common for the Agency to recommend denial of such petitions and instead propose a policy or methodology that reflects the spirit of the petition's request that utilizes language and provisions appropriate to the SMFP that conform to the requirements of the CON Law and rules. Policy TE-4 is the result of this type of process.

Current Petitions:

On July 27, 2020, Novant and on July 29, 2020, Williams Mullen/Alliance both submitted petitions requesting removal of the Proposed Policy TE-4 from the Proposed 2021 SMFP (Current Petitions).

Novant requests removal of Proposed Policy TE-4 from the Proposed 2021 SMFP for the following assertions, as stated in its Petition: 1) 2020 is not the year to make significant changes to the policies in the SMFP, 2) the SMFP offers two pathways for facilities to replace contracted MRIs, and 3) Policy TE-4 appears to be a response to concerns that certain customers have about their vendor MRI services.

Williams Mullen/Alliance requests removal of Proposed Policy TE-4 from the Proposed 2021 SMFP based on assertions in its Petition that Proposed Policy TE-4: 1) was first revealed after the March comment deadline, 2) undermines the standard MRI methodology, 3) creates MRI scanner proliferation in markets with no need, 4) eliminates competition from the CON process, 5) uses undefined terms and ambiguous standards, 6) would cause numerous unintended consequences, and 7) cannot be rewritten.

Analysis/Implications:

The SMFP currently includes two Technology & Equipment (TE) policies that allow qualified applicants to apply for CONs for MRI scanners without a need determination, under specific conditions. Policy TE-2 provides the opportunity for qualified applicants to apply for a CON to acquire an intraoperative MRI to be utilized in an operating room suite. Policy TE-3 provides the opportunity for qualified applicants to apply for a CON to acquire a fixed MRI scanner in a hospital that currently does not have an existing or approved fixed MRI scanner. Proposed Policy TE-4 generates an opportunity for providers who lease fixed or mobile MRI equipment from a vendor to “substitute” that machine for one owned by the provider when the provider is unable to apply for an MRI pursuant to a need determination in the SMFP. The policy sets out conditions under which providers can seek to meet the needs of their patients without relying on a vendor.

Both Petitioners and interested parties who made comments expressed numerous concerns about the development and impact of proposed Policy TE-4. With one exception, this document does not detail the Agency’s position regarding specific claims, arguments, and rationales expressed in the current petitions, comments, or oral remarks made at the public hearings.

The exception pertains to the process for approving inclusion of Policy TE-4 in the Proposed 2021 SMFP. Williams Mullen/Alliance stated in its petition and several public comments that the Agency did not correctly follow the required procedures when acting on Policy TE-4 because the policy was “first revealed after the close of the comment period” (Williams Mullen/Alliance, Petition page 4). Policy TE-4 was drafted after receiving the Spring Petitions that were received on or before March 4, 2020. The deadline for the March comment period in 2020 was March 18, 2020. This was the first comment period in 2020. On March 17, 2020, Alliance submitted two sets of comments in opposition to the policies proposed in each of the Spring Petitions. On March 18, 2020, Novant submitted two sets of comments in opposition to the policies proposed in each of the Spring Petitions. On April 15, 2020, after review of the petitions and comments, the Agency recommended denial of the Spring Petitions to the Technology and Equipment Committee. Instead, the Agency recommended approval of Policy TE-4 as developed by the Agency as a result of the Spring Petitions. As discussed above, this process and type of response is standard. The Technology and Equipment Committee voted to recommend inclusion of Policy TE-4 in the Proposed 2021 SMFP to the SHCC. The SHCC approved this recommendation at its meeting on June 10, 2020, and Policy TE-4 was included in the Proposed 2021 SMFP. Public comments on the Proposed 2021 SMFP were accepted during the July public hearings and public comment period.

Williams Mullen/Alliance stated that the Agency failed to follow proper procedure because there was no opportunity for the public to comment between the April 15, 2020 Technology and Equipment Committee meeting and the inclusion of Policy TE-4 in the Proposed 2021 SMFP. The Agency followed the process that has remained unchanged in the SMFP for over 10 years. The July public hearing and comment period is the first opportunity for the public to share any concerns with the SHCC surrounding new or adjusted policies and methodologies that appear in the Proposed SMFP. The process does not include an opportunity for comment between the March public comment period and the July public comment period. Therefore, the Agency maintains that it followed the prescribed process and proper procedure.

Agency Recommendation:

Given available information submitted by the August 12, 2020 deadline, the Agency recommends approval of the relief requested by the Petitioners, i.e., the removal of Policy TE-4 from the 2021 SMFP. This recommendation does not imply agreement with all assertions presented in the Current Petitions, public comments, or the oral remarks made at the public hearings. Rather, the totality of information gathered from public hearings, petitions and comments led the Agency to determine that the language of the policy should be further developed. The Agency also recommends creating an opportunity for interested parties to offer more input regarding the proposed policy.