

WILLIAMS MULLEN

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MEMORANDUM

Via email to Dr. Amy Craddock
amy.craddock@dhhs.nc.gov

TO: Technology & Equipment Committee

FROM: Joy Heath & Anderson Shackelford, Williams Mullen

DATE: May 6, 2020

RE: Comments in Opposition to Proposed Policy TE-4
Submitted on Behalf of Alliance Healthcare Services, Inc.

On behalf of our client, Alliance Healthcare Services, Inc., Joy Heath and Anderson Shackelford of the law firm Williams Mullen (the “Commenters”) ask that the Technology and Equipment Committee present and address the following Comments in opposition to Proposed Policy TE-4.

Specifically, the Commenters 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.

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.

Background

- At the April 15, 2020 Technology and Equipment Committee Meeting, Agency staff proposed a new policy, Proposed Policy TE-4.
- Proposed Policy TE-4 was first posted to the Agency web site on or about April 8, 2020, the Wednesday prior to the April 15 Committee Meeting.

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- Proposed Policy TE-4 is novel – until April 8, no one knew the Agency was formulating the Proposed Policy and no one had any way of knowing what would be included in its terms.¹
- By the time Proposed Policy TE-4 was first revealed on the web site on April 8, the March 18 deadline for submission of Comments on pending Petitions had already passed.
- No one could have commented on Proposed Policy TE-4 within the period for Comments on the pending Petitions because the Proposed Policy was not revealed until after the Comment deadline.
- And, prior to the April 15 Committee Meeting, no Comments on Proposed Policy TE-4 had in fact been received by the Committee.
- The April 15 Committee was not a “public hearing,” meaning no one could be heard to speak on Proposed Policy TE-4 absent a Committee member asking for input.
- No requests for information were made during the meeting and no one from the public was recognized to speak on Proposed Policy TE-4.
- No discussion of Proposed Policy TE-4 occurred at the April 15 Committee meeting.
- On April 15, 2020, the Committee voted to recommend approval of Proposed Policy TE-4.
- Only three of the seven Committee members voted to recommend approval of Proposed Policy TE-4; the remaining four recused/abstained.
- Members voting to recommend approval of the Proposed Policy were Harnett County Commissioner McKoy and Dr. Perry of North Carolina Eye Ear Nose & Throat, PA, joined by Dr. Ullrich of Charlotte Radiology.

¹ In contrast, Dr. Amy Craddock, Assistant Chief of Healthcare Planning, recently circulated an email to the Interested Persons listserv in advance of the Long-Term and Behavioral Health Committee’s May 14, 2020 meeting to bring attention to potential changes to the psychiatric and substance use disorder methodologies. *See Exhibit A.* Dr. Craddock’s email indicated that the Committee would accept comments through May 6, and such comments would be considered at the May 14 meeting. No similar procedure was followed in advance of the Technology and Equipment Committee Meeting.

Proposed Policy TE-4

Proposed Policy TE-4 would allow CON Applications to be filed for fixed or mobile MRI scanners when the Standard Methodology shows no need for a new scanner.

The Proposed Policy would allow CON Applications to be filed by any provider using a contract MRI scanner if the utilization of that scanner exceeded a stated volume in the prior year. Applicants would only be required to provide future volume projections for its own scanners.

Comments

The Commenters raise three issues:

First, Proposed Policy TE-4 is a radical departure from the Standard Methodology and ignores all data on MRI scanners in a Service Area or Mobile MRI Region other than that of the applicant's single contract scanner.

Second, Proposed Policy TE-4 is unnecessary because Step 8 of the Standard Methodology already allows those using contract scanners to seek an Adjusted Need Determination and present information on perceived efficiencies in replacing a contract scanner. The Proposed Policy would instead eliminate the possibility of competitive reviews and could be more widely used than anticipated.

Third, Proposed Policy TE-4 as drafted is problematic in numerous respects. The Proposed Policy creates an obvious legal problem by setting different standards than those in the existing MRI Regulations without explaining whether or how the duly adopted Rules will apply. The Proposed Policy uses multiple terms not defined in the CON Law or Regulations and sets ill-defined standards.

As to the first issue, the Commenters believe Proposed Policy TE-4 runs counter to fundamental tenets of North Carolina's health planning process by creating an opportunity to apply for a CON for a new MRI scanner without reference to ***any*** of the information relied on in the Standard Methodology, including:

- the total inventory of MRI scanners in the MRI Service Area;
- the total number of MRI procedures performed by type;
- the total number of procedures per MRI scanner; or
- the planning thresholds for additional MRI scanners for the Service Area.

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The Agency Report which proposes Policy TE-4 indicates support for the Standard Methodology. Yet, ignoring all information on the number of scanners and procedures performed in the relevant Service Area, Proposed Policy TE-4 creates an opportunity to apply ***based on utilization data for just one scanner in 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 so-called “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 of the MRI scanners that others own and operate in the relevant Service Area. Consequently, a Service Area could have multiple underutilized MRI scanners and Proposed Policy TE-4 would still allow a new scanner to be acquired and located in that Service Area.

As a second issue, the Commenters believe Policy TE-4 ignores Step 8 of the Standard Methodology. Step 8 already specifically acknowledges that a provider relying on a contract MRI scanner can petition for an Adjusted Need Determination. And, Step 8 already recognizes that a provider with a contract MRI scanner can be CON-approved to acquire its own scanner “if the acquisition . . . will allow the facility to reduce the cost of providing the MRI service at that facility.” Given Step 8, Proposed Policy TE-4 is wholly unnecessary.

When a provider secures an Adjusted Need Determination, anyone can apply to fill that 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 significant factors to choose the most effective alternative.

In contrast, because Proposed Policy TE-4 defines a “qualified applicant” as a party to a contract for a MRI scanner, 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 of several important comparative factors.

The Agency Report expresses concern over the “possible impact to the state inventory,” but includes charts which suggest only a limited number of providers could qualify to apply under Proposed Policy TE-4. Not so. If adopted, Proposed Policy TE-4 would have the unintended consequence of allowing any provider to direct procedure volume to a contract scanner, perform the requisite number of procedures on that scanner within a one-year period, and qualify under the Proposed Policy to apply to obtain a new scanner, *even in a Service Area where application of the*

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Standard Methodology shows a significant surplus of MRI scanners based on the inventory of scanners and the total procedures performed in that Service Area.

Using the Proposed Policy, a provider could add MRI scanners to a Service Area, increasing the MRI surplus and thereby reducing or eliminating any likelihood of future Need Determinations and stifling the ability of others to apply for new MRI scanners.

As a third issue, the Comments state that Proposed Policy TE-4, as drafted, is problematic in numerous respects. Its wording and word choices have not been sufficiently perfected and are likely to create several problems and ambiguities giving rise to legal issues. Among other things, the Proposed Policy relies on a number of terms that are not defined in the Proposed Policy nor in regulation.

For example, Proposed Policy TE-4 defines “qualified applicant” as a “provider who has an executed contract with an unrelated person” (emphasis supplied). However, “provider” is not defined in Policy TE-4, the North Carolina Administrative Code, or the CON Law. As currently written, a vendor could conceivably qualify as a “provider” – especially to the extent it staffs the scanner at issue – and utilize Policy TE-4 to secure its own CON. Is this the intent of Policy TE-4?

Also, Proposed Policy TE-4 contemplates that a qualified applicant can apply only where the provider can demonstrate “[t]he contracted scanner remains at the existing host site and is not moved to other host sites.” (emphasis supplied). This requirement has no time parameter (not moved for how long?). There is no 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 which it could lawfully do at any time, including during the pendency of the Review of a CON Application.

The Proposed Policy in its present form has not received adequate scrutiny to avoid a myriad of potential issues. Further study of the subject matter of Policy TE-4 is warranted before the Technology and Equipment Committee recommends its adoption by the State Health Coordinating Council.

The Commenters ask that the Committee, considering the above statements, entertain a Motion and vote to recommend disapproval of Proposed Policy TE-4 in 2020.

Shackelford, Anderson

From: dhsr.mfp.interested.parties-bounces@lists.ncmail.net on behalf of Craddock, Amy D <amy.craddock@dhhs.nc.gov>
Sent: Tuesday, April 21, 2020 11:36 AM
To: DHHS.DHSR.MFP.Interested.Parties; dhunter; DHSR.Certificate.Need; DHHS.DHSR.SHCC.Members; Sauer, maggie; Powell, Elyse S; Terrell, Sandra D; Frisone, Martha; Boyette, Melinda T; Brown, Elizabeth; Dickson, Tom E; Emanuel, Andrea N; Michael, Trenesse M
Subject: [DHSR.MFP.Interested.Parties] SMFP psychiatric and substance use disorder methodologies
Attachments: PsychSudPresDiscFINALPub.pptx; ATT00001.txt

Attached please find an annotated PowerPoint presentation discussing potential changes to the psychiatric and substance use disorder methodologies in the State Medical Facilities Plan (SMFP). This presentation was postponed from the April Long-Term and Behavioral Health Committee meeting.

We are seeking comments both on this presentation and on these methodologies more generally. Comments should be submitted to DHHS.SMFP.Petitions-Comments@dhhs.nc.gov. **The deadline for comments is May 6.**

At their May 14 meeting, the Long-Term and Behavioral Health Committee will discuss the methodologies and comments received. We do not yet know whether this meeting will be held via WebEx or in Brown 104.

The document has been saved in the PowerPoint "Notes Page" view. Use this view to see the complete annotations.

Please contact me if you have questions or if you have trouble accessing the document.

Thank you for your interest in this work.

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