Comment on Petitions Opposing Policy TE-4 in the *Proposed 2021 SMFP*

COMMENTER

Carolina Neurosurgery & Spine Associates
225 Baldwin Avenue
Charlotte, North Carolina 28204

Mary Cloninger
Chief Executive Officer
(704) 831-3100
Mary.Cloninger@CNSA.com

Carolina Neurosurgery & Spine Associates (CNSA) is providing the following comments on the two petitions filed by Novant Health and Alliance Healthcare Services, both of which oppose Policy TE-4 in the *Proposed 2021 State Medical Facilities Plan* (*SMFP*), as well as comments from Raleigh Radiology. While numerous oral and written comments were filed, CNSA has attempted to summarize the issues raised on this Policy in its response to follow.

One foundational issue that CNSA believes the SHCC must consider is that the treatment of mobile MRIs and fixed MRIs are different under the standard methodology. While Policy TE-4 addresses providers vendor contracts for either fixed or mobile scanners, some of the comments raised regarding the standard methodology are clearly factually inaccurate regarding mobile MRIs, as there is no methodology for mobile MRIs and any need determination can only be generated through the petition process, or otherwise by special action of the SHCC. While CNSA does not oppose the language of the Policy that combines fixed and mobile sites for consideration, it does wish to note this distinction, so that the SHCC's consideration of the petitions and comments does not include these misstatements regarding the status quo for mobile MRI scanners.

<u>Comments from Alliance Healthcare Services (Alliance)</u>

Comment:
The 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.

Response:
Numerous *SMFP* policies that have been adopted by the SHCC are separate from the health planning process in the standard methodology. In fact, that is clearly one of the reasons for the creation of such a policy—to enable providers with unique circumstances to apply for services or equipment without necessitating either a special need petition for each potential applicant or a wholesale change to the methodology. Such policies include the following:

Policy AC-3: Allows academic medical center teaching hospitals to apply for beds, services, or equipment when there is no need determination, with the requirement that they meet certain criteria.

Policy AC-6: Allows open heart surgery providers to apply for a heart-lung bypass machine to be used as backup, without a need determination. While now only needed in special cases, since there is no need determination required for heart-lung bypass machines, for many years it allowed providers to apply for these units irrespective of the need determination.

Policy ESRD-2: Allows for the relocation of dialysis stations between counties, irrespective of the county need determination.

Policy ESRD-3: Allows for the development of outpatient dialysis stations in a hospital, without regard to a facility or county need.

Policy NH-2: Allows for the development of nursing beds in a CCRC, without regard to the need determination for nursing beds.

Policy NH-5 and **Policy NH-6**: Allow for the relocation of existing nursing beds from state facilities or between counties, irrespective of the county need determination.

Policy LTC-1: Allows for the development of adult care home beds in a CCRC, without regard to the need determination for those beds.

Policy LTC-2: Allows for the relocation of existing adult care home beds between counties, irrespective of the county need determination.

Policy PSY-1: Allows for the relocation of existing psychiatric inpatient beds from state facilities, irrespective of the service area need determination.

Policy TE-1: Allows for the development of new mobile PET scanners through the conversion of fixed PET scanners, without any need determination for mobile PET scanners.

Policy TE-2: Allows for the acquisition of an iMRI, without regard to a need determination in the service area for MRI scanners.

Policy TE-3: Allows for the development of fixed MRI scanners by hospitals without a fixed scanner, and regardless of the need determination for fixed MRI scanners.

Thus, at least 12 of the existing policies in the *SMFP* specifically exempt applicants from the need determination generated by the standard methodology. Further, none of the CON applications developed pursuant to these policies would be considered “competitive,” as the approval of one would not necessitate the denial of another. As such, Alliance’s comments that Policy TE-4 would create a “dangerous precedent” are wholly false.

Comment:
Policy TE-4 ignores Step 8 of the Standard Methodology, which already specifically recognizes that a provider with a contract MRI scanner can be CON-approved to acquire its own scanner. Given Step 8, Proposed Policy TE-4 is wholly unnecessary.

Response:
As noted above, there is no "standard methodology" for mobile MRI scanners. Thus, the portion of Policy TE-4 that would allow CNSA to replace a vendor-owned mobile scanner with its own mobile scanner cannot be addressed by the standard methodology.

Alliance's comments, both in the multiple oral presentations its representatives made and its written statements, are clearly hyperbolic and written without regard to the strong historical precedent established by the SHCC over the last few decades in its creation of the various policies. Nothing about the creation of Policy TE-4 would be novel or unique, as noted by the numerous policies that exist specifically to allow applications outside of the standard methodology.

Alliance's comments include numerous other factual errors, the most egregious of which is perhaps the notion that the public was somehow unaware of the creation of the policy. Alliance representatives stated that the policy was created without public knowledge, input or ability to comment. This is not only incredibly inaccurate; **it intentionally ignores the comments that Alliance itself wrote in opposition to CNSA's petition to create such a policy**[1]. This position also implies that the SHCC cannot develop policies or methodologies in the spring of each year, like it has for decades, allowing the public to comment on the changes during the summer petition/comment cycle. Alliance states that the public had no opportunity to comment, yet it had multiple representatives appear at each of the virtual public hearings and it filed comments on the petitions in the spring and the policy itself during the summer. CNSA believes such clear obfuscation should invalidate the Alliance comments.

Comments from Novant Health (Novant):

Comment:
Due to the COVID-19 pandemic, which the Policy does not address, the Policy should not be adopted.

Response:
Like all providers, CNSA has been dealing with the public health emergency for several months. While the impact of the crisis has been severe and is ongoing, CNSA disagrees that the policy will not address the impacts of COVID-19. In particular, as a practice that has experienced significant loss in volume and revenue resulting from the deferrals in elective cases, the ability to control costs by substituting a vendor-owned mobile MRI scanner with its own scanner is even more pressing than it was in early March when CNSA filed its petition. Moreover, CNSA disagrees with Novant's assertion that anything not directly dealing with the pandemic should not be considered by the SHCC. If Novant truly believes that, then why did it not file a single petition for an adjusted need determination to help it address the crisis? Why did it not petition the SHCC to place a moratorium on all need determinations, if they're not helpful in addressing the public health emergency? Clearly the reference to COVID-19 is a red herring argument, meant to detract from the merits of the Policy and its ability to address the need raised in CNSA's spring petition.

[1] https://info.ncdhhs.gov/dhsr/mfp/pets/2020/tec/Comments-CNSA-Alliance.pdf

Comment:
Policy TE-4 is about the relationship between vendors and MRI hosts and should not be regulated by the *SMFP*.

Response:
CNSA notes that the SHCC has previously acknowledged the difficulty in regulating services, such as MRI, that involve "grandfathered," unregulated units functioning in the same market as regulated units. For both fixed and mobile MRI sites using these "grandfathered" units, there are relationships between the host and the vendor, and the substitution of the vendor-provided unit does not and cannot impose regulations on the vendor.

Comment:
The policy fosters the unnecessary duplication of services, which is directly contrary to the principles of the *SMFP*. By definition, this policy allows CON applications in service areas where there is no published need determination for an additional MRI scanner.

Response:
As noted above in response to Alliance's comments, most of the existing *SMFP* policies allow providers to submit CON applications without a need determination. Clearly the SHCC does not believe, per its development of these policies, that applications outside of a need determination are unnecessary duplication. The applications are reviewed under the statutory criteria established for CON reviews, which include an examination of unnecessary duplication.

Comment:
Since Policy TE-4 only applies when applicants cannot apply under a need determination, the petitioners cannot apply in 2021. There is a need determination in Mecklenburg County, where the petitioner is located.

Response:
This is untrue. There is no need determination for mobile MRI scanners and fixed MRI scanners cannot operate in more than one location. Therefore, mobile host sites have no pathway to apply for a mobile scanner to replace the vendor-owned mobile scanner. Further, CNSA made it clear that it needs a mobile MRI scanner to replace the scanner serving sites in Mecklenburg and Guilford counties. There is no need determination that would allow a mobile scanner to serve sites in multiple counties.

Comments from Raleigh Radiology

In addition to submitting comments on statements made by Alliance, with which CNSA largely agrees, Raleigh Radiology has also submitted comments in opposition to the portion of Policy TE-4 that addressed the need raised in CNSA's petition last spring[2]. CNSA believes that the SHCC acknowledged the issue raised in its petition, as demonstrated by its inclusion of language related to the substitution of mobile MRI scanners in the policy. While it is unclear why Raleigh Radiology stands in opposition to CNSA and the mobile portion of the policy, CNSA does not believe that an equitable solution would be to excise the mobile portion of the policy, leaving mobile MRI scanners completely out of both the standard

[2] https://info.ncdhhs.gov/dhsr/mfp/pets/2020/tec/Mobile-MRI-Policy-Petition-2021-SMFP.pdf

methodology and the policy, while giving hosts of fixed vendor-owned units two opportunities to apply for a scanner, the standard methodology and Policy TE-4. As such, CNSA believes that if a portion of the policy is to be deleted, it should be the portion of the policy relating to fixed MRI scanners.

Conclusion

As one of the highest volume services regulated by the *SMFP*, MRI scanners are operated by many providers across the state. Notwithstanding this fact, it is noteworthy that the two healthcare organizations that oppose the Policy, Alliance and Novant, are existing vendors of MRI services to third parties (Novant through its relationship with MedQuest Associates).

In its petition filed in the spring, CNSA noted that one alternative to Policy TE-4 would be an adjusted need determination for a mobile MRI scanner. Absent the policy, because of the lack of a methodology for mobile MRI scanners, there is no pathway for CNSA to apply for a mobile MRI scanner. Since the SHCC elected to include Policy TE-4 in the Proposed 2021 SMFP, CNSA refrained from applying for an adjusted need determination by the summer petition deadline. However, if the SHCC determines that it will modify or remove Policy TE-4 such that CNSA is unable to apply under the policy for a mobile MRI scanner, it requests that the SHCC consider its denied spring petition as a petition for an adjusted need determination for a mobile MRI scanner that would serve at least Mecklenburg and Guilford counties. Alternatively, the SHCC can, even without a petition to do so, create an adjusted need determination for a mobile MRI scanner for which CNSA could apply. Absent the policy or a need determination for a mobile MRI scanner, CNSA will be forced to wait another year before petitioning for a need determination. Since it has already submitted a petition this year, it respectfully requests that the SHCC either keep Policy TE-4 as written or create a need determination to enable it to apply in 2021.