

**NORTH CAROLINA STATE HEALTH COORDINATING COUNCIL  
PETITION FOR ADJUSTMENT TO THE 2021 STATE MEDICAL FACILITIES PLAN  
REGARDING PROPOSED SMFP POLICY TE-4  
NOVANT HEALTH, INC.  
July 27, 2020**

Sent via email to: [DHSR.SMFP.Petitions-Comments@dhhs.nc.gov](mailto:DHSR.SMFP.Petitions-Comments@dhhs.nc.gov)

**1. Name, address, email address and phone number of petitioner.**

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Novant Health, Inc. (“Novant”) respectfully submits the following petition for adjustment to the *2021 State Medical Facilities Plan* (“SMFP”) regarding proposed new Policy TE-4. This proposed policy, titled *Substitution of Vendor Owned MRI Scanner for Provider Owned MRI Scanner*, is attached as Exhibit A. For the reasons stated in this petition, Novant respectfully submits that proposed Policy TE-4 should not be included in the *2021 SMFP*. There are three main reasons supporting Novant’s position.

First, 2020 is not the year to make significant changes to the policies in the SMFP. North Carolina is still in the midst of the COVID-19 pandemic, and our health care delivery system is still grappling with its effects. As of July 26, 2020, NCDHHS reported 112,713 lab confirmed cases and 1,785 deaths due to COVID-19.<sup>1</sup> While some of the effects of COVID-19 on healthcare delivery are known (*e.g.*, the increase in telehealth, increased costs, concerns over access to PPE, ventilators, ICU beds and job losses), the long term effects of COVID-19 on North Carolina and on healthcare delivery in particular, are unknown. Policy changes, which can last indefinitely, should only be made after appropriate study and consideration of the benefits and possible unintended consequences. As the discussion at the June 10, 2020 State Health Coordinating Council (“SHCC”) meeting revealed, the pandemic has consumed enormous resources, and there simply has not been the opportunity to analyze this proposed policy change carefully to understand its potential long-term consequences on health planning and health care delivery in North Carolina. Simply stated, North Carolina is in the midst of the greatest public health crisis in modern times. Since Policy TE-4 has no connection to helping North Carolina deal with the pandemic, there is no need to act on this policy now.<sup>2</sup>

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<sup>1</sup> <https://covid19.ncdhhs.gov/dashboard/cases>.

<sup>2</sup> The Acute Care Services Committee of the SHCC deferred discussion on proposed amendments to Policy AC-3, which exempts Academic Medical Center Teaching Hospitals from need determinations in the SMFP under certain circumstances.

Second, the SMFP already offers two pathways for facilities to replace contracted MRI service with their own scanners. There is no need to create an exemption from the SMFP need determinations.

Third, Policy TE-4 appears to be a response to concerns that certain customers have about their vendor of MRI services. Neither the SHCC nor the SMFP can regulate vendor/customer relationships. Private party contracts, in which the State has no role, do not serve as a basis for making a significant and long-lasting policy change, especially in the absence of complete review and analysis.

**2. A statement of the requested adjustment, citing the provision or need determination within the Proposed State Medical Facilities Plan for which the adjustment is proposed.**

Novant respectfully requests that proposed Policy TE-4 **not** be included in the *2021 SMFP*. The policy is currently found on page 26 of the *Proposed 2021 SMFP*.

**3. Reasons for the proposed adjustment, including:**

**a. Statement of the adverse effects on the population of the affected area that are likely to ensue if the adjustment is not made, and**

Policy TE-4 originated from two petitions filed in March 2020 by Carolina Neurosurgery & Spine Associates (“CNSA”) in Mecklenburg County and Raleigh Radiology in Wake County (collectively, the “Original Petitioners”). Both Original Petitioners have contracts with third-party vendors for MRI service.<sup>3</sup> While the petitions are somewhat different, their ultimate goal is the same: Original Petitioners seek a non-competitive CON pathway to replace their vendor service with their own MRI service. In other words, they would like to be able to apply for MRI scanners without any need determination in the SMFP. The absence of a need determination means that such CON applications would be “non-competitive,” meaning the approval of their application would not cause the denial of another application received in the same review cycle. See 10A NCAC 14C.0202(f).<sup>4</sup> Other applicants that are not eligible for Policy TE-4 would be required to: (a) wait for a need determination in the SMFP before they could apply; and (b) undergo a competitive CON review, assuming more than one application for an MRI scanner is received in the same review period for the same service area. Clearly, Policy TE-4 confers a competitive advantage on certain providers and a disadvantage on others.

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<sup>3</sup> CNSA already owns a freestanding fixed MRI scanner, Project ID # F-008106-08, in addition to a mobile MRI scanner, Project ID # F-006734-03. On April 28, 2020, Raleigh Radiology Cary was approved for a fixed MRI scanner in a competitive MRI review in Wake County, Project ID # J-011825-19. <https://info.ncdhhs.gov/dhsr/coneed/decisions/2020/april/findings/2019-Wake-MRI-Findings.pdf>.

<sup>4</sup> While non-applicants may appeal decisions approving CON applications in non-competitive CON reviews, the likelihood of a successful appeal is small due to the inability of the non-applicant to demonstrate substantial prejudice to its legal rights under N.C. Gen. Stat. § 150B-23(a). See, e.g., *Parkway Urology, P.A. v. NCDHHS*, 205 N.C. App. 529, 539, 696 S.E.2d 187, 195 (2010), *rev. denied*, 365 N.C. 78, 705 S.E.2d 739 (2011).

Novant, which owns a fleet of mobile MRI scanners that service many third-party sites, and Alliance Healthcare Services (“Alliance”), another vendor of MRI services, filed comments against these petitions. The Agency recommended denial of the petitions.<sup>5</sup> While that should have been the end of the matter, the Agency nevertheless created Policy TE-4. Policy TE-4 is essentially a combination of the two petitions. The Technology and Equipment (“T&E”) Committee of the SHCC took up Policy TE-4 at its April 15, 2020 meeting. There was no substantive discussion about the policy at this meeting. Due to the number of conflicts of interest, several members of the T&E Committee recused themselves from voting. Those members of the T&E Committee who were present and could vote, voted in favor of the policy.

### **1. 2020 is not the year to make significant policy changes.**

Each year, Agency staff and SHCC members spend hundreds of hours developing the need methodologies and need determinations in the annual SMFP. According to the SMFP planning process, a need for an additional fixed MRI scanner in a service area exists only when there is a need determination in the SMFP. Only then may applicants apply for a CON to meet that need. Policy TE-4 is a significant departure that exempts certain providers from this comprehensive planning process.<sup>6</sup> Before implementing a significant policy change that undermines the work of the SHCC, there should at least be discussion about the benefits and unintended consequences of the proposed policy, including its impact on the basic SMFP principles of quality, access and value. If necessary, a discussion group or work group should be formed so that an informed decision can be made, after considering all sides of the issue. Given the COVID-19 pandemic, when resources are stretched thin and attention is understandably diverted to other matters, it is particularly important to exercise caution when making significant policy changes. Policy changes like TE-4, which can have permanent consequences, should not be made hastily and without a full understanding of their effect.

Proposed Policy TE-4 has several problems that warrant further study. First, it may adversely impact future need determinations. As the Agency Report notes, “the possible impact to the state inventory must be considered.” Agency Report, p. 4. *See also* Agency Report, p. 2 (“Adding more fixed and/or MRI units to a service area could reduce the likelihood of need determinations.”). No consideration has been given to the possible impact of Policy TE-4 on the inventory or future need determinations.

Second, Policy TE-4 makes arbitrary distinctions and confers advantages on certain CON applicants depending on whether or not they have a contract with an unrelated MRI vendor. Adoption of Policy TE-4 would essentially create five categories of MRI providers: those who have vendor-provided MRI service from an unrelated person; those who have vendor-provided

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<sup>5</sup> [https://info.ncdhhs.gov/dhsr/mfp/pdf/2020/tec/TEC-Joint\\_MRI\\_Agency\\_Report\\_FINAL.pdf](https://info.ncdhhs.gov/dhsr/mfp/pdf/2020/tec/TEC-Joint_MRI_Agency_Report_FINAL.pdf).

<sup>6</sup> Policy TE-3 creates an exemption for licensed acute care hospitals with 24/7 emergency coverage to apply for fixed MRI scanners if the facility does not currently have an existing or approved fixed MRI scanner. Policy TE-3 primarily benefits rural providers and has been used on only two occasions since its introduction in the SMFP. The circumstances under which Policy TE-3 are used are quite different from the circumstances presented by the Original Petitioners, large medical practices in urban settings that do not offer 24/7 emergency coverage. There is also a plan exemption for intraoperative MRI scanners in Policy TE-2. Policy TE-2 applies in limited circumstances and is not relevant here.

MRI service from a related entity; those who own their own MRI scanners; those who have neither vendor service nor own their own scanners, and vendors themselves. The first category of providers is exempt from the need determinations in the SMFP and can apply under Policy TE-4, provided the applicant meets the requirements of the policy. Unless there is a need determination in the SMFP, the second through fifth categories of providers cannot apply. There is no basis for distinguishing among providers on the basis of whether they have a vendor contract with an unrelated person. For example, assume in County A, there are 3 providers of MRI services: Physician Practice B, which contracts with an unrelated third party for MRI service; Physician Practice C, which contracts which with a related third party for MRI service, using a grandfathered scanner; and Hospital D, which owns its MRI scanner. There is no need determination in County A because the hospital's utilization is too low. B and C's utilization meets the relevant performance standard under Policy TE-4. Only B can use Policy TE-4 because its MRI service is provided by an unrelated third party. C cannot use Policy TE-4 because its MRI service is provided by a related third party. C's related entity would like to relocate the scanner to County E to serve a rural hospital but cannot do so because it would leave C without MRI service. C's arrangement must remain in place until such time as there is a need determination in County A. Two similarly-situated applicants could be treated differently simply because of their vendor of MRI services.

Third, Policy TE-4 allows certain applicants to bypass competitive CON reviews. A competitive CON review can be useful in determining which applicant is the most effective alternative with regard to important factors such as charity care, Medicare and Medicaid access, competition and geographic access. Policy TE-4 would allow certain applicants to skip this process. Simply because Policy TE-4 applicants have vendor-supplied MRI service from an unrelated person is not a sufficient reason to allow them to bypass competitive MRI reviews.

Fourth, 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, simply because an applicant has a contract with an unrelated third party vendor. The policy considers only the performance of the "qualified applicant," not the service area's utilization, as is the case with the current need methodology. Thus, the policy puts the individual applicant's perceived need over the community's need. For example, assume Physician Practice A has MRI service through an unrelated vendor. It applies for an MRI scanner in Year 1 pursuant to a need determination in County B. The review is competitive with several applicants applying for the MRI scanner. Practice A is successful with its application, and the other applications are denied. The disapproved applicants appeal their disapproval and Practice A's approval. In the meantime, Policy TE-4 is published, and Practice A applies in Year 2 through Policy TE-4 to acquire a second scanner, even though there is no need in the SMFP. Practice A is still receiving service from the vendor during the litigation. Practice A is ultimately successful in the litigation arising from the competitive review and keeps its CON approval. If Practice A's TE-4 application is successful, the result is two additional MRI scanners in the Service Area, one through the need determination and the other through Policy TE-4. It also cannot be assumed that under Policy TE-4, the contracted MRI scanner would leave the service area when the

provider owned substitution arrives. The contracted scanner could shift to a different site in the same service area, and therefore duplication between it and the substitution may occur.

Fifth, the Policy contains drafting flaws. Although the title of Policy TE-4 is “Substitution of Vendor Owned MRI Scanner for Provider Owned MRI Scanner,” the policy language itself actually contains **no requirement** that the applicant substitute a vendor owned scanner for a provider owned MRI scanner, when the substitution must occur, what evidence of substitution must be provided or the circumstances under which the applicant has the ability to terminate its vendor contract. The policy also does not contain any definition of “unrelated person.” While the MRI rules at 10A NCAC 14C.2701(16) define “related entity,” it is unknown whether “unrelated person” means the opposite of “related entity.”

Sixth, at least as to the Original Petitioners, proposed Policy TE-4 is superfluous. Proposed Policy TE-4 applies only when “the applicant is unable to apply pursuant to a need determination in the SMFP.” *See Proposed 2021 SMFP*, p. 26. In 2021, there are projected fixed MRI need determinations in both Wake and Mecklenburg Counties, so the Original Petitioners would not be able to use proposed Policy TE-4 in 2021. *See Proposed 2021 SMFP*, Table 17E-3, p. 352. This might actually incentivize the Original Petitioners to wait until sometime in the future to replace their vendor-provided MRI service, when they could apply in a non-competitive review. It is not reasonable to include a policy in the *2021 SMFP* when the Original Petitioners cannot even use it. This also underscores why there is no need to hurry to include this policy in the *2021 SMFP*.

Novant respectfully submits that 2020 is not the year to make major changes to North Carolina’s health planning process, especially when those changes have no connection to addressing the pandemic. As the above discussion illustrates, there are simply too many unanswered questions for this policy to be included in the *2021 SMFP*.

The Acute Care Services (“ACS”) Committee of the SHCC paused consideration of proposed changes to Policy AC-3, which exempts academic medical teaching hospitals from the need determinations in the SMFP under certain conditions. Due to the impact of COVID-19 in North Carolina and the resulting inability to give focused attention to the implications of this policy change, the ACS Committee decided to pause discussions on changes to Policy AC-3. Novant respectfully submits that the same process should be followed here.

The discussion at the end of the June 10, 2020 SHCC meeting underscores the importance of not hurrying to make significant changes. SHCC members candidly described the challenges that they, the organizations they work for and the constituents they serve are facing due to the pandemic. These challenges cover a range of pressing issues such as health equity, economic hardships, concerns about sufficient supplies of PPE, and the separation of families and loved ones. Clearly, there is no immediate need to exempt from the organized health planning process certain providers desiring to purchase MRI scanners.

Nor is there any legitimate concern that North Carolinians will have less access to MRI services if proposed Policy TE-4 is not approved. According to the *2020 SMFP*, there are 242 fixed MRI

scanners in North Carolina, and 50 mobile scanners operated by 24 providers. *See 2020 SMFP*, p. 439. The *Proposed 2021 SMFP* reports 246 fixed MRI scanners. *See Proposed 2021 SMFP*, p. 350. The *2020 SMFP* contains need determinations for five (5) additional fixed scanners, and the *Proposed 2021 SMFP* contains a need for seven (7) additional fixed MRI scanners. *See 2020 SMFP*, p. 441; *Proposed 2021 SMFP*, p. 352. Raleigh Radiology, one of the Original Petitioners, was approved for a fixed scanner in the competitive 2019 Wake County MRI review<sup>7</sup>, and CNSA has the opportunity to apply for a fixed scanner in the upcoming 2020 Mecklenburg County MRI Review. *See 2020 SMFP*, Table 17E-3, p. 441. The *Proposed 2021 SMFP* contains fixed MRI need determinations for both Mecklenburg County and Wake County, where the Original Petitioners are located. The Original Petitioners could apply for scanners pursuant to these need determinations. *See Proposed 2021 SMFP*, Table 17E-3, p. 352.

**Table 17E-3: Fixed MRI Scanner Need Determination\***  
*(Proposed for Certificate of Need Review Commencing in 2021)*

Services Area	Fixed MRI Scanners Need Determination**	Certificate of Need Application Deadline***	Certificate of Need Beginning Review Date
Buncombe/Graham/Madison/Yancey	1	To be determined	To be determined
Mecklenburg	1	To be determined	To be determined
New Hanover	1	To be determined	To be determined
Orange	1	To be determined	To be determined
Pasquotank/Camden/Currituck/Perquimans	1	To be determined	To be determined
Stanly	1	To be determined	To be determined
Wake	1	To be determined	To be determined
It is determined that there is no need anywhere else in the state and no other reviews are scheduled.			

Source: *Proposed 2021 SMFP*, p. 352.

The Original Petitioners could also petition for special need determinations. There is no need for an exemption from the need determinations in the SMFP.

All health care providers would like to reduce their vendor expenses. While saving money is important, achieving that goal cannot come at the expense of other health planning principles, like safety and quality, access and value. A policy such as Policy TE-4, which benefits only certain providers, and therefore only the patients served by those providers, may only lead to the unnecessary duplication of services, overutilization of MRI services and increased costs for patients. While avoiding a competitive CON review may be beneficial for the provider applying in the non-competitive review, competitive reviews can help the public because they will indicate who among the competing providers is superior with respect to important metrics like access for medically underserved populations, costs, and geographic access. These are all important considerations that have not been examined with respect to proposed Policy TE-4.

<sup>7</sup> <https://info.ncdhhs.gov/dhsr/coneed/decisions/2020/april/findings/2019-Wake-MRI-Findings.pdf>.

In short, the SHCC has been asked to make an important and long-lasting health planning decision without the benefit of complete analysis and discussion. Novant respectfully requests that the SHCC take its time and defer a decision on proposed Policy TE-4 until it can be evaluated without the diversions created by the pandemic. Making important health planning decisions based on incomplete information adversely affects the interests of North Carolina residents by undermining the careful work of the SHCC in developing the need methodologies and need determinations.

## **2. The SMFP already offers two pathways for facilities to replace contracted MRI services.**

An SMFP policy should only be implemented or changed when there is an actual health planning problem to solve, such as problems related to the SMFP basic principles of quality, access and value. Proposed Policy TE-4 solves no such problems; rather, it appears to be a solution in search of a problem. The SMFP already offers two mechanisms for the Original Petitioners and others who are similarly situated to solve their perceived problems. First, the SMFP enables contracted parties who offer full-time MRI service from a vendor to file a petition *for a need determination* to replace their contracted service with owned service. *See, e.g., 2020 SMFP*, p. 419, ¶ 8; *Proposed 2021 SMFP*, p. 331, ¶ 8. Even contracted parties that do not offer full-time service from a vendor can always petition the SMFP for a need determination in a summer petition. Parties who wish to acquire their own mobile scanners may also petition the SHCC for a need determination for mobile MRI in a summer petition. These mechanisms allow contracted providers the opportunity to seek their own scanners while still remaining faithful to the established health planning process; no exemption from the SMFP is needed.

Second, even without filing a petition, contracted providers can always apply for a CON when there is a need determination in the SMFP. Raleigh Radiology, one of the Original Petitioners, was approved on April 28, 2020 in a *competitive* Wake County MRI Review, for its Raleigh Radiology Cary proposal, Project ID # J-011825-19. As discussed above, the Original Petitioners will also have opportunities to apply in 2021 based on the need determinations in the *Proposed 2021 SMFP*. As shown in Table 17E-3 above, the proposed need determinations in the *Proposed 2021 SMFP* cover a broad geography in North Carolina, including urban and rural settings. Notably, there are proposed need determinations in both Mecklenburg and Wake Counties, where the Original Petitioners are located.

Since the SMFP already provides pathways to achieve the Original Petitioners' goals, there is no need to create an exemption.

## **3. Neither the SHCC nor the SMFP regulates vendor-customer relationships.**

Both Original Petitioners express concern about their current MRI services agreements. Recognizing that the “Agency does not have any influence on service agreements between providers and vendors,” *see* Agency Report, p. 4, proposed Policy TE-4 nevertheless wields enormous influence on service agreements by tacitly encouraging customers to end their service agreements. Policy TE-4 therefore puts the SHCC and the SMFP squarely in the middle of

relationships that they have no jurisdiction to regulate. Private party contractual concerns are not a health planning reason to make a major change in the SMFP.

**b. A statement of alternatives to the proposed adjustment that were considered and found not feasible.**

Novant considered as an alternative that Policy TE-4 should simply be adopted. For the reasons stated above, this was not deemed feasible.

**4. Evidence that health service development permitted by the proposed adjustment would not result in unnecessary duplication of health resources in the area.**

By circumventing the need determinations in the SMFP, proposed Policy TE-4 promotes unnecessary duplication of health resources. This Petition, which seeks to eliminate Policy TE-4, helps to reduce the likelihood of unnecessary duplication of services.

**5. Evidence that the requested adjustment is consistent with the three Basic Principles governing the development of the North Carolina State Medical Facilities Plan: safety and quality, access and value.**

This Petition was filed in order to support the three Basic Principles: safety and quality, access and value. By advocating that the SHCC not make a significant and long-lasting change during a time of tremendous upheaval and uncertainty, Novant's objective is to ensure that the SMFP is developed with the interests of all North Carolinians in mind. As earlier discussed, MRI resources are plentiful in North Carolina and more resources are projected to come on line, based on the need determinations in the SMFP. Not having Policy TE-4 in the *2021 SMFP* will not harm safety and quality, access and value. Policy TE-4, by contrast, allows certain applicants to file applications without any determination of need simply because they have a vendor contract with an unrelated person. This is not a sufficient reason to exempt these providers from North Carolina's health planning process.

Novant appreciates the SHCC's consideration of this Petition.



## EXHIBIT A

### **Policy TE-4: Substitution of Vendor Owned MRI Scanner for Provider Owned MRI Scanner**

A qualified applicant is a provider who has an executed service contract with an unrelated person for magnetic resonance imaging (MRI) scanner services and is unable to apply pursuant to a need determination.

The qualified applicant applying for a certificate of need for a fixed MRI scanner pursuant to this policy shall demonstrate all the following in the CON application:

1. The contracted MRI scanner remains at the existing host site and is not moved to other host sites.
2. The contracted MRI scanner currently is or should be treated as a fixed MRI Scanner in the current SMFP.
3. As reported in the most recent Registration and Inventory form or License Renewal Application (either the one submitted during the same year the CON application is submitted or the form submitted the previous year), the contracted MRI scanner performed at least:
  - a. 4,805 weighted procedures if there are four or more fixed MRI scanners in the service area;
  - b. 4,462 weighted procedures if there are three fixed MRI scanners in the service area;
  - c. 4,118 weighted procedures if there are two fixed MRI scanners in the service area;
  - d. 3,775 weighted procedures if there is one fixed MRI scanner in the service area; or
  - e. 1,716 weighted procedures if there are no fixed MRI scanners in the service area.
4. Projected utilization is consistent with the performance standards promulgated in 10A NCAC 14C .2703 and is based on reasonable and adequately supported assumptions.

The qualified applicant applying for a certificate of need for a mobile MRI scanner pursuant to this policy shall demonstrate all the following in the CON application:

1. As reported in the most recent Registration and Inventory form or License Renewal Application (either the one submitted during the same year the CON application is submitted or the form submitted the previous year), the applicant:
  - a. contracts for mobile MRI services using a mobile MRI scanner owned by an unrelated person.
  - b. performed at least 3,328 weighted MRI procedures combined for all service sites owned and operated by the applicant or a related entity and located in the proposed service area.
2. The proposed mobile MRI scanner will provide services at two or more sites each week and one of those sites must be an existing site where the applicant currently offers mobile MRI services using a mobile MRI owned by an unrelated person.
3. Projected utilization is consistent with the performance standards promulgated in 10A NCAC 14C .2703 and is based on reasonable and adequately supported assumptions.