

**COMMENTS BY NOVANT HEALTH, INC.  
TO PETITION FILED BY RALEIGH RADIOLOGY, LLC TO  
MODIFY POLICY TE-3 IN THE  
2021 STATE MEDICAL FACILITIES PLAN  
MARCH 18, 2020**

**1. NAME, ADDRESS, EMAIL ADDRESS AND PHONE NUMBER OF COMMENTER:**

Novant Health, Inc.  
Andrea M. Gymer  
Vice President, Operational Planning and Innovation  
2085 Frontis Plaza Boulevard  
Winston-Salem, North Carolina 27103  
[amgymer@novanthealth.org](mailto:amgymer@novanthealth.org)  
(336) 277-1523

**2. COMMENTS ON PROPOSED MODIFICATION TO POLICY TE-3**

On March 4, 2020, Raleigh Radiology, LLC (“Raleigh Radiology”) submitted a petition seeking to modify Policy TE-3 to allow “freestanding health service facilities” to add fixed MRI capacity without a need determination in the State Medical Facilities Plan (“SMFP”). After careful analysis of Raleigh Radiology’s proposal, Novant Health, Inc. (“Novant”) respectfully offers the following comments for the State Health Coordinating Council’s (“SHCC”) review and consideration.

**A. The Petition Should be Denied.**

Novant operates multiple fixed MRI scanners at its hospitals and freestanding imaging centers throughout North Carolina. Novant also operates a fleet of mobile MRI scanners serving host sites throughout North Carolina. Novant is committed to providing high-quality, convenient, cost-effective MRI services using the latest technology in a variety of settings (inpatient, outpatient and mobile service) to meet the needs of patients.

Policy TE-3 was added to the 2017 SMFP to allow hospitals that do not already have fixed MRI capacity to add MRI capacity without a need determination in the SMFP. Such hospitals are required to file a Certificate of Need (“CON”) application demonstrating that they will perform at least 850 weighted MRI scans during the third full operating year. Policy TE-3 was primarily intended to allow smaller community hospitals to bring essential technology to their patients, without having to meet a challenging performance standard. Current Policy TE-3’s scope is carefully tailored to meet a particular purpose. It strikes the right balance between making sure that technology is widely available throughout North Carolina while guarding against unnecessary duplication. Unnecessary duplication can lead to overutilization which drives up

cost. Some providers do not need full-time fixed MRI services, and for them, mobile MRI services may be an appropriate option. Since its adoption, three hospitals have received CONs pursuant to Policy TE-3. Two of these hospitals are in Hoke County and one of them is in Davie County.

Raleigh Radiology seeks to expand Policy TE-3 well beyond its original principles by allowing “freestanding health service facilities” to add fixed MRI capacity without a need in the SMFP, provided certain conditions are met. Raleigh Radiology defines “freestanding” as not hospital based for purposes of CMS payment. *See* Petition, page 3. “Health service facility” encompasses a vast array of facilities ranging from diagnostic centers to home health agency offices to ambulatory surgery centers. *See* Petition, page 3. According to Raleigh Radiology, to qualify for special treatment under expanded Policy TE-3, the applicant must meet various conditions such as already offering MRI service in a fixed location via a service agreement with a third party for at least three years. Unlike current Policy TE-3, under expanded Policy TE-3, the freestanding applicant must meet the performance standards at 10A NCAC 14C.2703. *See* Petition, page 3.

Raleigh Radiology’s petition fails to explain why a special exception needs to be made for freestanding centers. In fact, Raleigh Radiology itself has two MRI CON applications currently under review pursuant to the need determination in the 2019 SMFP for Wake County. The first application is for Raleigh Radiology Cary, Project I.D. No. J-11825-19. The second application is for Raleigh Radiology Knightdale, Project I.D. No. J-11826-19. Decisions on these applications are expected in the Spring of 2020. Clearly, Raleigh Radiology is able to participate in the health planning process as it currently exists. It appears, however, that Raleigh Radiology is hedging its bets by filing the Petition, so in case neither of its applications succeeds in the 2019 review, it has a backup plan. *See* discussion on page 7 of the Petition describing competitive CON reviews. Changes to SMFP policies should only be made where there is a genuine health planning need to do so, *i.e.*, to bring needed services to the people of North Carolina, not to create revenue opportunities for particular providers or to help certain providers avoid competitive CON reviews. The current “facts on the ground” strongly suggest that the current Wake County MRI Review should be decided *before* the SHCC considers an amendment to Policy TE-3. Even if Raleigh Radiology is not successful in the current Wake County review, elects not to appeal, *and* there is no MRI need organically generated for Wake County in the 2021 SMFP, Raleigh Radiology always has the opportunity file a special need petition for Wake County. Such a petition would be filed in July 2020. Raleigh Radiology and all other freestanding centers have the ability to utilize the special need petition process, which exemplifies the lack of necessity for this special exemption under Policy TE-3.

On page 3 of its Petition, Raleigh Radiology provides a chart of facilities that could potentially qualify for expanded Policy TE-3. Two of these facilities are Raleigh Radiology sites, and one of them, Raleigh Radiology Cary, has a pending CON application. Raleigh Radiology’s chart indicates that some of the facilities on this chart “almost” qualify for expanded Policy TE-3. “Almost” refers to whether the facilities meet the service area threshold as defined in the table of MRI fixed and mobile procedures by service area in the current SMFP. Since Raleigh Radiology’s expanded Policy TE-3 makes the service area threshold a condition for special treatment, these “almost” qualifying facilities would not benefit from the expanded policy



anyway. Raleigh Radiology indicates that “updated data filed during 2020 could increase the number of qualifying health service facilities by 2021,” *see* Petition, page 3, but there is no way to know that. Two of these “almost” facilities are owned by Wake Radiology, and Wake Radiology does have its own CON application for its Cary location under review in the pending Wake County review, Project I.D. No. J-11830-19. The other “almost” facilities are in Iredell County and Pitt County. Again, these facilities would not benefit from expanded Policy TE-3 based on present information. But if their data does improve, as Raleigh Radiology suggests it might, then a need may be generated organically, or these providers may submit special need petitions for their respective counties for the 2021 or subsequent SMFP.

Of the “yes” facilities on the chart, one of them is in Guilford County, and there is a need for a fixed MRI scanner in the 2020 SMFP for Guilford County. There is no reason why the facility could not apply in the 2020 Guilford County review. *See* 2020 SMFP, page 441. The other “yes” facilities are located in counties that do not show a need in the 2020 SMFP. The draft 2021 SMFP should be available by June 2020, and if these counties do not show a need in the draft SMFP, the facilities may petition the SHCC in July 2020 for special need determinations in these counties. Thus, there are other avenues for such facilities to petition without requiring the SHCC to make a massive change to the SMFP which could subvert the health planning process.

Much of the Petition is devoted to criticizing MRI service agreements. *See, e.g.*, Petition, pages 5 and 6. Novant can only speak to its own agreements, which are intended to provide high-quality, efficient and cost-effective MRI access to facilities that desire the service. Novant has invested substantially in acquiring state of the art equipment and hiring and training highly qualified staff. For some facilities, owning a fixed MRI is simply not a cost-effective option, as they lack the capital, the expertise and perhaps the patient volume to make full-time fixed MRI service a reasonable option. This is why service by vendors such as Novant plays such a vital role in the delivery of healthcare in North Carolina.<sup>1</sup>

The Petition touts the benefits of freestanding centers and states that “unfair treatment of freestanding facilities disadvantages patients.” Petition, p. 6. Raleigh Radiology’s suggestion that hospitals have an unfair advantage is completely untrue. In fact, in the competitive 2019 Mecklenburg County MRI review, a freestanding facility, Atrium Health Kenilworth, was chosen over the hospital applicant, Novant Health Matthews Medical Center. *See* <https://info.ncdhhs.gov/dhsr/coneed/decisions/2020/january/findings/Mecklenburg%20%20MRI%20Review%20Findings.pdf>. Hospitals have no unfair advantage, and as Raleigh Radiology’s own participation in the pending Wake County review demonstrates, freestanding facilities are perfectly capable of participating in and prevailing in competitive CON reviews. There is no need to create a broad exception in the SMFP for freestanding facilities.<sup>2</sup>

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<sup>1</sup> Alliance Healthcare Services (“Alliance”) is the current MRI provider at Raleigh Radiology Cary. In the pending Wake County review, Alliance filed comments opposing Raleigh Radiology’s criticisms of vendor-provided MRI service. *See* <https://info.ncdhhs.gov/dhsr/coneed/comments/2019/201912/Alliance-Healthcare-Services-Inc-Project-ID-J-11825-19.pdf>.

<sup>2</sup> Raleigh Radiology’s analogy to Policy TE-2, intraoperative MRI (iMRI) scanners, is not persuasive. An iMRI has a limited application and is not something Raleigh Radiology could offer.



In fact, Raleigh Radiology's Petition leads to an unfair result in that freestanding providers *who can meet a performance standard* would be able to add MRI capacity as they wish. They would need to file a CON application, but they would not need to wait for a need determination, nor would they undergo a competitive review. Thus, freestanding sites have much greater flexibility to add capacity. Hospitals on the other hand, would be treated differently. Except in situations where they do not already own a fixed MRI scanner and can use Policy TE-3 in its original version, they would have to wait for a need determination in the SMFP and go through what would likely be a competitive CON review. There is no reason why freestanding providers *who can meet a performance standard* should be exempted from the need determination.

On page 7 of the Petition, Raleigh Radiology suggests that there has not been "enough" need in the SMFP because "the current need methodology now generates a need for one or fewer MRI units per service area per year...." This argument misses the point. The basic principle of health planning in North Carolina is embodied Policy GEN-3, which promotes safety and quality, equitable access and maximizing healthcare value. The point of health planning is not to ensure that everyone who wants a fixed MRI has one. There is no reason to make significant changes to the health planning process based on an unsubstantiated claim that "service areas with more than one fixed MRI operating under third-party service agreements will be at higher risk of losing MRI services as the agreements become more expensive."

Raleigh Radiology's argument that "qualified freestanding MRI health service facilities must compete with one another and with new entrants for the single fixed MRI need determination in the annual SMFP" is also unavailing. *See* Petition, page 7. Raleigh Radiology and other freestanding providers should not fear competition. If they prepare compelling applications based on reasonable and supported assumptions, they have as much chance of success as any other applicant. As the recent Mecklenburg MRI review shows, they do not need an exemption or any special treatment.

## **B. The Petition Leads to Unintended Consequences**

Most of North Carolina's hospitals are not-for-profit institutions who must treat all patients regardless of their ability to pay. Raleigh Radiology's Petition states that freestanding providers would be required to maintain service to Medicare, Medicaid and other underserved populations. *See* Petition, page 1. This is a very vague standard that does nothing to protect medically-underserved populations. If a freestanding provider is offering little to no service to medically underserved populations now, it would only be required to maintain the little to no service it currently offers. A competitive CON review, which is what Raleigh Radiology seeks to avoid, can be a useful tool to measure the levels of care that applicants will offer to medically underserved populations.

Another problem created by Raleigh Radiology's Petition is that it has no limitations in terms of the number of times it could be used. Provided the freestanding applicant meets the requirements, it could continually add MRI capacity without a need determination, thus promoting overutilization and increased costs. This would be a particular issue with freestanding providers like Raleigh Radiology that operate multiple sites. By contrast, Policy TE-3 in its

current form is limited in nature; a hospital can use it only once. Although Raleigh Radiology posits that MRIs at freestanding centers are less expensive than at hospital based sites, *see* Petition, page 4, scans at freestanding centers are not free. By allowing freestanding providers to freely add capacity, the SMFP would be encouraging overutilization which drives up costs. Further, costs to patients under the expanded Policy TE-3 are only prohibited from increasing for twelve months. Thereafter, providers would have the ability to pass along costs to patients without limitation.

### **Conclusion**

Raleigh Radiology's Petition is the type of exception that swallows the rule. It leads to unintended consequences, is unnecessary and places hospitals at an unfair disadvantage. For the above-stated reasons, Novant respectfully requests that the SHCC deny Raleigh Radiology's Petition.