

**COMMENTS OPPOSING
RALEIGH RADIOLOGY’S PETITION FOR SPECIAL NEED FOR
FIXED MAGNETIC RESONANCE IMAGING EQUIPMENT IN WAKE COUNTY**

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1. Commenter Contact.

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2. Introduction.

On July 24, 2019, Raleigh Radiology (Raleigh Radiology or the “Petitioner”) submitted its “Petition to the State Health Coordinating Council Regarding Special Need for Fixed Magnetic Resonance Equipment for Wake County 2020 State Medical Facilities Plan” (the “Petition”). Wake Radiology Diagnostic Imaging, Inc. (“WRDI”) and WR Imaging, LLC (“WRI”) hereby submit the following comments opposing the Petition. For the reasons set forth below, Petitioner has failed to demonstrate that a special need exists requiring an adjusted need determination, or that granting the Petition would mitigate an adverse effect on the population of Wake County. WRDI and WRI encourage the State Health Coordinating Council (“SHCC”) to deny the Petition.

3. Comments.

A. Petition Does Not Meet the Minimum Requirements for Petitions Seeking an Adjusted Need Determination.

The State Medical Facilities Plan (“SMFP”) sets forth the minimum requirements for requesting an adjustment to a need determination. These include: (i) the reasons for the proposed adjustment, including a statement of the adverse effects on the population of the service area if the adjustment is not made and a statement of the alternatives that were considered and found infeasible; (ii) evidence that the adjustment would not result in unnecessary duplication of services; and (iii) evidence that the adjustment is consistent with the three Basic Principles governing the SMFP. The Petition fails to meet these requirements.

- i. *Petition Fails to Demonstrate Adverse Effects on Wake County Residents if the Adjustment is not made.*

Petitioner asserts that Wake County residents have reduced access to MRI services compared with Durham, Forsyth, Guilford, and Mecklenburg Counties, making Wake County residents uniquely dependent on mobile MRI scanners relative to these other large population centers. The Petitioner’s assertion is misleading for several reasons. First, the 2016 and 2019 SMFP each identified the need for an additional fixed MRI scanner in Wake County, but neither of these scanners is currently in service. The Petitioner unsuccessfully applied for a Certificate of Need (“CON”) to operate the 2016 scanner and, failing to secure the CON, appealed the decision. Although the Petitioner’s challenge was ultimately unsuccessful, as result of the litigation the 2016 scanner is not yet in service. Applications for the Wake County MRI Scanner need determination identified in the 2019 SMFP are due on November 15, 2019. Given that the SHCC has identified the need for two additional MRI scanners in Wake County using the statewide policies and methodology and that neither scanner is in service, Petitioner’s claim that Wake County residents are underserved with regard to MRI services is both premature and misleading.

Rather than compare the number of fixed equivalent magnets per capita in these population centers, as the Petitioner does, a better way of determining whether Wake County residents are relatively underserved would be to compare the average number of procedures per fixed equivalent scanner. This approach takes into account both the number of scanners available as well as the demand for MRI services in the service area. Table 1, below, summarizes the relevant data from Table 17E-1 of the 2020 Proposed SMFP. These data show that, when the 2016 and 2019 scanners are considered, Wake County procedure volume by scanner is less than Mecklenburg and Durham Counties and is on par with Forsyth and Guilford Counties.

TABLE 1

COUNTY	AVERAGE PROCEDURE VOLUME PER FIXED EQUIVALENT SCANNER	AVERAGE VOLUME AS A MULTIPLE OF WAKE
Durham	4,916	1.06
Forsyth	4,635	1.00
Guilford	4,596	0.99
Mecklenburg	5,142	1.11
Wake	4,626	1.00

Similarly, given that Mecklenburg and Wake Counties have a nearly identical number of fixed equivalent scanners comprised of mobile units, it is misleading to argue that Wake County residents are uniquely dependent on mobile MRI vendors.

The Petitioner asserts that, to many patients and payers, Raleigh Radiology is the low-cost provider of choice, that it serves as a safety net provider for the area’s uninsured and underinsured patients, and that its reliance on Alliance-owned scanners undermines its ability to provide maximum value and quality to Wake County patients and providers. In oral comments delivered by Petitioner’s Chief Operating Officer, Petitioner sought to bolster this argument by stating that “NC Medicare reimburses \$216.98 global for MRI of the head. Our Alliance cost per hour is higher.” However, the Petitioner provided no actual data regarding its profit margins for any study and failed to provide its reimbursement for

other payors or services to support its contention that it is “offering low out of pocket cost to Wake County residents in a model that is not sustainable.” In addition, according to the 2019 SMFP, Petitioner performs only 30.1% of its total MRI scans (31.0% of the adjusted total) using scanners owned by Alliance. By comparison, it conducts 59% of its total MRI scans (57.9% of the adjusted total) using scanners owned by Pinnacle Health Services of North Carolina, LLC (“Pinnacle”). Petitioner does not address whether or how its arrangements with Pinnacle are similarly unsustainable.

Petitioner’s assertion that Raleigh Radiology serves as a safety net provider is inappropriate. Similar to its peers in the Wake County service area, the Petitioner undoubtedly serves some patients without insurance or the ability to pay insurance cost-sharing payments (co-pays and deductibles). Petitioner is not, however, a safety net provider. Among other factors, the Institute of Medicine defines safety net providers as those with a legal mandate to offer services regardless of an individual’s ability to pay (*e.g.*, emergency departments) and whose patient population includes a substantial share of uninsured, Medicaid, and other vulnerable patients. The Petitioner is a for-profit entity, and nothing in the Petition demonstrates that it is a safety net provider or that the numerous MRI scanners owned by nonprofit entities in Wake County are insufficient to serve those unable to pay for the service. Petitioner offers no evidence that patients requiring MRI services are not receiving MRI services, nor has the Petitioner demonstrated that a special need determination favoring the Petitioner would improve the health and wellbeing of any particular demographic.

The Petitioner asserts that there is special need in Wake County for an additional fixed MRI scanner. Even assuming, for the sake of argument, that a special need does exist and will not be met by the 2016 and 2019 MRI need determinations, Petitioner requests that the SHCC restrict applicants for the additional scanner to freestanding imaging centers that do not currently own an MRI scanner. While it is clear that these restrictions would benefit the Petitioner, however, the Petition does not address how such a limitation would benefit Wake County residents. Instead, Raleigh Radiology is effectively asking the SHCC for special treatment because it fears that it will not be able to effectively compete under the current methodology by applying for the Wake County MRI scanner identified in the 2019 SMFP. While situations warranting adjustments to the need determination arise from time to time, the Petitioner’s request is tailored for the benefit of Petitioner, rather than the residents of Wake County. Granting the Petitioner an end-run around the established need methodology undermine the primary objective of the SMFP, which is “to provide individuals, institutions, state and local government agencies, and community leadership with policies and projections of need to guide local planning for specific health care facilities and services.”

ii. *Petition Fails to Consider Reasonable Alternatives to a Special Need Adjustment.*

The Petitioner states that it considered, and rejected as infeasible, the following alternatives to a special need adjustment: maintain the status quo; risk an application for the Wake County MRI Need in the 2019 SMFP; ask for a larger need determination; cancel

or reduce the Alliance contract (not actually addressed by the Petitioner); and wait for a change in the SMFP MRI methodology. In rejecting the status quo, the Petitioner states that its forced reliance on Alliance means that it is unable to control its MRI service line and is subject to issues related to staffing, the timing of scanner maintenance and replacement, image quality, and increased costs. As is demonstrated above, however, Raleigh Radiology performs less than a third of its overall volume on scanners owned by Alliance. In addition, the Petitioner provides no evidence to support its contention that staffing concerns have caused significant problems for the Petitioner or its patients, that ongoing maintenance issues are resulting in consistently reduced image quality, or that Alliance's CPI adjustments are detrimental to residents of Wake County. While the Petitioner referred to the inconvenience caused when one of its MRI scanners failed on two occasions in June, which required temporary use of a mobile unit while the fixed unit underwent repairs, all providers must deal with the inconvenience of "stop action" events when an existing scanner requires repairs. These issues are not unique to Raleigh Radiology and would not be solved by the Petitioner's request for a special need adjustment.

The Petitioner discards the option of applying for the Wake County need identified in the 2019 SMFP, stating that "counting on this alternative in a competitive environment would not be prudent. It would not guarantee award to an existing provider seeking replacement of an MRI. [or] assure focus on Raleigh Radiology's particular dilemma." In other words, the Petitioner recognizes that its arguments related to its own profit margins are not competitive when reviewed in comparison to other providers in Wake County. This statement reveals an underlying motivation for the Petition that also explains why the Petitioner is not willing to wait for a change in the SMFP MRI methodology: Raleigh Radiology seeks special dispensation to circumvent the statewide methodology rather than compete under the rules applicable to every other provider in the service area. It is also possible that the Petitioner anticipates that its Petition will function as self-serving "evidence" that its November, 2019 application should be approved and that the Petition will engender comments from other interested parties stating that it should apply for the 2019 need, and that it intends to use these comments to support its 2019 application. In short, the Petition is narrowly tailored to serve the objectives of the Petitioner and not the needs of Wake County residents.

iii. *Petition Provides No Evidence of Non-Duplication of Services.*

The Petition states that a special need adjustment in Wake County would result in no duplication of services, because Wake County is underserved. For the reasons set forth above, however, the Petitioner's claim that Wake County is underserved with regard to MRI services is misleading when considering the scanners that will be brought into service based on the need identified in the 2016 and 2019 SMFPs. This is the very reason for a need methodology – and one that has been refined over many years – to exist in the first place. When the 2016 and 2019 scanners are factored in, the average procedure volume per fixed-equivalent scanner in Wake County is 10% less than average volume per scanner

in Mecklenburg County, 5.7% less than average volume per scanner in Durham County, and is on par with Forsyth and Guilford Counties.

iv. *Petition is not Consistent with the State Medical Facilities Plan Basic Principles of Safety and Quality and Access.*

The Petitioner states that “providing an option for an established, ACR accredited provider to reduce the MRI deficit in Wake County would meet the safety and quality principle.” However, under the MRI need methodology as applied in the 2020 Proposed SMFP, there is no present MRI deficit in Wake County. In addition, Raleigh Radiology does not demonstrate how its Petition, intended to give the practice a competitive advantage relative to other service providers in the area, would improve the quality or safety of patient care. With regard to the principle of access, the Petitioner asserts that “proposed restrictions would assure that a (*sic*) historically underserved group -- outpatients with high deductibles and copay insurance -- has affordable MRI access.” As is discussed above, however, Raleigh Radiology is a for profit entity and does not function as a safety net provider in Wake County and the Petition does not provide any support for the claim that insured patients with high cost-sharing obligations are an historically underserved group.

B. Other Comments and Conclusions.

Petitioner cites two precedents for its request. First, the methodology for cardiac catheterization mobile units, which allows applicants to apply to replace a mobile unit with a shared fixed unit if the existing service demonstrates a history of 16% or more of the capacity of a fixed unit. In addition, Policy TE-3 enables hospitals with an emergency department but no MRI scanner to apply for a single fixed MRI even if no determination of need has been made under the statewide methodology. However, both of these examples are distinguishable from Raleigh Radiology’s Petition. First, both are intended to address situations in which patients require immediate access to the service, on an emergency basis, for a potentially life-saving intervention. A freestanding MRI located in an outpatient imaging center is not generally used for an immediate life-saving intervention. In addition, it is logical for hospitals to have at least one (1) MRI scanner because, unlike Raleigh Radiology, hospitals can serve as safety net providers that not only provide emergency services but also play a key role in providing medical services to the uninsured in their communities. Policy TE-3 is intended to make sure that these actual safety net providers have at least one (1) MRI scanner.

In conclusion, Raleigh Radiology provides no evidence that the statewide methodology for determining MRI need is insufficient to adequately serve the people of Wake County at the present time. Although its Petition is clearly intended to confer a competitive advantage to Raleigh Radiology, it does not meet the minimum requirements for petitions for an adjusted need determination and provides no evidence that granting the request would mitigate an actual adverse effect on the population of Wake County. For the foregoing reasons, WRDI and WRI encourage the SHCC to deny the Petition.