Comment on Raleigh Radiology's Petition for One Additional Fixed MRI Scanner in the 2020 State Medical Facilities Plan

COMMENTER

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INTRODUCTION

UNC REX Hospital ("UNC REX") opposes the petition filed by Raleigh Radiology for one additional fixed MRI scanner in the 2020 State Medical Facilities Plan (SMFP). UNC REX appreciates the process for requesting adjusted need determinations; however, it believes that it should be reserved for truly unique situations that cannot otherwise be resolved through the standard methodology. As demonstrated in these comments, UNC REX believes the Raleigh Radiology petition falls short of demonstrating the merits of an adjusted need, and the State Health Coordinating Council ("SHCC") should deny the petition.

FLAWED ANALYSIS AND CONCLUSIONS

UNC REX believes that the petition presents several analyses that are flawed, resulting in incorrect conclusions drawn from those analyses. These issues are discussed below.

1. Wake County MRI Access

Raleigh Radiology's petition provides data that, on the surface, make it appear that Wake County has less access to MRI services than other comparable counties in the state. UNC REX agrees that Wake County is one of the largest, fastest growing counties in the state, which will likely continue to drive the need for expanding healthcare services. However, the simple analysis performed by Raleigh Radiology fails to encompass several mitigating facts which indicate that the standard methodology is appropriately addressing the current need in Wake County for MRI services.

First, while the petition decries the existence of so many mobile sites in the county, given the size of Wake County, in terms of both population and geography¹, it benefits from so many different freestanding fixed/mobile sites compared with other counties. For example, as shown in the table provided in Attachment B to the petition, Wake County has more than 50 freestanding fixed/mobile MRI sites, while Mecklenburg has only 35, and the other counties have even fewer. The number of sites benefits a county with such a large geography, as patients generally have to travel shorter distances for care. So while some high volume mobile sites may be better served

According to https://www.indexmundi.com/facts/united-states/quick-facts/north-carolina/land-area#chart, Wake County is 7th in size in the state, while Mecklenburg is 38th.

with fixed scanners, the presence of such a large number of sites in the county does not indicate an overall access problem.

Second, the ratio of MRI scanners to population of the county in which they are located is not the most effective health planning tool, nor does it allow for valid comparisons among counties. In particular, several of the counties listed in the petition's analysis, including Mecklenburg, Forsyth and Durham, include one of the state's academic medical center teaching hospitals, which by their nature serve patients from a broad geography and therefore may require more healthcare service capacity than is needed by the population of the county in which they are located. In other words, the MRI scanners in those counties are predominately serving patients from outside the county. For example, nine (9) of Durham County's general fixed MRI scanners are located at Duke University Hospital ("Duke"), the most of any single site in the state; however, only one-fourth of Duke's MRI capacity is used for Durham County residents. According to Duke's 2019 Hospital License Renewal Application, Durham County residents accounted for 6,868 of 26,416 total MRI patients, or 25.9 percent. Similar observations can be made for other academic medical centers across the state, including Wake Forest Baptist Medical Center in Forsyth County and Vidant Medical Center in Pitt County. In contrast, even as tertiary providers, nearly three-fourths of UNC REX's and two-thirds of WakeMed's MRI patients are from Wake County.

Wake County residents also have access to two academic medical centers in close proximity to their home county in Orange and Durham counties, and some choose to leave their home county for medical care at those facilities, which may include an MRI scan as part of their care. Indeed, over 14 percent of MRI scans performed at Duke University Hospital were performed on Wake County residents. Given the travel required from Wake County to Duke and the general complexities of navigating a large medical center campus, clearly patients from Wake County are not choosing Duke for an MRI because of a lack of access close to home. A similar situation exists at UNC Hospitals in Orange County, where more than 3,300 Wake County residents had an MRI scan in 2018.

An examination of the MRI patient use rate by county further demonstrates that Wake County does not have "half" the access of other large urban counties, as posited in the petition. Using the Healthcare Planning and Certificate of Need Section's database for MRI data collected from across the state, the following table shows the number of MRI patients in 2017 from each of the relevant counties. Please note that these data include county residents receiving MRI scans anywhere in the state, not just their home county, so they are generally helpful to use in comparing access to services.

County	2017 Population	2017 MRI Patients	2017 MRI Use Rate/1,000
Wake	1,052,120	60,228	57.2
Durham	307,007	17,003	55.4
Forsyth	373,625	25,067	67.1
Mecklenburg	1,074,596	67,286	62.6
Guilford	527,922	31,816	60.3

Source: Population from NC OSBM; MRI data from Healthcare Planning and CON Section database; 2017 data used as aggregated 2018 data for non-hospital equipment providers are not yet available.

As shown, the MRI patient use rate for Wake County is higher than Durham County's, notwithstanding the petition's assertion that Wake County has "half" the MRI access of Durham County. Wake County's use rate is also comparable to other large counties in the state, indicating that access to MRI services is currently not a significant impediment to receiving care.

Moreover, a higher percentage of Wake County patients receive MRI scans in their home county compared to Durham County, as shown below.

County	2017 Total MRI Scans	2017 MRI Scans in Home County	2017 Percentage of MRI Scans in Home County
Wake	60,228	48,089	79.8%
Durham	17,003	13,242	77.9%

Source: Healthcare Planning and CON Section database; 2017 data used as aggregated 2018 data for non-hospital equipment providers are not yet available.

Thus, despite having a lower MRI scanner to population ratio, a higher percentage of Wake County residents receive their MRI scans in their home county compared to Durham County. Clearly Wake County does not have "half" the MRI access of Durham County using data that more accurately measure access to care.

It is true that given the current utilization of MRI scanners in Wake County and the projected population growth, additional MRI capacity is needed; however, as noted at the Raleigh public hearing on the *Proposed 2020 SMFP*, the *2019 SMFP* includes a need determination for a fixed MRI scanner in the county. Moreover, the MRI allocation from the *2016 SMFP* has not yet been resolved; once it is, that MRI scanner can be developed to provide additional access in the county.

2. Alliance Owned Scanners

UNC REX understands the challenges associated with providing services through a mobile, vendorowned unit. However, it does not believe that the information provided in the petition accurately describes the situation in Wake County or across the state.

First, the petition refers to a "1993 loophole," by which the State permits Alliance to use its MRI scanners as fixed. However, this is not a loophole, but rather the fact that these scanners were operating in North Carolina prior to the inclusion of MRI in the CON statute. These are therefore "grandfathered" and not subject to the same CON requirements as scanners developed after this time. Although the petition presents this as a negative factor, this grandfathered status has allowed the petitioner to have access to an MRI scanner, stationed inside its practice, for more than a decade. While the Alliance scanner may not be owned by Raleigh Radiology, the ability to locate it inside the building, rather than in a mobile trailer in the parking lot, would seem to be an advantage of its grandfathered status, not a disadvantage.

The petition also discusses issues with the MRI equipment, stating that in case of equipment failure, it has no backup other than "leftovers" from the vendor. While equipment downtime is never pleasant, even if the petition is approved and Raleigh Radiology is eventually approved to develop its own MRI scanner, it will continue to have no backup option in case of downtime, other

than mobile scanners. While UNC REX agrees that temporary mobile scanners in lieu of stationary units are not ideal, the petition implies that the only inventory available to the vendor are those that exist in the state already. This is not accurate; any provider with rights to operate equipment in the state (either through a CON or grandfathered status) can temporarily replace that equipment with another unit from out-of-state following submission of appropriate notice to the Healthcare Planning and Certificate of Need Section.

It appears from the discussion in the petition that Raleigh Radiology is actually arguing in favor of a methodology to allow it to convert from a vendor-owned mobile scanner to a fixed MRI scanner that it owns. While such a methodology change may result in a favorable outcome for the petitioner, the timing of the petition during the summer is not conducive to a full discussion and review of the methodology. It should also be noted that the MRI methodology did include a "conversion" factor during the 2000s, but that part of the methodology was abandoned in favor of the current methodology which combines all MRIs as fixed equivalents.

The petition also argues that the CON process does not favor its need to "replace" its vendor-owned MRI with a fixed MRI that it owns. As discussed in further detail below, this is a misrepresentation of the facts. The Agency Findings in the 2016 MRI review found that Raleigh Radiology adequately demonstrated the need for its proposed replacement of the Alliance-owned unit with its own fixed MRI scanner. The petitioner's 2016 CON application was denied because of errors in the application relating to its projected care to the underserved, not because the Agency determined that it had no need for the proposed fixed scanner. As such, the basis of the petitioner's request is without merit.

3. Accessibility

Raleigh Radiology misrepresents the benefits of approving the petition on improving access to the underserved. While the petition carefully states that the practice *accepts* Medicare, Medicaid, VA, and uninsured, **it critically fails to identify how much of its MRI service is actually comprised of medically underserved patients**. Based on information provided in its MRI Certificate of Need application filed in 2016 (Project ID # J-11159-16), at that time the practice had the following MRI payor mix (medically underserved classes in bold):

Payor	Percentage	
Self-Pay/Indigent/Charity	1.0%	
Medicare	23.0%	
Medicaid	1.0%	
Commercial	3.0%	
Managed Care	64.0%	
Workers Comp and TriCare	8.0%	
Total	100.0%	
Percentage Medically Underserved	25.0%	

As shown, **only one-quarter of Raleigh Radiology's patients are medically underserved**. As such, it is <u>not</u> a safety net provider as the petition asserts. While the petition fails to define this term,

according to the Institute of Medicine, "'core safety net providers' are those that maintain an 'open door' to patients, regardless of ability to pay and whose case mix primarily includes uninsured, Medicaid and other" underserved populations². It is clear from the only available data regarding its payor mix that Raleigh Radiology does not provide a significant amount of care to the underserved, and it is not a safety net provider.

This is also an important issue as the CON Section's denial of Raleigh Radiology's 2016 MRI application was based on its questionable payor mix, particularly its projections of care to the uninsured, Medicaid and Medicare populations, which were unreasonably high compared to its historical record of care to these populations³.

As such, UNC REX believes that the SHCC should not approve a petition which could result in the only qualified applicant being a provider with a poor record of care to the medically underserved.

4. Alternatives

The primary alternative noted in the petition is the opportunity to file a CON application pursuant to the need determination in the 2019 SMFP. The information provided in response to this alternative in the petition is misleading. Specifically, referring to its application in the 2016 review, the petition states that Raleigh Radiology "offered the lowest net revenue and the lowest cost, but the state rejected the application...." This phrasing suggests that the application was denied on the basis of the comparative analysis involving revenue and costs; however, that is not the case. Instead, Raleigh Radiology was found to have errors in its projected payor mix, particularly regarding care to the medically underserved, as noted above. The Agency did note that Raleigh Radiology's application projected the lowest net revenue and costs but was unable to be approved due to the errors it made in its application regarding payor assumptions. Thus, while the petition essentially argues that Raleigh Radiology cannot be approved in a traditional review such as that presented in the 2019 SMFP, the evidence actually suggests that, apart from its own errors in its CON application, Raleigh Radiology could have been found conforming with the CON review criteria and could have been approved.

Further, as noted in the petition, the appeal of the 2016 MRI review continues. It appears that the NC Court of Appeals granted Raleigh Radiology's petition for rehearing the case. As such, it is possible that the MRI scanner in the 2016 SMFP will ultimately be awarded to the petitioner, and certainly Raleigh Radiology hopes for such an outcome. Since the petitioner is still arguing in its appeal of the 2016 review that it should be awarded a fixed MRI scanner and because that possibility exists, which would then render the petitioner, as an owner of a fixed MRI scanner, unqualified to apply for the adjusted need determination it now seeks, the SHCC should deny the petition.

Another alternative may be a closer examination of the MRI data for Wake County. UNC REX also notes that the data reported in Table 17E-1 may be incomplete, particularly with regard to the petitioner. Of note, the Registration and Inventory report filed by Alliance Imaging for Raleigh Radiology Cary shows a total of 6,743 MRI scans in FFY 2018; however, there is no line in the table

https://www.ahrq.gov/professionals/prevention-chronic-care/improve/system/pfhandbook/mod2.html

See pages 50-53 at https://info.ncdhhs.gov/dhsr/coneed/decisions/2016/sept/1007 wake mri find.pdf

that shows either that facility or that number of MRI scans in Wake County. If these data are missing, then the actual number of MRI scans in the county may be understated.

ADDITIONAL CONSIDERATIONS

UNC REX also believes that the petition fails to provide compelling evidence that the need determination should include the recommended qualifications for applicants. The language provided in the petition is unclear and contradictory. For example, the qualifying language states that the scanner should be located in a facility with an "accredited freestanding fixed MRI," yet it also states that "the applicant must not own a fixed MRI." While this may be possible, it certainly is not well-defined and seems to be an unusual situation. Further, the petition suggests that the facility should have "at least four years of CPT evidence of sustained performance of all types of MRI scans for patients referred by primary care, internal medicine and other specialties," yet it does not define any of those terms, including "CPT evidence," "sustained performance," or "all types of MRI scans...." For example, does that include every possible MRI scan with a CPT code? The language also includes "a history of low charges," without any basis for determining what constitutes "low" charges or how they would be demonstrated. Given these significant issues with the recommended language in the petition, UNC REX believes it should not be approved.

Of note, if the SHCC believes that the need for additional MRI capacity in Wake County is as compelling as the petition suggests, then a more prudent approach would be to allow anyone to apply, particularly for a service as commonplace as MRI. In that way, the CON Section can then review applications using the many criteria established by the General Assembly to more thoroughly determine the most effective application to provide the needed access.

SUMMARY

In conclusion, UNC REX requests that the SHCC deny Raleigh Radiology's petition for an adjusted need determination for a fixed MRI scanner in Wake County with the proposed qualifying language. The petition is not supported by appropriate data analysis, and if approved, would result in a confusing, unnecessary, and ill-conceived need determination in the 2020 SMFP.

Thank you for your consideration.