Comments on Competing Applications for a Fixed MRI Scanner in Wake County

submitted by

WR Imaging, LLC and Wake Radiology Diagnostic Imaging, Inc.

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), WR Imaging, LLC and Wake Radiology Diagnostic Imaging, Inc. (collectively, "Wake Radiology" or "WR") submit the following comments related to competing applications to develop one additional fixed MRI scanner in Wake County. WR's comments on these competing applications include "*discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with the relevant review criteria, plans and standards*[1]." *See* N.C. GEN. STAT. § 131E-185(a1)(1)(c). To facilitate the Agency's review of these comments, WR has organized its discussion by issue, noting some of the general CON statutory review criteria and specific regulatory criteria and standards creating the non-conformity on the following applications:

- **Duke University Health System, Inc. ("Duke"), Project ID # J-11829-19**
- **EmergeOrtho, Project ID # J-11821-19**
- **Raleigh Radiology, LLC, Cary site ("RRC"), Project ID # J-11825-19**
- **Raleigh Radiology, LLC, Knightdale site ("RRK"), Project ID #J-11826-19**
- **Pinnacle Health Services of North Carolina, LLC ("PHSNC"), Project ID # J-11820-19**

GENERAL COMMENTS ON COMPETITIVE REVIEW

Among the six competing applications in this review, all propose to develop a fixed MRI scanner in a freestanding (i.e. non-hospital based) setting, which is a lower cost environment compared to existing hospital-based scanners. While all six applications proport to be applying for the need identified in the *2019 State Medical Facilities Plan* (*SMFP*), most of the proposals will actually result in a *decrease* in MRI capacity in the Wake County service area, and as such, will not effectively meet the need in the *2019 SMFP* for additional MRI capacity in the service area. Specifically, the proposals by Duke, EmergeOrtho, RRC, and PHSNC all propose to decrease or completely discontinue mobile MRI capacity they are providing at various sites in Wake County, which would result in a decrease in fixed equivalent MRI capacity in the service area, if approved. While it may be reasonable to reduce mobile MRI capacity at a particular site if that site will be acquiring a fixed MRI scanner, to then eliminate the mobile MRI service completely or to significantly reduce its availability in the county, as proposed by four of the six applicants, would not best meet the need identified in the *2019 SMFP* for additional MRI capacity. Of the six applicants, only Wake Radiology proposes to replace the full-time mobile scanner at its Cary facility, while maintaining the mobile contract to offer services at other underserved locations in the county. As such, the Wake Radiology proposal is the only one that meets the need for an additional fixed MRI scanner in Wake County at an existing high-volume mobile site, without reducing the overall MRI capacity in the service area. In addition, the competing applications are non-conforming with review criteria and comparatively inferior to the WR proposal and should not be approved, as detailed in the comments below.

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[1] Wake Radiology is providing comments consistent with this statute; as such, none of the comments should be interpreted as an amendment to its application as filed November 15, 2019.

COMMENTS REGARDING COMPARATIVE ANALYSIS

On a cursory level, all of the applications appear to expand access to non-hospital-based outpatient MRI services. However, the comparative factors should be considered in light of the issues with several of the applications, as well as the overall need for additional MRI capacity in Wake County. For the comparative factors involving financial metrics, WR notes that several of the competing applications have errors or omissions that render their projected financial statements invalid, including projected revenue, expenses and payor mix; therefore, a meaningful comparison is not possible. Further, the competing applications should be found to be less effective on a comparative basis for those factors derived from statutory review criteria with which they are non-conforming. In addition to these factors, WR believes that the Agency should include the factor of "Best Meets the Need Determination." In particular, as noted above, WR believes that it is the only approvable application that will result in an increase in MRI capacity in the service area if approved, which renders it the most effective application under this criteria, which is important at ensuring increased access to MRI services in Wake County.

COMMENTS ON DUKE RADIOLOGY GREEN LEVEL

General Comments

The most recent need determination for a fixed MRI in Wake County was awarded to Duke for a location in Holly Springs. The application now under review proposes another fixed MRI scanner in Apex, which is adjacent to Holly Springs, with overlapping service areas. Given the most recent award to Duke and the capacity available on its approved MRI scanner in Holly Springs, WR does not believe that it should be awarded the proposed MRI scanner.

Further, WR believes the Duke application should be denied, based on the issues outlined below.

Issue-Specific Comments

1. Duke fails to adequately identify its patient population.

   In Section Q, on page 1, Duke presents Step 1 of its methodology as the identification of the patient population in its primary service area, which identifies patients by ZIP code and county. Page 2 of Section Q presents of map, which the application states is a map of the primary service area ZIP codes. There are multiple errors and inconsistencies, however, with both the ZIP code list and the map, which render both the identification of the patient population and the subsequent utilization projections unreasonable.

   First, the ZIP code list in Step 1 incorrectly lists ZIP 27330 as Chatham County. This ZIP is the primary ZIP code for Lee County, not Chatham. While a small portion may include Chatham County, the majority of the population, including the Lee County seat of Sanford, is certainly not in Chatham County. Given that Duke projects that nearly 100 MRI scans will be performed on residents of this ZIP in the third project year (see page 17), this is a significant error. Moreover, it is unlikely, if not impossible, that Duke selected patients from only the Chatham County portion of that ZIP code, and it has failed to correctly and reasonably identify its patient population.

   Second, the map for the primary service area includes ZIP codes which are not identified in the list. Specifically, ZIPs 27526 and 27592 are shown as being in the primary service area but are not listed in the ZIP code list on the previous page. As such, it is unclear whether the ZIP code list is correct, the map is correct, or if both are incorrect. Further, since the application fails to provide a list of procedures by ZIP code (either historical in Step 2 or projected in Step 3, see discussion below), it is impossible to determine which definition of primary service area and patient population is correct.

   Based on these issues, the application should be found non-conforming with Criteria 1, 3, 5, and 6, as well as the performance standards at 10A NCAC 14C .2103.

2. Duke fails to demonstrate that its utilization projections are reasonable.

   The methodology used in the application to project volume for the proposed service is based on unreasonable assumptions; therefore, the projected utilization is unreliable.

a. In Step 2, Duke presents its reported MRI volume from the proposed service area at all DUHS facilities in Wake and Durham counties. However, as noted above, it fails to provide the actual historical volume by ZIP code, which would allow the reasonableness of the data to be confirmed, as well as the reasonableness of the projected shifts in Step 3. Step 3 projects various percentages of historical volume from the service area to shift to the proposed facility; however, given the lack of information regarding the facilities from which the proposed shift would occur, the reasonableness of these shifts has not been demonstrated. Duke also fails to provide any historical trend for this data, which is particularly important given the expansiveness of its proposed service area. For example, it is important to know whether the number of patients served in any of the ZIP codes were growing or declining, and which existing Duke facilities are currently being used by patients from those ZIP codes. Absent these data, the application's assumptions are not adequately supported and are unreliable.

b. In Step 5, Duke projects market share increases by ZIP code that it expects to result from the proposed project. These assumptions are unreasonable for several reasons. First, in a previous step (#3), Duke assumes no shift of existing patients from certain Durham County ZIP codes, but then assumes the proposed site will result in market share gains from those ZIP codes. It is irrational to assume that existing market share will not shift from those ZIP codes, based on the factors stated in the application, but that the proposed project would attract new market share from those same ZIPs. The application fails to provide any reasonable explanation for this projection. Next, the assumptions included regarding the reason for market share increases overall are not logical. In particular, Duke cites "increase in population and overall service area utilization" as reasons for market share increase; however, those factors are not valid bases for market share gains. While population and utilization growth may drive volume increases, that does not automatically follow that those factors will also drive market share increases, which measure how much of that volume growth a particular provider captures. This error results in an effective double-counting of market volume growth, which the application accounted for in Step 1. Similarly, the application cites geographic access as a factor, but the proposed site is not closer for some service area ZIP codes than other existing or approved MRI scanners, including those owned by Duke; thus, there is no improved geographic access for those areas. Most notable among these areas are those closer to the approved Holly Springs MRI location. Since that unit is not even operational yet, it is unreasonable to assume that patients will bypass that site to travel to the proposed site.

Based on these issues, the application should be found non-conforming with Criteria 1, 3, 4, 5, 6, and 18a, as well as the performance standards at 10A NCAC 14C .2103, and the Duke application should not be approved.

COMMENTS ON EMERGEORTHO

Issue-Specific Comments

1. EmergeOrtho fails to demonstrate that its utilization projections are reasonable.

   In Step 3 of its methodology, the application projects market share to increase by 64 percent (from 2.6 percent to 4.3 percent), without a reasonable basis for this massive increase of nearly two-thirds of its current estimated share. For the interim period, the application assumes a market share increase due to an increased number of mobile days; however, even assuming that its volume could increase with additional capacity, that does not support a market share increase. To that point, from 2018 to 2019, the applicant's MRI market share at the site decreased (as did overall volume), as shown in Step 2, even with no change in mobile capacity. Further, the methodology already projects growth of four percent as a baseline; while growth in overall MRI volume in Wake County is likely to occur, there is no reasonable basis provided in the application for growth of market share on top of the baseline growth projected in Step 2.

   For the project years, the application projects market share growth in each year, again in addition to the four percent baseline growth projected for the county overall, and without a reasonable explanation for the market share growth. The rationale provided in the application on page 115 does not explain why it is reasonable to assume market share growth in addition to the growth in the market overall. While the applicant attempts to compare its projected market share to its share in other counties, the sites identified on page 115 are in counties with significantly different circumstances, including vastly different numbers of MRI providers, different numbers of physicians and physician groups, and a different history of providing MRI services, among others. Of note, the application fails to even identify the county for the first row of data in its table, rendering the analysis useless. Moreover, the applicant's comparison is wholly specious, in that it compares its projected market share for a single site in Wake County (i.e. the proposed site) to its entire complement of MRI scanners in the other counties; in Wake County, however, the applicant proposes to continue offering MRI services at numerous other sites, yet fails to provide its overall projected market share for all sites. Nonetheless, the comparison is invalid and does not support the application's projected market share.

   As a result of the unreasonable compounding effects of projecting both baseline MRI volume growth and unsupported market share increases, the application projects an implausible growth rate of over 14 percent from 2018 to the third project year, increasing to nearly 19 percent during the project years, as shown in the table below.

	FY2018	*FY2019*	*CY2020*	*CY2021*	*CY2022*	*CY2023*
Unweighted Scans	2,629	2,592	2,939	3,603	4,315	5,078
Unweighted Year Over Year % increase		-1.4%	13.4%	22.6%	19.8%	17.7%
Unweighted FY18-FY23 CAGR						14.1%
Unweighted FY21-FY23 CAGR						18.7%

While this incredible growth rate is obfuscated in the multiple steps of the methodology, as noted above, the impact of the applicant's assumptions of both market volume growth and market share growth result in unreasonable utilization projections.

Based on these issues, the application fails to demonstrate that the project is needed or that its utilization projections are reasonable. As such, the application **should be found non-conforming with Criteria 1, 3, 5, 6, and 18(a) and the performance standards at 10A NCAC 14C .2103**.

2. <u>The application fails to demonstrate that its financial projections are based on reasonable assumptions and that the proposal is financially feasible</u>.

   The assumptions provided for Form F.3 are inconsistent with the actual financial projections on the pro forma financial statements. As such, the application has failed to demonstrate reasonable projections and the financial feasibility of its project.

   a. Medical supplies: According to the assumptions for Form F.3, "Medical Supplies are based on the 2018 actual average of $2.30 per MRI procedure…with 2% annual increases." However, the projected expenses on Form F.3 Operating Costs are understated, as shown below.

	Prior Full Fiscal Year	*Interim* Full Fiscal Year*	*Interim* Full Fiscal Year*	*1st Full Fiscal Year*	*2nd Full Fiscal Year*	*3rd Full Fiscal Year*
	CY2018	*CY2019*	*CY2020*	*CY2021*	*CY2022*	*CY 2023*
# of MRI Scans	2,747	2,592	2,939	3,603	4,315	5,078
Per scan expense (2018 inflated 2% annually)	$2.30	$2.35	$2.39	$2.44	$2.49	$2.54
Medical Supplies calculated based on assumptions		$6,081	$7,033	$8,794	$10,743	$12,895
Understated expense		**$3,903**	**$4,503**	**$172**	**$418**	**$744**

   b. Other supplies: The assumptions for Form F.3 state, "Other supplies are budgeted for the expense of forms at $300 per year with 2% inflation." However, the actual

expense for these supplies for 2018 was $314 and the application fails to inflate these expenses per year as the assumption suggests. Moreover, the application omits this expense for 2019 without any reason. Thus, the basis for this expense is understated and erroneous.

c. Other overhead: The assumptions state that, "Other Expenses (Other Overhead) based on $10 per MRI scan and increases 2% annually…." However, the actual expense per scan is not inflated in the second and third project years, leading to an understatement of this expense, as shown below.

	Prior Full Fiscal Year	***Interim* Full Fiscal Year***	***Interim* Full Fiscal Year***	***1st Full Fiscal Year***	***2nd Full Fiscal Year***	***3rd Full Fiscal Year***
	CY2018	***CY2019***	***CY2020***	***CY2021***	***CY2022***	***CY 2023***
# of MRI Scans	2,747	2,592	2,939	3,603	4,315	5,078
Overhead Expenses per MRI Scan (inflated 2% per year)	$10.00	$10.20	$10.40	$10.61	$10.82	$11.04
Overhead Expenses with 2% inflation	$27,470	$26,438	$30,577	$38,235	$46,707	$56,065
Projected expense (Form F.3)	$27,470	$26,438	$30,577	$38,235	$45,791	$54,966
Understated amount					**$916**	**$1,099**

Based on these issues, the application should be found non-conforming with Criteria 1 and 5 and should not be approved. Further, the application should not be compared with others in the comparative analysis regarding costs and charges.

COMMENTS ON RALEIGH RADIOLOGY CARY

General Comments

As noted above, the RRC application is one that proposes to substitute a fixed MRI scanner it would own for the vendor-owned stationary scanner at the same facility. While the application presents the benefits of this change for the applicant, the greatest effect of this proposal would be its negative impact on patient access by maintaining, not increasing the number of equivalent MRI scanners in the service area per the need determination in the *2019 SMFP*.

Issue-Specific Comments

1. RRC fails to demonstrate that its utilization projections are reasonable.

   In Step 3 of the application's utilization methodology, page 135, the application attempts to determine the need for MRI scanners in Wake County by applying a use rate to the Wake County population. The step of the methodology fails to account for out-migration of Wake County residents to other counties, particularly Durham and Orange counties, and erroneously assumes that all Wake County residents receiving an MRI will have the procedure performed in Wake County. The methodology also notes that it includes an assumption that all scans are performed on fixed scanners, without any volume performed on mobiles. Given the applicant's own history of performing scans on a mobile unit, this assumption is clearly unreasonable. The invalid results of this flawed analysis are shown in Table 3, which indicates a deficit of more than six MRI scanners in Wake County, which is clearly not supported by the *SMFP* methodology, which is driven by the actual number of procedures performed in Wake County, not just those performed on residents of Wake County. Thus, the application significantly overstates the need for MRI scanners in Wake County.

   Despite its finding in Step 3, the methodology's subsequent steps inexplicably include residents from other counties in assumed growth in MRI procedures. While an applicant may serve residents of other counties, the application fails to reconcile its conflicting assumptions that all Wake County residents should have their MRI scan performed in Wake County, while also projecting to serve patients from multiple other counties.

   In Step 6, the methodology projects growth in MRI procedures based on the population growth in the service area. While such growth may increase MRI procedures overall, the application fails to demonstrate why it is reasonable to assume that RRC will obtain this same growth rate. In particular, the Table 8 on page 140 demonstrates that the number of MRI scans performed at RRC has declined since 2017, with a decrease of 5.2 percent in the most recent year. The application makes no attempt to explain why this trend will reverse, and the projected utilization is unsupported.

   Because of these issues, the application should be found non-conforming with Criterion 1, 3, 4, 5, 6, and 18(a) and the performance standards at 10A NCAC 14C .2103.

2. RRC fails to demonstrate that its financial projections are based on reasonable projections and that the proposal is financially feasible.

First, the application asserts that the proposed project is more financially "sustainable" than the status quo, stating on page 43 that its commitment to lower costs is at risk given the current vendor-provided MRI service. The application fails to provide any evidence to support this statement, however, and actually provides documentation to the contrary. The historical financial statements on page 158 show net income of over $1.5 million in 2019, while projecting net income of over $914,000 in Project Year 3. Clearly, the status quo is more sustainable than the proposed project given the historical and projected bottom line for the project.

Second, the financial assumptions regarding projected gross revenue are either incorrectly stated, unsupported, or unreasonable. MRI gross revenue for 2019 is shown to exceed $12 million, which equates to approximately $1,887 per unweighted scan, based on 6,424 scans on Form C for 2019. The application projects a charge of $1,553 per scan in 2020 and subsequent years, purportedly based on Raleigh Radiology's experience, although the results from 2019 at the Cary facility indicate this is incorrect. More simply, it is unreasonable (and unexplained) to project such a significant decrease in gross revenue from 2019 to 2020, particularly in light of no projected change from 2020 to 2023.

Third, the application fails to provide a full historical year of actual financial data. While the financial forms include a "prior" year for January through December 2019, since the application was filed in November 2019, those data are clearly not actual historical results. As such, the application fails to provide the requested historical data and the projections based on the information for 2019 are unsupported.

Based on these issues, the application should be found non-conforming with Criteria 1 and 5, and the RRC application should be denied.

3. RRC fails to demonstrate that it will accommodate professional training programs.

In response to Section M, the application provides vague references to "support" for training programs as well as letters to and from various training programs in the region. The application also states that the "proposed diagnostic center" will "support these efforts." While these efforts might be minimally acceptable for new programs, RRC is an existing, not proposed, diagnostic center (see page 10), and the responses to this section do not indicate that the facility, which has existed for many years, has any history of accommodating the needs of health professional training programs. Given the length of time this facility has operated, its failure to demonstrate any existing accommodation for health professional training programs, which was also a requirement of its CON to become a diagnostic center (see Project ID J-8139-08), the application has failed to reasonably demonstrate how it will accommodate these programs, and that it will actually follow through on the statements in its application regarding this criterion.

As a result of this issue, the application should be found non-conforming with Criterion 14, and it should be denied.

COMMENTS ON RALEIGH RADIOLOGY KNIGHTDALE

Issue-Specific Comments

1. The application fails to demonstrate that it proposes the least costly or most effective alternative.

   In Section E, the application plainly states that the proposed project is neither the least costly nor the most effective alternative compared to the alternative proposed in the applicant's competing project to develop a fixed MRI scanner at its Cary facility. On page 79 of the application, it states, "*Should the Agency reject the Raleigh Radiology Cary application, Raleigh Radiology determined that a new 'fixed' MRI at Raleigh Radiology Knightdale is the next least costly and most effective alternative*." In other words, the same applicant proposed two alternatives in competing applications—one for Cary and one for Knightdale. The applicant stated that its Cary proposal was more effective and less costly than its Knightdale proposal. Further, it clearly prefers the approval of the Cary location and would accede to the approval of the Knightdale proposal only if the Agency denied the Cary proposal. On its face, as admitted by the applicant, the Knightdale proposal is not the least costly or most effective alternative.

   This admission in the application renders it non-conforming with Criterion 4 and the application should be denied.

2. The application fails to demonstrate that its projected utilization is reasonable.

   In Step 6 of its methodology, the application projects to achieve a 22 percent market share of MRI scans performed on residents of the service area. While the application presents this projection as reasonable, it provides no basis for the assumption, such as Raleigh Radiology's experience at other facilities in Wake County that operate MRI services. While there may be few MRI scanners within the proposed service area, there are many existing scanners that are proximate to the majority of the service area population. Of note, as shown by the map in the application on page 44, there are a total of 16 MRI providers in Quadrants D and H, which include the two Raleigh ZIP codes proposed as part of the application's service area. Given the location of these existing providers and the general tendency for patient migration into a urban area, not out of it, it is unreasonable to assume that patients living in Raleigh would drive to a new facility in a more rural area, farther away from better known, existing facilities. The application also fails to provide any information about the applicant's historical service to patients from these ZIP codes to demonstrate how many patients from the service area are already familiar with and choosing a facility owned by the applicant.

   Similarly, it should be noted that the majority of the patient population identified by the applicant resides in Raleigh, not Knightdale. By 2025, the application projects that more than 60 percent of the patients will live in Raleigh, given the growth rate of those ZIP codes. As such, the projected market share of those ZIP codes representing such a large portion of the patient population that resides close to other existing scanners, is unreasonable.

Based on these issues, the application should be found non-conforming with Criteria 1, 3, 4, 5, 6, and 18a, and the performance standards at 10A NCAC 14C .2103.

3. RRK fails to adequately identify its patient population.

   In Section C.3(a), the application projects patient origin for a *portion* of its patient population but fails to identify where *all* its proposed patients will originate. In Table C.1, the application shows patient origin for the first three project years totaling 1,802, 2,744 and 3,714 patients, respectively. In Form C, the application projects a total of 2,071, 3,154 and 4,269 procedures in the first three years, respectively. The methodology in the application is based on a use rate applied to the population, which necessarily results in one procedure per patient. As such, the application fails to project patient origin for hundreds of patients each year, or, alternatively, the projected number of patients is correct, and the utilization projections are overstated. In either case, **the application is inconsistent and non-conforming with Criterion 3.**

4. The application projects payor mix using unreasonable assumptions.

   In Section L.3, the application projects payor mix for the proposed project. The methodology used in the application includes errors and unreasonable assumptions. In Section L.3(a), the application notes that "Other" includes "Champus…TRICARE…" and other payors. However, Champus has not existed for many years and has been replaced by TRICARE. Thus, the application is either incorrect in listing Champus as a payor, or it is double-counting TRICARE patients.

   In Step 4, RRK attempts to "balance" its projected payor mix by assuming that the balance will be 100 percent Medicare. This assumption is not reasonable. Although the application cites aging population and use rate by the Medicare population as factors, the previous steps in its methodology already account for these trends, based on the historical change in the Medicare population, which the application assumes will be 0.71 percent. There is simply no valid reason to assume that the entire balance should be attributed to Medicare patients, and the application's projected payor mix is invalid. Of note, the Agency found payor mix assumptions used by the applicant in its previous MRI application in 2016 to be unreasonable, and WR believes the projections in the instant application should similarly **result in a finding of non-conformity with Criterion 13(c).**

COMMENTS ON PINNACLE HEALTH SERVICES OF NC

Issue-Specific Comments

PHSNC fails to demonstrate that its utilization projections are reasonable.

The utilization projections and assumptions in Form C including several unreasonable and unsupported assumptions, as detailed below.

First, in Step 1, the application states that its three-year CAGR at Cedarhurst is 7.02 percent; however, that calculation appears to omit results for the most recent year, in which utilization declined significantly. The application asserts the decline was "primarily" due to changes in referral patterns; however, the CAGR for 2015 through 2019 is -1.7 percent. The application fails to demonstrate that its projected growth rate is reasonable, given this issue. Further, the applicant projects utilization by applying a use rate increase (scans per 1,000 population) to an increase in total scans. Given the historical decline and the lack of any discussion regarding the reason for assuming its scan volume should increase at the same rate as the Wake County use rate, the utilization projections for Cedarhurst are unsupported.

In Step 3, the application projects total Wake County MRI procedures. While the application states that it applied a use rate to Wake County population, the application omits the population data or methodology used to calculate the projected procedures. As such, the resulting projects are unsupported.

In the same step, the application projects future volume at Wake Forest assuming an annual growth rate plus market share growth. While the application states that is baseline growth rate is conservative compared to its historical growth, it fails to demonstrate why it is reasonable to assume that its baseline growth does not already include any potential market share increases. In other words, the application fails to demonstrate why it is not reasonable to assume that its projected growth rate of 3.11 percent already includes market share increases.

In Step 4, the application projects additional volume growth at Wake Forest from shifts from Cedarhurst. As in Step 3, the application fails to demonstrate why it is not reasonable to assume that its projected growth rate of 3.11 percent does not already include a shift in patients from the Cedarhurst site.

The combination of the various "growth" and "shift" assumptions in the application results in an unreasonably high and unsupported growth in utilization projections for the proposed MRI at Wake Forest. Although the application fails to show this combined growth rate, the table below provides this calculation.

	2019	*2020*	*2021*	*2022*	*2023*	*2020-2023 CAGR*
Unweighted Procedures	2,565	2,565	3,680	4,172	4,686	22.2%

As shown, the application projects an incredible CAGR of more than 22 percent, which is clearly unreasonable and unsupported.

The application projects utilization for its mobile MRI scanner starting on page 108. These projections are also unsupported and lack necessary information to demonstrate that they are reasonable. In particular, the application omits data for each site (Cedarhurst, Wake Forest and Clayton) to demonstrate what has historically been performed and what is projected on the mobile unit by site and by year. Without these data, it is impossible to recreate or verify the application's assumptions. Further, the application states that the mobile scanner will continue to serve Cedarhurst, without demonstrating the need to do so or the projected volume for this site. As shown in Step 1 of the methodology, only 180 mobile procedures were performed at Cedarhurst in 2019 and the total projected procedures for the fixed unit at Cedarhurst are projected to be more than 1,000 procedures lower than the highest reported volume year, 2018. In addition, the projected number of procedures for fixed unit at Cedarhurst already includes the procedures performed on the mobile unit, as shown in the table in Step 1 on page 98. The application provides no explanation for assuming the projected volume for the mobile unit at Cedarhurst, since the projected fixed volume already includes volume historically performed on the mobile. Finally, the methodology for the mobile MRI scanner fails to consider the proposed decrease in service at the Wake Forest site following the approval of the proposed fixed scanner, thereby significantly overstating the utilization of the unit for the project years.

Based on these issues, the application should be found non-conforming with Criteria 1, 3, 4, 5, 6 and 18(a), as well as the performance standards at 10A NCAC 14C .2103, and the PHSNC application should be denied.