



May 30, 2023

Gregory Yakaboski, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
North Carolina Department of Health and Human Services
809 Ruggles Drive
Raleigh, North Carolina 27603

RE: Comments regarding competing Statewide Mobile MRI Scanner CON Applications

Dear Mr. Yakaboski:

Enclosed please find comments prepared by Pinnacle Health Services of North Carolina, LLC regarding the competing CON applications to develop additional statewide mobile MRI scanners, to meet the need identified in the *2023 State Medical Facilities Plan (SMFP)*. We appreciate your consideration of these comments regarding the competing applications during your review.

If you have any questions about the information presented here, please contact me at 919.247.1227 or shawkins@oiarad.com.

Sincerely,

Susan Hawkins

Susan Hawkins
Senior Director of Operations, Outpatient Imaging Affiliates

COMMENTS ABOUT COMPETING STATEWIDE MOBILE MRI SCANNER CERTIFICATE OF NEED APPLICATIONS

Submitted by Pinnacle Health Services of North Carolina, LLC
May 31, 2023

In accordance with N.C.G.S. §131E-185(a.1)(1), Pinnacle Health Services of North Carolina, LLC (PHSNC) submits these written comments regarding the competing applications to develop three additional mobile MRI scanners in North Carolina, in response to the need identified in the *2023 State Medical Facilities Plan (SMFP)*. The discussion below describes how the competing applications do not conform to all the Certificate of Need review criteria and applicable MRI administrative rules. These comments also address the issue of how the PHSNC application represents a comparatively more effective alternative than the competing applications for development of an additional statewide mobile MRI scanner.

Specific comments regarding the Alliance Healthcare Services application (G-12365-23)

Criterion (1) *The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.*

Alliance Healthcare does not adequately demonstrate the need for the proposed project, did not propose the least costly or most effective alternative, did not demonstrate the financial feasibility and availability of funds for capital needs, did not show that its proposal is not unnecessarily duplicative of existing MRI resources, and did not show evidence of the availability of manpower resources. Therefore, Alliance fails to adequately demonstrate how the proposed project will maximize healthcare value for resources expended in meeting the need identified in the 2023 SMFP. The discussions regarding analysis of need in Criterion (3), alternative methods in Criterion (4), financial feasibility (5) unnecessary duplication in Criterion (6), availability of manpower resources (7), and the applicable .2703 MRI Scanner administrative rules, are incorporated herein by reference. Therefore, the Alliance application is not conforming to Criterion 1 because the applicant does not adequately demonstrate that the proposal is consistent with Policy GEN-3.

Criterion (3) *“The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.”*

The Alliance application completely fails to demonstrate the need that the population has for the services proposed. Alliance provides just two brief paragraphs in response to Section C.4 regarding demonstration of need. Moreover, in Section Q, Alliance provides absolutely no narrative or justification for the utilization projections it offers. Rather, Alliance simply states that it projects a certain number of MRI scans per day at each host site, without providing any supporting foundation for justifying the utilization projection.

Further, the Alliance application did not include any documentation from any of the three proposed host sites indicating or confirming willingness to serve as a mobile MRI host site. Nor did the Alliance application include any letters of support from referring providers.

Alliance failed to demonstrate the need for an additional mobile MRI scanner, and therefore, the Alliance application is nonconforming to Criterion 3.

Criterion (4) *“Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.”*

Alliance does not adequately demonstrate that the alternative proposed in the application is the most effective to meet the need because 1) Alliance provided just one brief paragraph in response to Section E.2 regarding alternatives, and 2) the application is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be the most effective alternative. Therefore, the Alliance application is not conforming to Criterion (4).

Criterion (5) *“Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.”*

Novant Health does not adequately demonstrate the financial feasibility of the proposal because 1) its financial projections are founded upon unjustified utilization projections, 2) it does not include sufficiently detailed assumptions for the Form F.3b operating expense assumptions, and 3) it does not include sufficient staffing expense (see Criterion 7). As two specific examples, Alliance includes no detailed explanation of how the equipment moving expenses were calculated (which appear to be much too low), and Alliance projects just 1.0

FTE MRI Technologist position, which is insufficient to cover the weekly operational staffing needs.

Therefore, the Alliance application is not conforming to Criterion (5).

Criterion (6) *“The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.”*

Alliance fails to demonstrate that its proposal would not result in unnecessary duplication of existing mobile MRI capacity. As stated in its application, Alliance currently operates 30 mobile MRI scanners throughout North Carolina, which is by far the largest mobile MRI scanner inventory in North Carolina. In Section G, Alliance provides no discussion at all regarding this vast existing mobile MRI inventory and why its proposal is not unnecessarily duplicative. An application cannot be approved when it cannot demonstrate that the project will not result in unnecessary duplication of existing capacity. Therefore the Alliance application is not conforming to Criterion (6).

Criterion (7) *“The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.”*

Alliance fails to show evidence of the availability of health manpower personnel resources for the provision of the proposed mobile MRI scanner project. Specifically, Alliance projects only a 1.0 FTE MRI Technologist position to staff the proposed mobile MRI scanner. This is clearly insufficient to cover the weekly operational staffing needs, plus the needed time off for the employee. Therefore, the Alliance application is not conforming to Criterion (7).

Criteria (18a) *“The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.”*

Alliance’s application fails to conform to Criterion (18a) because the proposal does not adequately demonstrate that it will promote cost-effective services. The discussion regarding demonstration of need, alternatives, financial feasibility, and unnecessary duplication are found in Criteria (3), (4), (5), and (6), and are incorporated herein by reference.

**SECTION .2700 - CRITERIA AND STANDARDS FOR MAGNETIC
RESONANCE IMAGING SCANNER**

10A NCAC 14C .2703 PERFORMANCE STANDARDS

(a) An applicant proposing to acquire a fixed MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:

(3) identify the existing mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites located in the proposed fixed MRI scanner service area during the 12 months before the application deadline for the review period;

The Alliance application does not conform to the .2703(a)(3) performance standard applicable for the review of MRI scanners. Alliance did not project the need for additional mobile MRI capacity at the three proposed host sites based upon reasonable and supported assumptions. The discussion regarding this is found in Criterion (3) and is incorporated herein by reference.

Specific comments regarding the Novant Health, Inc. & Novant Health-Norfolk, LLC applications (G-12372-23 & G-12373-23)

Criterion (1) *The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.*

Novant Health does not adequately demonstrate the need for either proposed project, did not propose the least costly or most effective alternative, did not demonstrate the financial feasibility and availability of funds for capital needs, did not show that its proposal is not unnecessarily duplicative of existing MRI resources, and did not show evidence of the availability of manpower resources. Therefore, Novant Health fails to adequately demonstrate how the proposed project will maximize healthcare value for resources expended in meeting the need identified in the 2023 SMFP. The discussions regarding analysis of need in Criterion (3), alternative methods in Criterion (4), financial feasibility (5) unnecessary duplication in Criterion (6), availability of manpower resources (7), and the applicable .2703 MRI Scanner administrative rules, are incorporated herein by reference. Therefore, the Novant Health applications are not conforming to Criterion 1 because the applicant does not adequately demonstrate that either proposal is consistent with Policy GEN-3.

Criterion (3) *“The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.”*

The eastern Novant Health application projected 527 MRI procedures in Project Year 3 at the UNC Lenoir host site. According to the 2023 SMFP, UNC Lenoir’s existing fixed MRI scanner performed only 3,797 weighted MRI procedures. This is not a high volume for a hospital fixed MRI scanner, and calls into question the need for additional mobile MRI scanning capacity at the hospital site. Furthermore, 527 projected MRI scans represents 14% of the hospital’s annual utilization volume. Novant Health failed to demonstrate the need the UNC Lenoir host site has based upon reasonable and supported assumptions, and therefore, the Novant Health application is nonconforming to Criterion 3.

Criterion (4) *“Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.”*

Novant Health does not adequately demonstrate that the alternative proposed in either application is the most effective to meet the need because the application is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be the most effective alternative. Therefore, the Novant Health applications are not conforming to Criterion (4).

Criterion (5) *“Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.”*

Novant Health does not adequately demonstrate the availability of funds for the eastern North Carolina project (G-12372-23) because it did not include Form F.1a Capital Cost in the application form. An applicant cannot demonstrate the availability of funds for capital and operating needs, nor can it demonstrate the financial feasibility of the proposal if it does not document the project capital cost, and fails to include a required application form.

Further, neither Novant Health application included sufficiently detailed assumptions for the Form F.3b operating expense assumptions. For example, the equipment moving expenses appear to be much too low at only \$30K and \$45K respectively for each application, and the applications include no detailed explanation of how the costs were calculated.

Therefore, the Novant Health applications are not conforming to Criterion (5).

Criterion (6) *“The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.”*

Novant Health fails to demonstrate that its proposals would not result in unnecessary duplication of existing mobile MRI capacity. As stated in its applications, Novant Health currently operates 10 mobile MRI scanners throughout North Carolina. Aside from Alliance Health, this is the largest mobile MRI scanner inventory in North Carolina. An application cannot be approved when it cannot demonstrate that the project will not result in unnecessary duplication of existing capacity. Therefore the Novant Health applications are not conforming to Criterion (6).

Criterion (7) *“The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.”*

Novant Health fails to show evidence of the availability of health manpower and management personnel resources for the provision of the proposed western mobile MRI scanner project (G-12373-23). Specifically, Novant’s application failed to include Form H Staffing, and includes no itemized listing of projected staffing for the proposed service. Therefore, the Novant Health application is not conforming to Criterion (7).

Criteria (18a) *“The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.”*

Novant Health’s applications fail to conform to Criterion (18a) because the proposals do not adequately demonstrate that they will promote cost-effective services. The discussion regarding demonstration of need, alternatives, financial feasibility, and unnecessary duplication are found in Criteria (3), (4), (5), and (6), and are incorporated herein by reference.

SECTION .2700 - CRITERIA AND STANDARDS FOR MAGNETIC RESONANCE IMAGING SCANNER

10A NCAC 14C .2703 PERFORMANCE STANDARDS

(a) An applicant proposing to acquire a fixed MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:

- (3) identify the existing mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites located in the proposed fixed MRI scanner service area during the 12 months before the application deadline for the review period;*

The Novant Health application does not conform to the .2703(a)(3) performance standard applicable for the review of MRI scanners. Novant Health did not reasonably project the need for additional mobile MRI capacity at the UNC Lenoir host site. The discussion regarding this is found in Criterion (3) and is incorporated herein by reference.

Specific comments regarding the Duke University Health System/Duke Imaging application (J-12378-23)

Criterion (1) *The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.*

Duke does not adequately demonstrate the need for the proposed project, did not propose the least costly or most effective alternative, did not demonstrate the financial feasibility, and did not show that its proposal is not unnecessarily duplicative of existing MRI resources. Therefore, Duke fails to adequately demonstrate how the proposed project will maximize healthcare value for resources expended in meeting the need identified in the 2023 SMFP. The discussions regarding analysis of need in Criterion (3), alternative methods in Criterion (4), financial feasibility (5) unnecessary duplication in Criterion (6), and the applicable .2703 MRI Scanner administrative rules, are incorporated herein by reference. Therefore, the Duke application is not conforming to Criterion 1 because the applicant does not adequately demonstrate that the proposal is consistent with Policy GEN-3.

Criterion (3) *“The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.”*

The Duke application fails to demonstrate the need that the population has for the proposed services. Duke’s projected need hinges primarily on projected utilization at the Duke Health Heritage host site in Wake Forest. Duke projects the utilization at the Heritage site to jump from the annualized historical level of 1,378 MRI scans in FY2023 (p. 115) to 2,000 scans in the first project year (and 2,400 scans in PY3) without sufficient justification, and based solely upon the availability of additional MRI capacity. “Build it and they will come.” Duke fails to provide sufficient and reasonable foundation for justifying the projection.

Duke failed to demonstrate the need, and therefore, the Duke application is nonconforming to Criterion 3.

Criterion (4) *“Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.”*

Duke does not adequately demonstrate that the alternative proposed in the application is the most effective to meet the need because the application is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be the most effective alternative. Therefore, the Duke application is not conforming to Criterion (4).

Criterion (5) *“Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.”*

Duke does not adequately demonstrate the financial feasibility of the proposal because the financial projections are founded upon unjustified and unreasonable utilization projections. Therefore, the Duke application is not conforming to Criterion (5).

Criterion (6) *“The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.”*

Duke fails to demonstrate that its proposal will not result in unnecessary duplication of existing vast MRI capacity. As stated in its application, within Wake and Durham counties (which are included in Duke’s projected mobile MRI service area), Duke currently operates 16 MRI scanners and has approval for one additional MRI scanner. This represents one of the largest MRI scanner inventories in all of North Carolina, and certainly the largest in Duke’s target mobile MRI service area. An application cannot be approved when it cannot demonstrate that the project will not result in unnecessary duplication of existing capacity. Therefore the Duke application is not conforming to Criterion (6).

Criteria (18a) *“The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.”*

Duke’s application fails to conform to Criterion (18a) because the proposal does not adequately demonstrate that it will promote cost-effective services. The discussion regarding demonstration of need, alternatives, financial feasibility, and unnecessary duplication are found in Criteria (3), (4), (5), and (6), and are incorporated herein by reference.

**SECTION .2700 - CRITERIA AND STANDARDS FOR MAGNETIC
RESONANCE IMAGING SCANNER**

10A NCAC 14C .2703 PERFORMANCE STANDARDS

(a) An applicant proposing to acquire a fixed MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:

(3) identify the existing mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites located in the proposed fixed MRI scanner service area during the 12 months before the application deadline for the review period;

The Duke application does not conform to the .2703(a)(3) performance standard applicable for the review of MRI scanners. Duke did not reasonably project the need for mobile MRI capacity at the proposed host sites, in addition to the 17 existing and approved MRI scanners that Duke operates in the proposed mobile MRI service area. The discussion regarding this is found in Criterion (3) and is incorporated herein by reference.

Specific comments regarding the Carolina Neurosurgery & Spine Associates applications (F-12368-23 & F-12381-23)

Criterion (1) *The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.*

CNSA did not propose the least costly or most effective alternative, does not adequately demonstrate the financial feasibility, and did not show evidence of the availability of manpower resources. Therefore, CNSA fails to adequately demonstrate how the proposed project will maximize healthcare value for resources expended in meeting the need identified in the 2023 SMFP. The discussions regarding alternatives (4), financial feasibility (5) and health manpower (7) are incorporated herein by reference. Therefore, the CNSA applications are not conforming to Criterion 1 because the applicant does not adequately demonstrate that the proposal is consistent with Policy GEN-3.

Criterion (4) *“Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.”*

CNSA does not adequately demonstrate that the alternative proposed in either application is the least costly to meet the need because the applications are not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be the most effective alternative. Therefore, the CNSA applications are not conforming to Criterion (4).

Criterion (5) *“Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.”*

CNSA does not adequately demonstrate the financial feasibility of either proposal because the financial projections are not founded upon reasonable assumptions. As a specific example, CNSA projects less than \$90,000 annually for central office overhead. This is unreasonably low to cover all such supporting costs, including billing fees. Further, the Form H Staffing lists only the MRI Technologist and MRI Assistant positions, and not any other supporting staff. Thus, one would expect to find such additional staffing costs in the Central Office Overhead expense line. However, that expense is much too small to include

such staffing expenses. Therefore, the CNSA applications are not conforming to Criterion (5).

Criterion (7) *“The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.”*

CNSA fails to show evidence of the availability of health manpower and management personnel resources for the provision of the proposed mobile MRI scanner projects. Specifically, CNSA’s applications list only the MRI Technologist and MRI Assistant on the Form H Staffing, and do not include sufficient expenses in the Central Office Overhead expense line in Form F.3b to cover ancillary and support staffing needs. Therefore, the CNSA applications are not conforming to Criterion (7).

Criteria (18a) *“The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.”*

CNSA’s applications fail to conform to Criterion (18a) because the proposals do not adequately demonstrate that they will promote cost-effective services. The discussion regarding alternatives, financial feasibility and staffing are found in Criteria (4), (5) and (7), and are incorporated herein by reference.

Specific comments regarding the EmergeOrtho applications (J-12357-23, J-12358-23, & J-12359-23)

Criterion (1) *The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.*

EmergeOrtho does not adequately demonstrate the need for any proposed project, did not propose the least costly or most effective alternative, did not demonstrate the financial feasibility and availability of funds for capital needs, and did not show that its proposal is not unnecessarily duplicative of existing MRI resources. Therefore, EmergeOrtho fails to adequately demonstrate how each proposed project will maximize healthcare value for resources expended in meeting the need identified in the 2023 SMFP. The discussions regarding analysis of need in Criterion (3), alternative methods in Criterion (4), financial feasibility (5) unnecessary duplication in Criterion (6), and the applicable .2703 MRI Scanner administrative rules, are incorporated herein by reference. Therefore, the EmergeOrtho applications are not conforming to Criterion 1 because the applicant does not adequately demonstrate that the proposals are consistent with Policy GEN-3.

Criterion (3) *“The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.”*

The EmergeOrtho applications fail to demonstrate the need that the population has for the proposed services. In its applications, EmergeOrtho indicates that it currently owns and operates eight mobile and fixed MRI scanners in North Carolina, which during CY2022 performed 34,815 unweighted MRI procedures (Form C.2a). EmergeOrtho is proposing to add three mobile MRI scanners to increase this already large MRI inventory by 38%. In PY1 (CY2025), for the three proposed additional mobile MRI scanners, EmergeOrtho projects a total of 12,936 additional unweighted MRI scans (4,023 Foothills + 4,317 Triad + 4,596 Triangle). This represents a 37.2% utilization increase (12,936/34,815) in the first project year, based solely upon the availability of additional MRI capacity. This is not reasonable and without sufficient justification. EmergeOrtho fails to provide sufficient reasonable foundation for justifying the projection.

EmergeOrtho failed to demonstrate the need, and therefore, the EmergeOrtho applications are nonconforming to Criterion 3.

Criterion (4) *“Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.”*

EmergeOrtho does not adequately demonstrate that the alternative proposed in its applications are the most effective to meet the need because the application is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be the most effective alternative. Therefore, the EmERGEOrtho applications are not conforming to Criterion (4).

Criterion (5) *“Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.”*

EmergeOrtho does not adequately demonstrate the financial feasibility of the proposals because the financial projections are founded upon unjustified and unreasonable utilization projections.

Also, it is unclear whether any of the EmERGEOrtho applications include acquisition of the necessary mobile trailer to house and transport the mobile MRI scanner. Each application includes a mobile scanner equipment quotation from Nationwide Imaging Services for \$900,988. The quote does not reference inclusion of a trailer, and the relatively low amount of the pricing would indicate that the quotation is solely for the MRI scanner.

Therefore, the EmERGEOrtho applications are not conforming to Criterion (5).

Criterion (6) *“The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.”*

EmergeOrtho fails to demonstrate that its proposals would not result in unnecessary duplication of existing MRI capacity. Statewide EmERGEOrtho currently owns and operates eight mobile and fixed MRI scanners. An application cannot be approved when it cannot demonstrate that the project will not result in unnecessary duplication of existing capacity. Therefore the EmERGEOrtho applications are not conforming to Criterion (6).

Criteria (18a) *“The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to*

the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.”

EmergeOrtho’s applications fail to conform to Criterion (18a) because the proposals do not adequately demonstrate that they will promote cost-effective services. The discussion regarding demonstration of need, alternatives, financial feasibility, and unnecessary duplication are found in Criteria (3), (4), (5), and (6), and are incorporated herein by reference.

SECTION .2700 - CRITERIA AND STANDARDS FOR MAGNETIC RESONANCE IMAGING SCANNER

10A NCAC 14C .2703 PERFORMANCE STANDARDS

(a) An applicant proposing to acquire a fixed MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:

- (3) identify the existing mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites located in the proposed fixed MRI scanner service area during the 12 months before the application deadline for the review period;*

The EmmergeOrtho applications do not conform to the .2703(a)(3) performance standard applicable for the review of MRI scanners. EmmergeOrtho did not reasonably project the need for additional mobile MRI capacity in addition to the existing mobile and fixed MRI scanner inventory that EmmergeOrtho operates in North Carolina. The discussion regarding this is found in Criterion (3) and is incorporated herein by reference.

Comparative Analysis

The Agency typically performs a comparative analysis when evaluating competing MRI scanner applications in a need determination batch review. The purpose is to identify the application that would provide the greatest overall benefit to the service area community. The table below summarizes standard metrics that the Agency has previously used for comparing applications in a competitive MRI scanner batch review.

2023 Statewide Mobile MRI Scanner Review CON Application Comparative Analysis

| | Pinnacle | All Competing Applicants |
|--|-------------------|--------------------------|
| Conformity with Review Criteria & Administrative Rules | Yes | No |
| Scope of Services | Equally Effective | Not approvable |
| Historical Utilization | Unable to Compare | Unable to Compare |
| Competition (Access to New Provider) | Equally Effective | Not approvable |
| Ownership of MRI Scanners in Service Area | Most Effective | Not approvable |
| Geographic Accessibility | Most Effective | Not approvable |
| Access by Service Area Residents | Unable to Compare | Unable to Compare |
| Access by Medically Underserved | Unable to Compare | Unable to Compare |
| Projected Average Net Revenue per MRI procedure | Unable to Compare | Unable to Compare |
| Projected Average Operating Expense per MRI procedure | Unable to Compare | Unable to Compare |

As the table objectively portrays, aside from the competing applications not being approvable, the Pinnacle application is the more effective alternative, and will enable the greatest benefit to North Carolina residents. Specifically:

- **Conformity with Review Criteria.** The Pinnacle application is conforming to all CON review criteria. In contrast, the competing applications fail to conform to multiple review criteria and to the MRI administrative rules and are not approvable.

- **Scope of Services.** Each applicant proposes to acquire and operate a mobile MRI scanner and to serve host provider sites in North Carolina. Therefore, the applications are comparable as to scope of services in this review. However, each of the competing applications is not conforming to all CON review criteria, and thus is not approvable. Therefore, Pinnacle is the more effective alternative.
- **Historical Utilization.** All applicants have a history of offering MRI services in North Carolina, yet not all applicants currently operate a mobile MRI scanner. Therefore, the Agency cannot compare the applications with respect to historical utilization in this review.
- **Competition (Access to a New Provider).** All applicants currently provide MRI services in North Carolina, so the applications are equally effective as to access to a new provider. However, the competing applications are not conforming to all CON review criteria, and thus is not approvable. Therefore, Pinnacle is the more effective alternative.
- **Ownership of MRI Scanners in North Carolina.** According to the 2023 SMFP and the various applications submitted in this review, each applicant currently operates MRI equipment in North Carolina. As shown in the following table, Alliance owns and operates 30 MRI scanners in North Carolina and Novant Health operates 31 fixed MRI scanners and 10 mobile MRI scanners in North Carolina. These two providers currently hold dominant positions in the statewide MRI scanner marketplace. Approval of either the Alliance or Novant Health applications would result in even more dominant MRI control for those providers.

MRI Scanner Ownership in North Carolina

| Applicant | PHSNC | Duke | Alliance | Novant Health | CNSA | EmergeOrtho |
|---------------------|-------|------|----------|---------------|------|-------------|
| Fixed MRI Scanners | 1 | 17 | 0 | 31 | 1 | 5 |
| Mobile MRI Scanners | 1 | 0 | 30 | 10 | 1 | 3 |

In addition, Duke operates or is approved for 17 MRI scanners in North Carolina, and EmergeOrtho owns and operates eight MRI scanners in North Carolina. Approval of either the Duke or EmergeOrtho applications would result in even more dominant MRI control for those providers. By contrast, Pinnacle and CNSA each own and operate one fixed MRI scanner and one mobile MRI scanner in North Carolina. Consistent with the 2023 SMFP goal of promoting “a balance of competition and market advantage” (page 4, 2023 SMFP), the Agency should seek to improve the competitive balance within the North Carolina service area via this mobile MRI scanner review. Competition in the North Carolina marketplace will be enhanced with approval of PHSNC for a mobile MRI scanner, while approval of Alliance, Novant Health, Duke or EmergeOrtho will not have a positive effect on MRI competition. Clearly, the Pinnacle application is a more effective alternative as to ownership of MRI scanners in North Carolina.

- **Geographic Accessibility.** The 2023 SMFP defines the service area for mobile MRI scanners as “statewide”. Thus the service area for this review is statewide. The six applicants (10 applications) propose to serve various geographic locations throughout North Carolina, as summarized in the table below.

Geographic Access

| Applicant | PHSNC | Duke | Alliance | Novant East | Novant West | CNSA 1 | CNSA 2 | EmergeOrtho Foothills | EmergeOrtho Triad | EmergeOrtho Triangle |
|----------------------|-------|------|----------|-------------|-------------|--------|--------|-----------------------|-------------------|----------------------|
| # of HSAs Served | 2 | 2 | 2 | 3 | 1 | 1 | 2 | 1 | 1 | 2 |
| # of Counties Served | 3 | 3 | 3 | 4 | 3 | 2 | 2 | 4 | 4 | 4 |
| # of Host Sites | 5 | 4 | 3 | 5 | 3 | 3 | 2 | 4 | 4 | 4 |
| Combined Total | 10 | 9 | 8 | 12 | 7 | 6 | 6 | 9 | 9 | 10 |

The PHSNC application is an effective alternative for enhancing geographic access to mobile MRI scanners in North Carolina because it portrays the second highest combined total number of HSAs, counties and host sites projected to be served. Although the Novant East application projects a higher score, that application is not approvable, and thus the Pinnacle application is the most effective alternative as to geographic accessibility.

- **Access by Service Area Residents.** As previously stated, the 2023 SMFP defines the service area for mobile MRI scanners as “statewide”. Thus the service area for this review is statewide. Generally, regarding this comparative factor, the application projecting to serve the largest number of service area residents is the more effective alternative based on the assumption that residents of a service area should be able to derive a benefit from a need determination for additional MRI scan procedures in the service area where they live. Each applicant in this review projects to serve North Carolina residents living in various portions of the state. Therefore, because all applicants are projecting to service North Carolina residents (e.g. residents of the statewide service area), the Agency cannot compare the applications with respect to projected access by service area residents in this review.
- **Access for the Medically Underserved.** Several applicants propose to execute a service agreement with each host site. Each host site will pay a flat fee to the applicant for the service and the host site will bill the patient or third party payor. Access to medically underserved groups would be the responsibility of each host site and not the applicants. Therefore, the Agency cannot compare all the applications with respect to projected access to underserved groups in this review.
- **Projected Average Net Revenue per MRI Procedure.** Several applicants propose to execute a service agreement with host sites. Each host site will pay a flat fee to the applicant for the service and the host site will bill the patient or third party payor. Patient billing would be the responsibility of each host site and not the applicants. Therefore, the Agency cannot compare all the applications with respect to projected average net revenue per MRI procedure in this review.
- **Projected Average Operating Expense per MRI Procedure.** PHSNC offers cost-effective operating expenses for its mobile MRI service; its application projects a reasonable average operating expense per unweighted MRI procedure. The competing applications are not approvable. Therefore, the PHSNC application is a more effective alternative.

Competitive Comparison Conclusion

Although the competing applications are not approvable, as described in the above comparative analysis, Pinnacle ranks more favorably on the comparative metrics that can be compared. Thus, Pinnacle is a more effective alternative for development of a need-determined mobile MRI scanner in North Carolina.