

566 Ruin Creek Road | Henderson, NC 27536

December 23, 2019

Ms. Martha Frisone, Chief Greg Yakaboski, Project Analyst Certificate of Need Section Division of Health Service Regulation NC Department of Health and Human Services 809 Ruggles Drive Raleigh, North Carolina 27603

Re: Comments on Competing Applications for a Certificate of Need for a fixed MRI scanner in Wake County, Health Service Area IV; CON Project ID Numbers:

J-011820-19, Pinnacle Health Services of North Carolina, LLC

J-011821-19, EmergeOrtho, P.A.

J-011825-19, Raleigh Radiology Cary

J-010826-19, Raleigh Radiology Knightdale

J-011829-19, Duke University Health System, Inc.

J-011830-19, Wake Radiology Diagnostic Imaging, Inc.

Dear Ms. Frisone and Mr. Yakaboski,

On behalf of Maria Parham Health, Duke LifePoint Healthcare, thank you for allowing us to comment on these six competitive applications for the 2019 Need Determination for one fixed MRI scanner in Wake County. Realizing that the Agency can award only one Certificate of Need, we believe it important to share our concerns about one of these applications and how it would negatively affect our safety net rural health system.

We understand that the Certificate of Need (CON) award for the fixed MRI scanner will be based on the CON health planning objectives, and review criteria outlined in the Certificate of Need statute and the 2019 State Medical Facilities Plan ("SMFP"). Criterion 1 addresses the SMFP need determinations and policies. In evaluating the applications, please give careful consideration to the extent to which each applicant adversely affects a rural health care system. Statutory Findings of Fact GS131E-175(3a) set the context:

"That access to health care services and facilities is critical to the welfare of rural North Carolinians, and to the continued viability of rural communities, and that the needs of rural North Carolinians should be considered in the certificate of need review process."

The statute is reinforced in 2019 SMFP, Basic Principles, 2. Access, page 3, which describes Maria Parham Health:

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"...In rural and small communities, selective competition that disproportionately captures profitable services may threaten the viability of sole providers of comprehensive care and emergency services...."

One application, J-011820-19, from Pinnacle Health Services of North Carolina, LLC, proposes to place a fixed 3T MRI in Wake Forest, NC, arguing that this area is underserved with regard to fixed MRI services. The application proposes a service area that reaches into Franklin, Vance, and Granville counties (application at page 29). In fact, the proposed address is only 5.4 miles from Youngsville in Franklin County (Attachment A). The application claims that 28.2 percent of patients served will be from Franklin County and 3.4 percent from Vance (page 23). (The address is called "Raleigh Radiology Wake Forest," but Pinnacle owns and operates the service.)

The application in fact shows that the Wake Forest community has a lot of MRI capacity and most of it is in facilities that like the proposed Pinnacle unit – are freestanding offices or IDTF's and not hospital outpatient departments. On page 65, the application provides a table showing four MRI mobile units already located in Wake Forest. Three will remain if the proposed MRI comes on line and Pinnacle will replace its own mobile MRI with the proposed fixed equipment. The proposal will not enhance competition in Wake Forest. It will provide excess capacity in Franklin and Vance Counties.

As the Agency knows, Franklin Hospital closed not long ago. A rural hospital, owned by Franklin County, it could not sustain competition, with nearby Wake County. Recently, with persistence of Franklin County leadership, DLP LifePoint, and the State of North Carolina, Maria Parham Health reopened Franklin Hospital, modernizing, right sizing and gradually bringing services back on line. Last year, we restored Franklin's MRI operation. The MRI is not yet at breakeven volume. Rural Maria Parham Health in Henderson, Vance County also has MRI services that are not yet at capacity. On page 23, the Pinnacle application indicates intent to draw 1,477 (1,319 +158) MRI procedures from Franklin and Vance counties. That is more than half the number of procedures Maria Parham MRI expects for 2019. Claims of market share increase on application page 102 are not well supported. Certainly, with, Franklin and Vance capacity not yet fully used, adding a fixed MRI scanner in Wake Forest would be harmful to our rural health system.

One of the statutory review criteria is (3) "demonstrate the need that this population [to be served] has for the services proposed." Another criterion, (6) states, "The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities." Maria Parham does not believe that the applicant met the necessary demonstration burden for these two review criteria.

The application discusses features of the 3T magnet, but absence of a 3T in Wake Forest is the only reason it gives for asking to place such a powerful and unique MRI in the northernmost part of one of the state's largest counties. This is an unusual place for the only 3T in Wake County.

The application notes that patients endure travel hurdles going from Wake Forest to Pinnacle offices in Cedarhurst, but claims that patients will "shift" from Cedarhurst to Wake Forest. Maria Parham experience says otherwise. We believe the projections are not well grounded in reality;

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and that financial success of the proposed unit depends heavily on patients from Franklin and Vance.

Criterion 13 requires that the application address "needs of the elderly and of members of medically underserved groups." The proposed payor mix suggests that this applicant is not interested in the medically underserved groups in this service area. This year, Maria Parham's outpatient MRI procedures are 49.3% percent Medicare. Pinnacle proposes 23.1 percent (page82). Our outpatient MRI Medicaid is 13.9% percent and self-pay/charity is at 3.9%. Pinnacle proposes 3.4 percent (page 82).

Maria Parham understands the value of competition and we are working on ways to offer MRI at freestanding prices where it is appropriate, for example, when not associated with inpatient or emergency care. We do not believe that the Pinnacle project would enhance competition in a positive way. Three of the four MRI units in Wake Forest are freestanding. They provide price competition and their prices would not change if Pinnacle Wake Forest office gets a fixed 3T MRI. Pinnacle operates the Wake Forest office as an IDTF. It is not a physician office and does not bill globally. Patients, including Medicare beneficiaries, get two bills, each subject to deductibles and copayments.

Finally, as noted in the 2019 SMFP, Pinnacle owns both a fixed MRI and a mobile MRI. It controls where to place its own mobile. There is an implicit message in the fact that Pinnacle has not placed its own mobile unit full time in Wake Forest, choosing instead to split time with a location in Johnston County. The split time suggests that Pinnacle is not totally convinced that Wake Forest needs full time MRI.

We urge the Agency to look to the other options available in this competitive CON batch, and to find the application J-011820-19, Pinnacle Health Services of North Carolina, LLC nonconforming to statutory review criteria, 1, 3, 6, 13 and by extension 5, financial feasibility. Please deny this Pinnacle application.

Thank you for taking the time to consider the importance of sustaining our rural health delivery system, and for the help the Agency and State have provided in getting keeping this rural health care system viable. We hope you will consider our concerns carefully and thoughtfully during your review.

Sincerely,

Bert Beard

Chief Executive Officer

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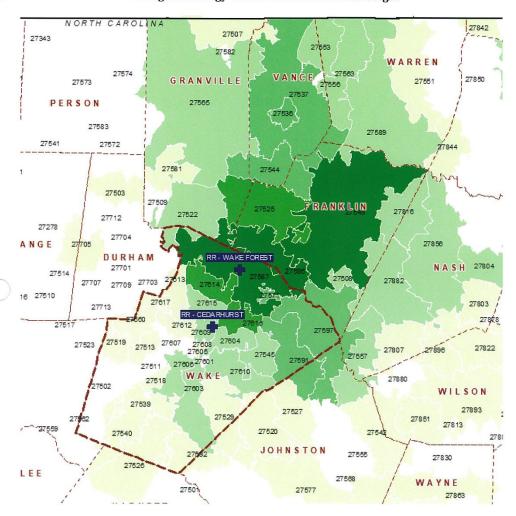
ATTACHMENTS

Service area Mai	n Raleigh Radiology	Wake Forest MRIA	
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Attachment A

Pinnacle Health Services of North Carolina Raleigh Radiology Wake Forest Fixed MRI Scanner Section C – Criterion (3)

Raleigh Radiology Wake Forest MRI Patient Origin



(b) If the proposal involves the entire facility or campus, provide the number of patients by county of residence or other geographic area who used the entire facility or campus during the last full fiscal year by completing the table below.