Petition to the State Health Coordinating Council
Regarding MRI Methodology and Policies
2021 State Medical Facilities Plan

March 4, 2020

Petitioner		***Contact***	
Company:	Raleigh Radiology, LLC	*Name:*	Joanne Watson, COO
Address:	5220 Greens Dairy Road Raleigh, NC 27616	*Email:*	joanne.watson@raleighrad.com
		Phone:	919.322.4537

STATEMENT OF REQUESTED ADJUSTMENT

Raleigh Radiology, LLC requests a change to the *2021 State Medical Facilities Plan ("SMFP")* to address limitations in the policies and need methodology for magnetic resonance imaging ("MRI"). Specifically, it requests parity for qualified freestanding health service facilities that offer MRI by means of service agreements.

An amendment to Policy TE-3 to include, in addition to hospitals, an exemption for qualified freestanding health service facilities would accomplish this. Policy TE-3 permits hospitals that do not own MRI equipment to apply for a Certificate of Need to replace the service agreement MRI with their own fixed MRI equipment, regardless of the need determination in the SMFP. The requested policy amendment would give qualified freestanding non-hospital providers the same option if they meet certain conditions:

- Current equipment operates as fixed;
- Annual weighted MRI procedures are equal or exceed the SMFP's service area threshold;
- Service to Medicare, Medicaid, and other underserved patients is maintained;
- Cost to patients will not increase for 12 months;
- Service agreement for MRI will be terminated when the new fixed MRI scanner becomes operational, and,
- New fixed MRI will obtain accreditation by a body recognized by the Centers for Medicare and Medicaid Services ("CMS").

For discussion purposes, Raleigh Radiology proposes wording for the amendment to Policy TE-3.

CURRENT WORDING POLICY TE-3: PLAN EXEMPTION FOR FIXED MAGNETIC RESONANCE IMAGING SCANNERS

Qualified applicants may apply for a fixed magnetic resonance imaging scanner (MRI).

To qualify, the health service facility proposing to acquire the fixed MRI scanner shall demonstrate in its certificate of need application that it is a licensed North Carolina acute care hospital with emergency care coverage 24 hours a day, seven days a week and does not currently have an existing or approved fixed MRI scanner as reflected in the inventory in the applicable State Medical Facilities Plan.

The applicant shall demonstrate that the proposed fixed MRI scanner will perform at least 850 weighted MRI procedures during the third full operating year.

The performance standards in 10A NCAC 14C .2703 would not be applicable.

The fixed MRI scanner must be located on the hospital's "main campus" as defined in G.S. 131E-176- (14n) a.

Source: p 27 2020 SMFP

PROPOSED WORDING FOR AMENDMENT ADDITION TO POLICY TE-3

At the end of the policy, add the following wording:

Or, to qualify, the freestanding health service facility[1] proposing the fixed MRI shall demonstrate in its certificate of need application that it:

- *Currently offers MRI services in a fixed location by means of a service agreement with an unrelated party and will terminate that agreement when the new fixed MRI scanner becomes operational;*
- *Has offered MRI services at this location for at least three years;*
- *Will obtain MRI accreditation from an advanced diagnostic imaging accrediting organization that is recognized for certification by the Center for Medicare & Medicaid Services ("CMS");*
- *Provided adjusted total MRI procedures in an amount equal to or exceeding its service area threshold as defined in the table of MRI fixed and mobile procedures by service area in the current SMFP;*

[1] Health service facility is defined in G.S. 131-E176(9b) as a "hospital; long-term care hospital; psychiatric facility; rehabilitation facility; nursing home facility; adult care home; kidney disease treatment center, including freestanding hemodialysis units; intermediate care facility for individuals with intellectual disabilities; home health agency office; chemical dependency treatment facility; diagnostic center; hospice office, hospice inpatient facility, hospice residential care facility; and ambulatory surgical facility."

- *Provided services to Medicare, Medicaid, and other underserved groups in the applicant's most recent fiscal year; and will provide the same or increased service in future years; and,*
- *Will not result in increased cost to patients for the first 12 months of operation.*

In this second instance, the Performance Standards in 10A NCAC 14C .2703 would be applicable.

The fixed MRI scanner must be located on the same campus as the MRI service it will replace.

"Unrelated party" means a legal entity in which the applicant or its parent company has no ownership interest.

"Freestanding" means not treated as hospital-based for CMS payment.

STATEWIDE IMPACT

The proposed policy expansion would have statewide impact. A review of Table 17E-1 in the 2020 SMFP suggests it would affect at least five entities. Those data are for 2019. Updated data filed during 2020 could increase the number of qualifying health service facilities by 2021.

Qualify	County	Facility (Unrelated Vendor)	Adjusted Total Procedures FY18	Service Area Threshold
Yes	Guilford	Southeastern Orthopedics (*Alliance*)	5,100	4,805
Almost	Iredell	Piedmont Healthcare (*Alliance*)	3,805	4,805
Yes	Moore	Pinehurst Surgical Clinic, PA (*Alliance*)	5,586	4,805
Almost	Pitt	Physicians East (*Kings Medical*)	3,345	4,805
Yes	Wake	Raleigh Neurology (*Alliance*)	5,988	4,805
Yes	Wake	Raleigh Radiology Blue Ridge (*Alliance*)	6,004	4,805
Yes	Wake	Raleigh Radiology Cary (*Alliance*)	7,511	4,805
Almost	Wake	Wake Radiology (*Alliance*)	4,123	4,805
Almost	Wake	Wake Radiology (*Alliance*)	3,300	4,805

REASONS FOR THE PROPOSED ADJUSTMENT

ADVERSE EFFECTS OF CURRENT PLAN ON PROVIDERS AND OR CONSUMERS IF THE ADJUSTMENT IS NOT MADE

MRI Access Constraints

An MRI scan is as an extremely accurate method of disease detection throughout the body and most often used after other testing fails to provide sufficient information to confirm a patient's diagnosis. In the head, trauma to the brain can be seen as bleeding or swelling. Other abnormalities often found include brain aneurysms, stroke, tumors of the brain, as well as tumors or inflammation of the spine. MRI provides valuable information on glands and organs within the abdomen, and accurate information about the structure of joints, soft tissues, and bones of the body.[2]

Most MRI procedures are outpatient, 85 percent.[3] MRI's do not require hospital back up. In fact, freestanding MRI units boost patient access in terms of location and cost. They are smaller than hospitals, can locate closer to patients, and generally cost patients and payers less than hospital-based MRIs.

Because MRI acquisition is subject to CON and regulated by a methodology published in the annual State Medical Facilities Plan, opportunities for new providers to enter markets are very limited. The only assured way for a provider to start offering MRI services is to contract with a service agreement vendor. The party providing the MRI service to patients is typically at-risk for collecting enough in patient and third-party payments to cover the service agreement cost.

The SMFP methodology is demand driven and based on cumulative supply and use in a service area. Most service areas are counties. An individual provider can exceed the threshold year after year, but has no assured means of transitioning from service agreement to owned equipment, unless the provider is a hospital with an emergency room that does not own an MRI. That provider can use the exemption provided by Policy TE-3.

Low Freestanding MRI Payments

Payors are putting pressure on beneficiaries and on referring physicians to seek care in low cost settings. Uninsured or underinsured patients already seek low cost settings in order to afford recommended care. Government and third parties pay freestanding health service facilities less than hospitals for identical MRI procedures; and other payors follow suit. Thus, for outpatients, MRI scans at these non-hospital settings typically cost less. To sustain this value proposition, freestanding health service facilities need to keep costs and charges in line with the third-party reimbursement.

Even among freestanding health service facilities, competition is important to containing consumer costs.

[2] Medicine Net, MRI scan center, medically reviewed on 11/15/19 https://www.medicinenet.com/mri_scan/article.htm
[3] Per data from NC DHSR database for 2019 Hospital License Renewal Applications and Registration and Inventory of Medical Equipment Forms.

MRI Vendor Service Agreement Costs

One way to control costs is to minimize overhead. Offering MRI through service agreements starts with an extra layer of overhead – that of the service vendor. Moreover, the service vendors decide equipment type, when to upgrade or service the equipment, and how to deploy staff. Those who offer MRI under service agreements operate under constraints set by the vendor. Equipment can remain unchanged well beyond the recommended depreciable life; individual staff techs can vary from day to day and week to week; and price escalations generally accompany service agreement renewals, even when equipment is not improved.

MRI came under North Carolina certificate of need regulation in 1993; the State grandfathered all MRIs in service before then. Among the grandfathered MRIs, three mobile vendors have grandfathered CON authority and offer service agreements that function like fixed units with the vendor providing both staff and equipment.

Many service agreements involve MRI units in mobile trailers, located outside the health service facility. Some grandfathered "mobile" MRI units involved in the service agreements are actually located inside health service facilities. The Agency has ruled that to maintain certificate of need material compliance, the service agreement vendors must staff the MRI, regardless of location, outside or inside buildings. These employees are subject to the vendor's service policies and answer to the vendor's managers. The health service facility that is responsible to the patient for quality of the MRI can only recommend hiring, firing, or disciplinary action; it has no direct authority.

Under the service agreements, health service facilities cannot modify or alter the unit without vendor consent, which, if granted, usually requires an extension of the service agreement, at additional cost to the health service facility. Facilities offering MRI under service agreements are at the mercy of the vendors. For example, the health care facility cannot provide its own equipment or arrange favorable equipment financing to contain operating costs. Vendors negotiate the equipment maintenance agreements. Vendors may condition the service agreement to give themselves right of first refusal on another agreement for any new site the health service facility wishes to pursue. Vendors can remove units from service sites – even those inside the building – if the service agreement expires or terminates, with or without cause.

These disadvantages translate to quality and cost challenges that will ultimately extend to patients.

Unintended Consequence – Plan Protection of Service Agreements

In Chapter 17 of the SMFP, the MRI methodology/algorithm for calculating need determinations implicitly assumes that procedures offered at existing locations will continue at reported levels. A service area need determination occurs when the area's adjusted total MRI procedures divided by its threshold exceeds the number of fixed equivalent MRI units located there.

Basic Assumption #8 reinforces that implicit assumption

> *A facility that offers MRI services on a full-time basis pursuant to a service agreement with an MRI provider* ***is not precluded*** [emphasis added] *from applying for a need determination to replace the existing contracted service with a fixed MRI scanner under the applicant's ownership and control. It is consistent with the purposes of the Certificate of Need law and the State Medical Facilities Plan for a facility to acquire and operate an MRI scanner to replace such a contracted service, if the acquisition and operation of the facility's own MRI scanner will allow the facility to reduce the cost of providing the MRI service at that facility.* [Source 2020 SMFP page 419.]

If a health service facility with a service agreement applies to replace the MRI under a need determination, the service vendor may, or may not, remain in the service area. Most service vendors can place their equipment anywhere in the state. Hence, the SMFP provides no assurance that a replacement unit obtained under a need determination will increase MRI capacity in the service area.

We agree that service agreements play an important role in expanding geographic access, providing new MRI access points for *start-up* and *small volume* settings; and they help providers that need immediate expansion capacity.

We also believe that in today's health care cost environment, the SMFP should provide for qualified freestanding health service facilities to replace fixed equipment service agreements with their own fixed equipment.

Unfair Treatment of Freestanding Facilities Disadvantages Patients

Today, SMFP MRI policies address hospitals that depend on service agreements, but not freestanding health service facilities. Policy TE-3 provides an SMFP need exemption and relief for hospitals. Policy TE-3 was a step in the right direction. However, the policy should be more inclusive; otherwise, the SMFP puts freestanding health service facilities with a demonstrated track record of patient service at a competitive disadvantage.

Another Policy, TE-2, provides SMFP need exemptions for hospital intraoperative MRI units.

Equity between hospitals and other qualified entities who offer MRI services is important to maintaining access and value in the health care delivery system. In today's payment environment, freestanding health service facilities are more likely to offer patients and payors lower charges for the same procedure and their lower out-of-pocket costs to consumers adds important competition to a service area.

Risk of Losing MRI Providers That Offer Low Out-of-Pocket Costs

With low MRI reimbursement, freestanding health service facilities cannot sustain year after year price increases from the service agreement vendors. At some point, the cost of offering MRI exceeds reimbursement, even when the number of adjusted annual MRIs exceeds the service area threshold. When that happens, discontinuing MRI service is the only choice, because otherwise, offering MRI drains resources from other services. Because MRI is a common, non-invasive imaging modality that involves no radiation, discontinuation of a busy, value priced MRI provider would hurt many consumers.

Data in Table 17E-1 of the 2020 SMFP indicate 23 fixed MRI units operate under service agreements; two vendors own 19. Some appear to be owned by parties related to the freestanding health service facility. In some service areas, service agreements account for as much as 23 percent of the fixed equivalent MRI equipment; four to five MRI service sites. [4]

The SMFP MRI methodology now generates a need for one or fewer MRI units per service area per year; and that has been the case for all but *three of the last 21 years.* In those three years, the need involved multi-county service areas. As a result, qualified freestanding MRI health service facilities must compete with one another and with new entrants for the single fixed MRI need determination in the annual SMFP. New entrants can claim a new geography or propose an untested payor mix. With only one MRI unit needed in the service area, only one can receive a CON. The others risk multiple rounds of expensive CON applications and appeals**.** The situation also gives undue leverage to the service agreement vendors, who have no pressure to improve service. Thus, service areas with more than one fixed MRI operating under third-party service agreements will be at higher risk of losing MRI services as the agreements become more expensive.

MRI Fixed Need Determination History

Year	No. of Service Areas with More than One Fixed MRI Needed
2020	0
2019	0
2018	0
2017	0
2016	0
2015	0
2014	0
2013	0
2012	0
2011	0
2010	0

Year	No. of Service Areas with More than One Fixed Unit Needed
2009	0
2008	0
2007	0
2006	0
2005	0
2004	1
2003	0
2002	0
2001	2
2000	1

Source: SMFPs 2000-2020

[4] Per data from Table 17E-1, 2020 SMFP; third-party vendor fixed equivalent MRIs as a percent of total fixed equivalent MRIs in the service area.

Clearly, when a qualified freestanding health service facility reaches the service area threshold for annual fixed equivalent MRI procedures, the public will benefit, if the SMFP provides an option to exit the service agreement and replace it with a fixed MRI owned by the health service facility itself.

ALTERNATIVES CONSIDERED

Raleigh Radiology considered and rejected several other alternatives. With one exception, the following paragraphs describe the alternatives considered and rejected.

Maintain Status Quo

Status quo is not reasonable. Left unchecked, the service agreements can ultimately force higher than necessary prices for MRI. Vendors can raise prices without improving the equipment.

Service agreements are by nature time limited**.** They have two other downsides. First, the agreement favors the equipment owner's interest in neither upgrading nor replacing the equipment. Second, the agreement puts the party offering the service at risk that in a time of payment reductions, the cost of offering MRI through a service agreement may exceed what third parties and patients pay for the service, consequently putting the whole service at risk. Service agreement vendors may increase charges to the health service facility at every renewal. Status quo provides no exit, other than MRI service discontinuation, for facilities that are not hospitals and have no other MRI equipment.

Change the SMFP Need Methodology

A complete change in the SMFP MRI Need Methodology would be time consuming for the SHCC and for Agency staff; and it is unnecessary. Need methodology changes generally require a work group and extensive staff work to review the impact of different formulas and algorithms. At the end, any new formula may not address the problem. Formulas are more rigid than a policy that sets boundaries and puts the burden of proof on the certificate of need applicant.

Establish a New Threshold

This, too, is unnecessary. The SMFP has clear service area thresholds that the SHCC has vetted through public hearings. The thresholds increase as the number of MRIs in the service area increase. A minimum applied universally across the state could have an unrelated impact of adding too much or too little competition.

The SMFP assumes that MRI capacity is 6,864 adjusted scans for planning purposes. The thresholds are:

Number of Fixed Scanners in Service Area	Planning Threshold	Inpatient and Contrast Adjusted Thresholds
4 and over	70%	4,805
3	65%	4,462
2	60%	4,118
1	55%	3,775
0	25%	1,716

Source: 2020 SMFP p 419

Moreover, this request proposes to retain the Performance Standard in 10A NCAC .2703. With that standard included, the proposed policy amendment would limit exemptions to qualified freestanding health service facilities that demonstrate high utilization.

Policy TE-3 exempts hospitals that have an emergency room and do not own an MRI from the planning thresholds. In that instance, the SHCC concluded that every such hospital in the state should have the option of owning an MRI and agreed to set a low qualifying bar. To prevent unnecessary duplication, this proposed change sets a higher bar for freestanding health service facilities.

Apply Proposed Policy to "Related Party" Service Agreements

A health service facility offering MRI services though a related party service agreement does not suffer the same disadvantage. The related party has less incentive to increase costs or delay capital improvements, and the two may share MRI employees. It also has access to the Replacement Equipment option.

Eliminate the Performance Standard

10A NCAC 14C .2703 requires an applicant to demonstrate that all of its owned fixed and mobile MRIs located in the service area have provided in the previous 12 months, and will reasonably provide by the third year of operation following completion of the project, 3,328 weighted MRI procedures. This standard prevents an applicant from adding capacity to a service area in excess of what the applicant's referral base can justify. This is an important control to prevent unnecessary duplication. It is also important to prevent unnecessary competition with rural hospitals.

Treat the Service Agreement MRI Equipment as "Replacement Equipment" G.S. 131E-176 (22a)

This alternative has certain appeal. The CON statute defines Replacement Equipment and vetted administrative rules exist. This alternative would apply to service agreement equipment that has been in service at the location for at least three years and would require removal of the existing equipment from the service area. Replacement equipment requires the requesting party to guarantee removal of that existing equipment from the service area. However, the health service facility providing MRI under a service agreement has no control over MRI equipment location because it lacks CON rights to the equipment. For that reason, Raleigh Radiology rejected this otherwise ideal solution.

This concludes discussion of alternatives considered and rejected.

Set a Three-Year Minimum of MRI Operations before Replacement

Although Policy TE-3 does not apply this restriction to hospitals, Raleigh Radiology considered, and accepted, this alternative. Raleigh Radiology's own qualified MRI locations have been in place for nine years. Replacement equipment rule 10A NCAC 14C .0303(e) also requires three years of service at the location. This qualifier would align the proposed amendment with the Replacement Equipment rule.

EVIDENCE THAT THE PROPOSED CHANGE WOULD NOT RESULT IN UNNECESSARY DUPLICATION OF HEALTH RESOURCES IN THE AREA

The proposed change could increase MRI capacity in the state. However, the proposed policy amendment includes limits to assure that the additional MRI capacity is necessary. It qualifies only those applicants who meet access, service, and quality requirements. By including language that applies the MRI Performance Standard 10A NCAC 14C .2703, the amendment will require applicants to demonstrate sufficient need in the population to be served to justify the fixed unit in the service area. In addition, CON statutory Criterion 6 requires applicants to demonstrate that the proposal will not result in unnecessary duplication.

Policy TE-3 has been in place since 2017. Three institutions have applied for the exemption. Two eligible facilities have not yet applied. MRI equipment is expensive to acquire and operate. History demonstrates that not every health service facility will find it reasonable to incur the expense of acquiring its own MRI equipment. For those that do, controls built into the proposed change require demonstration of utilization consistent with other MRI equipment in the service area, shared savings with patients, and access to medically underserved groups.

Thus, the proposed change would not result in unnecessary duplication of health resources in the area

EVIDENCE THAT THE REQUESTED CHANGE IS CONSISTENT WITH THE THREE BASIC PRINCIPLES

SAFETY AND QUALITY

The proposed wording would require applicants to obtain and maintain accreditation by a body approved by CMS for participation in Medicare and Medicaid reimbursement. This assures continuous updating and objective third-party quality oversight. North Carolina does not license freestanding MRIs and, because MRI does not involve radiation, it does not have NC Radiation Safety oversight like CT and x-ray equipment. The accreditation requirement would be a strong quality assurance provision.

ACCESS

The requirements for service to government third party beneficiaries, Medicare and Medicaid, and other underserved groups, not increase charges to the public because of the conversion from service agreement to fixed ownership, directly address access to care. The proposed amendment incorporates one of the biggest access issues in health care today, the price of service. Finally, most freestanding MRI locations add to geographic access because they are not located at hospitals.

VALUE

"The SHCC defines health care value as the maximum health care benefit per dollar expended….Cost per unit of service is an appropriate metric when comparing like services for like populations" (SMFP p.3). The proposed amendment builds in safeguards to assure that the proposed conversion shares value with the population served. It requires service to Medicare and Medicaid and other underserved groups; and it puts a cap on price escalation.

CONCLUSION

We are asking for an expansion of Policy TE-3 to include qualified freestanding health service facilities that offer MRI procedures. The request is in keeping with the Basic Principles governing the *State Medical Facilities Plan* of maximizing quality, access, and value.

BACKGROUND ON RALEIGH RADIOLOGY

Raleigh Radiology, LLC is a multi-specialty radiology provider owned by a group of 42 radiologists who provide services to their own and other health service facilities in Wake County. Although Raleigh Radiology was the first to offer freestanding MRI in Wake County, it does not own any fixed MRI equipment.