

North Carolina State Health Coordinating Council
c/o Medical Facilities Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Re: Cape Fear Valley Health System Petition/Comment¹ Regarding *Proposed 2017 SMFP Policy TE-3: Plan Exemption for Fixed Magnetic Resonance Imaging Scanners*

I. Petitioner

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II. Requested Change

First, Cape Fear Valley Health System (CFVHS) would like to thank the SHCC and SHP staff for their attention to the need for MRI services at rural hospitals and for including Policy TE-3: Plan Exemption for Fixed Magnetic Resonance Imaging Scanners in the *Proposed 2017 SMFP*.

CFVHS requests the following two changes be made in the Proposed Policy TE-3.

1. The policy should be amended to allow an individual community hospital with a 24-hour emergency department to apply for a CON for a fixed MRI.
2. The threshold in the policy should be changed to 500 weighted MRI procedures.

¹ CFVHS has labeled this written submission as both a petition and a comment. It is not entirely clear which label is most appropriate to give input to the SHCC on Policy TE-2 included in the Proposed 2017. The point of the series of 6 public hearings during July 2016 is to solicit input on the entire contents of the Proposed 2017 SMFP. We trust the SHCC and its Medical Equipment Committee will study and take into consideration the suggestions made herein by CFVHS. There is no need determination on which to seek adjustment for the new policy included in the Proposed 2017 SMFP.

These proposed changes are reflected in the following Policy TE-3 language.

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 ~~is located in a county~~ that the hospital 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 ~~900~~ 500 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 131E-176 (14n).

III. Reasons for Proposed Adjustment

MRI is widely used in hospitals and clinics for medical diagnosis, staging of disease and follow-up without exposing the body to ionizing radiation. An MRI scan is a painless radiology technique that has the advantage of avoiding x-ray radiation exposure. There are no known side effects of an MRI scan. The benefits of an MRI scan relate to its precise accuracy in detecting structural abnormalities of the body. **As discussed below, MRI is the current standard of care and should be available in ALL hospitals that determine it is a financially viable option for the community served by the hospital.**

A. MRI Expansion at Community Hospitals

MRI is now an essential non-invasive diagnostic tool, particularly for soft tissues and organs. When the *SMFP* first included MRI Planning Threshold Tiers in 2005, use rates for MRI were growing rapidly and the State Health Coordinating Council (SHCC) wanted to provide a mechanism to both rationalize distribution of the technology and assure that community hospitals could obtain MRI scanners. For most hospitals and communities, the SHCC achieved its goal.²

² 2016 Petition submitted by J. Arthur Doshier for Fixed MRI Policy for Community Hospitals

Nationwide and statewide, the health care system is under pressure to reduce cost. Policy GEN-3 and the Basic Principles of the *SMFP* encourage and require projects to reduce cost to the consumer. While not intended, the *SMFP* MRI methodology holds a hospital that leases MRI services hostage to a vendor contract.³ The cost of expanding mobile MRI services at a community hospital for a second or third day at the hospital often is more than the cost to purchase fixed MRI equipment which is then available to physicians and patients 24 hours per day, 7 days per week. As a result, community hospitals cannot expand volumes without experiencing costly expenses and are placed in a catch-22 situation; they must spend more to expand mobile MRI availability a day or two to reach existing thresholds, but the cost of the lease arrangement is greater than investing in fixed equipment which would always be available. This arrangement currently results in increasing the cost of care.

In order to align the MRI Chapter with the spirit of the Basic Assumptions of the current MRI Methodology and the Basic Principles of the *SMFP*, Policy TE-3 should be included in the final 2017 *SMFP* and should provide an alternative for any hospital without a fixed MRI to pursue one through the CON process, independent of a need determination in the MRI equipment needed in a service area.

B. MRI is the Accepted Standard of Care

“Standard of care” is a diagnostic and/or treatment process that a clinician should follow for a certain type of patient, illness, or clinical circumstance. An MRI scan can be used as an extremely accurate method of disease detection throughout the body and is the standard of care 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.⁴

MRI provides valuable information on glands and organs within the abdomen, and accurate information about the structure of the joints, soft tissues, and bones of the body. Often, surgery can be deferred or more accurately directed after knowing the results of an MRI scan. MRI has a wide range of applications in medical diagnosis and over 25,000 scanners are estimated to be in use worldwide. MRI has an impact on diagnosis and treatment in many specialties. Since MRI does not use any ionizing radiation, its use is generally favored in preference to CT when either modality could yield the same information.⁵

Musculoskeletal Uses of MRI

Applications in the musculoskeletal system includes spinal imaging, assessment of joint disease and soft tissue tumors.

³ Ibid.

⁴ www.medicinenet.com/mri_scan

⁵ https://en.wikipedia.org/wiki/Magnetic_resonance_imaging

Oncological Uses of MRI

MRI is the investigation of choice in the preoperative staging of rectal and prostate cancer, and has a role in the diagnosis, staging, and follow-up of other tumors.

Neurological Uses of MRI

MRI is the investigative tool of choice for neurological cancers, as it has better resolution than CT and offers better visualization of the posterior fossa. The contrast provided between grey and white matter makes it the best choice for many conditions of the central nervous system, including demyelinating diseases, dementia, cerebrovascular disease, infectious diseases and epilepsy. Since many images are taken milliseconds apart, it shows how the brain responds to different stimuli; researchers can then study both the functional and structural brain abnormalities in psychological disorders. MRI is also used in MRI-guided stereotactic surgery and radiosurgery for treatment of intracranial tumors, arteriovenous malformations and other surgically treatable conditions using a device known as the N-localizer.

Cardiovascular Uses of MRI

Cardiac MRI is complementary to other imaging techniques, such as echocardiography, cardiac CT and nuclear medicine. Its applications include assessment of myocardial ischemia and viability, cardiomyopathies, myocarditis, iron overload, vascular diseases and congenital heart disease.

Liver and Gastrointestinal Uses of MRI

Hepatobiliary MRI is used to detect and characterize lesions of the liver, pancreas and bile ducts. Focal or diffuse disorders of the liver may be evaluated using diffusion-weighted, opposed-phase imaging and dynamic contrast enhancement sequences. Extracellular contrast agents are widely used in liver MRI and newer hepatobiliary contrast agents also provide the opportunity to perform functional biliary imaging. Anatomical imaging of the bile ducts is achieved by using a heavily T2-weighted sequence in magnetic resonance cholangiopancreatography (MRCP). Functional imaging of the pancreas is performed following administration of secretin. MR enterography provides non-invasive assessment of inflammatory bowel disease and small bowel tumors. MR-colonography can play a role in the detection of large polyps in patients at increased risk of colorectal cancer.

C. Improved Access to MRI Utilization at Community Hospitals

While a community hospital may not have the specialist necessary for all of the above procedures, most of North Carolina's community hospitals are part of larger systems which share services and are linked through electronic medical records (EMR). Having access to MRI equipment at the community level allows improved access for rural populations and can decrease travel time and trips to larger urban hospitals. A community physician can work with a specialist

in Raleigh, Asheville, Fayetteville, Charlotte or elsewhere; order necessary tests locally and then if a patient must travel for the referral visit, needed MRI scans are already part of the patient record, making diagnosis and treatment seamless for the patient. This process not only results in high quality patient care at a lower cost, the community hospital also benefits by providing a needed service in the community.

In addition, with state-of-the-art standard of care technology, community hospitals can increase their ability to recruit physicians and develop new community services. This again decreases the cost of care to the patient via, saved travel time and time off from work.

Developing this seamless process becomes even more important as health care in North Carolina moves toward Accountable Care Organizations (ACO). ACO will require providers to utilize the lowest cost alternative for care, and to meet patient satisfaction requirements. Improving access to care at the local level at community hospitals are a critical part of the process. Having valuable diagnostic tools locally makes sense when the cost of acquiring the equipment and providing the services is less than the cost of leasing mobile services.

The proposed Policy TE-3 will not result in an influx of new MRI equipment across North Carolina. **The policy, with the proposed amendment, will allow ALL community hospitals to analyze where they are in the continuum of care, working collaboratively with other related entities, to determine the most cost effective way to deliver care to the population they serve.** If current mobile MRI capacity is insufficient to meet the needs of the population served, the community hospital will analyze the impact of adding additional mobile MRI time or acquiring a fixed MRI. During the CON process the community hospital will have to justify the need for the fixed MRI equipment and demonstrate that it is financially viable to acquire the equipment.

D. MRI Utilization in Emergency Departments

For many years MR imaging (MRI) has been considered a second-line procedure required for further diagnostic work-up after first-line imaging with x-ray, ultrasound or even computed tomography (CT) in the emergency room. However, the increasing performance of modern MR equipment and sequence design have broadened the range of indications, now making MRI the first-line imaging modality of choice for a number of clinical conditions. This is most obvious in neurovascular emergencies, but it also applies to a number of other indications. More and more, an 'emergency MRI' is being requested at night or during weekends. In most cases, the decision whether to perform it is taken according to the particular circumstances, such as the availability of sufficiently skilled staff and radiological expertise.⁶

The use of CT and MRI scans for injury-related emergency room visits in the United States has tripled since 1998. Of 324,569 emergency department visits between 1998 and 2007, 20% were injury-related, the researchers found. Of 5,237 sample injury-related visits in 1998, 6% of the patients received an MRI or CT. By 2007, 15% of 6,567 patients sampled had scans. While the

⁶ Indications for 24 Hours/7 Days Emergency MRI, www.siemens.com/magnetom-world ; Attachment 1

increase in the likelihood of getting a CT or MRI scan during visits to emergency departments has not resulted in corresponding increase in the likelihood of diagnosing life threatening injuries during those visits, the technological ability to provide CT and MRI provides assurance that the ER physician has made a correct diagnosis, reduces the wait time and uncertainty anxiety for the patient, and reduces health-care costs.

Reporting a negative medical imaging procedure, such as, being able to tell patients that they definitively do not have an intracranial hemorrhage, is invaluable, according to Dr. Uppot, director of the Abdominal Imaging Fellowship Division at Massachusetts General Hospital in Boston. In addition, ER doctors are under pressure to get patients discharged as quickly as possible according to Uppot. By ordering an imaging test, doctors think they can get a quicker diagnosis and move the patient out of the emergency department faster, he said.⁷

When mobile MRI is not present it is not easily accessible for emergency patients or inpatients. Patients admitted to community hospital inpatient units, or the emergency departments, cannot be scheduled for an MRI during their stay if the mobile MRI is not present, and instead must be transferred or scheduled as an outpatient, thus delaying the diagnosis and treatment of a potential medical condition. As a result, physicians and emergency providers direct many hospital service area patients out of the county rather than risk delays associated with obtaining an MRI scan. This again makes care less seamless and costlier. An onsite, fixed MRI will allow physicians to provide efficient, quality care.

E. Rural MRI Service Areas

Small hospitals throughout North Carolina have part-time MRI services. Currently, Alleghany, Anson, Avery, Bladen, Chatham, Duplin, Hoke, Martin, Montgomery, Pender, and Polk counties have community hospitals which provide limited MRI service with mobile MRI equipment. While these hospitals may reach the full time MRI equivalents needed to generate a need in the SMFP in the future, it will cost them significantly more over the next several years than acquiring fixed equipment. Presently, these hospitals have less than one full time equivalent MRI, according to data in the *2016 SMFP*.

In addition, Hoke County is an MRI Service Area according to Table 9P which now has two new community hospitals. The *2016 SMFP* currently shows no MRI need in that MRI Service area. As MRI services at those hospitals develop, they too will face similar problems and when a need is finally identified, expensive litigation will result, as both hospitals will apply for the one MRI identified as needed in the SMFP and only one could be approved based upon the current methodology in the SMFP and the current language in proposed Policy TE-3. **Policy TE-3, with the amended language, provides a more reasonable alternative, allowing each hospital to determine its own need and justify that need through the CON process.**

⁷ http://www.healthleadersmedia.com/content/TEC-257_4_78/CT-MRI-Use-in-Emergency-Department-Soaring

F. Financial Feasibility of Fixed MRI in a Community Hospital

North Carolina rural community hospitals struggle daily to provide cost-effective high quality care to the population they serve. Fixed MRI equipment can be purchased for \$1.0 to \$1.5 million for new equipment which is less expensive than continuing to lease a mobile with extended days. In addition, it is even less expensive to purchase refurbished MRI equipment if a community hospital decides that would be a better alternative. Furthermore, acquiring and operating its own MRI service will result in additional income for the community hospital instead of funding dividend payments for for-profit vendors.

Further, the cost of expanding Mobile MRI services is a less attractive financial alternative for community hospitals. Often the current cost to lease a Mobile MRI is nearly equivalent to MRI revenues generated leaving the community hospital with a very vulnerable operating margin. Adding additional days to the current contract often will not result in improved operating margins as the cost of leasing for an additional day is almost equivalent to the revenues received. In addition, if a community hospital adds additional days per week to the lease, lease cost over the course of three years would compare to what they could have paid to purchase a fixed MRI. Since the life of a MRI is approximately 7 years, the community hospital will pay more than twice what they would have paid for a fixed MRI to be available at for 7 years, 7 days per week.

CFV-Bladen County Hospital, a Critical Access Hospital currently pays nearly \$170,000 per year for MRI services for one day of mobile services a week. An analysis of costs at CFV-Bladen County Hospital, including staffing an MRI service full-time, shows that with a volume of just over 400 cases, the acquisition of a fixed MRI scanner makes more financial sense than expanding the mobile service. Attachment 1 provides this analysis. Weighted MRI volume in North Carolina in 2015, based upon data in the *Proposed 2017 SMFP*, averaged around 1.2 times total MRI scans. **Therefore, a break-even point of 400 cases results in an estimated 480 weighted cases, which CFVHS recommends rounding to 500 weighted cases.**

If a community hospital has physician and community support, and can justify the purchase of fixed MRI equipment, the installation of a fixed MRI unit at a community hospital has the potential to result in:

- At least a 30-40% increase in volume and revenue.
- Reduction in operating cost by approximately 50%.
- Provide flexible and improved staffing 5 days per week.
- Positive Return on investment and payback within 3 years or less.
- The unit will not require replacement for approximately 7 years, thus leaving years 3-7 with no capital expense for the unit itself.

The following table shows all hospital MRI volume in rural counties⁸ in North Carolina in FFY 2015.

Hospital	Fixed/Mobile	Rural Only	FFY 2015 Volume
FirstHealth Moore Regional Hospital	Fixed	R	13,298
Wayne Memorial Hospital	Fixed	R	6,457
Southeastern Regional Medical Center	Fixed	R	5,949
Carolina East Medical Center	Fixed	R	5,353
Johnston Memorial Hospital	Fixed	R	5,077
Pardee Memorial Hospital	Fixed	R	5,061
Nash General Hospital	Fixed	R	5,009
CMC-Union	Fixed	R	4,855
Randolph Hospital	Fixed	R	4,149
CMC-Blue Ridge	Fixed	R	4,122
MedWest Haywood	Fixed	R	4,030
CMC-Lincoln	Fixed	R	3,904
Novant Brunswick	Fixed	R	3,867
Carteret General Hospital	Fixed	R	3,642
Onslow Memorial Hospital	Fixed	R	3,623
Cleveland Regional Medical Center	Fixed	R	3,596
Wilson Medical Center	Fixed	R	3,552
Maria Parham Medical Center	fixed	R	3,470
Hugh Chatham Memorial Hospital	Fixed	R	3,185
Park Ridge Hospital	Fixed	R	3,182
Watauga Medical Center	Fixed	R	3,056
Scotland Memorial Hospital	Fixed	R	2,983
Lexington Memorial Hospital	Fixed	R	2,959
Albemarle Hospital	Fixed	R	2,864
MedWest Harris	Fixed	R	2,827
Annie Penn Hospital	Fixed	R	2,819
Wilkes Regional Medical Center	Fixed	R	2,747
Northern Hospital of Surry	Fixed	R	2,743
Betsy Johnson Regional Hospital	fixed	R	2,700
Central Carolinas Hospital	Fixed	R	2,690
Lenoir Memorial Hospital	Fixed	R	2,635
Stanly Regional Medical Center	Fixed	R	2,590
Rutherford Hospital	Fixed	R	2,524
Novant Thomasville	Fixed	R	2,427
Sampson Regional Medical Center	Fixed	R	2,330
Columbus Regional Healthcare System	Fixed	R	2,248
Transylvania Community Hospital	Fixed	R	2,158
Morehead Memorial Hospital	Fixed	R	2,131
Caldwell Memorial Hospital	Fixed	R	2,099
Vidant Chowan Hospital (CAH)	Fixed	R	1,914

⁸ Rural definition based upon NC Rural Economic Development Center @ www.ncruralcenter.org

Outer Banks Hospital (CAH)	Fixed	R	1,895
Vidant Beaufort Hospital	Fixed	R	1,895
Vidant Roanoke-Chowan Hospital	Fixed	R	1,849
Vidant Edgecombe Hospital	Fixed	R	1,845
Murphy Medical Center	Fixed	R	1,803
Angel Medical Center (CAH)	Fixed	R	1,622
Halifax Regional Medical Center	Fixed	R	1,599
Granville Medical Center	Fixed	R	1,360
Blue Ridge Regional	Fixed	R	1,294
Dosher Memorial Hospital ("Grandfathered" Alliance Mobile) (CAH)	Fixed	R	1,193
Ashe Memorial Hospital (Alliance Healthcare Services lease) (CAH)	Fixed	R	881
Person Memorial Hospital (Alliance Mobile)	Fixed	R	727
Kings Mountain Hospital	Fixed	R	705
McDowell Hospital	Fixed	R	601
Highlands-Cashiers Hospital (CAH)	Fixed	R	374
Sandhills Regional Medical Center	Fixed	R	321
FirstHealth Richmond Memorial Hospital	Mobile	R	2,011
First Health Hoke	Mobile	R	1,344
FirstHealth Montgomery Memorial Hospital	Mobile	R	997
St. Luke's Hospital (Carolinas Imaging Services Mobile)	Mobile	R	856
Vidant Duplin Hospital (Alliance Mobile)	Mobile	R	837
Davie County Hospital (Alliance Mobile)	Mobile	R	832
Cannon Memorial (Alliance Mobile)	Mobile	R	561
Martin General Hospital (Alliance Mobile)	Mobile	R	551
Chatham Hospital, Inc. (Alliance Mobile)	Mobile	R	549
Pender Memorial Hospital (Alliance Mobile)	Mobile	R	338
Cape Fear - Bladen County Hospital (Mobile Imaging of NC)	Mobile	R	331
Alleghany Memorial Hospital (Alliance Mobile)	Mobile	R	198
Yadkin Valley Community Hospital (Alliance Mobile)	Mobile	R	57
CMC-Anson (Carolina Imaging Services Mobile)	Mobile	R	50
Washington County Hospital (Alliance Mobile)	Mobile	R	0

Source: Proposed 2017 SMFP Table 9P

Note: "0" volume reflects data reported in LRA under main location

As shown in the previous table 11 hospital with fixed MRI have volumes below or well below the minimum threshold of 1,716 included in the MRI Methodology in the annual SMFP. All are rural hospitals and four are critical access hospitals. This illustrates that a viable MRI service can be maintained to meet the needs in the community when MRI volume is considerably less than the defined threshold in the SMFP. Further, there are 11 hospitals operating a viable fixed or mobile service with less than 500 unweighted MRI procedures.

The proposed Policy requests that community hospitals be allowed to determine the need for MRI services in their community and be allowed the opportunity to justify that need through the CON Process without a defined need in the annual SMFP.

IV. Response to Issues Raised by Alliance

During the Public Hearing process Alliance Healthcare Services spoke against TE-3 as reflected in the Proposed 2017 SMFP and raised several issues. CFVHS believes that none of the issues raised by Alliance have merit. These are discussed below in the order presented at the Greensboro Public Hearing.

1. First, Alliance believes that the concept of "qualified applicants" is clearly discriminatory because community hospitals are certainly not the only safety net providers in rural NC counties. Physician groups, Rural Health Centers and Federally Qualified Health Centers also provide tremendous benefit and access to care for medically underserved populations. The needs of the populations in certain rural counties could probably be better served by improving access to mobile MRI at both hospital and non-hospital sites.

CFVHS agrees that physician groups, rural health centers and Federally Qualified Health Centers (FQHC) do provide a needed service in rural communities and provide care to indigent and underserved populations. However, ONLY hospitals are governed under the EMTALA regulations requiring hospital to provide care to any and all patients that present in the emergency department 24 hours per day, 365 days per year. ONLY hospitals open their doors 24 hours per day, 365 days per year. Therefore, the definition of "qualified applicants" is clearly NOT discriminatory because ONLY community hospitals will be available to meet the needs of the population served all day, every day.

2. Secondly, Alliance believes is unreasonable for the proposed policy to require the "qualified applicant" to provide 24 hour 7 day per week emergency department coverage but have absolutely no minimum staffing requirement or weekly hours of operation for the fixed MRI service. This disconnect between the definition of "qualified applicant" and the absence of an MRI staffing requirement sets the stage for a small community hospital to have severely underutilized MRI scanners. For this reason, the proposed policy fails to ensure that a fixed MRI scanner with no minimum staffing would be a more effective option to improve access as compared to mobile MRI service.

CFVHS disagrees with Alliance. Many hospitals currently provide 24 hours 7 day per week emergency department coverage without staffing MRI services 24 hours 7 day per week. Hospitals with MRI services do have qualified staff on call to provide coverage when needed requirement or weekly hours of operation for the fixed MRI service. A hospital providing MRI services should provide on-call coverage with qualified staff. Small rural hospitals have a unique ability to respond to staffing needs for the facility by cross training staff to function in many roles. The ability to provide necessary staffing for the project is documented in the CON application and reviewed by the CON Agency during the CON process. Minimum staffing requirements or

weekly hours of operation for the fixed MRI service need not be defined in the Policy as the demand in the community will dictate hours of operation versus hours of on-call services for nights and weekends.

3. The third concern raised by Alliance is that the statement, "The performance standards in 10A NCAC 14C .2703 would not be applicable" has not been incorporated into the administrative rules through the Office of Administrative Hearings (OAH) rule-making process. Previous changes to the State Medical Facilities Plan for new policies and demonstration projects have followed the OAH rule making process. But in this instance, the proposed Policy TE-3 is circumventing the rule-making process that is in place to ensure a thorough analysis of the proposed changes and much greater opportunity for public comments.

The language in Policy TE-3 is consistent with the language included in Policy TE-2 regarding the applicability of CON Criteria and Standards. In addition, similar language regarding the applicability of CON Criteria and Standards also was included in the criteria for the Dental Single Specialty Ambulatory Surgical Facility Demonstration Project in the *2016 SMFP*. Therefore, it appears that the SHCC and the DHSR do not believe this is an issue of concern.

4. The final issue raised by Alliance addressed the proposed threshold of 850 annual weighted scans. Alliance believes this level of utilization fails to demonstrate or ensure financial feasibility. Community hospitals in rural counties are financially vulnerable because they often serve very high percentages of Medicare and Medicaid patients. The overall average reimbursement per MRI scan at these facilities will be lower than that at hospitals in urbanized areas. Setting the standard so low at 850 annual weighted scans will put these hospitals at risk if reimbursement decreases or if a new MRI competitor enters the market. It does not make sense for many small community hospitals to increase both their fixed costs and risk by acquiring a fixed MRI scanner

As discussed in this Petition for language changes in Policy TE-3 the financial feasibility of fixed MRI services can be measured in many ways. The basic need for services and the generation of funds to cover those services as presented by Alliance is only one of these. As reflected in Attachment 1, the cost of expanding mobile services versus acquiring a fixed unit is another methodology to determine the financial feasibility of MRI services in a community hospital. Finally, the financial impact of having MRI services can be measured by the impact of expanding other service lines at the hospital and providing access to services in a community with few resources. Therefore, the financial viability of adding fixed MRI services at a community hospital should be reviewed based upon each individual hospitals unique circumstances and the information provided in their CON Application.

CFVHS respectfully disagrees with the assertions made by Alliance.

V. Statement of Adverse Effects on the Population if the Adjustment is Not Made

There would be no adverse effect on local populations in communities where the community hospital does not currently have a fixed MRI. In fact, there are only positive effects for the population from the addition of a policy which would allow a local decision to be made regarding when it was financially viable for a community hospital to acquire fixed MRI services.

Rural residents choose to stay home for their health care whenever possible. Unfortunately, many rural residents across North Carolina cannot have an MRI locally unless the mobile MRI happens to be present when a MRI scan is needed. Residents must experience travel times of 30 - 60+ minutes to the nearest fixed MRI scanner equipment. Given the frequency of demand for MRI scans, it is unreasonable for residents to travel to another county if the service can be provided locally.

Again, it is important to realize that the proposed Policy TE-3 will not result in an influx of new MRI equipment across North Carolina. The policy will allow community hospitals to analyze where they are in the continuum of care, working collaboratively with other related entities, to determine the most cost effective way to deliver care to the population they serve. If it is financially reasonable, the addition of a need determination for one fixed MRI scanner will decrease out-migration for MRI services in that community, and improve access to MRI services for the residents. The community hospital will continue to have CON review and will have to justify the acquisition of the equipment in the CON application.

VI. Options for acquiring MRI services in North Carolina

A. Maintain the Status Quo

Existing mobile providers in North Carolina provide quality mobile MRI equipment. Mobile service, however, is at best, an interim solution. Mobile service is inefficient, adds overhead, and is always at risk of a truck breakdown and/or damage to the equipment on the road. It can compromise patient privacy during transport to and from the mobile unit. The scanning rooms in mobile trailers may be smaller than the scanning rooms at fixed sites so more patients may experience claustrophobia.

Patients may be treated in a space that is physically outside the hospital exposing patients to the elements while being transported between hospital and mobile unit. The service is not available every day. Patients get sick every day, and patients need access to MRI services every day.

Any time that a mobile service nears its capacity, scheduling becomes increasingly difficult. Patients become frustrated, physicians become frustrated, which results in more referrals to other counties. Patient word of mouth is powerful. The more patients that must be referred to providers outside of the county, the more other patients choose to seek service out of the county.

A community hospital can relieve capacity and scheduling constraints by adding another day. That, however, would result in a vicious cycle - ease scheduling for a period, utilization increases, requiring additional days. Then, capacity/scheduling issues once again force referrals to fixed MRI providers outside of the county to the frustration of patients and their physicians and costs continue to escalate. This arrangement limits service.

Although many MRI's can be scheduled on an outpatient basis, MRI still performs an important role in emergency care and inpatient care. Adding service hours under most mobile MRI lease arrangement requires the hospital to negotiate with the vendor. The contract is scaled to keep the vendor whole and profitable. Status quo is not a reasonable alternative.

B. Wait for a Need in the Annual SMFP

Without fixed MRI in the county most community hospitals will never generate the volume needed to identify a need through the annual state planning process for MRI. Further, extending the lease for mobile MRI to achieve higher volumes is costlier than acquiring fixed MRI equipment. In today's health care environment which emphasized high quality care, cost effective solutions and patient satisfaction, increasing mobile utilization is not a reasonable alternative. Therefore, having to travel for MRI services outside of the community is not a reasonable alternative.

C. Pursue a Special Need Adjustment

A special need adjustment might provide an opportunity for a community hospital to apply to a new MRI scanner, but such a change in the *SMFP* would not address the unreasonable productivity requirement. Moreover, it could result in more scanners than the county truly needs. Another applicant could pursue a CON for such a need and locate a scanner elsewhere in the county and the community hospitals problem would remain. This approach would not serve residents of the community. Moreover, other hospitals located in rural counties, for example, Bladen, Martin, Duplin, or Hoke, would not benefit from a special need adjustment for another county and could face the same dilemma in future years. Presently, none of these have full time MRI service. Three have part-time mobile service. Clearly, a special need adjustment is not a reasonable and complete alternative.

D. Eliminate MRI Services at Community Hospitals

MRI is the standard of care for many diagnosis as discussed previously. Eliminating all MRI services from community hospitals may be a decision that some communities make. However, it is not the solution for all. Many of the community hospitals which currently utilize mobile MRI services are Critical Access Hospitals, which by definition provide care to an underserved population. If MRI services were no longer available, many in the community would have no access to this level of care.

VII. Duplication of Health Resources

Replacement of mobile MRIs services in community hospitals with a less costly alternative results in improved access to care for residents of the community. The community hospital without fixed MRI are in less populated rural counties across North Carolina.

In addition, each community hospital that takes advantage of Policy TE-3 would have to illustrate in the CON application that the proposed project would not result in a duplication of existing services.

VIII. Consistency with SMFP Basic Principles

The petition is consistent with the provisions of the Basic Principles of the *State Medical Facilities Plan*.

A. Safety and Quality Basic Principle

The State of North Carolina recognizes the importance of systematic and ongoing improvement in the quality of health services. Emerging measures of quality address both favorable clinical outcomes and patient satisfaction, while safety measures focus on the elimination of practices that contribute to avoidable injury or death and the adoption of practices that promote and ensure safety. Providing appropriate care in the appropriate setting works to assure quality care for patients. As a result of the Affordable Care Act, quality, transparency and accountability in community hospitals is more important than ever. In the future payment will be based upon quality measures and community hospitals are moving rapidly to assure high quality, cost effective care.

B. Access Basic Principle

Equitable access to timely, clinically appropriate and high quality health care for all the people of North Carolina is a foundation principle for the formulation and application of the *North Carolina State Medical Facilities Plan*. The formulation and implementation of the *North Carolina State Medical Facilities Plan* seeks to reduce all of those types of barriers to timely and appropriate access. The first priority is to ameliorate economic barriers and the second priority is to mitigate time and distance barriers. The *SMFP* is developed annually as a mechanism to assure the availability of necessary health care services to a population.

The proposed Policy will improve geographic access to fixed MRI services for residents in rural communities. Approval of this Petition furthers the policy statement regarding MRI technology in the Introduction to the Chapter 9, Magnetic Resonance Imaging in the *2016 SMFP*:

Geographic accessibility is a significant planning issue, and it is important to assure that rural areas of the State have the opportunity to access this important technology through both fixed and mobile scanners, as it has become a standard of care.

Approval of this Petition will allow improved access to basic inpatient, outpatient and emergency MRI services when appropriately provided at the local level.

C. Value Basic Principle

All MRI procedures currently must receive prior approval and ACO will be directing patients to the low cost high quality provider. Therefore, it is unreasonable for a community hospital to consider the development of fixed MRI services unless they are sure it will meet standards defined by third party payors and ACOs.

The SHCC defines health care value as maximum health care benefit per dollar expended. Disparity between demand growth and funding constraints for health care services increases the need for affordability and value in health services. Measurement of the cost component of the value equation is often easier than measurement of benefit. Cost per unit of service is an appropriate metric when comparing providers of like services for like populations.

The cost of providing mobile MRI services is expensive for a hospital and its patients. The development of fixed MRI services can be a more cost effective alternative in a community setting than expanding mobile MRI services. The proposed Policy will allow community hospital to provide care locally in a lower cost community hospital when clinically and financially viable. The proposed Policy will help to maximize health care benefit per dollar expended.

IX. Conclusion

The proposed Policy TE-3, as amended by CFVHS, will not result in an influx of new MRI equipment across North Carolina. **With these changes, the policy will allow ALL community hospitals to analyze where they are in the continuum of care, working collaboratively with other related entities, to determine the most cost effective way to deliver care to the population they serve.** If it is financially reasonable, the addition of a fixed MRI scanner will decrease out-migration for MRI services in that community, and improve access to MRI services for the residents. The community hospital will continue to have CON review and will have to justify the acquisition of the equipment in the CON application.

Policy TE-3, with the amendments proposed by CFVHS, is a reasonable addition to the 2017 State Medical Facilities Plan.

Fixed vs. Mobile MRI Breakeven Analysis

PROJECTED INCREMENTAL STATEMENTS OF INCOME

YEAR 1 THROUGH 3

	<u>YEAR 1</u>	<u>YEAR 2</u>	<u>YEAR 3</u>
<u>PROCEDURE VOLUME - Breakeven</u>	400	400	400
<u>NET REVENUE</u>			
Net Revenue	300,000	300,000	300,000
Total Net Revenue	\$ 300,000	\$ 300,000	\$ 300,000
<u>EXPENSES</u>			
Labor Exp	134,784	137,480	140,229
Savings On Mobile	(170,000)	(170,000)	(170,000)
Repairs and Maint		37,500	37,500
Depr Exp	285,714	285,714	285,714
	250,498	290,694	293,444
TOTAL NET SAVINGS(EXPENSE)	49,502	9,306	6,556
PURCHASE OF MRI	<u>(\$2,000,000)</u>		

Assumptions:

Staffing = 1.5 FTEs

Inflation = 2% Annually

Repairs and Maintenance based upon annual expense for existing CFVHS MRI units

MRI Purchase includes both equipment and facility upfit

Reimbursement = \$750 per case held constant

Note: Reimbursement for outpatient MRI currently higher than \$750 per case