

**Technology & Equipment Committee**  
**Magnetic Resonance Imaging Petition-1**  
**Regarding the Proposed 2009 SMFP**  
**For the Final 2009 SMFP**

**Agency Analysis:**

Petitioner:

**Carolinas HealthCare System**

Charlotte, North Carolina

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**Request**

This petition requests that the Magnetic Resonance Imaging (MRI) portion of Chapter Nine of the 2009 State Medical Facilities Plan (SMFP) state that "It is determined that there is no need for an additional mobile MRI scanner anywhere in the State." Carolinas HealthCare System (CHS) further requests that a workgroup be formed to examine the potential of developing a methodology for mobile magnetic resonance imaging (MRI) scanners, either as part of the existing methodology for fixed MRI scanners or as a separate methodology.

**Background Information**

The current methodology for MRI scanners includes need thresholds arranged in tiers based on the number of fixed scanners in each service area and weighting of procedures based on complexity. The methodology for determining need is based on the number of both fixed and mobile MRI procedures performed in the State. In addition, the MRI inventory includes equivalent values for the mobile MRI scanners operating or approved to operate in each service area. The current methodology was the result of an MRI workgroup convened in 2004, which recommended major revisions in the MRI methodology, including combining fixed and mobile MRI scanners and procedures into a single methodology to determine the need for additional fixed MRI scanners. The revised methodology also introduced tiered planning thresholds and "weighting" of MRI procedures, two concepts that exist in the current methodology.

**Analysis/Implications**

The petitioner explains that the current MRI need methodology includes the utilization and capacity of both fixed and mobile MRI scanners yet only determines need for fixed MRI scanners. Since the SMFP has no need methodology for mobile MRI scanners, there is no determinative limit on the number of mobile MRI scanners that can be awarded in a given year under the certificate of need program. As a result, the petitioner believes that the ability of providers to obtain a certificate of need for new mobile MRI scanners without regard to the need determinations in the SMFP has considerable potential to unnecessarily duplicate existing health care services. Therefore, the petition requests a one-year moratorium on additional mobile MRI scanners and creation of a workgroup to study the issues.



However, because the SMFP does not currently include a need determination of mobile MRI scanners, the petitioner's proposal does not constitute an adjustment to a particular need determination contained in the SMFP. Rather the petition requests a change which has a statewide effect with regard to the need for mobile MRI scanners for which there is not currently a need methodology or need determination. As explained in Chapter Two of the 2008 NC SMFP,

“People who wish to recommend changes that may have a statewide effect are asked to contact the Medical Facilities Planning staff as early in the year as possible, and to submit petitions no later than **March 5, 2008**. Changes with the potential for a statewide effect are the addition, deletion, and revision of policies and revision of the projection methodologies. These types of changes will need to be considered in the first four months of the calendar year as the ‘Proposed SMFP’ ... is being developed.”

Thus, the petitioner's proposal is not timely filed as set forth in procedures in Chapter Two of the SMFP.

Further, it should be noted that only three applications for mobile MRI scanners were submitted in 2007. Two of these applications were approved for development of mobile MRI services in Gaston, Cleveland and Mecklenburg Counties and one application was disapproved for development of services in Craven and Jones Counties. The disapproved application has been appealed.

#### **Agency Recommendation**

This petition has a statewide effect with regard to the need for mobile MRI scanners. Therefore, this petition should have been filed before March 5, 2008 to be considered during the first four months of the calendar year for potential inclusion of changes in the “Proposed SMFP.” Consequently, the Agency recommends denial of the portion of the petition relating to placing a need determination in the 2009 SMFP that states there is no need for additional mobile MRI scanners in the State. The Agency also recommends that the Technology and Equipment Committee, in the development of the 2010 SMFP, study the issues raised by the petitioner and the efficacy of a separate methodology for mobile MRI scanners.





## Carolinah HealthCare System

### *Petition to Adjust the Need Determination for MRI Scanners*

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Medical Facilities  
PLANNING SECTION

#### ***Requested Adjustment***

Carolinah HealthCare System ("CHS") requests that the MRI portion of Chapter 9 of the 2009 *State Medical Facilities Plan (SMFP)* state that "It is determined that there is no need for an additional mobile MRI scanner anywhere in the State." CHS further requests that a workgroup be formed to examine the potential of developing a methodology for mobile MRI scanners, either as part of the existing methodology for fixed MRI scanners or as a separate methodology.

#### ***Reason for Requested Adjustment***

The current MRI need methodology includes the utilization and capacity of both fixed and mobile MRI scanners yet only determines need for fixed MRI scanners. Since the *SMFP* has no need methodology for mobile MRI scanners, there is no determinative limit on the number of mobile MRI scanners that can be awarded in a given year under the certificate of need program. As a result, CHS believes that the ability of providers to obtain a certificate of need for new mobile MRI scanners without regard to the need determinations in the *SMFP* has considerable potential to unnecessarily duplicate existing health care services.



## Introduction—Evolution of MRI Methodology

### 1999-2002

Although the CON law has regulated MRI scanners since 1993, the 1999 SMFP was the first to introduce a need methodology for MRI scanners. The 1999 methodology determined need for fixed MRI scanners based on either conversion from a mobile MRI site to a fixed or the need for an additional fixed scanner based on the volume of an existing fixed site. The methodology did not include mobile MRI scanners; in fact, the MRI section of the 1999 SMFP stated, “[i]t has not been possible to develop a feasible statewide methodology for the determination of need for a mobile provider to add another mobile unit, or for the entry of another mobile provider into the State. Some mobile units are used both in North Carolina and in an adjacent state, and mobile providers may regularly add or give up client sites. Also, it was not feasible to specify a general criterion for the initiation of service at a mobile site, because the uses of MRI are evolving rapidly.<sup>1</sup>”

Thus, the MRI methodology did not allocate a need for mobile MRI scanners and, as such, placed no determinative limit on the number of mobile MRI scanners that could be approved.

In addition, because the MRI methodology included one volume threshold for the “conversion” of a mobile site to a fixed MRI and a higher volume threshold for an additional MRI scanner at a fixed site, the mobile and fixed MRI inventory and volumes were provided in separate tables. Unlike the fixed inventory, however, the mobile inventory did not list every scanner that operated in the state, but listed the sites at which mobile MRI scanners provided service.

### 2003-2004

In response to a petition, the 2003 SMFP included a need for two mobile MRI scanners in the state; one to serve HSA's I, II, and III and one to serve HSA's IV, V, and VI. These allocations set the determinative limit on mobile MRI scanners at two for 2003. The remainder of the MRI methodology remained unchanged in the 2003 SMFP.

The 2004 SMFP did not include a need determination for mobile MRI scanners, but reverted to the pre-2004 system of not allocating mobile MRI scanners. The methodology for fixed MRI scanners remained unchanged from the previous year.

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<sup>1</sup> 1999 SMFP, page 98.



2005

Following the considerable effort of a MRI workgroup, the 2005 SMFP included a major revision in the MRI methodology, which, for the first time, combined the fixed and mobile MRI tables. The new methodology also introduced the tiered planning thresholds and "weighting" of MRI procedures, two concepts that exist in the current methodology.

In addition to combining the mobile and fixed MRI volume, the methodology also noted which sites were served by mobile MRI scanners; however, the methodology did not include these sites in the inventory to determine the total (fixed and mobile) MRI capacity of a service area. The methodology continued to address need for fixed MRI scanners only; however, unlike previous years, the methodology no longer assessed need for fixed scanners on the basis of "converting" mobile sites that had achieved a certain volume.

It should be noted that the MRI workgroup recognized the limitations of the revised methodology at the time, particularly the challenges of a fixed MRI methodology driven by both mobile and fixed volume; however, given the difficulties of determining the capacity and service area of mobile MRI scanners, the workgroup decided not to develop a need methodology for mobile MRI scanners.

#### *2006-Proposed 2009*

The current methodology is based on changes made for the 2006 SMFP, which further refined the combined inventory table to account for mobile MRI scanners by "fixed equivalent magnets." This methodology includes all procedures performed on mobile or fixed MRI scanners, and, through the "fixed equivalent" calculation for mobile sites, includes the most complete inventory of MRI capacity to date. The current methodology, however, still does not determine need for mobile MRI scanners; thus, providers are allowed to apply and demonstrate need for mobile MRI scanners, notwithstanding the presence or absence of need for fixed MRI scanners in the service area.

#### *Recent Trends in Mobile Service*

Since the beginning of the MRI need methodology in 1999, the focus of the methodology has been on determining need for additional fixed scanners, whether they are intended to "replace" mobile MRI scanners at sites with volumes that can sustain a fixed MRI scanner, or to increase capacity in areas with well-utilized fixed MRI scanners. In fact, beginning with the first methodology in 1999, the SMFP stated, "[b]ecause MRI technology is mobile, and

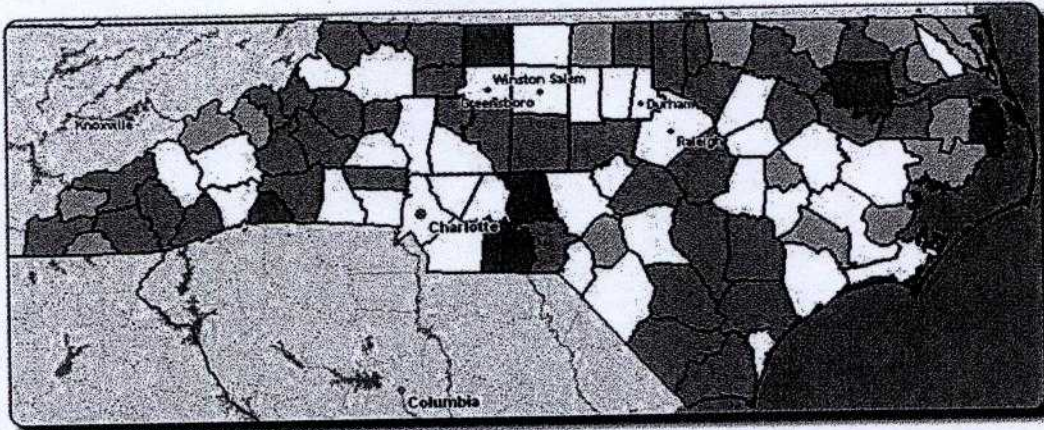


*apparently is financially feasible at relatively small-volume mobile sites, geographic accessibility is not a significant planning issue...Because of the availability of mobile units, MRI technology is accessible within a reasonable distance and travel time to all of the population of the state."* Thus, mobile MRI scanners have historically been expected to expand access in rural areas that cannot support a fixed scanner. However, since 1999, the increased utility of MRI technology, combined with ever-improving access to MRI services through the approval of additional fixed and mobile MRI CONs, has driven up the use rate for MRI services and thus, has greatly increased the ability of rural areas to support a fixed MRI.

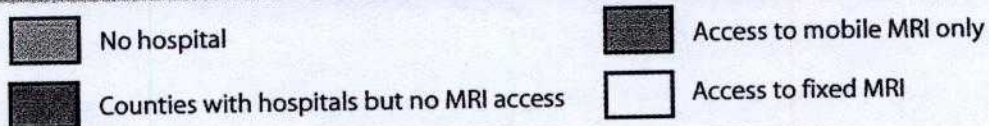
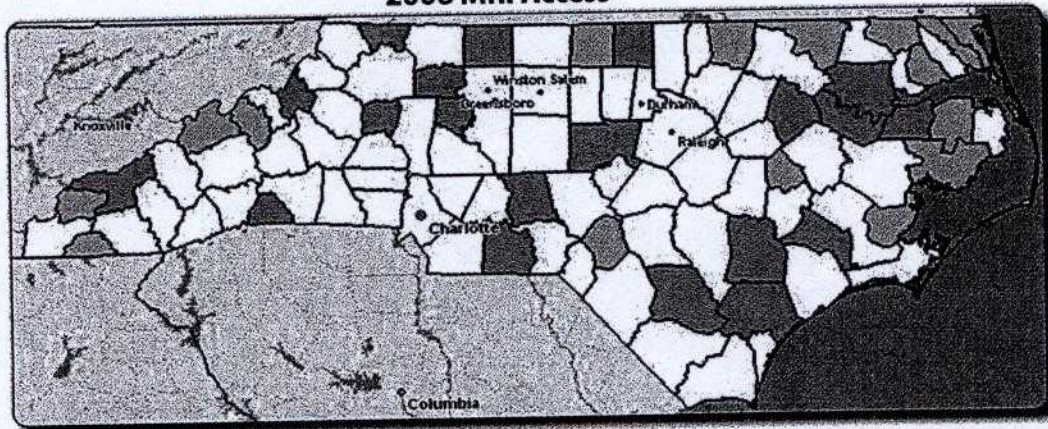
As shown in the maps on the following page, in 1999, several counties (shown in red) had hospitals but no access to MRI services—neither fixed nor mobile. Additionally, dozens of counties (shown in orange) had mobile MRI service but no access to permanent, fixed MRI scanners. After nearly a decade of MRI allocations, the 2008 map shows that all of the counties in the state with a hospital (and thus, some level of acute care services) have some type of MRI access, either fixed or mobile. Further, the number of counties with only mobile MRI service has declined dramatically.



1999 MRI Access



2008 MRI Access



Thus, over the past decade, the MRI need methodology has expanded access to the service across the state, primarily through the establishment of fixed MRI scanners in areas without access, as well as the expansion of fixed MRI capacity in areas with growing MRI utilization.

#### Limitations of MRI Methodology

Although the 10-year evolution of the MRI need methodology has clearly resulted in refinements and improvements over time, the current methodology can be enhanced, relative to the following issues:

1. The MRI methodology has only ever applied to fixed MRI scanners. The SMFP has never attempted to address need for additional mobile capacity, with the exception of the petition-generated need determination in 2003.



On the contrary, as noted above, as early as the 1999 SMFP, the MRI portion of the SMFP stated that sufficient MRI capacity existed through mobile technology to ensure adequate access to all areas of the state.

2. While the current methodology has greatly improved upon the approximation of mobile MRI capacity, it has not and cannot adequately determine future need within a service area because mobile scanners, by their nature, are mobile and can relocate from site to site and from service area to service area. Further, the current mobile MRI inventory includes many of unregulated mobile MRI scanners, which can relocate without any need for regulatory approval.
3. Although there is no separate need methodology for mobile MRI scanners, and thus, no determinative limit on the number of providers that can be issued a mobile MRI CON, the mobile volume is included in the methodology to determine need for fixed MRI scanners. Therefore, most importantly, any additional mobile MRI scanners that are approved are duplicative of the existing fixed MRI methodology.

#### Unclear Need for Additional Mobile MRI Scanners

##### *Rural Counties Have Access*

As clearly demonstrated in the maps on the previous page, the allocation of more than 100 fixed MRI scanners in the state since 1999 has greatly expanded access to MRI services. Nearly all hospitals in the state have or have been approved to develop fixed MRI scanners. A few small rural hospitals continue to use mobile MRI services, and to date, only a few have petitioned the SHCC to make a special allocation in their service area when a need has not been generated by the standard methodology. For those that have petitioned the SHCC, such as Highland-Cashiers Hospital in Highlands and Ashe Memorial Hospital in Jefferson, the SHCC has responded positively, allocating fixed MRI scanners in those areas to expand the service outside of the standard methodology. Thus, with the option of petitioning for fixed scanners, it appears that the hospitals with only mobile MRI service that have not been allocated fixed MRI scanners are adequately served by the mobile scanners.

##### *Additional Mobile MRIs Have Been Placed in Urban Counties*

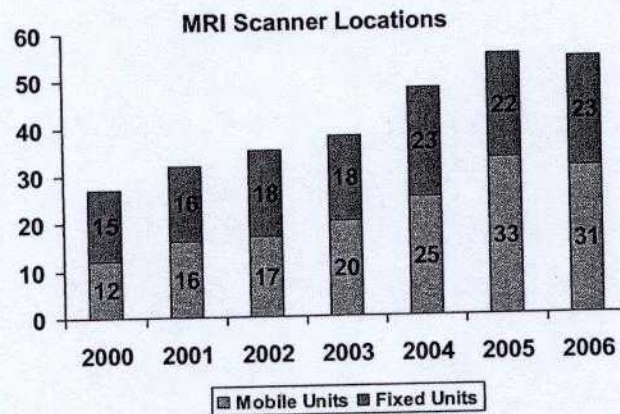
Since 1999, at least 40 mobile MRI sites have been replaced with fixed MRI scanners, in large part based on the historical methodology that encouraged such conversions. With the increase in the number of fixed MRI scanners in the state, particularly those that replaced mobile MRI scanners in rural areas, the number of



available mobile MRI capacity has also increased. Many of the mobile sites that were replaced with fixed sites contracted with “grandfathered” (unregulated) mobile scanners, which remained in the state after the mobile host site acquired a fixed scanner. This mobile MRI capacity remains in the state, even with the “conversion” of mobile sites to fixed. However, rather than continuing to provide access to rural areas (since many if not most of these areas gained access to a fixed scanner), they have migrated to urban counties, as shown below.

### *Urban MRI Scanner Sites in Freestanding Settings*

(Buncombe, Cumberland, Durham, Forsyth, Guilford, Mecklenburg, and Wake Counties)



Note: Urban defined as counties with 200,000 population or more.  
Source: State Medical Facilities Plans.

Since many of the rural counties have relatively low populations, they often cannot support more than one fixed MRI scanner; therefore, it is natural that mobile providers that are replaced by fixed scanners in rural areas would relocate to higher population urban areas, which can support additional scanners.

The majority of the mobile scanners that account for this shift in mobile sites from rural to urban are likely unregulated “grandfathered” mobile MRI scanners. However, the “open door” provided by the absence of a need methodology for mobile MRI scanners in the SMFP has encouraged providers to continue applying for mobile MRI scanners, most of which would serve urban areas. Since 2005, approximately 12 CON applications for new mobile MRI scanners have been filed; of these, fewer than half were approved, indicating that the CON Section is also finding little need for additional mobile MRI capacity. However, it is important to note that of the 12 applications filed, only one proposed a site in a county without MRI access (it, incidentally, was denied.) The other applicants proposed sites predominately in urban areas with substantial existing MRI capacity.



The key factor in this analysis is that none of the 12 mobile MRI applications were competitive with fixed MRI need determinations; that is, the applicants were not applying to meet an identified need in the SMFP. *As such, each of the approved applications proposed sites in counties with no determined need for additional fixed MRI capacity—the existing MRIs in those counties were not operating at the average threshold required to generate a need determination—thus, those mobile MRI scanners effectively duplicated capacity that already existed in the area.* It is because of this central issue that CHS believes the 2009 SMFP should specify no need for mobile MRI scanners in the state while this issue can be addressed, possibly through a workgroup.

#### Adverse Effects on Population

Given the analysis provided in this petition and the fact that the *Proposed 2009 SMFP* includes a need determination for seven additional fixed MRI scanners in the state, CHS does not believe that approval of the petition would result in the loss of access to MRI services for any area of the state.

#### Alternatives Considered

The only realistic alternative to the proposed request is to maintain the status quo, which, as explained throughout this petition, could ultimately result in additional mobile MRI capacity in the state without regard to any need determination.

#### *Impact of Proposed Adjustment on Unnecessary Duplication*

The primary impact of this request would be to provide a one-year moratorium on additional mobile MRI scanners and to provide an opportunity for a workgroup to study these issues. Since the proposed adjustment would actually prevent the awarding of certificates of need for any additional mobile MRI scanners in 2009, its approval would not result in any duplication of existing services, but would in fact prevent any unnecessary duplication of MRI capacity.

We appreciate your careful consideration of this petition.

Thank you.