Technology and Equipment Committee
Agency Report
Intraoperative MRI Technology and Equipment Policy
Proposed 2016 State Medical Facilities Plan

Petitioner:

The Charlotte-Mecklenburg Hospital Authority
d/b/a Carolinas HealthCare System
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Request:

"The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System (CHS) respectfully petitions the State Health Coordinating Council (SHCC) to create a special allocation for one intraoperative magnetic resonance imaging (iMRI) unit in the western portion of the state (Health Service Areas I, II, and III) in the *2016 State Medical Facilities Plan (2016 SMFP)*."

Background Information:

Chapter Two of the North Carolina State Medical Facilities Plan (SMFP) allows petitioners to recommend changes that may have a statewide effect early in the year. According to the plan, "Changes with the potential for a statewide effect are the addition, deletion, and revision of policies and revision of the projection methodologies."

CHS has submitted a petition requesting a special allocation of an iMRI for the western region of North Carolina for Health Service Areas (HSA) I, II, and III. In addition, the petitioner suggested the following conditions: "An applicant shall demonstrate that the iMRI unit shall be located in or adjacent to an operating room. The proposed iMRI unit shall not be counted in the regular inventory of MRI scanners in the *SMFP*. Applicants shall not be required to meet the MRI equipment performance standards and shall be required to demonstrate that the iMRI will not result in an increase in charges to patients or payors. Finally, the applicant shall demonstrate that it is not able to apply for an iMRI through Policy AC-3."

Analysis/Implications:

Historically, the SHCC has provided opportunities through adjusted need determinations and special demonstration projects for MRI technology that is to be used for research, specific parts of the body (e.g. breasts), and particular patient populations. Furthermore, the SHCC approved the removal of the one intraoperative MRI scanner, located at Duke University Medical Center, from the Plan inventory.

Operating rooms with iMRI scanners combine the elements of surgery and radiology. Currently, this technology is being used predominantly in neurosurgery. According to Mislow et al. (2009, p. 137) the iMRI has made a significant difference in the treatment of neurosurgical patients:

> Successful neurosurgical procedures hinge on the accurate targeting of regions of interest. Resection of brain tumors is enhanced by the surgeon's ability to accurately define margins. …targets must be pinpointed with submillimetric accuracy for surgical efficacy. Specialized neuronavigational tools have been developed over the last 20 years to assist surgeons in these endeavors; the development of MRI-guided navigation systems represents a significant improvement in the surgical treatment of various intracranial lesions.

The iMRI scanner provides the ability for neurosurgeons to isolate and resect tumors to a degree of accuracy during a surgical procedure that is not available in a conventional operating room. Thus, reducing the need for the patient to undergo multiple procedures for complete excision.

While iMRI is still expanding and relatively new, it has existed long enough for researchers to look at the various benefits of utilizing this technology. Hall et al. (2003), reports that data for both adult and child brain tumor resections were retrospectively reviewed. Comparisons were made between patients treated in a conventional operating room to those patients who were treated using an iMRI. Length of stay (LOS) is one of the areas where iMRI showed significant difference as compared to the conventional operating room (OR). This is evidenced by the data in Table 1.

Table 1: Comparison of iMRI and Conventional OR Length of Stay in Days

		Length of Stay in Days	
		iMRI	**Conventional OR**
Adults	First Resection	3.7	8.2
	Repeat Resection	6.0	8.7
Children	First Resection	4.5	14.1
	Repeat Resection	8.0	13.3

Data: Hall et al., 2003

Length of stay is not the only outcome that showed improvement in this study. Both hospital costs and charges demonstrate significant differences. The article summarizes the information by succinctly stating, "This data suggests that surgery using iMRI technology improves net health outcomes by reduced LOS, reduced [repeat resection] RR, and reduced hospital charges and costs."

The Value Basic Principle section of the SMFP addresses technology and the benefits to the patients despite the expenditure. "Development of new technology has the potential to add value by improving outcome and enhancing early detection. Capital costs of such new technology may be greater but justified by the added population benefit." As previously discussed, available research indicates the iMRI technology provides a clear benefit to patients not only in costs, but in outcomes as well.

The Agency supports incorporating new technologies in the SMFP. However, the petitioner's proposal restricts the special iMRI allocation to HSA (I, II, and III) and includes terms that restrict the group of potential applicants.

Agency Recommendation:
Given available information submitted by the March 20, 2015 deadline date for comments on petitions and comments, and in consideration of factors discussed above, the Agency recommends that the petition be denied, but proposes the creation of a policy (TE-2) as follows:

POLICY TE-2: Intraoperative Magnetic Resonance Scanners
Qualified applicants may apply for an intraoperative Magnetic Resonance Scanner (iMRI) to be used in an operating room suite.

To qualify, the health service facility proposing to acquire the iMRI scanner shall demonstrate in its certificate of need application that it is a licensed acute care hospital which:

1. Performed at least 500 inpatient neurosurgical cases during the 12 months immediately preceding the submission of the application; and
2. Has at least two neurosurgeons that perform intracranial surgeries currently on its Active Medical Staff; and
3. Is located in a metropolitan statistical area as defined by the US Census Bureau with at least 350,000 residents.

The iMRI scanner shall not be used for outpatients and may not be replaced with a conventional MRI scanner.

Intraoperative procedures and inpatient procedures performed on the iMRI shall be reported separately on the hospital license renewal application.

These scanners shall not be counted in the inventory of fixed MRI scanners; the procedures performed on the iMRI will not be used in calculating the need methodology and will be reported in a separate table in Chapter 9.

Supporting language for Policy TE-2 to add to Chapter 9: MRI:

Intraoperative Magnetic Resonance Scanners (iMRI) approved through Policy TE-2 shall not be counted in the inventory of fixed MRI scanners and the procedures performed on the iMRI will not be used in calculating the need methodology. Intraoperative procedures and inpatient procedures performed on the iMRI shall be reported separately on the hospital license renewal application and will be reported in a separate table in Chapter 9Q (7). The iMRI scanner shall not be used for outpatients and may not be replaced with a conventional MRI scanner.

Hall, W.A., & Kowalik, K., & Liu, H., & Truwit, C.L., & Kucharczyk, J. (2003). Costs and benefits of intraoperative MR-Guided brain tumor resection [Abstract]. In R. L. Bernays, & H.G. Imhof, & Y. Yonekawa (Eds.), *Intraoperative imaging in neurosurgery* (pp 137 – 142). Vienna: Springer. Retrieved April 6, 2015, from http://link.springer.com/chapter/10.1007/978-3-7091-6043-5_19#

Mislow, J. M. K., & Golby, A. J., & Black, P. M. (2009). Origins of intraoperative MRI. *Neurosurgery clinics of North America*, *20*(2), (pp 137–146). Retrieved April 6, 2015, from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2902263/