

Comments on Proposed 2016 State Medical Facilities Plan

Submitted by:

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The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System (CHS) is submitting these comments related to the Proposed 2016 State Medical Facilities Plan (SMFP). CHS supports the proposed addition of Policy TE-2 to the SMFP. We appreciate the acknowledgement of the State Health Coordinating Council (SHCC) that intraoperative MRI (iMRI) scanners are an important technology for the citizens of North Carolina. The proposed policy will expand access to this very important technology.

The proposed policy includes several qualifications for applicants proposing to acquire an iMRI scanner. CHS supports each of those requirements, but we would like to propose the following clarification to qualification number one.

- 1. Performed at least 500 inpatient **intracranial** neurosurgical cases during the 12 months immediately preceding the submission of the application; and*

We suggest this change for the following reasons:

- 1) Virtually all use of this technology (in a neurosurgical context) is being directed to **intracranial** procedures. In particular, skull base surgery, pituitary surgery, deep brain stimulation/lesioning, stereotactic biopsies, brain tumors, certain cerebrovascular cases, certain trauma cases, pediatric intracranial surgery and select functional procedures can be augmented by use of iMRI. Although certain spine cases *may* potentially benefit from iMRI (particularly complex spine tumors), very little iMRI use to date has been directed to spinal surgery. There has been virtually no application for degenerative spine disease which is by far the most common indication for spinal procedures. In this respect, intracranial procedures are the only clinical volume relevant to this technology.

- 2) The principal benefits of iMRI in neurosurgical settings to date have been focused on the following clinical objectives:
 - a. Confirmation of extent of resection
 - b. Facilitation of safe resection of intracranial lesions through the real-time identification of adjacent “eloquent” brain areas
 - c. Early identification of correctable surgical complications such as deep brain hemorrhage or ischemia
 - d. Real-time confirmation of targeting and/or placement of intracranial devices
 - e. Location confirmation in deep brain procedures and/or minimally invasive intracranial approaches

- 3) Most of the recent expansion of iMRI is also directed to intracranial applications including laser induced thermal therapy (LITT) and MRI-guided high-intensity ultrasound ablation.

Adding this clarification will ensure this new technology is approved for facilities performing a sufficient volume of procedures for which iMRI has proven efficacious, rather than for facilities performing other types of neurosurgery for which there is no current clinical use for iMRI. Our recent analysis of Truven data shows, for example, that at least ten facilities in North Carolina perform a significant number of inpatient neurosurgery cases, while only four perform over 500 intracranial cases.

We are in general agreement with the other qualifications, although we suspect this technology would be more efficiently applied in a setting with considerably more than two neurosurgeons performing intracranial procedures as described in the second qualification.

We appreciate the opportunity to provide these comments. We would be happy to respond to any questions you may have.