

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR
MAGNETIC RESONANCE IMAGING (MRI) SERVICES STANDARDS
SUMMARY OF PROPOSED CHANGES

Highlights of Proposed Changes to Include Hybrid Modalities

Section 2 - Definitions

(1)(bb): Added definition for "MRI-Guided Electrophysiology intervention" or "MRI-Guided EPI" means equipment specifically designed for the integrated use of MRI technology for the purposes of electrophysiology interventional procedures within a cardiac catheterization lab.

(cc): Added to the definition of "MRI procedure" to include: Positron Emission Tomography (PET)/MRI Scanner Hybrids if used for MRI only procedures.

Section 11 - Hospital based MRI-Guided EPI Service

- The Department drafted requirements for this NEW section as requested by the CON Commission and is modeled after the Intra-operative magnetic resonance imaging (IMRI) language. It will allow for an MRI-guided EPI service to be located at a hospital that has an existing fixed MRI service that has been operational for 36 months and is meeting its minimum volume requirements. The proposed site has an existing and operational therapeutic cardiac catheterization service and is meeting its minimum volume requirements. Its open heart surgery service must be meeting its minimum volume requirements too.

The MRI-guided EPI unit will not be subject to MRI volume requirements, and the applicant shall not utilize the procedures performed on the MRI-guided EPI unit to demonstrate need or to satisfy MRI CON review standards requirements.

Section 12 - FDA-Approved PET/MRI Scanner Hybrid

- The Department drafted requirements for this NEW section as requested by the CON Commission. This language is modeled after the PET/CT language which will allow the use of the PET/MRI scanner hybrid to be used for stand-alone MRI procedures. There must be an approved PET CON, and it must be in compliance with applicable project delivery requirements as set forth in the CON review standards for PET.

The FDA-approved PET/MRI scanner hybrid unit will not be subject to MRI volume requirements, and the applicant shall not utilize the procedures performed on the FDA-approved PET/MRI scanner hybrid unit to demonstrate need or to satisfy MRI CON review standards requirements.

Section 14 - Project Delivery Requirements

(1)(d)(iii): Added project delivery requirements for data reporting for the MRI-Guided EPI UNIT similar to IMRI. At a minimum, the data reported shall include how often the MRI-guided EPI unit is used and for what type of services, i.e., electrophysiology or diagnostic.