

MDCH Recommendations for CON Standards Scheduled for 2012 Review

Magnetic Resonance Imaging (MRI) Services (Please refer to the attached MDCH staff analysis for additional details)		
Should the covered service continue to be regulated?	Yes.	The regulation of MRI Services ensures appropriate utilization of each MRI to keep Michigan right-sized.
All Identified Issues	Recommended for Review	Comments
1. Consider streamlining the process for documenting actual MRI utilization & volume thresholds	Yes.	Form a standard advisory committee (SAC) to review weighting issues and volume requirements to ensure right-sizing Michigan.
2. Consider language that would allow for greater clinical use of MRI, specifically hybrid equipment	Yes.	Form a SAC to explore hybrid modalities used in conjunction with MRI's. With FDA approval, PET/MRI scanners are available for clinical use and should be examined to draft appropriate volume requirements and prevent over utilization. A discussion group, lead by Commissioner Keshishian, will be discussing and making recommendation on this issue as it relates to the PET standards pursuant to the Commission's action at its December 15, 2011 meeting.
3. Modifications to the Standards as recommended by the Department, including project delivery requirements	Yes.	Technical/editorial changes to the standards. Reduce number of project delivery requirements for approved services that are enforceable and achieve major objectives of assuring affordable, quality MRI services without overwhelming providers.
4. Consider language similar to PET and CT requiring no minimum volume for replacement or relocation	Yes.	Draft language to address threshold utilization for replacement & relocation to a new geographical site.

MDCH Staff Analysis of the Magnetic Resonance Imaging (MRI) Services Standards

Pursuant to MCL 333.22215 (1) (m), the Certificate of Need (CON) Commission is to "...review, and if necessary, revise each set of CON standards at least every 3 years." In accordance with

the established review schedule on the Commission Workplan, the (MRI Services Standards are scheduled for review in calendar year 2012.

Public Hearing Testimony

The Department held a Public Hearing to receive testimony regarding the Standards on October 12, 2011, with written testimony being received for an additional seven (7) days after the hearing. Testimony was received from six (6) organizations and is summarized as follows:

1. *Patrick O'Donovan, Beaumont Health System*
 - Supports continued regulation of MRI services.
 - Recommends the Commission consider streamlining the process for documenting actual MRI utilization (Section 14) to increase efficiency and ease applicant compliance.
2. *Azzam S. Kanaan, M.D., Southwest Michigan Imaging Center, LLC*
 - Supports continued regulation of MRI services.
 - Recommends the Department draft replacement language similar to PET and CT that address the threshold utilization concern.
 - Supports using the same language for all covered clinical equipment standards to prevent interruption or loss of service to smaller communities.
3. *Dennis McCafferty, Economic Alliance for Michigan (EAM)*
 - Supports continued regulation of MRI services.
 - Recommends the formation of a SAC to review the burdensome reporting requirements for providers.
4. *Steven Szelag, University of Michigan Health System (UMHS)*
 - Supports the continued regulation of MRI services.
 - Recommends lowering the MRI Adjusted Procedure volume threshold below the current average of 11,000.
 - Recommends exploring the benefits and the allowance of greater clinical use of MRI within a hybrid configuration. These modalities include, but should not be limited to: MRIs used in conjunction with a Linear Accelerator, Positron Emission Tomography, or an Electro-Physiology laboratory.
 - Recommends modification(s) to the replacement and relocation language, to improve "point-of service" care based on changing demographics and demand, currently it is somewhat restrictive.
 - Suggests using similar language to that of moving licensed medical/surgical beds between multiple licensed facilities under common ownership.
5. *Loren Rhoad, Alliance- HNV*
 - Supports the continued regulation of MRI services.
 - Recommends that the MRI Standards should be adjusted consistently with the policy premise articulated in the CT and PET Standards.

- Recommends reviewing the existing replacement and upgrade language, and proposes if the project costs are less than \$750,000, the entire project be considered part of the upgrade.

6. *Robert Meeker, Spectrum Health*

- Supports the continued regulation of MRI services.
- Recommends modifying the MRI data reporting system to streamline some of the processes involved, as it is overly-burdensome to both the providers and the Department.

Summary of the Covered Service and Consideration of “Guiding Principles for Determining Whether a Clinical Service should Require Certificate of Need Review”

Michigan is one of 22 states which regulate MRI Services within CON. The regulation of MRI Services ensures appropriate utilization of each MRI to keep Michigan right-sized. As part of the review, the Department considered the “Guiding Principles...” as follows:

The costs of initiating a fixed MRI service vary considerably, ranging from \$1,607,373 to \$4,975,000, according to CON applications dated January 1, 2010 to November 1, 2010. MRI services are ubiquitous throughout the state of Michigan, served by both mobile and fixed sites at hospitals and freestanding centers. The number of MRIs performed in the state over the past three years has declined slightly (<3 percent), as follows:

2008: 764,076
2009: 763,195
2010: 742,399

Despite the slight decline, MRI is a standard of care for many conditions and will likely remain so for several reasons, including high quality views and concerns about ionizing radiation usage in other imaging modalities.

MRI services are not monitored under any other agencies within the State of Michigan. Effective January 1, 2012, an outpatient MRI facility must be accredited by the American College of Radiology (ACR) in order to receive reimbursement for the technical component of the procedure under Medicare Part B.¹

In order to initiate a fixed MRI service, the proposed site must demonstrate 6,000 available adjusted procedures (3,000 in the case of a hospital with 24-hour emergency care and a minimum of 20,000 visits in the past year).

Geographic access to MRI services is not compromised by CON requirements. MRI quality is not linked to volume.

The Patient Protection and Affordable Care Act (PPACA) of 2010 contain provisions that discourage self-referral, mandating that providers furnish a list of local alternatives for the patient to choose from when receiving MRI services. In addition, prior authorization for outpatient MRI services is a requirement of many private health insurance plans, limiting the number of

¹ http://www.acr.org/accreditation/mri/m_faq.aspx

unnecessary scans performed. Accreditation through the ACR does not address cost or access. The focus is on image quality, safety practices, quality control protocols, and staff qualifications.²

Department Recommended Modifications

The Department is recommending that the Standards be reviewed and modified for clarity, administrative efficiencies, and relevance in the following instances:

- The Department recommends modifying the reporting process in order to capture actual MRI utilization. The November 2011 MRI report is the first that has reported 100% of data.
- The weighting of scans should be reviewed, through the formation of a SAC. The volume requirements for facilities that perform complex scans should be reviewed to offset patient time(s) and visit(s) for facilities that perform simple scans.
- The Department recommends forming a SAC to address the emerging MR hybrid modalities i.e.; Linear Accelerator, Positron Emission Tomography, or an Electro-Physiology laboratory. The advancement of this technology will impact the practice of many services including nuclear medicine. Patients will benefit from early detection because physicians will acquire more data simultaneously, consequently improving personalized treatment planning. The Department will assist with drafting language within the Standards to aid facilities accessibility to this new technology.
- The Department recommends technical modifications only for consistency with other CON review standards along with project delivery requirements. Project delivery requirements are those requirements that a recipient of an approved CON must comply with throughout the life of the services, or unless modified by a subsequent CON approval. Review is to assure that each requirement is measurable, comports with today's standard of care, does not duplicate other regulatory requirements already established, and have cost-effective value in achieving the goals and objectives of the program to assure affordable, quality health care services for both the consumer and provider.
- The Department recommends eliminating the volume requirement for replacement of MRI equipment, similar to the PET and CT standards. Upgrades to existing MRI equipment, without replacement of the equipment would not require CON review/approval.

² http://www.acr.org/accreditation/mri/mri_reqs.aspx