

## MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

### CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR MAGNETIC RESONANCE IMAGING (MRI) SERVICES

(By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207, and 24.208 of the Michigan Compiled Laws.)

#### Section 1. Applicability

Sec. 1. These standards are requirements for the approval of the initiation, expansion, replacement, or acquisition of MRI services and the delivery of services under Part 222 of the Code. Pursuant to Part 222 of the Code, MRI is a covered clinical service. The Department shall use these standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

#### Section 2. Definitions

Sec. 2. (1) For purposes of these standards:

(a) "Acquisition of an existing MRI service or existing MRI unit(s)" means obtaining control or possession of an existing fixed or mobile MRI service or existing MRI unit(s) by contract, ownership, lease, or other comparable arrangement.

(b) "Actual MRI Adjusted Procedures" or "MRI Adjusted Procedures," means the number of MRI procedures, adjusted in accordance with the applicable provisions of Section 16, performed on an existing MRI unit, or if an MRI service has two or more MRI units at the same site, the average number of MRI adjusted procedures performed on each unit, for the 12-month period reported on the most recently published "MRI Service Utilization List," as of the date an application is deemed submitted by the Department.

(c) "Available MRI Adjusted Procedures" means the number of MRI adjusted procedures performed by an existing MRI service in excess of 8,000 per fixed MRI unit and 7,000 per mobile MRI unit. For either a fixed or mobile MRI service, the number of MRI units used to compute available MRI adjusted procedures shall include both existing and approved but not yet operational MRI units. In determining the number of available MRI adjusted procedures, the Department shall use data for the 12-month period reported on the most recently published list of available MRI adjusted procedures as of the date an application is deemed submitted by the Department.

In the case of a mobile MRI unit, the term means the sum of all MRI adjusted procedures performed by the same mobile MRI unit at all of the host sites combined that is in excess of 7,000. For example, if a mobile MRI unit serves five host sites, the term means the sum of MRI adjusted procedures for all five host sites combined that is in excess of 7,000 MRI adjusted procedures.

(d) "Central service coordinator" means the organizational unit that has operational responsibility for a mobile MRI unit(s).

(e) "Certificate of Need Commission" or "CON Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

(f) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.

(g) "Contrast MRI Procedure" means an MRI procedure involving either of the following: (i) a procedure following use of a contrast agent or (ii) procedures performed both before and after the use of a contrast agent.

~~(h) "Critical Access Hospital" or "CAH" means, a hospital designated by CMS pursuant to 42 CFR 485.606.~~

(i) "Dedicated pediatric MRI" means an MRI unit on which at least 80% of the MRI procedures are performed on patients under 18 years of age.

(j) "Department" means the Michigan Department of Health and Human Services (MDHHS).

**(j) "DESIGNATED RURAL HOSPITAL" MEANS A LICENSED HOSPITAL DESIGNATED BY CMS AS A CRITICAL ACCESS HOSPITAL [PURSUANT TO 42 CFR 485.606], SOLE COMMUNITY HOSPITAL [PURSUANT TO 42 CFR 412.92], MEDICARE DEPENDENT HOSPITAL [PURSUANT TO 42 CFR 412.108], OR RURAL EMERGENCY HOSPITAL [PURSUANT TO 42 USC 1395X].**

(k) "Doctor" means an individual licensed under Article 15 of the Code to engage in the practice of medicine, osteopathic medicine and surgery, chiropractic, dentistry, or podiatry.

(l) "Existing MRI service" means either the utilization of a CON-approved and operational MRI unit(s) at one site in the case of a fixed MRI service, and in the case of a mobile MRI service, the utilization of a CON-approved and operational mobile MRI unit(s) at each host site, on the date an application is submitted to the Department.

(m) "Existing MRI Unit" means a CON-approved and operational MRI unit used to provide MRI services.

(n) "Expand an Existing Fixed MRI Service" means an increase in the number of fixed MRI units to be operated by the applicant.

(o) "Expand an Existing Mobile MRI Service" means the addition of a mobile MRI unit that will be operated by a central service coordinator that is approved to operate one or more mobile MRI units as of the date an application is submitted to the Department.

(p) "Group Practice" means a group practice as defined pursuant to the provisions of 42 U.S.C. 1395nn (h)(4), commonly known as Stark II, and the Code of Federal Regulations, 42 CFR, Part 411, published in the Federal Register on August 14, 1995, or its replacement.

(q) "Health Service Area" or "HSA" means the geographic areas set forth in Section 22.

(r) "Hospital-based portable MRI" means an MRI unit that can be transported into patient care areas (e.g., dedicated neuroscience unit, ICU, operating room) to provide imaging of the brain.

(s) "Host Site" means the site at which a mobile MRI unit is authorized by CON to provide MRI services.

(t) "Initiate a Fixed MRI Service" means begin operation of a fixed MRI service at a site that does not provide or is not CON approved to provide fixed MRI services as of the date an application is submitted to the Department. The term does not include the acquisition or replacement of an existing fixed MRI service to a new site or the renewal of a lease.

(u) "Initiate a Mobile MRI Host Site" means the provision of MRI services at a host site that has not received any MRI services within 12 months from the date an application is submitted to the Department. The term does not include the renewal of a lease.

(v) "Initiate a Mobile MRI Service" means begin operation of a mobile MRI unit that serves two or more host sites.

The term does not include the acquisition of an existing mobile MRI service or the renewal of a lease.

(w) "Inpatient" means an MRI visit involving an individual who has been admitted to the licensed hospital at the site of the MRI service/unit or in the case of an MRI unit that is not located at that licensed hospital site, an admitted patient transported from a licensed hospital site by ambulance to the MRI service.

(x) "Institutional Review Board" or "IRB" means an institutional review board as defined by Public Law 93-348 that is regulated by Title 45 CFR 46.

(y) "Intra-operative Magnetic Resonance Imaging" or "IMRI" means the integrated use of MRI technology during surgical and interventional procedures within a licensed operative environment.

(z) "Licensed Hospital Site" means the location of the hospital authorized by license and listed on that licensee's certificate of licensure.

(aa) "Magnetic Resonance Imaging" or "MRI" means the analysis of the interaction that occurs between radio frequency energy, atomic nuclei, and strong magnetic fields to produce cross sectional images similar to those displayed by computed tomography (CT) but without the use of ionizing radiation.

(bb) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396 to 1396g and 1396i to 1396u.

**(cc) "METROPOLITAN COUNTIES" MEANS COUNTIES DESIGNATED BY THE FEDERAL OFFICE OF RURAL HEALTH POLICY (FORHP) AS NON-FULLY ELIGIBLE COUNTIES.**

(~~ddcc~~) "Mobile MRI Unit" means an MRI unit operating at two or more host sites and that has a central service coordinator. The mobile MRI unit shall operate under a contractual agreement for the provision of MRI services at each host site on a regularly scheduled basis.

(~~edcd~~) "MRI Adjusted Procedure" means an MRI visit, at an existing MRI service, that has been adjusted in accordance with the applicable provisions of Section 16.

(~~feed~~) "MRI Database" means the database, maintained by the Department pursuant to Section 15 of these standards, that collects information about each MRI visit at MRI services located in Michigan.

(~~ggff~~) "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.

(~~hhgg~~) "MRI Procedure" means a procedure conducted by an MRI unit approved pursuant to sections 3, 4, 5, 6, 7, or 9 of these standards which is either a single, billable diagnostic magnetic resonance procedure or a procedure conducted by an MRI unit at a site participating with an approved diagnostic radiology residency program, under a research protocol approved by an IRB. The capital and operating costs related to the research use are charged to a specific research account and not charged to or collected from third-party payors or patients. -The term does not include a procedure conducted by an MRI unit approved pursuant to Section 7.

(~~iihh~~) "MRI Services" means either the utilization of an authorized MRI unit(s) at one site in the case of a fixed MRI service or in the case of a mobile MRI service, the utilization of an authorized mobile MRI unit at each host site.

(~~jjii~~) "MRI Unit" means the magnetic resonance system consisting of an integrated set of machines and related equipment necessary to produce the images and/or spectroscopic quantitative data from scans including FDA-approved positron emission tomography (PET)/MRI scanner hybrids if used for MRI only procedures. The term does not include MRI simulators used solely for treatment planning purposes in conjunction with a Megavoltage Radiation Therapy (MRT) unit.

(~~kkjj~~) "MRI Visit" means a single patient visit to an MRI service/unit that may involve one or more MRI procedures.

(~~llkk~~) "Ownership Interest, Direct or Indirect" means a direct ownership relationship between a doctor and an applicant entity or an ownership relationship between a doctor and an entity that has an ownership relationship with an applicant entity.

(~~mmll~~) "Pediatric Patient" means a patient who is 12 years of age or less, except for Section 8.

(~~nnmm~~) "Planning Area" means:

(i) in the case of a proposed fixed MRI service or unit, the geographic area within a 20-mile radius from the proposed site if the proposed site is not in a rural ~~or micropolitan statistical area~~ county and a 75-mile radius from the proposed site if the proposed site is in a rural ~~or micropolitan statistical area~~ county, or is ~~A~~ designated ~~RURAL HOSPITAL by the Centers for Medicare and Medicaid Services (CMS) as a Critical Access Hospital (CAH), or Sole Community Hospital (SCH).~~

(ii) in the case of a proposed mobile MRI service or unit, except as provided in subsection (iii), the geographic area within a 20-mile radius from each proposed host site if the proposed site is not in a rural ~~or micropolitan statistical area~~ county and within a 75-mile radius from each proposed host site if the proposed site is in a rural ~~or micropolitan statistical area~~ county, or is ~~A~~ designated ~~RURAL HOSPITAL by the Centers for Medicare and Medicaid Services (CMS) as a Critical Access Hospital (CAH), or Sole Community Hospital (SCH).~~

(iii) in the case of a proposed mobile MRI service or unit meeting the requirement of Section 16(2)(d), the health service area in which all the proposed mobile host sites will be located.

(~~ppnn~~) "Public Health Epidemic" means an epidemic identified and controlled pursuant to MCL 333.2253(1) or MCL 333.2453(1), or an epidemic or pandemic as declared by the Centers for Disease Control (CDC) or the World Health Organization (WHO).

(~~ppoe~~) "Referring Licensed Healthcare Professional" means:

(i) the doctor of record who ordered the MRI procedure(s) and either to whom the primary report of the results of an MRI procedure(s) is sent, or in the case of a teaching facility, the attending doctor who is responsible for the house officer or resident that requested the MRI procedure; or

(ii) a non-physician licensed healthcare professional acting within the scope of their practice.

(~~qqqq~~) "Renewal of a Lease" means extending the effective period of a lease for an existing MRI unit that does not involve either replacement of the MRI unit, as defined in Section 4, or (ii) a change in the parties to the lease.

(~~rrrr~~) "Research Scan" means an MRI scan administered under a research protocol approved by the applicant's IRB.

(~~ssss~~) "Re-sedated Patient" means a patient, either pediatric or adult, who fails the initial sedation during the scan time and must be extracted from the unit to rescue the patient with additional sedation.

(tt) "RURAL AREA" MEANS THE COUNTIES DESIGNATED BY THE FEDERAL OFFICE OF RURAL HEALTH POLICY (FORHP) AS BEING FULLY ELIGIBLE FOR RURAL HEALTH GRANT PROGRAMS OR THE CENSUS TRACTS WITHIN METROPLITAN COUNTIES THAT HAVE BEEN DETERMINED BY THE FORHP TO MEET THE CRITERIA TO BE ELIGIBLE FOR RURAL HEALTH GRANT PROGRAMS. THE DEPARTMENT SHALL UTILIZE THE MOST RECENT LIST OF AREAS ELIGIBLE FOR RURAL HEALTH GRANT PROGRAMS PUBLISHED BY FORHP IN MAKING THIS DETERMINATION.<sup>1</sup>

(~~uuuu~~) "Sedated Patient" means a patient that meets all of the following:

(i) whose level of consciousness is either conscious-sedation or a higher level of sedation, as defined by the American Society of Anesthesiologists, the American Academy of Pediatrics, the Joint Commission on the Accreditation of Health Care Organizations, or an equivalent definition.

(ii) who is monitored by mechanical devices while in the magnet.

(iii) who requires observation while in the magnet by personnel, other than employees routinely assigned to the MRI unit, who are trained in cardiopulmonary resuscitation (CPR).

(~~vvvv~~) "Site" means

(i) in the case of a licensed hospital site, a location that is part of the licensed hospital site or a location that is contiguous to the licensed hospital site or

(ii) in the case of a location that is not a licensed hospital site, a location at the same address or a location that is contiguous to that address.

(~~uu~~) "Sole Community Hospital or "SCH" means a hospital designated by CMS pursuant to 42 CFR 412.02.

(~~wwww~~) "Special Needs Patient" means a non-sedated patient, either pediatric or adult, with any of the following conditions: down syndrome, autism, attention deficit hyperactivity disorder (ADHD), developmental delay, malformation syndromes, Hunter's syndrome, multi-system disorders, psychiatric disorders, implantable cardiac devices (ICDS), and other conditions that make the patient unable to comply with the positional requirements of the exam or is unable to comply with the motionless requirements and whose resulting movements result in non-diagnostic quality images therefore requiring the technologist to repeat the same sequence in an attempt to obtain a diagnostic quality image.

(~~xxxx~~) "Teaching Facility" means a licensed hospital site, or other location, that provides either fixed or mobile MRI services and at which residents or fellows of a training program in diagnostic radiology engage in the care of a patient (including protocoling/interpretations of studies), and that is approved by the Accreditation Council on Graduate Medical Education or American Osteopathic Association, are assigned. A teaching facility shall be identified as meeting the definition if at least one (1) of the following is true:

(i) the participating hospital site or other location's facility name is listed on the Accreditation Council on Graduate Medical Education or American Osteopathic Association's accreditation letter as having a training program in diagnostic radiology.

(ii) the participating hospital site or other location is owned by an entity that is listed on the Accreditation Council on Graduate Medical Education or American Osteopathic Association's accreditation letter as having a training program in diagnostic radiology.

<sup>1</sup> HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA) - RURAL SERVICE AREAS AND TARGET POPULATIONS – LIST OF RURAL COUNTIES AND DESIGNATED ELIGIBLE CENSUS TRACTS IN METROPOLITAN COUNTIES.

(v) "Unadjusted MRI Scan" means an MRI procedure performed on a single anatomical site as defined by the MRI database and that is not adjusted pursuant to the applicable provisions of Section 16.

(2) Terms defined in the Code have the same meanings when used in these standards.

### Section 3. Requirements to initiate an MRI service

Sec. 3. An applicant proposing to initiate an MRI service or a host site shall demonstrate the following requirements, as applicable:

(1) An applicant proposing to initiate a fixed MRI service shall demonstrate 6,000 available MRI adjusted procedures per proposed fixed MRI unit from within the same planning area as the proposed service/unit.

(2) An applicant proposing to initiate a fixed MRI service that meets the following requirements shall not be required to be in compliance with subsection (1):

(a) The applicant is currently an existing host site.

(b) The applicant has received in aggregate, one of the following:

(i) At least 6,000 MRI adjusted procedures.

(ii) At least 4,000 MRI adjusted procedures and the applicant meets all of the following:

(A) Is located in a county that has no fixed MRI machines that are pending, approved by the Department, or operational at the time the application is deemed submitted.

(B) The nearest fixed MRI machine is located more than 15 radius miles from the application site.

(iii) At least 3,000 MRI adjusted procedures and the applicant meets all of the following:

(A) The proposed site is a hospital licensed under Part 215 of the Code.

(B) The applicant hospital operates an emergency room that provides 24-hour emergency care services and at least 20,000 visits if located in a metropolitan ~~statistical area~~ county, or 10,000 visits if located in a rural ~~or micropolitan statistical area~~ county, or is ~~A~~ designated ~~RURAL HOSPITAL~~ by the Centers for Medicare and Medicaid Services (CMS) as a Critical Access Hospital (CAH), or Sole Community Hospital (SCH) within the most recent 12-month period for which data, verifiable by the Department, is available.

(c) All of the MRI adjusted procedures from the mobile MRI service referenced in Section 3(2)(b) shall be utilized even if the aggregated data exceeds the minimum requirements.

(d) The applicant shall install the fixed MRI unit at the same site as the existing host site or within the relocation zone. If applying pursuant to Section 3(2)(b)(iii), the applicant shall install the fixed MRI unit at the same site as the existing host site.

(e) The applicant shall cease operation as a host site and not become a host site for at least 12 months from the date the fixed service and its unit becomes operational.

(3) An applicant proposing to initiate a mobile MRI service shall demonstrate 5,500 available MRI adjusted procedures from within the same planning area as the proposed service/unit, and the applicant shall meet the following:

(a) Identify the proposed route schedule and procedures for handling emergency situations.

(b) Submit copies of all proposed contracts for the proposed host site related to the mobile MRI service.

(c) Identify a minimum of two (2) host sites for the proposed service.

(4) An applicant, whether the central service coordinator or the host site, proposing to initiate a host site on a new or existing mobile MRI service shall demonstrate the following, as applicable:

(a) 600 available MRI adjusted procedures, from within the same planning area as the proposed service/unit, for a proposed host site that is located in a metropolitan ~~statistical area~~ county, or

(b) 400 available MRI adjusted procedures from within the same planning area for a proposed host site that is located in a rural ~~or micropolitan statistical area~~ county, or is ~~A~~ designated ~~RURAL HOSPITAL~~ by the Centers for Medicare and Medicaid Services (CMS) as a Critical Access Hospital (CAH), or Sole Community Hospital (SCH) and

(c) The proposed host site has not received any mobile MRI service within the most recent 12-month period as of the date an application is submitted to the Department.

(d) An applicant that operates an existing fixed MRI service and is proposing to initiate a mobile MRI host site at the same site shall not be required to project available adjusted procedures if it meets the following requirements:

(i) Each mobile MRI service(s) that proposes to provide mobile MRI services to the applicant's site currently serves and will continue to serve at least two mobile host sites.

(5) An applicant proposing to add or change service on an existing mobile MRI service that meets the following requirements shall not be required to be in compliance with subsection (4):

(a) The host site has received mobile MRI services from an existing mobile MRI unit within the most recent 12-month period as of the date an application is submitted to the Department.

(b) Submit copies of all proposed contracts for the proposed host site related to the mobile MRI service.

(6) The applicant shall demonstrate that the available MRI adjusted procedures from the "Available MRI Adjusted Procedures List" or the adjusted procedures from the "MRI Service Utilization List," as applicable, are from the most recently published MRI lists as of the date an application is deemed submitted by the Department.

#### **Section 4. Requirements to replace an existing MRI unit**

Sec. 4. Replace an Existing MRI Unit means (i) any equipment change involving a change in, or replacement of, the entire MRI unit resulting in an applicant operating the same number and type (fixed or mobile) of MRI units before and after project completion or (ii) the renewal of a lease. Replacement also means the relocation of an MRI service or unit to a new site. The term does not include the replacement of the MRI system magnet that is under an existing service contract. The term does not include an upgrade to an existing MRI unit or repair of an existing MRI service or unit, and it does not include a host site that proposes to receive mobile MRI services from a different central service coordinator if the requirements of Section 3(5) have been met.

(1) "Upgrade an Existing MRI Unit" means any equipment change that does not involve a change in, or replacement of, the MRI system magnet, does not result in an increase in the number of MRI units; or does not result in a change in the type of MRI unit (e.g., changing a mobile MRI unit to a fixed MRI unit).

(2) "Repair an Existing MRI Unit" means restoring the ability of the system to operate within the manufacturer's specifications by replacing or repairing the existing components or parts of the system, including the magnet, pursuant to the terms of an existing maintenance agreement with the manufacturer of the MRI unit that does not result in a change in the strength of the MRI unit.

(3) An applicant proposing to replace an existing MRI unit shall demonstrate the following requirements:

(a) Equipment that is replaced shall be removed from service and disposed of or rendered considerably inoperable on or before the date that the replacement equipment becomes operational.

(b) The replacement unit shall be located at the same site.

(c) An applicant proposing to replace an existing MRI unit that does not involve a renewal of a lease shall demonstrate that the MRI unit to be replaced is fully depreciated according to generally accepted accounting principles; the existing equipment clearly poses a threat to the safety of the public; or the proposed replacement equipment offers a significant technological improvement which enhances quality of care, increases efficiency, and reduces operating costs.

(4) An applicant proposing to replace an existing mobile MRI host site to a new location shall demonstrate the following:

(a) The applicant currently operates the MRI mobile host site to be relocated.

(b) The MRI mobile host site to be relocated has been in operation for at least 12 months at its current site as of the date an application is submitted to the Department.

(c) The proposed new site is within a 5-mile radius of the existing site for a metropolitan ~~statistical area~~ county or within a 10-mile radius for a rural ~~or micropolitan statistical area~~ county or is ~~A~~ designated ~~RURAL HOSPITAL, by the Centers for Medicare and Medicaid Services (CMS) as a Critical Access Hospital (CAH), or Sole Community Hospital (SCH).~~

(d) The relocation will not involve a change in the current central service coordinator unless the requirements of Section 3(5) are met.

(e) The applicant confirms that the host site was not initiated under Section 3(4)(d).

(5) An applicant proposing to replace an existing fixed MRI service and its unit(s) to a new site shall demonstrate the following:

(a) The existing MRI service and its unit(s) to be replaced has been in operation for at least 36 months as of the date an application is submitted to the Department unless the applicant meets the requirement in subsection (c)(i) or (ii).

(b) The proposed new site is within a 10-mile radius of the existing site.

(c) Each existing MRI unit to be relocated performed at least the applicable minimum number of MRI adjusted procedures set forth in Section 15 based on the most recently published MRI Service Utilization List as of the date an application is deemed submitted by the Department unless one of the requirements of subsection (i), (ii), or (iii) are met. If the application is utilizing an MRI list where the Department determines that the reporting period is impacted by a public health epidemic and the facility was prevented by law from operating at full capacity due to the public health epidemic, the applicant may annualize their MRI adjusted procedures and shall include only those months and procedures performed when the facility was not prevented by law from operating at full capacity due to the public health epidemic. If using annualized data, the applicant shall submit an affidavit confirming the months that the facility was prevented by law from operating at full capacity due to the public health epidemic.

(i) the owner of the building where the site is located has incurred a filing for bankruptcy under chapter 7 within the last three years;

(ii) the ownership of the building where the site is located has changed within 24 months of the date of the service being operational; or

(iii) the MRI service being replaced is part of the replacement of an entire hospital to a new geographic site and has only one (1) MRI unit.

(6) An applicant proposing to replace a fixed MRI unit of an existing MRI service to a new site shall demonstrate the following:

(a) The applicant currently operates the MRI service from which the unit will be relocated.

(b) The existing MRI service from which the MRI unit(s) to be relocated has been in operation for at least 36 months as of the date an application is submitted to the Department.

(c) The proposed new site is within a 10-mile radius of the existing site.

(d) Each existing MRI unit at the service from which a unit is to be relocated performed at least the applicable minimum number of MRI adjusted procedures set forth in Section 15 based on the most recently published MRI Service Utilization List as of the date an application is deemed submitted by the Department.

(e) For volume purposes, the new site shall remain associated to the original site for a minimum of three years.

## **Section 5. Requirements to expand an existing MRI service**

Sec. 5. An applicant proposing to expand an existing MRI service shall demonstrate the following:

(1) An applicant shall demonstrate that the applicable MRI adjustable procedures are from the most recently published MRI Service Utilization List as of the date of an application is deemed submitted by the Department:

(a) Each existing MRI unit on the network has performed at least an average of 7,000 MRI adjusted procedures per MRI unit.

- (b) Each existing fixed MRI unit at the current site has performed at least an average of 9,000 MRI adjusted procedures per MRI unit.
- (c) Each existing dedicated pediatric MRI unit at the current site has performed at least an average of 3,500 MRI adjusted procedures per MRI unit.
- (d) the applicant operates both a fixed MRI and mobile MRI host site at the same site; and
  - (i) the site collectively performed at least an average of 9,000 MRI adjusted procedures per existing fixed MRI unit when its fixed and mobile host site MRI adjusted procedures are combined.
  - (ii) it is proposing to cease operation as a host site and not become a host site for at least 12 months from the date the proposed fixed MRI unit becomes operational.

(2) If the applicant is applying for expansion, and the application is utilizing an MRI list where the department determines that the reporting period is impacted by a public health epidemic, and the facility was prevented by law from operating at full capacity due to the public health epidemic, the applicant may annualize their MRI adjusted procedures and shall include only those months and procedures performed when the facility was not prevented by law from operating at full capacity due to the public health epidemic. If using annualized data, the applicant shall submit an affidavit confirming the months that the facility was prevented by law from operating at full capacity due to the public health epidemic.

(3) The additional fixed unit shall be located at the same site unless the requirements of the replacement section have been met.

#### **Section 6. Requirements to acquire an existing MRI service or an existing MRI unit(s)**

Sec. 6. An applicant proposing to acquire an existing fixed or mobile MRI service and its unit(s) shall demonstrate the following:

(1) The applicant shall not be required to be in compliance with the volume requirements applicable to a seller/lessor on the date the acquisition occurs if the proposed project meets one of the following:

- (a) It is the first application proposing to acquire the existing fixed or mobile MRI service and its unit(s) on or after July 1, 1997.
- (b) The existing fixed or mobile MRI service is owned by, is under common control of, or has a common parent as the applicant, and the MRI service and its unit(s) shall remain at the same site.

(2) For any application proposing to acquire an existing fixed or mobile MRI service and its unit(s), except an application approved pursuant to subsection (1), an applicant shall be required to document that the MRI service and its unit(s) to be acquired is operating in compliance with the volume requirements set forth in Section 15 of these standards applicable to an existing MRI service on the date the application is submitted to the Department.

(3) An applicant proposing to acquire an existing fixed or mobile MRI unit of an existing MRI service shall demonstrate that the proposed project meets all of the following, as applicable:

- (a) An applicant shall demonstrate that the applicable MRI adjustable procedures are from the most recently published MRI service utilization list as of the date of an application is deemed submitted by the Department:
  - (i) The fixed MRI unit(s) to be acquired performed at least 6,000 MRI adjusted procedures per fixed MRI unit.
  - (ii) The mobile MRI unit(s) to be acquired performed at least 5,500 MRI adjusted procedures per mobile MRI unit.
- (b) The project will not change the number of MRI units at the site from which the number of units are being acquired, subject to the applicable requirements under Section 4(6), unless the applicant demonstrates that the project is in compliance with the requirements of the initiation or expansion section, as applicable.

(c) The project will not result in the replacement of an MRI unit at the MRI service to be acquired unless the applicant demonstrates that the requirements of the replacement section have been met.

(4) If the applicant is applying for acquisition, and the application is utilizing an MRI list where the department determines that the reporting period is impacted by a public health epidemic, and the facility was prevented by law from operating at full capacity due to the public health epidemic, the applicant may annualize their MRI adjusted procedures and shall include only those months and procedures performed when the facility was not prevented by law from operating at full capacity due to the public health epidemic. If using annualized data, the applicant shall submit an affidavit confirming the months that the facility was prevented by law from operating at full capacity due to the public health epidemic.

(5) The MRI service and its unit(s) shall be operating at the applicable volume requirements set forth in Section 15 of these standards in the second 12 months after the effective date of the acquisition, and annually thereafter.

### **Section 7. Requirements to establish a dedicated research MRI unit**

Sec. 7. An applicant proposing an MRI unit to be used exclusively for research shall demonstrate the following:

(1) The applicant agrees that the dedicated research MRI unit will be used primarily (70% or more of the procedures) for research purposes only.

(2) Submit copies of documentation demonstrating that the applicant operates a diagnostic radiology residency program approved by the Accreditation Council for Graduate Medical Education, the American Osteopathic Association, or an equivalent organization.

(3) Submit copies of documentation demonstrating that the MRI unit shall operate under a protocol approved by the applicant's IRB.

(4) An applicant meeting the requirements of this section shall be exempt from meeting the requirements of sections to initiate and replace.

(5) The dedicated research MRI unit approved under this section may not utilize MRI adjusted procedures performed on the dedicated MRI unit to demonstrate need or to satisfy MRI CON review standards requirements.

### **Section 8. Requirements to establish a dedicated pediatric MRI unit**

Sec. 8. An applicant proposing to establish dedicated pediatric MRI shall demonstrate all of the following:

(1) The applicant shall have experienced at least 7,000 pediatric (< 18 years old) discharges (excluding normal newborns) in the most recent year of operation.

(2) The applicant shall have performed at least 5,000 pediatric (< 18 years old) surgeries in the most recent year of operation.

(3) The applicant shall have an active medical staff that includes, but is not limited to, physicians who are fellowship-trained in the following pediatric specialties:

- (a) pediatric radiology (at least two)
- (b) pediatric anesthesiology
- (c) pediatric cardiology
- (d) pediatric critical care

- (e) pediatric gastroenterology
- (f) pediatric hematology/oncology
- (g) pediatric neurology
- (h) pediatric neurosurgery
- (i) pediatric orthopedic surgery
- (j) pediatric pathology
- (k) pediatric pulmonology
- (l) pediatric surgery
- (m) neonatology

(4) The applicant shall have in operation the following pediatric specialty programs:

- (a) pediatric bone marrow transplant program
- (b) established pediatric sedation program
- (c) pediatric open-heart program

(5) An applicant meeting the requirements of this section shall be exempt from meeting the requirements of Section 5 of these standards.

### **Section 9. Requirements for all applicants proposing to initiate, replace, or acquire a hospital-based IMRI**

Sec. 9. An applicant proposing to initiate, replace, or acquire a hospital-based IMRI service shall demonstrate each of the following, as applicable to the proposed project.

(1) The proposed site is a licensed hospital under Part 215 of the Code.

(2) The proposed site has an existing fixed MRI service that has been operational for the previous 36 consecutive months and is meeting its minimum volume requirements.

(3) The proposed site has an existing and operational surgical service and is meeting its minimum volume requirements pursuant to the CON Review Standards for Surgical Services.

(4) The applicant has achieved one of the following:

- (a) at least 1,500 oncology discharges in the most recent year of operation; or
- (b) at least 1,000 neurological surgeries in the most recent year of operation; or
- (c) at least 7,000 pediatric (<18 years old) discharges (excluding normal newborns) and at least 5,000 pediatric (<18 years old) surgeries in the most recent year of operation.

(5) The proposed IMRI unit must be located in an operating room or a room adjoining an operating room allowing for transfer of the patient between the operating room and this adjoining room.

(6) Non-surgical diagnostic studies shall not be performed on an IMRI unit approved under this section unless the patient meets one of the following criteria:

- (a) the patient has been admitted to an inpatient unit;
- (b) the patient is having the study performed on an outpatient basis, but is in need of general anesthesia or deep sedation as defined by the American Society of Anesthesiologists; or
- (c) The patient is having a diagnostic or therapeutic procedure performed using an IMRI unit to target specific areas within the body, including biopsies, injections, ultrasounds, or other procedures that require accurate localization of tissues or structures.

(7) The approved IMRI unit will not be subject to MRI volume requirements.

(8) The applicant shall not utilize the procedures performed on the IMRI unit to demonstrate need or to satisfy MRI CON review standards requirements.

## **Section 10. Requirements for all applicants proposing to initiate, replace, or acquire a hospital-based MRI-guided EPI service**

Sec. 10. An applicant proposing to initiate, replace, or acquire a hospital-based MRI-guided EPI service shall demonstrate each of the following, as applicable to the proposed project.

- (1) The proposed site is a licensed hospital under part 215 of the Code.
- (2) The proposed site has an existing fixed MRI service that has been operational for the previous 36 consecutive months and is meeting its minimum volume requirements.
- (3) The proposed site has an existing and operational therapeutic cardiac catheterization service and is meeting its minimum volume requirements pursuant to the CON review standards for cardiac catheterization services and open-heart surgery services.
- (4) The proposed MRI-guided EPI unit must be located in a cardiac catheterization lab containing a fluoroscopy unit with an adjoining room containing an MRI scanner. The rooms shall contain a patient transfer system allowing for transfer of the patient between the cardiac catheterization lab and the MRI unit, utilizing one of the following:
  - (a) moving the patient to the MRI scanner, or
  - (b) installing the MRI scanner on a sliding gantry to allow the patient to remain stationary.
- (5) Non-cardiac MRI diagnostic studies shall not be performed in an MRI-guided EPI unit approved under this section unless the patient meets one of the following criteria:
  - (a) The patient has been admitted to an inpatient unit; or
  - (b) The patient is having the study performed on an outpatient basis as follows:
    - (i) is in need of general anesthesia or deep sedation as defined by the American Society of Anesthesiologists, or
    - (ii) has an implantable cardiac device.
- (6) The approved MRI-guided EPI unit shall not be subject to MRI volume requirements.
- (7) 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 11. Requirements for all applicants proposing to initiate, replace, or acquire an MRI simulator that will not be used solely for MRT treatment planning purposes**

Sec. 11. MRI simulation is the use of MRI to help simulate (or plan) a patient's MRT treatment and to incorporate superior delineation of soft tissues for MRT treatment plans. An applicant proposing to initiate, replace, or acquire an MRI simulator shall demonstrate each of the following, as applicable to the proposed project.

- (1) The proposed site has an existing fixed MRI service that has been operational for the previous 36 consecutive months and is meeting its minimum volume requirements.
- (2) The proposed site has an existing and operational MRT service and is meeting its minimum volume requirements pursuant to the CON review standards for MRT services/units.
- (3) MRI diagnostic studies shall not be performed using an MRI simulator approved under this section unless the patient meets one of the following criteria:
  - (a) The patient has been admitted to an inpatient unit; or
  - (b) The patient is having the study performed on an outpatient basis, but is in need of general anesthesia or deep sedation as defined by the American Society of Anesthesiologists.

(4) The approved MRI simulator will not be subject to MRI volume requirements.

(5) The applicant shall not utilize the procedures performed on the MRI simulator to demonstrate need or to satisfy MRI CON review standards requirements.

**Section 12. Requirements for approval of an FDA-approved PET/MRI scanner hybrid for initiation, expansion, replacement, and acquisition**

Sec. 12. An applicant proposing to initiate, expand, replace, or acquire an FDA-approved PET/MRI scanner hybrid shall demonstrate that it meets all of the following:

(1) There is an approved PET CON for the FDA-approved PET/MRI hybrid, and the FDA-approved PET/MRI scanner hybrid is in compliance with all applicable project delivery requirements as set forth in the CON review standards for PET.

(2) The applicant agrees to operate the FDA-approved PET/MRI scanner hybrid in accordance with all applicable project delivery requirements set forth in Section 15 of these standards.

(3) The approved FDA-approved PET/MRI scanner hybrid shall not be subject to MRI volume requirements.

(4) An FDA-approved PET/MRI scanner hybrid approved under the CON review standards for PET scanner services and the review standards for MRI scanner services may not utilize MRI procedures performed on an FDA-approved PET/MRI scanner hybrid to demonstrate need or to satisfy MRI CON review standards requirements.

**Section 13. Requirements for all applicants proposing to initiate, replace, or acquire an FDA-approved hospital-based portable MRI unit.**

Sec. 13. An applicant proposing to initiate, expand, replace, or acquire an FDA-approved hospital-based portable MRI unit shall demonstrate that it meets all of the following:

(1) An applicant is limited to the initiation, expansion, replacement, or acquisition of no more than two hospital-based portable MRI units.

(2) The proposed site is a hospital licensed under Part 215 of the Code.

(3) The proposed site has an existing fixed MRI service that has been operational for the previous 36 consecutive months and is meeting its minimum volume requirements.

(4) The applicant hospital is designated as a level I or II trauma facility by the American College of Surgeons and has been certified as a Comprehensive Stroke Center by the Joint Commission, the Accreditation Commission for Health Care, Inc., or Det Norske Veritas or has cared for more than 500 acute stroke patients in the most recent 12-month period if located in a metropolitan county, 300 acute stroke patients in the most recent 12-month period if located in a rural ~~AREA or micropolitan county~~, or is ~~A designated RURAL HOSPITAL, by the Centers for Medicare and Medicaid Services (CMS) as a Critical Access Hospital (CAH), or Sole Community Hospital (SCH).~~

(5) The applicant agrees to operate the FDA-approved hospital-based portable MRI unit in accordance with all applicable project delivery requirements set forth in Section 15 of these standards.

(6) The authorized FDA-approved hospital-based portable MRI unit will not be subject to MRI volume requirements.

(7) The applicant may not utilize MRI procedures performed on an FDA-approved hospital-based portable MRI unit to demonstrate need or to satisfy MRI CON review standards requirements.

#### **Section 14. Requirements for all applicants**

Sec. 14. An applicant shall provide verification of Medicaid participation. An applicant that is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services if a CON is approved.

#### **Section 15. Project delivery requirements – terms of approval**

Sec. 15. An applicant shall agree that, if approved, MRI services, whether fixed or mobile, shall be delivered and maintained in compliance with the following:

- (1) Compliance with these standards.
- (2) Compliance with the following quality assurance standards:
  - (a) An applicant shall develop and maintain policies and procedures that establish protocols for assuring the effectiveness of operation and the safety of the general public, patients, and staff in the MRI service.
  - (b) An applicant shall establish a schedule for preventive maintenance for the MRI unit.
  - (c) An applicant shall provide documentation identifying the specific individuals that form the MRI team. At a minimum, the MRI team shall consist of the following professionals:
    - (i) Physicians who shall be responsible for screening of patients to assure appropriate utilization of the MRI service and taking and interpretation of scans. At least one of these physicians shall be a board certified- radiologist.
    - (ii) An appropriately trained MRI Technologist who shall be responsible for taking an MRI scan.
    - (iii) An MRI physicist/engineer available as a team member on a full-time, part-time, or contractual basis.
  - (d) An applicant shall document that the MRI team members have the following qualifications:
    - (i) Each physician credentialed to interpret MRI scans meets the requirements of each of the following:
      - (A) The physician is licensed to practice medicine in the State of Michigan.
      - (B) The physician has had at least 60 hours of training in MRI physics, MRI safety, and MRI instrumentation in a program that is part of an imaging program accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association, and the physician meets the requirements of subdivision (1), (2), or (3):
        - (1) Board certification by the American Board of Radiology, the American Osteopathic Board of Radiology, or the Royal College of Physicians and Surgeons of Canada. If the diagnostic radiology program completed by a physician in order to become board certified did not include at least two months of MRI training, that physician shall document that he or she has had the equivalent of two months of postgraduate training in clinical MRI imaging at an institution which has a radiology program accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association.
        - (2) Formal training by an imaging program(s), accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association that included two years of training in cross-sectional imaging and six months training in organ-specific imaging areas.
        - (3) A practice in which at least one-third of total professional time, based on a full-time clinical practice during the most recent 5-year period, has been the primary interpretation of MR imaging.
      - (C) The physician has completed and will complete a minimum of 40 hours every two years of Category in Continuing Medical Education credits in topics directly involving MR imaging.
      - (D) The physician complies with the “American College of Radiology (ACR) Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging (MRI).”
    - (ii) An MRI technologist who is registered by the American Registry of Radiologic Technicians or by the American Registry of Magnetic Resonance Imaging Technologists (ARMRIT) and has, or will have

within 36 months of the effective date of these standards or the date a technologist is employed by an MRI service, whichever is later, special certification in MRI. If a technologist does not have special certification in MRI within either of the 3-year periods of time, all continuing education requirements shall be in the area of MRI services.

(iii) An applicant shall document that an MRI physicist/engineer is appropriately qualified. For purposes of evaluating this subdivision, the Department shall consider it *prima facie* evidence as to the qualifications of the physicist/engineer if the physicist/engineer is certified as a medical physicist by the American Board of Radiology, the American Board of Medical Physics, or the American Board of Science in Nuclear Medicine. However, the applicant may submit, and the Department may accept other evidence that an MRI physicist/engineer is qualified appropriately.

(e) The applicant shall have, within the MRI unit/service, equipment and supplies to handle clinical emergencies that might occur in the unit. MRI service staff will be trained in CPR and other appropriate emergency interventions. A Physician, Nurse Practitioner or Physician Assistant trained in the management of hypersensitivity and physiologic drug reactions to MRI contrast materials shall be on-site when patients are receiving intravenous contrast.

(3) Compliance with the following access to care requirements:

The applicant, to ensure that the MRI unit will be utilized by all segments of the Michigan population, shall

(a) provide MRI services to all individuals based on the clinical indications of need for the service and not on ability to pay or source of payment.

(b) maintain information by source of payment to indicate the volume of care from each source provided annually.

(c) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter.

(d) The operation of and referral of patients to the MRI unit shall be in conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

(4) Compliance with the following monitoring and reporting requirements:

(a) MRI units shall be operating at a minimum average annual utilization during the second 12 months of operation, and annually thereafter, as applicable:

(i) 5,000 MRI adjusted procedures per unit for fixed MRI services unless compliant with (A), (B) or (C),

(A) 4,000 MRI adjusted procedures for the fixed MRI unit initiated pursuant to Section 3(2)(b)(ii) and is the only fixed MRI unit at the current site,

(B) 3,000 MRI adjusted procedures for the fixed MRI unit initiated pursuant to Section 3(2)(b)(iii) and is the only fixed MRI unit at the hospital site licensed under Part 215 of the Code,

(C) 2,000 MRI adjusted procedures per unit per year for MRI services with one fixed unit located outside the 20-mile radius from the next closest fixed MRI service.

(ii) 3,500 MRI adjusted procedures per unit for mobile MRI services.

(iii) 3,500 MRI adjusted procedures per unit for dedicated pediatric MRI units.

(iv) Each mobile host site in a rural ~~or micropolitan statistical area~~ county or ~~A designated~~ **RURAL HOSPITAL**, by the Centers for Medicare and Medicaid Services (CMS) as a Critical Access Hospital (CAH), or Sole Community Hospital (SCH), shall have provided at least a total of 400 adjusted procedures during its second 12 months of operation, and annually thereafter, from all mobile units providing services to the site. Each mobile host site in a metropolitan ~~statistical area~~ county shall have provided at least a total of 600 adjusted procedures during its second 12 months of operation and annually thereafter, from all mobile units providing services to the site.

(v) In meeting these requirements, an applicant shall not include any MRI adjusted procedures performed on an MRI unit used exclusively for research and approved pursuant to Section 7 or for an IMRI unit approved pursuant to Section 9.

(b) The applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to, operating schedules, demographic and diagnostic information, and the volume of care provided to patients from all payor

sources, as well as other data requested by the Department or its designee and approved by the Commission. The applicant shall provide the required data in a format established by the Department and in a mutually agreed upon media no later than 30 days following the last day of the quarter for which data are being reported to the Department. An applicant shall be considered in violation of this term of approval if the required data are not submitted to the Department within 30 days following the last day of the quarter for which data are being reported. The Department may elect to verify the data through on-site review of appropriate records. Data for an MRI unit approved pursuant to Section 7, Section 8, Section 9, Section 10, or Section 11 shall be reported separately.

For purposes of Section 9, the data reported shall include, at a minimum, how often the IMRI unit is used and for what type of services, i.e., intra-operative or diagnostic. For purposes of Section 10, the data reported shall include, at a minimum, how often the MRI-guided EPI unit is used and for what type of services, i.e., electrophysiology or diagnostic. For purposes of Section 11, the data reported shall include, at a minimum, how often the MRI simulator is used and for what type of services, i.e., treatment plans or diagnostic services.

(c) The applicant shall provide the Department with a notice stating the first date on which the MRI unit became operational, and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules.

(d) An applicant who is a central service coordinator shall notify the Department of any additions, deletions, or changes in the host sites of each approved mobile MRI unit after the change(s) in host sites is made.

(e) The applicant shall provide notice to the department of any planned decrease or discontinuation of service(s) no later than 30 days after the planned decrease or discontinuation of the service(s).

(5) An applicant for an MRI unit approved under Section 7 shall agree that the services provided by the MRI unit are delivered in compliance with the following terms.

(a) The capital and operating costs relating to the research use of the MRI unit shall be charged only to a specific research account(s) and not to any patient or third-party payor.

(b) The MRI unit shall not be used for any purposes other than as approved by the IRB unless the applicant has obtained CON approval for the MRI unit pursuant to Part 222 and these standards, other than Section 7.

(c) The dedicated research MRI unit will be used primarily (70% or more of the procedures) for research purposes only.

(6) The dedicated pediatric MRI unit approved under Section 8 shall include at least 80% of the MRI procedures that are performed on patients under 18 years of age.

(7) An applicant approved under Section 3(4)(d) shall agree that the services provided by the mobile MRI service(s) are delivered in compliance with the following terms:

(a) Each mobile MRI service(s) that provides mobile MRI services to the applicant's site also serves and will continue to serve at least two mobile host sites.

(b) Each host facility must provide a properly prepared parking pad for the mobile MRI scanner of sufficient load-bearing capacity to support the vehicle, a waiting area for patients, and a means for patients to enter the vehicle without going outside (such as a canopy or enclosed corridor). Each host site facility must also provide the capability for processing the images and maintaining the confidentiality of patient records. A communication system must be provided between the mobile vehicle and each host site facility to provide for immediate notification of emergency medical situations.

(8) An applicant approved under Section 13 shall be in compliance with the following:

(a) The FDA-approved hospital-based portable MRI unit can only be used by a qualifying program for brain scanning of patients being treated in a dedicated neuroscience unit, an adult or pediatric intensive care unit (ICU) and/or an operating room.

(b) The approved applicant must have an institutional MRI safety committee.

(c) The approved applicant must provide annual reports to the Department by April 30th of each year for the preceding calendar year, which include at least all of the following visits performed on the FDA-approved hospital-based portable MRI unit:

- (i) Number of adult visits (age  $\geq$  18).
- (ii) Number of pediatric visits (age  $<$  18).
- (iii) Number of visits performed in an ICU.
- (iv) Number of visits performed in a dedicated neuroscience unit.
- (v) Number of visits performed in an operating room.

(9) The agreements and assurances required by this section shall be in the form of a certification agreed to by the applicant or its authorized agent.

## **Section 16. MRI procedure adjustments**

Sec. 16. (1) The Department shall apply the following formula, as applicable, to determine the number of MRI adjusted procedures that are performed by an existing MRI service or unit:

(a) The base value for each MRI procedure is 1.0. For functional MRI (fMRI) procedures, MRI-guided interventions, and cardiac MRI procedures, the base value is 2.0.

(i) fMRI means brain activation studies.

(ii) MRI-guided interventions means any invasive procedure performed requiring MRI guidance performed in the MRI scanner.

(iii) Cardiac MRI Procedure means dedicated MRI performed of the heart done for the sole purpose of evaluation of cardiac function, physiology, or viability.

(b) For each MRI visit involving a pediatric patient, 0.25 shall be added to the base value.

(c) For each MRI visit involving an inpatient, 0.50 shall be added to the base value.

(d) For each MRI procedure performed on a sedated patient:

(i) 0.75 shall be added to the base value for conscious sedation; or,

(ii) 1.50 shall be added to the base value for general anesthesia or deep sedation as defined by the American Society of Anesthesiologists.

(e) For each MRI procedure performed on a re-sedated patient, 0.25 shall be added to the base value.

(f) For each MRI procedure performed on a special needs patient, 0.25 shall be added to the base value.

(g) For each MRI visit that involves both a clinical and research scan on a single patient in a single visit, 0.25 shall be added to the base value.

(h) For each contrast MRI procedure performed after use of a contrast agent, and not involving a procedure before use of a contrast agent, 0.35 shall be added to the base value.

(i) For each contrast MRI procedure involving a procedure before and after use of a contrast agent, 1.0 shall be added to the base value.

(j) For each MRI procedure performed at a teaching facility, 0.15 shall be added to the base value.

(k) For each MRI visit involving an AIMD/Foreign Body Scan, only one of the following shall be added to the base value and shall only be reported for the first MRI procedure if the MRI visit involves more than one MRI procedure:

(i) 0.75 shall be added to the base value for a low complexity AIMD/Foreign Body Scan; or,

(ii) 1.25 shall be added to the base value for a medium complexity AIMD/Foreign Body Scan; or,

(iii) 1.50 shall be added to the base value for a high complexity AIMD/Foreign Body Scan; or,

(iv) 1.75 shall be added to the base value for a patient implanted with multiple AIMD's, and/or an MRI procedure performed "Off-Label".

(v) Definitions:

(A) Active Implant Medical Device (AIMD): An implanted device that requires an external power source to operate. Active implants often require the MRI unit to operate at a lower energy level and/or over a longer period to compensate for the whole-body specific absorption rate (SAR) or B1+RMS imaging limits as defined in the implant's FDA labeling for MRI imaging. examples include cardiac implantable electronic devices (CIEDs), stimulators, cochlear devices, and implanted infusion pumps.

(B) Foreign Body: An abnormal metallic object that is present within the human body as a result of an injury. Metal foreign bodies may also be present if they are ingested, inhaled, or inserted. These are not considered medical devices or implants but are subject to an MRI examination safety evaluation.

(C) MRI Examination Safety Evaluation: A patient evaluation where an implant and/or metallic foreign body is assessed for safety by a certified MRI Technologist, Licensed Physicist, Radiologist, or other appropriately trained healthcare professional. This includes identification and verification of implant components from appropriate sources (e.g., surgical reports, imaging reports, medical device databases, device vendors, review of prior imaging), analyzing current MRI conditional status of individual components and systems, and consulting published professional guidance with a written report.

(D) "Off-Label" Imaging of an Active Implant: Defined as imaging under conditions that contradict or exceed the FDA-approved labeling for MRI imaging or imaging an active implant when labeling does not exist. This should be performed if deemed appropriate after considering the risks and benefits of the procedure.

(E) Specific Absorption Rate (SAR): The dosimetric term used to estimate the rate of absorption of radiofrequency (RF) energy by human tissue in MRI. The most commonly used SAR metric presented by the scanner is the whole body averaged value. It is expressed in watts per kilogram (W/KG) on an MRI system.

(F) B1+RMS (Root-Mean-Square): The value of the transmitted radiofrequency (RF) magnetic field delivered to human tissue within a given MRI imaging sequence averaged over 10 seconds. It is measured in micro-tesla ( $\mu\text{T}$ ).

(G) High Complexity AIMD / Foreign Body Scan: An MRI visit involving a patient implanted with an active implant that has undergone an MRI examination safety evaluation and can be imaged when operating the MRI unit at a lower energy level to meet the implant's FDA labeling for MRI imaging. Applies when maximum whole-body SAR is 0.1 – 1.0 W/KG or B1+RMS is 2.0  $\mu\text{T}$  or below and a total imaging time limit exists, and/or at least one of the following roles are required to assist to ensure safe imaging: Onsite or remote physician specialist, onsite or remote physicist, onsite or remote vendor field rep, an onsite advanced cardiovascular life support (ACLS) or other appropriately trained personnel.

(H) Medium Complexity AIMD / Foreign Body Scan: An MRI visit involving a patient implanted with an active implant that has undergone an MRI examination safety evaluation and can be imaged when operating the MRI unit at a lower energy level to meet the implant's FDA labeling for MRI imaging. Applies when the whole-body SAR IS 1.1 – 2.0 W/KG or B1+RMS is 2.1 – 3.2  $\mu\text{T}$ , and/or a total imaging time limit exists.

(I) Low Complexity AIMD / Foreign Body Scan: An MRI visit involving a patient implanted with an active implant that has undergone an MRI examination safety evaluation and can be scanned under normal operating mode and/or a patient imbedded with a metallic foreign body from prior injury that has been deemed low risk.

(l) The results of subsections (a) through (k) shall be summed, and that sum shall represent an MRI-adjusted procedure.

(2) The Department shall apply not more than one of the adjustment factors set forth in this subsection, as applicable, to the number of MRI procedures adjusted in accordance with the applicable provisions of subsection (1) that are performed by an existing MRI service or unit.

(a) For a site located in a rural ~~or micropolitan statistical area~~ county or designated by the Centers for Medicare and Medicaid Services (CMS) as a Critical Access Hospital (CAH), number of MRI-adjusted procedures shall be multiplied by a factor of 1.4.

(b) For a mobile MRI unit that serves hospitals and other host sites located in ~~A rural, micropolitan statistical area~~, and metropolitan ~~statistical area~~ counties, the number of MRI adjusted procedures for a site located in a rural ~~or micropolitan statistical area~~ county or a site designated by the Centers for Medicare and Medicaid Services (CMS) as a Critical Access Hospital (CAH) shall be multiplied by a factor of 1.4, and for a site located in a metropolitan ~~statistical area~~ county, the number of MRI adjusted procedures shall be multiplied by a factor of 1.0.

(c) For a mobile MRI unit that serves only sites located in ~~A rural or micropolitan statistical area~~ counties or a site(s) designated by the Centers for Medicare and Medicaid Services (CMS) as a Critical Access Hospital (CAH) the number of MRI adjusted procedures shall be multiplied by a factor of 2.0.

(d) For a mobile MRI unit that serves only sites located in a health service area with one or fewer fixed MRI units and one or fewer mobile MRI units, the number of MRI adjusted procedures shall be multiplied by a factor of 3.5.

(e) Subsection (2) shall not apply to an application proposing a subsequent fixed MRI unit (second, third, etc.) at the same site.

(3) The number of MRI adjusted procedures performed by an existing MRI service is the sum of the results of subsections (1) and (2).

### **Section 17. Documentation of actual utilization**

Sec. 17. Documentation of the number of MRI procedures performed by an MRI unit shall be substantiated by the Department utilizing data submitted by the applicant in a format and media specified by the Department and as verified for the 12-month period reported on the most recently published "MRI Service Utilization List" as of the date an application is deemed submitted by the Department. The number of MRI procedures actually performed shall be documented by procedure records and not by application of the methodology required in Section 18. The Department may elect to verify the data through on-site review of appropriate records.

### **Section 18. Methodology for computing the number of available MRI adjusted procedures**

Sec. 18. (1) The number of available MRI adjusted procedures required pursuant to Section 3 shall be computed in accordance with the methodology set forth in this section. In applying the methodology, the following steps shall be taken in sequence, and data for the 12-month period reported on the most recently published "Available MRI Adjusted Procedures List," as of the date an application is deemed submitted by the Department, shall be used:

(a) Identify the number of actual MRI adjusted procedures performed by each existing MRI service as determined pursuant to Section 16.

(i) For purposes of computing actual MRI adjusted procedures, MRI adjusted procedures performed on MRI units used exclusively for research and approved pursuant to Section 7 and dedicated pediatric MRI approved pursuant to Section 8 shall be excluded.

(ii) For purposes of computing actual MRI adjusted procedures, the MRI adjusted procedures, from the host site routes utilized to meet the requirements of Section 3(2)(c), shall be excluded beginning at the time the application is submitted and for three years from the date the fixed MRI unit becomes operational.

(iii) For purposes of computing actual MRI adjusted procedures, the MRI adjusted procedures utilized to meet the requirements of Section 5(1) shall be reduced by 8,000 and shall be excluded beginning at the time the application is submitted and for three years from the date the fixed MRI unit becomes operational.

(b) Identify the number of available MRI adjusted procedures, if any, for each existing MRI service as determined pursuant to Section 2(1)(c).

(c) Determine the number of available MRI adjusted procedures that each referring licensed healthcare professional may commit from each service to an application in accordance with the following:

(i) Divide the number of available MRI adjusted procedures identified in subsection (b) for each service by the number of actual MRI adjusted procedures identified in subsection (a) for that existing MRI service.

(ii) For each licensed healthcare professional referring to that existing service, multiply the number of actual MRI adjusted procedures that the referring licensed healthcare professional made to the existing MRI service by the applicable proportion obtained by the calculation in subdivision (c)(i).

(A) For each licensed healthcare professional, subtract any available adjusted procedures previously committed. The total for each licensed healthcare professional cannot be less than zero.

(B) The total number of available adjusted procedures for that service shall be the sum of the results of (A) above.

(iii) For each MRI service, the available MRI adjusted procedures resulting from the calculation in (c)(ii) above shall be sorted in descending order by the available MRI adjusted procedures for each licensed healthcare professional. Then any duplicate values shall be sorted in descending order by the licensed healthcare professional's license numbers (last 6 digits only).

(iv) Using the data produced in (c)(iii) above, sum the number of available adjusted procedures in descending order until the summation equals at least 75 percent of the total available adjusted procedures. This summation shall include the minimum number of licensed healthcare professionals necessary to reach the 75 percent level.

(v) For the licensed healthcare professionals representing 75 percent of the total available adjusted procedures in (c)(iv) above, sum the available adjusted procedures.

(vi) For the licensed healthcare professionals used in subsection (c)(v) above, divide the total number of available adjusted procedures identified in (c)(ii)(B) above by the sum of those available adjusted procedures produced in (c)(v) above.

(vii) For only those licensed healthcare professionals identified in (c)(v) above, multiply the result of (c)(vi) above by the available adjusted procedures calculated in (c)(ii)(A) above.

(viii) The result shall be the "Available MRI Adjusted Procedures List."

(2) After publication of the "Available MRI Adjusted Procedures List" resulting from (1) above, the data shall be updated to account for a) licensed healthcare professional commitments of available MRI adjusted procedures in subsequent MRI CON applications and b) MRI adjusted procedures used in subsequent MRI CON applications received in which applicants apply for fixed MRI services pursuant to Section 3(2).

#### **Section 19. Procedures and requirements for commitments of available MRI adjusted procedures**

Sec. 19. (1) If one or more host sites on a mobile MRI service are located within the planning area of the proposed site, the applicant may access available MRI adjusted procedures from the entire mobile MRI service.

(2)(a) At the time the application is submitted to the Department, the applicant shall submit a signed data commitment on a form provided by the Department in response to the applicant's letter of intent for each licensed healthcare professional committing available MRI adjusted procedures to that application for a new MRI unit that requires licensed healthcare professional commitments.

(b) An applicant also shall submit, at the time the application is submitted to the Department, a computer file that lists, for each MRI service from which data are being committed to the same application, the name and license number of each licensed healthcare professional for whom a signed and dated data commitment form is submitted.

(i) The computer file shall be provided to the Department on mutually agreed upon media and in a format prescribed by the Department.

(ii) If the licensed healthcare professional commitments submitted on the Departmental forms do not agree with the data on the computer file, the applicant shall be allowed to correct only the computer file data which includes adding licensed healthcare professional commitments that were submitted at the time of application.

(c) If the required documentation for the licensed healthcare professional commitments submitted under this subsection is not submitted with the application on the designated application date, the application will be deemed submitted on the first applicable designated application date after all required documentation is received by the Department.

(3) Subsection 19(2) shall not apply if the proposed project involves the initiation of a mobile MRI host site under Section 3(4)(d) if the mobile MRI host site will be at the same site as a fixed MRI service and the host site will be owned by the same applicant entity as the fixed MRI service.

(4) The Department shall consider a signed and dated data commitment on a form provided by the Department in response to the applicant's letter of intent that meets the requirements of each of the following, as applicable:

(a) A committing licensed healthcare professional certifies that 100% of his or her available MRI adjusted procedures for each specified MRI service, calculated pursuant to Section 18, is being committed and specifies the CON application number for the MRI unit to which the data commitment is made. A licensed healthcare professional shall not be required to commit available MRI adjusted procedures from all MRI services to which his or her patients are referred for MRI services but only from those MRI services specified by the licensed healthcare professional in the data commitment form provided by the Department and submitted by the applicant in support of its application.

(b) A committing licensed healthcare professional certifies ownership interest, either direct or indirect, in the applicant entity. Indirect ownership includes ownership in an entity that has ownership interest in the applicant entity. This requirement shall not apply if the applicant entity is a group practice of which the committing licensed healthcare professional is a member. Group practice means a group practice as defined pursuant to the provisions of 42 U.S.C. 1395nn (h)(4), commonly known as Stark II, and the Code of Federal Regulations, 42 CFR, Part 411, published in the Federal Register on August 14, 1995, or its replacement.

(c) A committing licensed healthcare professional certifies that he or she has not been provided, or received a promise of being provided, a financial incentive to commit any of his or her available MRI adjusted procedures to the application.

(5)(a) The Department shall not consider a data commitment from a licensed healthcare professional for available MRI adjusted procedures from a specific MRI service if the available MRI adjusted procedures from that specific MRI service were used to support approval of an application for a new MRI unit, pursuant to Section 3, for which a final decision to approve has been issued by the Director of the Department until either of the following occurs:

(i) The approved CON is withdrawn or expires.

(ii) The MRI service or unit to which the data were committed has been in operation for at least 36 continuous months.

(b) The Department shall not consider a data commitment from a licensed healthcare professional for available MRI adjusted procedures from a specific MRI service if the available MRI adjusted procedures from that specific MRI service were used to support an application for a new fixed or mobile MRI unit pursuant to Section 3, for which a final decision to disapprove was issued by the Director of the Department until either of the following occurs:

(i) A final decision to disapprove an application is issued by the Director and the applicant does not appeal that disapproval or

(ii) If an appeal was made, the appeal is withdrawn by the applicant.

(6) The Department shall not consider a data commitment from a committing licensed healthcare professional for available MRI adjusted procedures from the same MRI service if that licensed healthcare professional has submitted a signed data commitment, on a form provided by Department, for more than one (1) application for which a final decision has not been issued by the Department. If the Department determines that a licensed healthcare professional has submitted a signed data commitment for the same available MRI adjusted procedures from the same MRI service to more than one CON application pending a final decision for a new fixed or mobile MRI unit or additional mobile MRI unit pursuant to Section 3, the Department shall,

(a) if the applications were submitted on the same designated application date, notify all applicants, simultaneously and in writing, that one or more licensed healthcare professional(s) have submitted data commitments for available MRI adjusted procedures from the same MRI service and that the licensed healthcare professionals' data from the same MRI service shall not be considered in the review of any of the pending applications submitted on the same designated application date until the licensed healthcare professional notifies the Department, in writing, of the one (1) application for which the data commitment shall be considered.

(b) if the applications were submitted on different designated application dates, consider the data commitment in the application submitted on the earliest designated application date and shall notify, simultaneously in writing, all applicants of applications submitted on designated application dates subsequent to the earliest date that one or more committing licensed healthcare professional(s) have submitted data commitments for available MRI adjusted procedures from the same MRI service and that the licensed healthcare professionals' data shall not be considered in the review of the application(s) submitted on the subsequent designated application date(s).

(7) The Department shall not consider any data commitment submitted by an applicant after the date an application is deemed submitted unless an applicant is notified by the Department, pursuant to subsection (6), that one or more committing licensed healthcare professional(s) submitted data commitments for available MRI adjusted procedures from the same MRI service. If an applicant is notified that one or more licensed healthcare professionals' data commitments will not be considered by the Department, the Department shall consider data commitments submitted after the date an application is deemed submitted only to the extent necessary to replace the data commitments not being considered pursuant to subsection (6).

(a) The applicant shall have 30 days to submit replacement of licensed healthcare professional commitments as identified by the Department in this section.

(8) The Department shall not consider a withdrawal of a signed data commitment on or after the date an application is deemed submitted by the Department.

(9) The Department shall consider a withdrawal of a signed data commitment if a committing licensed healthcare professional submits a written notice to the Department before the application is deemed submitted, that specifies the CON application number and the specific MRI services for which a data commitment is being withdrawn.

## **Section 20. Lists published by the Department**

Sec. 20. (1) On or before May 1 and November 1 of each year, the Department shall publish the following lists:

(a) A list, known as the "MRI Service Utilization List," of all MRI services in Michigan that includes at least the following for each MRI service:

- (i) The number of actual MRI adjusted procedures;
- (ii) The number of available MRI adjusted procedures, if any; and
- (iii) The number of MRI units, including whether each unit is a clinical, research, or dedicated pediatric.

(b) A list, known as the "Available MRI Adjusted Procedures List," that identifies each MRI service that has available MRI adjusted procedures and includes at least the following:

- (i) The number of available MRI adjusted procedures;
- (ii) The name, address, and license number of each referring licensed healthcare professional, identified in Section 18(1)(c)(v), whose patients received MRI services at that MRI service; and
- (iii) The number of available MRI adjusted procedures performed on patients referred by each referring licensed healthcare professional, identified in Section 18(1)(c)(v), and if any are committed to an MRI service. This number shall be calculated in accordance with the requirements of Section 18(1). A referring licensed healthcare professional may have fractional portions of available MRI adjusted procedures.

(c) For the lists published pursuant to subsections (a) or (b), the May 1 list will report 12 months of data from the previous January 1 through December 31 reporting period, and the November 1 list will report 12 months of data from the previous July 1 through June 30 reporting period. Copies of both lists shall be available upon request.

(d) The Department shall not be required to publish a list that sorts MRI database information by referring licensed healthcare professional, only by MRI service.

(2) When an MRI service begins to operate at a site at which MRI services previously were not provided, the Department shall include in the MRI database, data beginning with the second full quarter of operation of the new MRI service. Data from the start-up date to the start of the first full quarter will not be collected to allow a new MRI service sufficient time to develop its data reporting capability. Data from the first full quarter of operation will be submitted as test data but will not be reported in the lists published pursuant to this section.

(3) In publishing the lists pursuant to subsections (a) and (b), if an MRI service has not reported data in compliance with the requirements of Section 15, the Department shall indicate on both lists that the MRI service is in violation of the requirements set forth in Section 15, and no data will be shown for that service on either list.

### **Section 21. Effect on prior CON Review Standards; Comparative reviews**

Sec. 21. (1) These CON review standards supersede and replace the CON Review Standards for MRI Services approved by the CON Commission on ~~September 15, 2022~~ JUNE 12, 2025, and effective ~~January 26, 2023~~ AUGUST 27, 2025.

(2) Projects reviewed under these standards shall not be subject to comparative review.

**Section 22. Health Service Areas**

Sec. 22. Counties assigned to each of the health service areas are as follows:

<b>HSA</b>	<b>COUNTIES</b>		
1	Livingston Macomb Wayne	Monroe Oakland	St. Clair Washtenaw
2	Clinton Eaton	Hillsdale Ingham	Jackson Lenawee
3	Barry Berrien Branch	Calhoun Cass Kalamazoo	St. Joseph Van Buren
4	Allegan Ionia Kent Lake	Mason Mecosta Montcalm Muskegon	Newaygo Oceana Osceola Ottawa
5	Genesee	Lapeer	Shiawassee
6	Arenac Bay Clare Gladwin Gratiot	Huron Iosco Isabella Midland Ogemaw	Roscommon Saginaw Sanilac Tuscola
7	Alcona Alpena Antrim Benzie Charlevoix Cheboygan	Crawford Emmet Gd Traverse Kalkaska Leelanau Manistee	Missaukee Montmorency Oscoda Otsego Presque Isle Wexford
8	Alger Baraga Chippewa Delta Dickinson	Gogebic Houghton Iron Keweenaw Luce	Mackinac Marquette Menominee Ontonagon Schoolcraft

Rural Michigan counties are as follows:

Alcona	Gogebic	Ogemaw
Alger	Huron	Ontonagon
Antrim	Iosco	Osceola
Arenac	Iron	Oscoda
Baraga	Lake	Otsego
Charlevoix	Luce	Presque Isle
Cheboygan	Mackinac	Roscommon
Clare	Manistee	Sanilac
Crawford	Montmorency	Schoolcraft
Emmet	Newaygo	Tuscola
Gladwin	Oceana	

Micropolitan statistical area Michigan counties are as follows:

Allegan	Hillsdale	Mason
Alpena	Houghton	Mecosta
Benzie	Ionia	Menominee
Branch	Isabella	Missaukee
Chippewa	Kalkaska	St. Joseph
Delta	Keweenaw	Shiawassee
Dickinson	Leelanau	Wexford
Grand Traverse	Lenawee	
Gratiot	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry	Jackson	Muskegon
Bay	Kalamazoo	Oakland
Berrien	Kent	Ottawa
Calhoun	Lapeer	Saginaw
Cass	Livingston	St. Clair
Clinton	Macomb	Van Buren
Eaton	Midland	Washtenaw
Genesee	Monroe	Wayne
Ingham	Montcalm	

Source:

75 F.R., p. 37245 (June 28, 2010)  
Statistical Policy Office  
Office of Information and Regulatory Affairs  
United States Office of Management and Budget