

**MICHIGAN DEPARTMENT OF COMMUNITY HEALTH**  
**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 15, 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) "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

(i) "Department" means the Michigan Department of Community Health (MDCH).

- 53 (j) "Doctor" means an individual licensed under Article 15 of the Code to engage in the practice of  
54 medicine, osteopathic medicine and surgery, chiropractic, dentistry, or podiatry.
- 55 (k) "Existing MRI service" means either the utilization of a CON-approved and operational MRI  
56 unit(s) at one site in the case of a fixed MRI service, and in the case of a mobile MRI service, the  
57 utilization of a CON-approved and operational mobile MRI unit(s) at each host site, on the date an  
58 application is submitted to the Department.
- 59 (l) "Existing MRI unit" means a CON-approved and operational MRI unit used to provide MRI  
60 services.
- 61 (m) "Expand an existing fixed MRI service" means an increase in the number of fixed MRI units to  
62 be operated by the applicant.
- 63 (n) "Expand an existing mobile MRI service" means the addition of a mobile MRI unit that will be  
64 operated by a central service coordinator that is approved to operate one or more mobile MRI units as of  
65 the date an application is submitted to the Department.
- 66 (o) "Group practice" means a group practice as defined pursuant to the provisions of 42 U.S.C.  
67 1395nn (h)(4), commonly known as Stark II, and the Code of Federal Regulations, 42 CFR, Part 411,  
68 published in the Federal Register on August 14, 1995, or its replacement.
- 69 (p) "Health service area" or "HSA" means the geographic areas set forth in Section 21.
- 70 (q) "Host site" means the site at which a mobile MRI unit is authorized by CON to provide MRI  
71 services.
- 72 (r) "Initiate a fixed MRI service" means begin operation of a fixed MRI service at a site that does  
73 not provide or is not CON approved to provide fixed MRI services as of the date an application is  
74 submitted to the Department. The term does not include the acquisition or replacement of an existing  
75 fixed MRI service to a new site or the renewal of a lease.
- 76 (s) "Initiate a mobile MRI host site" means the provision of MRI services at a host site that has not  
77 received any MRI services within 12 months from the date an application is submitted to the Department.  
78 The term does not include the renewal of a lease.
- 79 (t) "Initiate a mobile MRI service" means begin operation of a mobile MRI unit that serves two or  
80 more host sites.  
81 The term does not include the acquisition of an existing mobile MRI service or the renewal of a  
82 lease.
- 83 (u) "Inpatient" means an MRI visit involving an individual who has been admitted to the licensed  
84 hospital at the site of the MRI service/unit or in the case of an MRI unit that is not located at that licensed  
85 hospital site, an admitted patient transported from a licensed hospital site by ambulance to the MRI  
86 service.
- 87 (v) "Institutional review board" or "IRB" means an institutional review board as defined by Public  
88 Law 93-348 that is regulated by Title 45 CFR 46.
- 89 (w) "Intra-operative magnetic resonance imaging" or "IMRI" means the integrated use of MRI  
90 technology during surgical and interventional procedures within a licensed operative environment.
- 91 (x) "Licensed hospital site" means the location of the hospital authorized by license and listed on  
92 that licensee's certificate of licensure.
- 93 (y) "Magnetic resonance imaging" or "MRI" means the analysis of the interaction that occurs  
94 between radio frequency energy, atomic nuclei, and strong magnetic fields to produce cross sectional  
95 images similar to those displayed by computed tomography (CT) but without the use of ionizing radiation.
- 96 (z) "MRI adjusted procedure" means an MRI visit, at an existing MRI service, that has been  
97 adjusted in accordance with the applicable provisions of Section 15.
- 98 (aa) "MRI database" means the database, maintained by the Department pursuant to Section 14 of  
99 these standards, that collects information about each MRI visit at MRI services located in Michigan.
- 100 (bb) "MRI-guided electrophysiology intervention" or "MRI-guided EPI" means equipment specifically  
101 designed for the integrated use of MRI technology for the purposes of electrophysiology interventional  
102 procedures within a cardiac catheterization lab.
- 103 (cc) "MRI procedure" means a procedure conducted by an MRI unit approved pursuant to sections  
104 3, 4, 5, 6, 7, or 9 of these standards which is either a single, billable diagnostic magnetic resonance  
105 procedure or a procedure conducted by an MRI unit at a site participating with an approved diagnostic

106 radiology residency program, under a research protocol approved by an IRB. The capital and operating  
107 costs related to the research use are charged to a specific research account and not charged to or  
108 collected from third-party payors or patients. The term does not include a procedure conducted by an MRI  
109 unit approved pursuant to Section 7.

110 (dd) "MRI services" means either the utilization of an authorized MRI unit(s) at one site in the case of  
111 a fixed MRI service or in the case of a mobile MRI service, the utilization of an authorized mobile MRI unit  
112 at each host site.

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

118 (ff) "MRI visit" means a single patient visit to an MRI service/unit that may involve one or more MRI  
119 procedures.

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

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

125 (ii) "Ownership interest, direct or indirect" means a direct ownership relationship between a doctor  
126 and an applicant entity or an ownership relationship between a doctor and an entity that has an ownership  
127 relationship with an applicant entity.

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

129 (kk) "Planning area" means

130 (i) in the case of a proposed fixed MRI service or unit, the geographic area within a 20-mile radius  
131 from the proposed site if the proposed site is not in a rural or micropolitan statistical area county and a 75-  
132 mile radius from the proposed site if the proposed site is in a rural or micropolitan statistical area county.

133 (ii) in the case of a proposed mobile MRI service or unit, except as provided in subsection (iii), the  
134 geographic area within a 20-mile radius from each proposed host site if the proposed site is not in a rural  
135 or micropolitan statistical area county and within a 75-mile radius from each proposed host site if the  
136 proposed site is in a rural or micropolitan statistical area county.

137 (iii) in the case of a proposed mobile MRI service or unit meeting the requirement of Section  
138 15(2)(d), the health service area in which all the proposed mobile host sites will be located.

139 (ll) "Referring doctor" means the doctor of record who ordered the MRI procedure(s) and either to  
140 whom the primary report of the results of an MRI procedure(s) is sent or in the case of a teaching facility,  
141 the attending doctor who is responsible for the house officer or resident that requested the MRI procedure.

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

145 (nn) "Research scan" means an MRI scan administered under a research protocol approved by the  
146 applicant's IRB.

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

149 (pp) "Sedated patient" means a patient that meets all of the following:

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

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

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

156 (qq) "Site" means

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

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

161 (rr) "Special needs patient" means a non-sedated patient, either pediatric or adult, with any of the  
162 following conditions: down syndrome, autism, attention deficit hyperactivity disorder (ADHD),  
163 developmental delay, malformation syndromes, hunter's syndrome, multi-system disorders, psychiatric  
164 disorders, IMPLANTABLE CARDIAC DEVICES (ICDS), and other conditions that make the patient unable  
165 to comply with the positional requirements of the exam OR IS UNABLE TO COMPLY WITH THE  
166 MOTIONLESS REQUIREMENTS AND WHOSE RESULTING MOVEMENTS RESULT IN NON-  
167 DIAGNOSTIC QUALITY IMAGES THEREFORE REQUIRING THE TECHNOLOGIST TO REPEAT THE  
168 SAME SEQUENCE IN AN ATTEMPT TO OBTAIN A DIAGNOSTIC QUALITY IMAGE.

169 (ss) "Teaching facility" means a licensed hospital site, or other location, that provides either fixed or  
170 mobile MRI services and at which residents or fellows of a training program in diagnostic radiology, that is  
171 approved by the Accreditation Council on Graduate Medical Education or American Osteopathic  
172 Association, are assigned.

173 (tt) "Unadjusted MRI scan" means an MRI procedure performed on a single anatomical site as  
174 defined by the MRI database and that is not adjusted pursuant to the applicable provisions of Section 15.

175  
176 (2) Terms defined in the Code have the same meanings when used in these standards.  
177

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

179  
180 Sec. 3. An applicant proposing to initiate an MRI service or a host site shall demonstrate the following  
181 requirements, as applicable:  
182

183 (1) An applicant proposing to initiate a fixed MRI service shall demonstrate 6,000 available MRI  
184 adjusted procedures per proposed fixed MRI unit from within the same planning area as the proposed  
185 service/unit.  
186

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

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

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

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

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

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

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

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

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

198 (B) The applicant hospital operates an emergency room that provides 24-hour emergency care  
199 services and at least 20,000 visits within the most recent 12-month period for which data, verifiable by the  
200 Department, is available.

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

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

206 (e) The applicant shall cease operation as a host site and not become a host site for at least 12  
207 months from the date the fixed service and its unit becomes operational.  
208

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

- 212 (a) Identify the proposed route schedule and procedures for handling emergency situations.  
213 (b) Submit copies of all proposed contracts for the proposed host site related to the mobile MRI  
214 service.  
215 (c) Identify a minimum of two (2) host sites for the proposed service.  
216  
217 (4) An applicant, whether the central service coordinator or the host site, proposing to initiate a host  
218 site on a new or existing mobile MRI service shall demonstrate the following, as applicable:  
219 (a) 600 available MRI adjusted procedures, from within the same planning area as the proposed  
220 service/unit, for a proposed host site that is not located in a rural or micropolitan statistical area county, or  
221 (b) 400 available MRI adjusted procedures from within the same planning area for a proposed host  
222 site that is located in a rural or micropolitan statistical area county, and  
223 (c) The proposed host site has not received any mobile MRI service within the most recent 12-  
224 month period as of the date an application is submitted to the Department.  
225  
226 (5) An applicant proposing to add or change service on an existing mobile MRI service that meets  
227 the following requirements shall not be required to be in compliance with subsection (4):  
228 (a) The host site has received mobile MRI services from an existing mobile MRI unit within the  
229 most recent 12-month period as of the date an application is submitted to the Department.  
230 (b) Submit copies of all proposed contracts for the proposed host site related to the mobile MRI  
231 service.  
232  
233 (6) The applicant shall demonstrate that the available MRI adjusted procedures from the "Available  
234 MRI Adjusted Procedures List" or the adjusted procedures from the "MRI Service Utilization List," as  
235 applicable, are from the most recently published MRI lists as of the date an application is deemed  
236 submitted by the Department.  
237

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

239  
240 Sec. 4. Replace an existing MRI unit means (i) any equipment change involving a change in, or  
241 replacement of, the entire MRI unit resulting in an applicant operating the same number and type (fixed or  
242 mobile) of MRI units before and after project completion or (ii) an equipment change that involves a capital  
243 expenditure of \$750,000 or more in any consecutive 24-month period or (iii) the renewal of a lease.  
244 Replacement also means the relocation of an MRI service or unit to a new site. The term does not include  
245 the replacement of components of the MRI system, including the magnet, under an existing service  
246 contract or required maintenance to maintain the system to operate within manufacturer specifications.  
247 The term does not include an upgrade to an existing MRI unit or repair of an existing MRI service or unit,  
248 and it does not include a host site that proposes to receive mobile MRI services from a different central  
249 service coordinator if the requirements of Section 3(5) have been met.  
250

- 251 (1) "Upgrade an existing MRI unit" means any equipment change that  
252 (i) does not involve a change in, or replacement of, the entire MRI unit, does not result in an  
253 increase in the number of MRI units; or does not result in a change in the type of MRI unit (e.g., changing  
254 a mobile MRI unit to a fixed MRI unit); and  
255 (ii) involves a capital expenditure related to the MRI equipment of less than \$750,000 in any  
256 consecutive 24-month period.  
257

258 (2) "Repair an existing MRI unit" means restoring the ability of the system to operate within the  
259 manufacturer's specifications by replacing or repairing the existing components or parts of the system,  
260 including the magnet, pursuant to the terms of an existing maintenance agreement WITH THE  
261 MANUFACTURER OF THE MRI UNIT that does not result in a change in the strength of the MRI unit.  
262

- 263 (3) An applicant proposing to replace an existing MRI unit shall demonstrate the following  
264 requirements, ~~as applicable:~~

265 (a) ~~An applicant shall demonstrate that the applicable MRI adjusted procedures are from the most~~  
266 ~~recently published MRI Service Utilization List as of the date an application is deemed submitted by the~~  
267 ~~Department. An applicant proposing to replace an existing MRI unit that is below 1 tesla with an MRI unit~~  
268 ~~that is a 1 tesla or higher, shall be exempt once, as of September 18, 2013, from the minimum volume~~  
269 ~~requirements for replacement:~~

270 ~~— (i) Each existing mobile MRI unit on the network has performed at least an average of 5,500 MRI~~  
271 ~~adjusted procedures per MRI unit.~~

272 ~~— (ii) Each existing fixed MRI unit at the current site has performed at least an average of 6,000 MRI~~  
273 ~~adjusted procedures per MRI unit unless the applicant demonstrates compliance with one of the following:~~

274 ~~— (A) The existing fixed MRI unit initiated pursuant to Section 3(2)(b)(ii) has performed at least 4,000~~  
275 ~~MRI adjusted procedures and is the only fixed MRI unit at the current site.~~

276 ~~— (B) The existing fixed MRI unit initiated pursuant to Section 3(2)(b)(iii) has performed at least 3,000~~  
277 ~~MRI adjusted procedures and is the only fixed MRI unit at the current site.~~

278 ~~— (iii) Each existing dedicated pediatric MRI unit at the current site has performed at least an average~~  
279 ~~of 3,500 MRI adjusted procedures per MRI unit.~~

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

282 ~~(eb) The replacement unit shall be located at the same site.~~

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

288  
289 (4) An applicant proposing to replace an existing mobile MRI host site to a new location shall  
290 demonstrate the following:

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

292 (b) The MRI mobile host site to be relocated has been in operation ~~for at least 36 months~~ as of the  
293 date an application is submitted to the Department.

294 (c) The proposed new site is within a 5-mile radius of the existing site for a metropolitan statistical  
295 area county or within a 10-mile radius for a rural or micropolitan statistical area county.

296 ~~(d) The mobile MRI host site to be relocated performed at least the applicable minimum number of~~  
297 ~~MRI adjusted procedures set forth in Section 14 based on the most recently published MRI Service~~  
298 ~~Utilization List as of the date an application is deemed submitted by the Department.~~

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

301  
302 (5) An applicant proposing to replace an existing fixed MRI service and its unit(s) to a new site shall  
303 demonstrate the following:

304 (a) The existing MRI service and its unit(s) to be replaced has been in operation for at least 36  
305 months as of the date an application is submitted to the Department UNLESS THE APPLICANT MEETS  
306 THE REQUIREMENT IN SUBSECTION (c)(i) OR (ii).

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

308 (c) Each existing MRI unit to be relocated performed at least the applicable minimum number of  
309 MRI adjusted procedures set forth in Section 14 based on the most recently published MRI Service  
310 Utilization List as of the date an application is deemed submitted by the Department, UNLESS ONE OF  
311 THE FOLLOWING REQUIRMENTS ARE MET-:

312 — (i) THE OWNER OF THE BUILDING WHERE THE SITE IS LOCATED HAS INCURRED A  
313 FILING FOR BANKRUPTCY UNDER CHAPTER SEVEN (7) WITHIN THE LAST THREE YEARS;

314 — (ii) THE OWNERSHIP OF THE BUILDING WHERE THE SITE IS LOCATED HAS CHANGED  
315 WITHIN 24 MONTHS OF THE DATE OF THE SERVICE BEING OPERATIONAL; OR

316 — (iii) THE MRI SERVICE BEING REPLACED IS PART OF THE REPLACEMENT OF AN ENTIRE  
317 HOSPITAL TO A NEW GEOGRAPHIC SITE AND HAS ONLY ONE (1) MRI UNIT.

- 318  
319 (6) An applicant proposing to replace a fixed MRI unit of an existing MRI service to a new site shall  
320 demonstrate the following:  
321 (a) The applicant currently operates the MRI service from which the unit will be relocated.  
322 (b) The existing MRI service from which the MRI unit(s) to be relocated has been in operation for at  
323 least 36 months as of the date an application is submitted to the Department.  
324 (c) The proposed new site is within a 10-mile radius of the existing site.  
325 (d) Each existing MRI unit at the service from which a unit is to be relocated performed at least the  
326 applicable minimum number of MRI adjusted procedures set forth in Section 14 based on the most  
327 recently published MRI Service Utilization List as of the date an application is deemed submitted by the  
328 Department.  
329 (e) For volume purposes, the new site shall remain associated to the original site for a minimum of  
330 three years.

331  
332 **Section 5. Requirements to expand an existing MRI service**

333  
334 Sec. 5. An applicant proposing to expand an existing MRI service shall demonstrate the following:

- 335  
336 (1) An applicant shall demonstrate that the applicable MRI adjustable procedures are from the most  
337 recently published MRI Service Utilization List as of the date of an application is deemed submitted by the  
338 Department:  
339 (a) Each existing MRI unit on the network has performed at least an average of 9,000 MRI adjusted  
340 procedures per MRI unit.  
341 (b) Each existing fixed MRI unit at the current site has performed at least an average of 11,000 MRI  
342 adjusted procedures per MRI unit.  
343 (c) Each existing dedicated pediatric MRI unit at the current site has performed at least an average  
344 of 3,500 MRI adjusted procedures per MRI unit.  
345  
346 (2) The additional fixed unit shall be located at the same site unless the requirements of the  
347 replacement section have been met.

348  
349 **Section 6. Requirements to acquire an existing MRI service or an existing MRI unit(s)**

350  
351 Sec. 6. ~~(1)~~ An applicant proposing to acquire an existing fixed or mobile MRI service and its unit(s)  
352 shall demonstrate the following:

353 ~~(a1)~~ For the first application proposing to acquire an existing fixed or mobile MRI service on or after  
354 July 1, 1997, the existing MRI service and its unit(s) to be acquired shall not be required to be in  
355 compliance with the volume requirements applicable to a seller/lessor on the date the acquisition occurs.  
356 The MRI service shall be operating at the applicable volume requirements set forth in Section 14 of these  
357 standards in the second 12 months after the effective date of the acquisition, and annually thereafter.

358  
359 ~~(b2)~~ For any application proposing to acquire an existing fixed or mobile MRI service and its unit(s), except  
360 the first application approved pursuant to subsection (a), an applicant shall be required to document that  
361 the MRI service and its unit(s) to be acquired is operating in compliance with the volume requirements set  
362 forth in Section 14 of these standards applicable to an existing MRI service on the date the application is  
363 submitted to the Department.

364  
365 ~~(23)~~ An applicant proposing to acquire an existing fixed or mobile MRI unit of an existing MRI service  
366 shall demonstrate that the proposed project meets all of the following, AS APPLICABLE:

367 (a) AN APPLICANT SHALL DEMONSTRATE THAT THE APPLICABLE MRI ADJUSTABLE  
368 PROCEDURES ARE FROM THE MOST RECENTLY PUBLISHED MRI SERVICE UTILIZATION LIST AS  
369 OF THE DATE OF AN APPLICATION IS DEEMED SUBMITTED BY THE DEPARTMENT:

370 (i)- THE FIXED MRI UNIT(S) TO BE ACQUIRED PERFORMED AT LEAST 6,000 MRI ADJUSTED  
371 PROCEDURES PER FIXED MRI UNIT.

372 (ii) THE MOBILE MRI UNIT(S) TO BE ACQUIRED PERFORMED AT LEAST 5,500 MRI  
373 ADJUSTED PROCEDURES PER MOBILE MRI UNIT.

374 (b) The project will not change the number of MRI units at the site of the MRI service FROM WHICH  
375 THE NUMBER OF UNITS ARE being acquired, subject to the applicable requirements under Section 4(6),  
376 unless the applicant demonstrates that the project is in compliance with the requirements of the initiation  
377 or expansion Section, as applicable.

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

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

381  
382  
383 Sec. 7. An applicant proposing an MRI unit to be used exclusively for research shall demonstrate the  
384 following:

385  
386 (1) The applicant agrees that the dedicated research MRI unit will be used primarily (70% or more  
387 of the procedures) for research purposes only.

388  
389 (2) Submit copies of documentation demonstrating that the applicant operates a diagnostic  
390 radiology residency program approved by the Accreditation Council for Graduate Medical Education, the  
391 American Osteopathic Association, or an equivalent organization.

392  
393 (3) Submit copies of documentation demonstrating that the MRI unit shall operate under a protocol  
394 approved by the applicant's IRB.

395  
396 (4) An applicant meeting the requirements of this section shall be exempt from meeting the  
397 requirements of sections to initiate and replace.

398  
399 (5) THE DEDICATED RESEARCH MRI UNIT APPROVED UNDER THIS SECTION MAY NOT  
400 UTILIZE MRI ADJUSTED PROCEDURES PERFORMED ON THE DEDICATED MRI UNIT TO  
401 DEMONSTRATE NEED OR TO SATISFY MRI CON REVIEW STANDARDS REQUIREMENTS.

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

403  
404  
405 Sec. 8. An applicant proposing to establish dedicated pediatric MRI shall demonstrate all of the  
406 following:

407  
408 (1) The applicant shall have experienced at least 7,000 pediatric (< 18 years old) discharges  
409 (excluding normal newborns) in the most recent year of operation.

410  
411 (2) The applicant shall have performed at least 5,000 pediatric (< 18 years old) surgeries in the  
412 most recent year of operation.

413  
414 (3) The applicant shall have an active medical staff that includes, but is not limited to, physicians  
415 who are fellowship-trained in the following pediatric specialties:

- 416 (a) pediatric radiology (at least two)
- 417 (b) pediatric anesthesiology
- 418 (c) pediatric cardiology
- 419 (d) pediatric critical care
- 420 (e) pediatric gastroenterology
- 421 (f) pediatric hematology/oncology
- 422 (g) pediatric neurology

- 423 (h) pediatric neurosurgery
- 424 (i) pediatric orthopedic surgery
- 425 (j) pediatric pathology
- 426 (k) pediatric pulmonology
- 427 (l) pediatric surgery
- 428 (m) neonatology

429  
430 (4) The applicant shall have in operation the following pediatric specialty programs:

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

434  
435 (5) An applicant meeting the requirements of this section shall be exempt from meeting the  
436 requirements of Section 5 of these standards.

437  
438 **Section 9. Requirements for all applicants proposing to initiate, replace, or acquire a hospital**  
439 **based IMRI**

440  
441 Sec. 9. An applicant proposing to initiate, replace, or acquire a hospital based IMRI service shall  
442 demonstrate each of the following, as applicable to the proposed project.

443  
444 (1) The proposed site is a licensed hospital under Part 215 of the Code.

445  
446 (2) The proposed site has an existing fixed MRI service that has been operational for the previous  
447 36 consecutive months and is meeting its minimum volume requirements.

448  
449 (3) The proposed site has an existing and operational surgical service and is meeting its minimum  
450 volume requirements pursuant to the CON Review Standards for Surgical Services.

451  
452 (4) The applicant has achieved one of the following:

- 453 (a) at least 1,500 oncology discharges in the most recent year of operation; or
- 454 (b) at least 1,000 neurological surgeries in the most recent year of operation; or
- 455 (c) at least 7,000 pediatric (<18 years old) discharges (excluding normal newborns) and at least  
456 5,000 pediatric (<18 years old) surgeries in the most recent year of operation.

457  
458 (5) The proposed IMRI unit must be located in an operating room or a room adjoining an operating  
459 room allowing for transfer of the patient between the operating room and this adjoining room.

460  
461 (6) Non-surgical diagnostic studies shall not be performed on an IMRI unit approved under this  
462 section unless the patient meets one of the following criteria:

- 463 (a) the patient has been admitted to an inpatient unit; or
- 464 (b) the patient is having the study performed on an outpatient basis, but is in need of general  
465 anesthesia or deep sedation as defined by the American Society of Anesthesiologists.

466  
467 (7) The approved IMRI unit will not be subject to MRI volume requirements.

468  
469 (8) The applicant shall not utilize the procedures performed on the IMRI unit to demonstrate need  
470 or to satisfy MRI CON review standards requirements.

471  
472 **Section 10. Requirements for all applicants proposing to initiate, replace, or acquire a hospital**  
473 **based MRI-guided EPI service**

474

475 Sec. 10. An applicant proposing to initiate, replace, or acquire a hospital based MRI-guided EPI  
476 service shall demonstrate each of the following, as applicable to the proposed project.  
477

478 (1) The proposed site is a licensed hospital under part 215 of the Code.  
479

480 (2) The proposed site has an existing fixed MRI service that has been operational for the previous  
481 36 consecutive months and is meeting its minimum volume requirements.  
482

483 (3) The proposed site has an existing and operational therapeutic cardiac catheterization service  
484 and is meeting its minimum volume requirements pursuant to the CON review standards for cardiac  
485 catheterization services and open heart surgery services.  
486

487 (4) The proposed MRI-guided EPI unit must be located in a cardiac catheterization lab containing a  
488 flouroscopy unit with an adjoining room containing an MRI scanner. The rooms shall contain a patient  
489 transfer system allowing for transfer of the patient between the cardiac catheterization lab and the MRI  
490 unit, utilizing one of the following:

491 (a) moving the patient to the MRI scanner, or

492 (b) installing the MRI scanner on a sliding gantry to allow the patient to remain stationary.  
493

494 (5) Non-cardiac MRI diagnostic studies shall not be performed in an MRI-guided EPI unit approved  
495 under this section unless the patient meets one of the following criteria:

496 (a) The patient has been admitted to an inpatient unit; or

497 (b) The patient is having the study performed on an outpatient basis as follows:

498 (i) is in need of general anesthesia or deep sedation as defined by the American Society of  
499 Anesthesiologists, or

500 (ii) has an implantable cardiac device.  
501

502 (6) The approved MRI-guided EPI unit shall not be subject to MRI volume requirements.  
503

504 (7) The applicant shall not utilize the procedures performed on the MRI-guided EPI unit to  
505 demonstrate need or to satisfy MRI CON review standards requirements.  
506

507 **Section 11. Requirements for all applicants proposing to initiate, replace, or acquire an MRI**  
508 **simulator that will not be used solely for MRT treatment planning purposes**  
509

510 Sec. 11. MRI simulation is the use of MRI to help simulate (or plan) a patient's MRT treatment and to  
511 incorporate superior delineation of soft tissues for MRT treatment plans. An applicant proposing to  
512 initiate, replace, or acquire an MRI simulator shall demonstrate each of the following, as applicable to the  
513 proposed project.  
514

515 (1) The proposed site has an existing fixed MRI service that has been operational for the previous  
516 36 consecutive months and is meeting its minimum volume requirements.  
517

518 (2) The proposed site has an existing and operational MRT service and is meeting its minimum  
519 volume requirements pursuant to the CON review standards for MRT services/units.  
520

521 (3) MRI diagnostic studies shall not be performed using an MRI simulator approved under this  
522 section unless the patient meets one of the following criteria:

523 (a) The patient has been admitted to an inpatient unit; or

524 (B) The patient is having the study performed on an outpatient basis, but is in need of general  
525 anesthesia or deep sedation as defined by the American Society of Anesthesiologists.  
526

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

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(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 14 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**

Sec. 13. 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 14. Project delivery requirements – terms of approval**

Sec. 14. 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 technician 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:

- 580 (i) Each physician credentialed to interpret MRI scans meets the requirements of each of the  
581 following:
- 582 (A) The physician is licensed to practice medicine in the State of Michigan.
- 583 (B) The physician has had at least 60 hours of training in MRI physics, MRI safety, and MRI  
584 instrumentation in a program that is part of an imaging program accredited by the Accreditation Council for  
585 Graduate Medical Education or the American Osteopathic Association, and the physician meets the  
586 requirements of subdivision (1), (2), or (3):
- 587 (1) Board certification by the American Board of Radiology, the American Osteopathic Board of  
588 Radiology, or the Royal College of Physicians and Surgeons of Canada. If the diagnostic radiology  
589 program completed by a physician in order to become board certified did not include at least two months  
590 of MRI training, that physician shall document that he or she has had the equivalent of two months of  
591 postgraduate training in clinical MRI imaging at an institution which has a radiology program accredited by  
592 the Accreditation Council for Graduate Medical Education or the American Osteopathic Association.
- 593 (2) Formal training by an imaging program(s), accredited by the Accreditation Council for Graduate  
594 Medical Education or the American Osteopathic Association that included two years of training in cross-  
595 sectional imaging and six months training in organ-specific imaging areas.
- 596 (3) A practice in which at least one-third of total professional time, based on a full-time clinical  
597 practice during the most recent 5-year period, has been the primary interpretation of MR imaging.
- 598 (C) The physician has completed and will complete a minimum of 40 hours every two years of  
599 Category in Continuing Medical Education credits in topics directly involving MR imaging.
- 600 (D) The physician complies with the "American College of Radiology (ACR) Practice [Guideline](#)  
601 [PARAMETER](#) for Performing and Interpreting Magnetic Resonance Imaging (MRI)."
- 602 (ii) An MRI technologist who is registered by the American Registry of Radiologic Technicians or by  
603 the American Registry of Magnetic Resonance Imaging Technologists (ARMRIT) and has, or will have  
604 within 36 months of the effective date of these standards or the date a technologist is employed by an MRI  
605 service, whichever is later, special certification in MRI. If a technologist does not have special certification  
606 in MRI within either of the 3-year periods of time, all continuing education requirements shall be in the area  
607 of MRI services.
- 608 (iii) An applicant shall document that an MRI physicist/engineer is appropriately qualified. For  
609 purposes of evaluating this subdivision, the Department shall consider it prima facie evidence as to the  
610 qualifications of the physicist/engineer if the physicist/engineer is certified as a medical physicist by the  
611 American Board of Radiology, the American Board of Medical Physics, or the American Board of Science  
612 in Nuclear Medicine. However, the applicant may submit and the Department may accept other evidence  
613 that an MRI physicist/engineer is qualified appropriately.
- 614 (e) The applicant shall have, within the MRI unit/service, equipment and supplies to handle clinical  
615 emergencies that might occur in the unit. MRI service staff will be trained in CPR and other appropriate  
616 emergency interventions. A physician shall be on-site, in, or immediately available to the MRI unit at all  
617 times when patients are undergoing scans.
- 618
- 619 (3) Compliance with the following access to care requirements:  
620 The applicant, to assure that the MRI unit will be utilized by all segments of the Michigan population, shall
- 621 (a) provide MRI services to all individuals based on the clinical indications of need for the service  
622 and not on ability to pay or source of payment.
- 623 (b) maintain information by source of payment to indicate the volume of care from each source  
624 provided annually.
- 625 (c) An applicant shall participate in Medicaid at least 12 consecutive months within the first two  
626 years of operation and continue to participate annually thereafter.
- 627 (d) The operation of and referral of patients to the MRI unit shall be in conformance with 1978 PA  
628 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).
- 629
- 630 (4) Compliance with the following monitoring and reporting requirements:
- 631 (a) MRI units shall be operating at a minimum average annual utilization during the second 12  
632 months of operation, and annually thereafter, as applicable:

633 (i) 6,000 MRI adjusted procedures per unit for fixed MRI services unless compliant with (4A) or  
634 (2B),

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

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

639 (ii) 5,500 MRI adjusted procedures per unit for mobile MRI services.

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

641 (iv) Each mobile host site in a rural or micropolitan statistical area county shall have provided at  
642 least a total of 400 adjusted procedures during its second 12 months of operation, and annually thereafter,  
643 from all mobile units providing services to the site. Each mobile host site not in a rural or micropolitan  
644 statistical area county shall have provided at least a total of 600 adjusted procedures during its second 12  
645 months of operation and annually thereafter, from all mobile units providing services to the site.

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

649  
650 (b) The applicant shall participate in a data collection network established and administered by the  
651 Department or its designee. The data may include, but is not limited to, operating schedules,  
652 demographic and diagnostic information, and the volume of care provided to patients from all payor  
653 sources, as well as other data requested by the Department or its designee and approved by the  
654 Commission. The applicant shall provide the required data in a format established by the Department and  
655 in a mutually agreed upon media no later than 30 days following the last day of the quarter for which data  
656 are being reported to the Department. An applicant shall be considered in violation of this term of  
657 approval if the required data are not submitted to the Department within 30 days following the last day of  
658 the quarter for which data are being reported. The Department may elect to verify the data through on-site  
659 review of appropriate records. Data for an MRI unit approved pursuant to Section 7, Section 8, Section 9,  
660 Section 10, or Section 11 shall be reported separately.

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

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

670 (d) An applicant who is a central service coordinator shall notify the Department of any additions,  
671 deletions, or changes in the host sites of each approved mobile MRI unit ~~within 10 days~~ after the  
672 change(s) in host sites is made.

673  
674 (5) An applicant for an MRI unit approved under Section 7 shall agree that the services provided by  
675 the MRI unit are delivered in compliance with the following terms.

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

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

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

683

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

686  
687 (7) The agreements and assurances required by this section shall be in the form of a certification  
688 agreed to by the applicant or its authorized agent.  
689

### 690 **Section 15. MRI procedure adjustments**

691  
692 Sec. 15. (1) The Department shall apply the following formula, as applicable, to determine the  
693 number of MRI adjusted procedures that are performed by an existing MRI service or unit:

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

696 (i) fMRI means brain activation studies.

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

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

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

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

703 (d) For each MRI procedure performed on a sedated patient, 0.75 shall be added to the base value.

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

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

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

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

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

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

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

717  
718 (2) The Department shall apply not more than one of the adjustment factors set forth in this  
719 subsection, as applicable, to the number of MRI procedures adjusted in accordance with the applicable  
720 provisions of subsection (1) that are performed by an existing MRI service or unit.

721 (a) For a site located in a rural or micropolitan statistical area county, the number of MRI adjusted  
722 procedures shall be multiplied by a factor of 1.4.

723 (b) For a mobile MRI unit that serves hospitals and other host sites located in rural, micropolitan  
724 statistical area, and metropolitan statistical area counties, the number of MRI adjusted procedures for a  
725 site located in a rural or micropolitan statistical area county, shall be multiplied by a factor of 1.4 and for a  
726 site located in a metropolitan statistical area county, the number of MRI adjusted procedures shall be  
727 multiplied by a factor of 1.0.

728 (c) For a mobile MRI unit that serves only sites located in rural or micropolitan statistical area  
729 counties, the number of MRI adjusted procedures shall be multiplied by a factor of 2.0.

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

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

735  
736 (3) The number of MRI adjusted procedures performed by an existing MRI service is the sum of the  
737 results of subsections (1) and (2).  
738

739 **Section 16. Documentation of actual utilization**  
740

741 Sec. 16. Documentation of the number of MRI procedures performed by an MRI unit shall be  
742 substantiated by the Department utilizing data submitted by the applicant in a format and media specified  
743 by the Department and as verified for the 12-month period reported on the most recently published "MRI  
744 Service Utilization List" as of the date an application is deemed submitted by the Department. The  
745 number of MRI procedures actually performed shall be documented by procedure records and not by  
746 application of the methodology required in Section 17. The Department may elect to verify the data  
747 through on-site review of appropriate records.  
748

749 **Section 17. Methodology for computing the number of available MRI adjusted procedures**  
750

751 Sec. 17. (1) The number of available MRI adjusted procedures required pursuant to Section 3 shall  
752 be computed in accordance with the methodology set forth in this section. In applying the methodology,  
753 the following steps shall be taken in sequence, and data for the 12-month period reported on the most  
754 recently published "Available MRI Adjusted Procedures List," as of the date an application is deemed  
755 submitted by the Department, shall be used:

756 (a) Identify the number of actual MRI adjusted procedures performed by each existing MRI service  
757 as determined pursuant to Section 15.

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

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

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

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

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

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

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

778 (A) For each doctor, subtract any available adjusted procedures previously committed. The total for  
779 each doctor cannot be less than zero.

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

782 (iii) For each MRI service, the available MRI adjusted procedures resulting from the calculation in  
783 (c)(ii) above shall be sorted in descending order by the available MRI adjusted procedures for each doctor.  
784 Then any duplicate values shall be sorted in descending order by the doctors' license numbers (last 6  
785 digits only).

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

790 (v) For the doctors representing 75 percent of the total available adjusted procedures in (c)(iv)  
791 above, sum the available adjusted procedures.

792 (vi) For the doctors used in subsection (c)(v) above, divide the total number of available adjusted  
793 procedures identified in (c)(ii)(B) above by the sum of those available adjusted procedures produced in  
794 (c)(v) above.

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

797 (viii) The result shall be the "Available MRI Adjusted Procedures List."  
798

799 (2) After publication of the "Available MRI Adjusted Procedures List" resulting from (1) above, the  
800 data shall be updated to account for a) doctor commitments of available MRI adjusted procedures in  
801 subsequent MRI CON applications and b) MRI adjusted procedures used in subsequent MRI CON  
802 applications received in which applicants apply for fixed MRI services pursuant to Section 3(2).  
803

#### 804 **Section 18. Procedures and requirements for commitments of available MRI adjusted procedures** 805

806 Sec. 18. (1) If one or more host sites on a mobile MRI service are located within the planning area of  
807 the proposed site, the applicant may access available MRI adjusted procedures from the entire mobile  
808 MRI service.  
809

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

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

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

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

823 (c) If the required documentation for the doctor commitments submitted under this subsection is  
824 not submitted with the application on the designated application date, the application will be deemed  
825 submitted on the first applicable designated application date after all required documentation is received  
826 by the Department.  
827

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

831 (a) A committing doctor certifies that 100% of his or her available MRI adjusted procedures for  
832 each specified MRI service, calculated pursuant to Section 17, is being committed and specifies the CON  
833 application number for the MRI unit to which the data commitment is made. A doctor shall not be required  
834 to commit available MRI adjusted procedures from all MRI services to which his or her patients are  
835 referred for MRI services but only from those MRI services specified by the doctor in the data commitment  
836 form provided by the Department and submitted by the applicant in support of its application.

837 (b) A committing doctor certifies ownership interest, either direct or indirect, in the applicant entity.  
838 Indirect ownership includes ownership in an entity that has ownership interest in the applicant entity. This  
839 requirement shall not apply if the applicant entity is a group practice of which the committing doctor is a  
840 member. Group practice means a group practice as defined pursuant to the provisions of 42 U.S.C.  
841 1395nn (h)(4), commonly known as Stark II, and the Code of Federal Regulations, 42 CFR, Part 411,  
842 published in the Federal Register on August 14, 1995, or its replacement.

843 (c) A committing doctor certifies that he or she has not been provided, or received a promise of  
844 being provided, a financial incentive to commit any of his or her available MRI adjusted procedures to the  
845 application.  
846

847 (4)(a) The Department shall not consider a data commitment from a doctor for available MRI adjusted  
848 procedures from a specific MRI service if the available MRI adjusted procedures from that specific MRI  
849 service were used to support approval of an application for a new ~~or additional~~ MRI unit, pursuant to  
850 Section 3, for which a final decision to approve has been issued by the Director of the Department until  
851 either of the following occurs:

852 (i) The approved CON is withdrawn or expires.

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

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

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

862 (ii) If an appeal was made, ~~either THE~~ that appeal is withdrawn by the applicant ~~or the committing~~  
863 ~~doctor withdraws his or her data commitment pursuant to the requirements of subsection (8).~~  
864

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

872 (a) if the applications were submitted on the same designated application date, notify all applicants,  
873 simultaneously and in writing, that one or more doctors have submitted data commitments for available  
874 MRI adjusted procedures from the same MRI service and that the doctors' data from the same MRI  
875 service shall not be considered in the review of any of the pending applications submitted on the same  
876 designated application date until the doctor notifies the Department, in writing, of the one (1) application  
877 for which the data commitment shall be considered.

878 (b) if the applications were submitted on different designated application dates, consider the data  
879 commitment in the application submitted on the earliest designated application date and shall notify,  
880 simultaneously in writing, all applicants of applications submitted on designated application dates  
881 subsequent to the earliest date that one or more committing doctors have submitted data commitments  
882 for available MRI adjusted procedures from the same MRI service and that the doctors' data shall not be  
883 considered in the review of the application(s) submitted on the subsequent designated application date(s).  
884

885 (6) The Department shall not consider any data commitment submitted by an applicant after the  
886 date an application is deemed submitted unless an applicant is notified by the Department, pursuant to  
887 subsection (5), that one or more committing doctors submitted data commitments for available MRI  
888 adjusted procedures from the same MRI service. If an applicant is notified that one or more doctors' data  
889 commitments will not be considered by the Department, the Department shall consider data commitments  
890 submitted after the date an application is deemed submitted only to the extent necessary to replace the  
891 data commitments not being considered pursuant to subsection (5).

892 (a) The applicant shall have 30 days to submit replacement of doctor commitments as identified by  
893 the Department in this Section.  
894

895 (7) ~~In accordance with either of the following, t~~The Department shall not consider a withdrawal of a  
896 signed data commitment:

897 ~~(a) on or after the date an application is deemed submitted by the Department.~~

898 ~~(b) after a proposed decision to approve an application has been issued by the Department.~~

899  
900 (8) The Department shall consider a withdrawal of a signed data commitment if a committing doctor  
901 submits a written notice to the Department **BEFORE THE APPLICATION IS DEEMED SUBMITTED**, that  
902 specifies the CON application number and the specific MRI services for which a data commitment is being  
903 withdrawn, ~~and if an applicant demonstrates that the requirements of subsection (7) also have been met.~~

## 904 **Section 19. Lists published by the Department**

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906  
907 Sec. 19. (1) On or before May 1 and November 1 of each year, the Department shall publish the  
908 following lists:

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

911 (i) The number of actual MRI adjusted procedures;

912 (ii) The number of available MRI adjusted procedures, if any; and

913 (iii) The number of MRI units, including whether each unit is a clinical, research, or dedicated  
914 pediatric.

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

917 (i) The number of available MRI adjusted procedures;

918 (ii) The name, address, and license number of each referring doctor, identified in Section  
919 17(1)(c)(v), whose patients received MRI services at that MRI service; and

920 (iii) The number of available MRI adjusted procedures performed on patients referred by each  
921 referring doctor, identified in Section 17(1)(c)(v), and if any are committed to an MRI service. This number  
922 shall be calculated in accordance with the requirements of Section 17(1). A referring doctor may have  
923 fractional portions of available MRI adjusted procedures.

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

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

930  
931 (2) When an MRI service begins to operate at a site at which MRI services previously were not  
932 provided, the Department shall include in the MRI database, data beginning with the second full quarter of  
933 operation of the new MRI service. Data from the start-up date to the start of the first full quarter will not be  
934 collected to allow a new MRI service sufficient time to develop its data reporting capability. Data from the  
935 first full quarter of operation will be submitted as test data but will not be reported in the lists published  
936 pursuant to this section.

937  
938 (3) In publishing the lists pursuant to subsections (a) and (b), if an MRI service has not reported  
939 data in compliance with the requirements of Section 14, the Department shall indicate on both lists that the  
940 MRI service is in violation of the requirements set forth in Section 14, and no data will be shown for that  
941 service on either list.

## 942 **Section 20. Effect on prior CON Review Standards; Comparative reviews**

943  
944  
945 Sec. 20. (1) These CON review standards supersede and replace the CON Review Standards for  
946 MRI Services approved by the CON Commission on ~~June 13, 2013~~September 25, 2014 and effective  
947 ~~September 18, 2013~~December 22, 2014.

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949  
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(2) Projects reviewed under these standards shall not be subject to comparative review.

952 **Section 21. Health Service Areas**

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954 Sec. 21. Counties assigned to each of the health service areas are as follows:

955

956 **HSA** **COUNTIES**

957

958

959 1 Livingston Monroe St. Clair  
 960 Macomb Oakland Washtenaw  
 961 Wayne

962

963 2 Clinton Hillsdale Jackson  
 964 Eaton Ingham Lenawee

965

966 3 Barry Calhoun St. Joseph  
 967 Berrien Cass Van Buren  
 968 Branch Kalamazoo

969

970 4 Allegan Mason Newaygo  
 971 Ionia Mecosta Oceana  
 972 Kent Montcalm Osceola  
 973 Lake Muskegon Ottawa

974

975 5 Genesee Lapeer Shiawassee

976

977 6 Arenac Huron Roscommon  
 978 Bay Iosco Saginaw  
 979 Clare Isabella Sanilac  
 980 Gladwin Midland Tuscola  
 981 Gratiot Ogemaw

982

983 7 Alcona Crawford Missaukee  
 984 Alpena Emmet Montmorency  
 985 Antrim Gd Traverse Oscoda  
 986 Benzie Kalkaska Otsego  
 987 Charlevoix Leelanau Presque Isle  
 988 Cheboygan Manistee Wexford

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990 8 Alger Gogebic Mackinac  
 991 Baraga Houghton Marquette  
 992 Chippewa Iron Menominee  
 993 Delta Keweenaw Ontonagon  
 994 Dickinson Luce Schoolcraft

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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