

**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  
109 MRI 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  
111 of a fixed MRI service or in the case of a mobile MRI service, the utilization of an authorized mobile MRI  
112 unit 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  
127 ownership 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  
132 75-mile radius from the proposed site if the proposed site is in a rural or micropolitan statistical area  
133 county.

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

138 (iii) in the case of a proposed mobile MRI service or unit meeting the requirement of Section  
139 15(2)(d), the health service area in which all the proposed mobile host sites will be located.

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

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

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

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

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

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

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

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

158 (qq) "Site" means

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

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

163 (rr) "Special needs patient" means a non-sedated patient, either pediatric or adult, with any of the  
164 following conditions: down syndrome, autism, attention deficit hyperactivity disorder (ADHD),  
165 developmental delay, malformation syndromes, hunter's syndrome, multi-system disorders, psychiatric  
166 disorders, and other conditions that make the patient unable to comply with the positional requirements of  
167 the exam.

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

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

174  
175 (2) Terms defined in the Code have the same meanings when used in these standards.  
176

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

178  
179 Sec. 3. An applicant proposing to initiate an MRI service or a host site shall demonstrate the  
180 following requirements, as applicable:  
181

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

238

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

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

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

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

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

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

271 (ii) Each existing fixed MRI unit at the current site has performed at least an average of 6,000 MRI  
272 adjusted procedures per MRI unit unless the applicant demonstrates compliance with one of the  
273 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 (c) The replacement unit shall be located at the same site.

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

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

307 (c) Each existing MRI unit to be relocated performed at least the applicable minimum number of  
308 MRI adjusted procedures set forth in Section 14 based on the most recently published MRI Service  
309 Utilization List as of the date an application is deemed submitted by the Department.

310

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

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

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

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

317 (d) Each existing MRI unit at the service from which a unit is to be relocated performed at least the  
318 applicable minimum number of MRI adjusted procedures set forth in Section 14 based on the most  
319 recently published MRI Service Utilization List as of the date an application is deemed submitted by the  
320 Department.

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

### 323 324 **Section 5. Requirements to expand an existing MRI service**

325  
326 Sec. 5. An applicant proposing to expand an existing MRI service shall demonstrate the following:

327  
328 (1) An applicant shall demonstrate that the applicable MRI adjustable procedures are from the  
329 most recently published MRI Service Utilization List as of the date of an application is deemed submitted  
330 by the Department:

331 (a) Each existing MRI unit on the network has performed at least an average of 9,000 MRI  
332 adjusted procedures per MRI unit.

333 (b) Each existing fixed MRI unit at the current site has performed at least an average of 11,000  
334 MRI adjusted procedures per MRI unit.

335 (c) Each existing dedicated pediatric MRI unit at the current site has performed at least an average  
336 of 3,500 MRI adjusted procedures per MRI unit.

337  
338 (2) The additional fixed unit shall be located at the same site unless the requirements of the  
339 replacement section have been met.

### 340 341 **Section 6. Requirements to acquire an existing MRI service or an existing MRI unit(s)**

342  
343 Sec. 6. ~~(1)~~ An applicant proposing to acquire an existing fixed or mobile MRI service and its unit(s)  
344 shall demonstrate the following:

345  
346 ~~(a1) For the first application proposing to acquire an existing fixed or mobile MRI service on or after~~  
347 ~~July 1, 1997, the existing MRI service and its unit(s) to be acquired~~ THE APPLICANT shall not be  
348 required to be in compliance with the volume requirements applicable to a seller/lessor on the date the  
349 acquisition occurs IF THE PROPOSED PROJECT MEETS ONE OF THE FOLLOWING:

350 ~~(a) For~~ IT IS the first application proposing to acquire an ~~THE~~ existing fixed or mobile MRI service  
351 ~~AND ITS UNIT(S) on or after July 1, 1997, the existing MRI service and its unit(s) to be acquired.~~

352 ~~(b) THE EXISTING FIXED OR MOBILE MRI SERVICE IS OWNED BY, IS UNDER COMMON~~  
353 ~~CONTROL OF, OR HAS A COMMON PARENT AS THE APPLICANT, AND THE MRI SERVICE AND~~  
354 ~~ITS UNIT(S) SHALL REMAIN AT THE SAME SITE. The MRI service shall be operating at the applicable~~  
355 ~~volume requirements set forth in Section 14 of these standards in the second 12 months after the~~  
356 ~~effective date of the acquisition, and annually thereafter.~~

357  
358 ~~(b2)~~ For any application proposing to acquire an existing fixed or mobile MRI service and its unit(s),  
359 except ~~the first~~ AN application approved pursuant to subsection ~~(a1)~~, an applicant shall be required to  
360 document that the MRI service and its unit(s) to be acquired is operating in compliance with the volume  
361 requirements set forth in Section 14 of these standards applicable to an existing MRI service on the date  
362 the application is submitted to the Department.

363  
364 ~~(23)~~ An applicant proposing to acquire an existing fixed or mobile MRI unit of an existing MRI  
365 service shall demonstrate that the proposed project meets all of the following:

366 (a) The project will not change the number of MRI units at the site of the MRI service being  
367 acquired, subject to the applicable requirements under Section 4(6), unless the applicant demonstrates  
368 that the project is in compliance with the requirements of the initiation or expansion Section, as  
369 applicable.

370 (b) The project will not result in the replacement of an MRI unit at the MRI service to be acquired  
371 unless the applicant demonstrates that the requirements of the replacement section have been met.  
372

373 (4) The MRI service AND ITS UNIT(S) shall be operating at the applicable volume requirements  
374 set forth in Section 14 of these standards in the second 12 months after the effective date of the  
375 acquisition, and annually thereafter.  
376

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

378  
379 Sec. 7. An applicant proposing an MRI unit to be used exclusively for research shall demonstrate the  
380 following:

381  
382 (1) The applicant agrees that the dedicated research MRI unit will be used primarily (70% or more  
383 of the procedures) for research purposes only.  
384

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

389 (3) Submit copies of documentation demonstrating that the MRI unit shall operate under a protocol  
390 approved by the applicant's IRB.  
391

392 (4) An applicant meeting the requirements of this section shall be exempt from meeting the  
393 requirements of sections to initiate and replace.  
394

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

396  
397 Sec. 8. An applicant proposing to establish dedicated pediatric MRI shall demonstrate all of the  
398 following:

399  
400 (1) The applicant shall have experienced at least 7,000 pediatric (< 18 years old) discharges  
401 (excluding normal newborns) in the most recent year of operation.  
402

403 (2) The applicant shall have performed at least 5,000 pediatric (< 18 years old) surgeries in the  
404 most recent year of operation.  
405

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

- 408 (a) pediatric radiology (at least two)
- 409 (b) pediatric anesthesiology
- 410 (c) pediatric cardiology
- 411 (d) pediatric critical care
- 412 (e) pediatric gastroenterology
- 413 (f) pediatric hematology/oncology
- 414 (g) pediatric neurology
- 415 (h) pediatric neurosurgery
- 416 (i) pediatric orthopedic surgery
- 417 (j) pediatric pathology
- 418 (k) pediatric pulmonology
- 419 (l) pediatric surgery
- 420 (m) neonatology
- 421

- 422 (4) The applicant shall have in operation the following pediatric specialty programs:  
423 (a) pediatric bone marrow transplant program  
424 (b) established pediatric sedation program  
425 (c) pediatric open heart program  
426

427 (5) An applicant meeting the requirements of this section shall be exempt from meeting the  
428 requirements of Section 5 of these standards.  
429

430 **Section 9. Requirements for all applicants proposing to initiate, replace, or acquire a hospital**  
431 **based IMRI**  
432

433 Sec. 9. An applicant proposing to initiate, replace, or acquire a hospital based IMRI service shall  
434 demonstrate each of the following, as applicable to the proposed project.  
435

436 (1) The proposed site is a licensed hospital under Part 215 of the Code.  
437

438 (2) The proposed site has an existing fixed MRI service that has been operational for the previous  
439 36 consecutive months and is meeting its minimum volume requirements.  
440

441 (3) The proposed site has an existing and operational surgical service and is meeting its minimum  
442 volume requirements pursuant to the CON Review Standards for Surgical Services.  
443

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

445 (a) at least 1,500 oncology discharges in the most recent year of operation; or

446 (b) at least 1,000 neurological surgeries in the most recent year of operation; or

447 (c) at least 7,000 pediatric (<18 years old) discharges (excluding normal newborns) and at least  
448 5,000 pediatric (<18 years old) surgeries in the most recent year of operation.  
449

450 (5) The proposed IMRI unit must be located in an operating room or a room adjoining an operating  
451 room allowing for transfer of the patient between the operating room and this adjoining room.  
452

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

455 (a) the patient has been admitted to an inpatient unit; or

456 (b) the patient is having the study performed on an outpatient basis, but is in need of general  
457 anesthesia or deep sedation as defined by the American Society of Anesthesiologists.  
458

459 (7) The approved IMRI unit will not be subject to MRI volume requirements.  
460

461 (8) The applicant shall not utilize the procedures performed on the IMRI unit to demonstrate need  
462 or to satisfy MRI CON review standards requirements.  
463

464 **Section 10. Requirements for all applicants proposing to initiate, replace, or acquire a hospital**  
465 **based MRI-guided EPI service**  
466

467 Sec. 10. An applicant proposing to initiate, replace, or acquire a hospital based MRI-guided EPI  
468 service shall demonstrate each of the following, as applicable to the proposed project.  
469

470 (1) The proposed site is a licensed hospital under part 215 of the Code.  
471

472 (2) The proposed site has an existing fixed MRI service that has been operational for the previous  
473 36 consecutive months and is meeting its minimum volume requirements.  
474

475 (3) The proposed site has an existing and operational therapeutic cardiac catheterization service  
476 and is meeting its minimum volume requirements pursuant to the CON review standards for cardiac  
477 catheterization services and open heart surgery services.  
478

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

- 483 (a) moving the patient to the MRI scanner, or
- 484 (b) installing the MRI scanner on a sliding gantry to allow the patient to remain stationary.

485  
486 (5) Non-cardiac MRI diagnostic studies shall not be performed in an MRI-guided EPI unit approved  
487 under this section unless the patient meets one of the following criteria:

- 488 (a) The patient has been admitted to an inpatient unit; or
- 489 (b) The patient is having the study performed on an outpatient basis as follows:
  - 490 (i) is in need of general anesthesia or deep sedation as defined by the American Society of  
491 Anesthesiologists, or
  - 492 (ii) has an implantable cardiac device.

493  
494 (6) The approved MRI-guided EPI unit shall not be subject to MRI volume requirements.  
495

496 (7) The applicant shall not utilize the procedures performed on the MRI-guided EPI unit to  
497 demonstrate need or to satisfy MRI CON review standards requirements.  
498

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

501  
502 Sec. 11. MRI simulation is the use of MRI to help simulate (or plan) a patient's MRT treatment and to  
503 incorporate superior delineation of soft tissues for MRT treatment plans. An applicant proposing to  
504 initiate, replace, or acquire an MRI simulator shall demonstrate each of the following, as applicable to the  
505 proposed project.  
506

507 (1) The proposed site has an existing fixed MRI service that has been operational for the previous  
508 36 consecutive months and is meeting its minimum volume requirements.  
509

510 (2) The proposed site has an existing and operational MRT service and is meeting its minimum  
511 volume requirements pursuant to the CON review standards for MRT services/units.  
512

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

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

518  
519 (4) The approved MRI simulator will not be subject to MRI volume requirements.  
520

521 (5) The applicant shall not utilize the procedures performed on the MRI simulator to demonstrate  
522 need or to satisfy MRI CON review standards requirements.  
523  
524

525 **Section 12. Requirements for approval of an FDA-approved PET/MRI scanner hybrid for initiation,**  
526 **expansion, replacement, and acquisition**  
527

528 Sec. 12. An applicant proposing to initiate, expand, replace, or acquire an FDA-approved PET/MRI  
529 scanner hybrid shall demonstrate that it meets all of the following:  
530

531 (1) There is an approved PET CON for the FDA-approved PET/MRI hybrid, and the FDA-approved  
532 PET/MRI scanner hybrid is in compliance with all applicable project delivery requirements as set forth in  
533 the CON review standards for PET.  
534

535 (2) The applicant agrees to operate the FDA-approved PET/MRI scanner hybrid in accordance  
536 with all applicable project delivery requirements set forth in Section 14 of these standards.  
537

538 (3) The approved FDA-approved PET/MRI scanner hybrid shall not be subject to MRI volume  
539 requirements.  
540

541 (4) An FDA-approved PET/MRI scanner hybrid approved under the CON review standards for PET  
542 scanner services and the review standards for MRI scanner services may not utilize MRI procedures  
543 performed on an FDA-approved PET/MRI scanner hybrid to demonstrate need or to satisfy MRI CON  
544 review standards requirements.  
545

546 **Section 13. Requirements for all applicants**  
547

548 Sec. 13. An applicant shall provide verification of Medicaid participation. An applicant that is a new  
549 provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided  
550 to the Department within six (6) months from the offering of services if a CON is approved.  
551

552 **Section 14. Project delivery requirements – terms of approval**  
553

554 Sec. 14. An applicant shall agree that, if approved, MRI services, whether fixed or mobile, shall be  
555 delivered and maintained in compliance with the following:  
556

557 (1) Compliance with these standards.  
558

559 (2) Compliance with the following quality assurance standards:

560 (a) An applicant shall develop and maintain policies and procedures that establish protocols for  
561 assuring the effectiveness of operation and the safety of the general public, patients, and staff in the MRI  
562 service.

563 (b) An applicant shall establish a schedule for preventive maintenance for the MRI unit.

564 (c) An applicant shall provide documentation identifying the specific individuals that form the MRI  
565 team. At a minimum, the MRI team shall consist of the following professionals:

566 (i) Physicians who shall be responsible for screening of patients to assure appropriate utilization  
567 of the MRI service and taking and interpretation of scans. At least one of these physicians shall be a  
568 board-certified radiologist.

569 (ii) An appropriately trained MRI technician who shall be responsible for taking an MRI scan.

570 (iii) An MRI physicist/engineer available as a team member on a full-time, part-time, or contractual  
571 basis.

572 (d) An applicant shall document that the MRI team members have the following qualifications:

573 (i) Each physician credentialed to interpret MRI scans meets the requirements of each of the  
574 following:

575 (A) The physician is licensed to practice medicine in the State of Michigan.

576 (B) The physician has had at least 60 hours of training in MRI physics, MRI safety, and MRI  
577 instrumentation in a program that is part of an imaging program accredited by the Accreditation Council

578 for Graduate Medical Education or the American Osteopathic Association, and the physician meets the  
579 requirements of subdivision (1), (2), or (3):

580 (1) Board certification by the American Board of Radiology, the American Osteopathic Board of  
581 Radiology, or the Royal College of Physicians and Surgeons of Canada. If the diagnostic radiology  
582 program completed by a physician in order to become board certified did not include at least two months  
583 of MRI training, that physician shall document that he or she has had the equivalent of two months of  
584 postgraduate training in clinical MRI imaging at an institution which has a radiology program accredited  
585 by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association.

586 (2) Formal training by an imaging program(s), accredited by the Accreditation Council for Graduate  
587 Medical Education or the American Osteopathic Association that included two years of training in cross-  
588 sectional imaging and six months training in organ-specific imaging areas.

589 (3) A practice in which at least one-third of total professional time, based on a full-time clinical  
590 practice during the most recent 5-year period, has been the primary interpretation of MR imaging.

591 (C) The physician has completed and will complete a minimum of 40 hours every two years of  
592 Category in Continuing Medical Education credits in topics directly involving MR imaging.

593 (D) The physician complies with the "American College of Radiology (ACR) Practice Guideline for  
594 Performing and Interpreting Magnetic Resonance Imaging (MRI)."

595 (ii) An MRI technologist who is registered by the American Registry of Radiologic Technicians or  
596 by the American Registry of Magnetic Resonance Imaging Technologists (ARMRIT) and has, or will have  
597 within 36 months of the effective date of these standards or the date a technologist is employed by an  
598 MRI service, whichever is later, special certification in MRI. If a technologist does not have special  
599 certification in MRI within either of the 3-year periods of time, all continuing education requirements shall  
600 be in the area of MRI services.

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

607 (e) The applicant shall have, within the MRI unit/service, equipment and supplies to handle clinical  
608 emergencies that might occur in the unit. MRI service staff will be trained in CPR and other appropriate  
609 emergency interventions. A physician shall be on-site, in, or immediately available to the MRI unit at all  
610 times when patients are undergoing scans.

611  
612 (3) Compliance with the following access to care requirements:  
613 The applicant, to assure that the MRI unit will be utilized by all segments of the Michigan population, shall

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

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

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

620 (d) The operation of and referral of patients to the MRI unit shall be in conformance with 1978 PA  
621 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

622  
623 (4) Compliance with the following monitoring and reporting requirements:

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

626 (i) 6,000 MRI adjusted procedures per unit for fixed MRI services unless compliant with (1) or (2),

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

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

631 (ii) 5,500 MRI adjusted procedures per unit for mobile MRI services.  
632 (iii) 3,500 MRI adjusted procedures per unit for dedicated pediatric MRI units.  
633 (iv) Each mobile host site in a rural or micropolitan statistical area county shall have provided at  
634 least a total of 400 adjusted procedures during its second 12 months of operation, and annually  
635 thereafter, from all mobile units providing services to the site. Each mobile host site not in a rural or  
636 micropolitan statistical area county shall have provided at least a total of 600 adjusted procedures during  
637 its second 12 months of operation and annually thereafter, from all mobile units providing services to the  
638 site.  
639 (v) In meeting these requirements, an applicant shall not include any MRI adjusted procedures  
640 performed on an MRI unit used exclusively for research and approved pursuant to Section 7 or for an  
641 IMRI unit approved pursuant to Section 9.  
642

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

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

663 (d) An applicant who is a central service coordinator shall notify the Department of any additions,  
664 deletions, or changes in the host sites of each approved mobile MRI unit within 10 days after the  
665 change(s) in host sites is made.  
666

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

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

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

674 (c) The dedicated research MRI unit will be used primarily (70% or more of the procedures) for  
675 research purposes only.  
676

677 (6) The dedicated pediatric MRI unit approved under Section 8 shall include at least 80% of the  
678 MRI procedures that are performed on patients under 18 years of age.  
679

680 (7) The agreements and assurances required by this section shall be in the form of a certification  
681 agreed to by the applicant or its authorized agent.  
682  
683

684 **Section 15. MRI procedure adjustments**

685

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

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

690 (i) fMRI means brain activation studies.

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

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

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

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

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

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

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

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

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

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

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

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

712

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

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

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

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

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

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

730

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

733

734 **Section 16. Documentation of actual utilization**

735

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

744 **Section 17. Methodology for computing the number of available MRI adjusted procedures**  
745

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

793 (viii) The result shall be the "Available MRI Adjusted Procedures List."  
794

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

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

801  
802 Sec. 18. (1) If one or more host sites on a mobile MRI service are located within the planning area of  
803 the proposed site, the applicant may access available MRI adjusted procedures from the entire mobile  
804 MRI service.  
805

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

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

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

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

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

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

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

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

839 (c) A committing doctor certifies that he or she has not been provided, or received a promise of  
840 being provided, a financial incentive to commit any of his or her available MRI adjusted procedures to the  
841 application.  
842

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

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

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

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

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

858 (ii) If an appeal was made, either that appeal is withdrawn by the applicant or the committing  
859 doctor withdraws his or her data commitment pursuant to the requirements of subsection (8).  
860

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

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

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

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

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

891  
892 (7) In accordance with either of the following, the Department shall not consider a withdrawal of a  
893 signed data commitment:

- 894 (a) on or after the date an application is deemed submitted by the Department.  
895 (b) after a proposed decision to approve an application has been issued by the Department.  
896

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

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

903

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

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

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

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

- 914 (i) The number of available MRI adjusted procedures;  
915 (ii) The name, address, and license number of each referring doctor, identified in Section  
916 17(1)(c)(v), whose patients received MRI services at that MRI service; and  
917 (iii) The number of available MRI adjusted procedures performed on patients referred by each  
918 referring doctor, identified in Section 17(1)(c)(v), and if any are committed to an MRI service. This  
919 number shall be calculated in accordance with the requirements of Section 17(1). A referring doctor may  
920 have fractional portions of available MRI adjusted procedures.

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

925 (d) The Department shall not be required to publish a list that sorts MRI database information by  
926 referring doctor, only by MRI service.  
927

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

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

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

941

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

945  
946 (2) Projects reviewed under these standards shall not be subject to comparative review.

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948

949 **Section 21. Health Service Areas**

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

952

953 **HSA** **COUNTIES**

954

955

956 1 Livingston Monroe St. Clair  
 957 Macomb Oakland Washtenaw  
 958 Wayne

959

960 2 Clinton Hillsdale Jackson  
 961 Eaton Ingham Lenawee

962

963 3 Barry Calhoun St. Joseph  
 964 Berrien Cass Van Buren  
 965 Branch Kalamazoo

966

967 4 Allegan Mason Newaygo  
 968 Ionia Mecosta Oceana  
 969 Kent Montcalm Osceola  
 970 Lake Muskegon Ottawa

971

972 5 Genesee Lapeer Shiawassee

973

974 6 Arenac Huron Roscommon  
 975 Bay Iosco Saginaw  
 976 Clare Isabella Sanilac  
 977 Gladwin Midland Tuscola  
 978 Gratiot Ogemaw

979

980 7 Alcona Crawford Missaukee  
 981 Alpena Emmet Montmorency  
 982 Antrim Gd Traverse Oscoda  
 983 Benzie Kalkaska Otsego  
 984 Charlevoix Leelanau Presque Isle  
 985 Cheboygan Manistee Wexford

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987 8 Alger Gogebic Mackinac  
 988 Baraga Houghton Marquette  
 989 Chippewa Iron Menominee  
 990 Delta Keweenaw Ontonagon  
 991 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