

**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, and other conditions that make the patient unable to comply with the positional requirements of  
165 the exam.

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

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

172  
173 (2) Terms defined in the Code have the same meanings when used in these standards.  
174

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

176  
177 Sec. 3. An applicant proposing to initiate an MRI service or a host site shall demonstrate the following  
178 requirements, as applicable:  
179

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

213  
214 (4) An applicant, whether the central service coordinator or the host site, proposing to initiate a host  
215 site on a new or existing mobile MRI service shall demonstrate the following, as applicable:

216 (a) 600 available MRI adjusted procedures, from within the same planning area as the proposed  
217 service/unit, for a proposed host site that is not located in a rural or micropolitan statistical area county, or

218 (b) 400 available MRI adjusted procedures from within the same planning area for a proposed host  
219 site that is located in a rural or micropolitan statistical area county, and

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

222  
223 (5) An applicant proposing to add or change service on an existing mobile MRI service that meets  
224 the following requirements shall not be required to be in compliance with subsection (4):

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

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

229  
230 (6) The applicant shall demonstrate that the available MRI adjusted procedures from the "Available  
231 MRI Adjusted Procedures List" or the adjusted procedures from the "MRI Service Utilization List," as  
232 applicable, are from the most recently published MRI lists as of the date an application is deemed  
233 submitted by the Department.

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

235  
236  
237 Sec. 4. Replace an existing MRI unit means (i) any equipment change involving a change in, or  
238 replacement of, the entire MRI unit resulting in an applicant operating the same number and type (fixed or  
239 mobile) of MRI units before and after project completion or (ii) an equipment change that involves a capital  
240 expenditure of \$750,000 or more in any consecutive 24-month period or (iii) the renewal of a lease.  
241 Replacement also means the relocation of an MRI service or unit to a new site. The term does not include  
242 the replacement of components of the MRI system, including the magnet, under an existing service  
243 contract or required maintenance to maintain the system to operate within manufacturer specifications.  
244 The term does not include an upgrade to an existing MRI unit or repair of an existing MRI service or unit,  
245 and it does not include a host site that proposes to receive mobile MRI services from a different central  
246 service coordinator if the requirements of Section 3(5) have been met.

247  
248 (1) "Upgrade an existing MRI unit" means any equipment change that

249 (i) does not involve a change in, or replacement of, the entire MRI unit, does not result in an  
250 increase in the number of MRI units; or does not result in a change in the type of MRI unit (e.g., changing  
251 a mobile MRI unit to a fixed MRI unit); and

252 (ii) involves a capital expenditure related to the MRI equipment of less than \$750,000 in any  
253 consecutive 24-month period.

254  
255 (2) "Repair an existing MRI unit" means restoring the ability of the system to operate within the  
256 manufacturer's specifications by replacing or repairing the existing components or parts of the system,  
257 including the magnet, pursuant to the terms of an existing maintenance agreement that does not result in  
258 a change in the strength of the MRI unit.

259  
260 (3) An applicant proposing to replace an existing MRI unit shall demonstrate the following  
261 requirements, as applicable:

262 (a) An applicant shall demonstrate that the applicable MRI adjusted procedures are from the most  
263 recently published MRI Service Utilization List as of the date an application is deemed submitted by the  
264 Department. An applicant proposing to replace an existing MRI unit that is below 1 tesla with an MRI unit

265 that is a 1 tesla or higher, shall be exempt once, as of September 18, 2013, from the minimum volume  
266 requirements for replacement:

- 267 (i) Each existing mobile MRI unit on the network has performed at least an average of 5,500 MRI  
268 adjusted procedures per MRI unit.
- 269 (ii) Each existing fixed MRI unit at the current site has performed at least an average of 6,000 MRI  
270 adjusted procedures per MRI unit unless the applicant demonstrates compliance with one of the following:
  - 271 (A) The existing fixed MRI unit initiated pursuant to Section 3(2)(b)(ii) has performed at least 4,000  
272 MRI adjusted procedures and is the only fixed MRI unit at the current site.
  - 273 (B) The existing fixed MRI unit initiated pursuant to Section 3(2)(b)(iii) has performed at least 3,000  
274 MRI adjusted procedures and is the only fixed MRI unit at the current site.
- 275 (iii) Each existing dedicated pediatric MRI unit at the current site has performed at least an average  
276 of 3,500 MRI adjusted procedures per MRI unit.
  - 277 (b) Equipment that is replaced shall be removed from service and disposed of or rendered  
278 considerably inoperable on or before the date that the replacement equipment becomes operational.
  - 279 (c) The replacement unit shall be located at the same site.
  - 280 (d) An applicant proposing to replace an existing MRI unit that does not involve a renewal of a lease  
281 shall demonstrate that the MRI unit to be replaced is fully depreciated according to generally accepted  
282 accounting principles; the existing equipment clearly poses a threat to the safety of the public; or the  
283 proposed replacement equipment offers a significant technological improvement which enhances quality  
284 of care, increases efficiency, and reduces operating costs.

285

- 286 (4) An applicant proposing to replace an existing mobile MRI host site to a new location shall  
287 demonstrate the following:
  - 288 (a) The applicant currently operates the MRI mobile host site to be relocated.
  - 289 (b) The MRI mobile host site to be relocated has been in operation for at least 36 months as of the  
290 date an application is submitted to the Department.
  - 291 (c) The proposed new site is within a 5-mile radius of the existing site for a metropolitan statistical  
292 area county or within a 10-mile radius for a rural or micropolitan statistical area county.
  - 293 (d) The mobile MRI host site to be relocated performed at least the applicable minimum number of  
294 MRI adjusted procedures set forth in Section 14 based on the most recently published MRI Service  
295 Utilization List as of the date an application is deemed submitted by the Department.
  - 296 (e) The relocation will not involve a change in the current central service coordinator unless the  
297 requirements of Section 3(5) are met.

298

- 299 (5) An applicant proposing to replace an existing fixed MRI service and its unit(s) to a new site shall  
300 demonstrate the following:
  - 301 (a) The existing MRI service and its unit(s) to be replaced has been in operation for at least 36  
302 months as of the date an application is submitted to the Department.
  - 303 (b) The proposed new site is within a 10-mile radius of the existing site.
  - 304 (c) Each existing MRI unit to be relocated performed at least the applicable minimum number of  
305 MRI adjusted procedures set forth in Section 14 based on the most recently published MRI Service  
306 Utilization List as of the date an application is deemed submitted by the Department.

307

- 308 (6) An applicant proposing to replace a fixed MRI unit of an existing MRI service to a new site shall  
309 demonstrate the following:
  - 310 (a) The applicant currently operates the MRI service from which the unit will be relocated.
  - 311 (b) The existing MRI service from which the MRI unit(s) to be relocated has been in operation for at  
312 least 36 months as of the date an application is submitted to the Department.
  - 313 (c) The proposed new site is within a 10-mile radius of the existing site.
  - 314 (d) Each existing MRI unit at the service from which a unit is to be relocated performed at least the  
315 applicable minimum number of MRI adjusted procedures set forth in Section 14 based on the most  
316 recently published MRI Service Utilization List as of the date an application is deemed submitted by the  
317 Department.

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

320  
321 **Section 5. Requirements to expand an existing MRI service**

322  
323 Sec. 5. An applicant proposing to expand an existing MRI service shall demonstrate the following:

324  
325 (1) An applicant shall demonstrate that the applicable MRI adjustable procedures are from the most  
326 recently published MRI Service Utilization List as of the date of an application is deemed submitted by the  
327 Department:

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

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

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

334  
335 (2) The additional fixed unit shall be located at the same site unless the requirements of the  
336 replacement section have been met.

337  
338 **Section 6. Requirements to acquire an existing MRI service or an existing MRI unit(s)**

339  
340 Sec. 6. ~~(1)~~ An applicant proposing to acquire an existing fixed or mobile MRI service and its unit(s)  
341 shall demonstrate the following:

342  
343 ~~(a1) For the first application proposing to acquire an existing fixed or mobile MRI service on or after~~  
344 ~~July 1, 1997, the existing MRI service and its unit(s) to be acquired THE APPLICANT shall not be required~~  
345 ~~to be in compliance with the volume requirements applicable to a seller/lessor on the date the acquisition~~  
346 ~~occurs IF THE PROPOSED PROJECT MEETS ONE OF THE FOLLOWING:~~

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

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

354  
355 ~~(b2) For any application proposing to acquire an existing fixed or mobile MRI service and its unit(s),~~  
356 ~~except the first AN application approved pursuant to subsection (a1), an applicant shall be required to~~  
357 ~~document that the MRI service and its unit(s) to be acquired is operating in compliance with the volume~~  
358 ~~requirements set forth in Section 14 of these standards applicable to an existing MRI service on the date~~  
359 ~~the application is submitted to the Department.~~

360  
361 ~~(23) An applicant proposing to acquire an existing fixed or mobile MRI unit of an existing MRI service~~  
362 ~~shall demonstrate that the proposed project meets all of the following:~~

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

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

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

372  
373 **Section 7. Requirements to establish a dedicated research MRI unit**  
374

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

377  
378 (1) The applicant agrees that the dedicated research MRI unit will be used primarily (70% or more  
379 of the procedures) for research purposes only.

380  
381 (2) Submit copies of documentation demonstrating that the applicant operates a diagnostic  
382 radiology residency program approved by the Accreditation Council for Graduate Medical Education, the  
383 American Osteopathic Association, or an equivalent organization.

384  
385 (3) Submit copies of documentation demonstrating that the MRI unit shall operate under a protocol  
386 approved by the applicant's IRB.

387  
388 (4) An applicant meeting the requirements of this section shall be exempt from meeting the  
389 requirements of sections to initiate and replace.

390  
391 **Section 8. Requirements to establish a dedicated pediatric MRI unit**  
392

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

395  
396 (1) The applicant shall have experienced at least 7,000 pediatric (< 18 years old) discharges  
397 (excluding normal newborns) in the most recent year of operation.

398  
399 (2) The applicant shall have performed at least 5,000 pediatric (< 18 years old) surgeries in the  
400 most recent year of operation.

401  
402 (3) The applicant shall have an active medical staff that includes, but is not limited to, physicians  
403 who are fellowship-trained in the following pediatric specialties:

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

417  
418 (4) The applicant shall have in operation the following pediatric specialty programs:

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

422  
423 (5) An applicant meeting the requirements of this section shall be exempt from meeting the  
424 requirements of Section 5 of these standards.

425  
426 **Section 9. Requirements for all applicants proposing to initiate, replace, or acquire a hospital**  
427 **based IMRI**

428  
429 Sec. 9. An applicant proposing to initiate, replace, or acquire a hospital based IMRI service shall  
430 demonstrate each of the following, as applicable to the proposed project.

431  
432 (1) The proposed site is a licensed hospital under Part 215 of the Code.

433  
434 (2) The proposed site has an existing fixed MRI service that has been operational for the previous  
435 36 consecutive months and is meeting its minimum volume requirements.

436  
437 (3) The proposed site has an existing and operational surgical service and is meeting its minimum  
438 volume requirements pursuant to the CON Review Standards for Surgical Services.

439  
440 (4) The applicant has achieved one of the following:

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

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

443 (c) at least 7,000 pediatric (<18 years old) discharges (excluding normal newborns) and at least  
444 5,000 pediatric (<18 years old) surgeries in the most recent year of operation.

445  
446 (5) The proposed IMRI unit must be located in an operating room or a room adjoining an operating  
447 room allowing for transfer of the patient between the operating room and this adjoining room.

448  
449 (6) Non-surgical diagnostic studies shall not be performed on an IMRI unit approved under this  
450 section unless the patient meets one of the following criteria:

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

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

454  
455 (7) The approved IMRI unit will not be subject to MRI volume requirements.

456  
457 (8) The applicant shall not utilize the procedures performed on the IMRI unit to demonstrate need  
458 or to satisfy MRI CON review standards requirements.

459  
460 **Section 10. Requirements for all applicants proposing to initiate, replace, or acquire a hospital**  
461 **based MRI-guided EPI service**

462  
463 Sec. 10. An applicant proposing to initiate, replace, or acquire a hospital based MRI-guided EPI  
464 service shall demonstrate each of the following, as applicable to the proposed project.

465  
466 (1) The proposed site is a licensed hospital under part 215 of the Code.

467  
468 (2) The proposed site has an existing fixed MRI service that has been operational for the previous  
469 36 consecutive months and is meeting its minimum volume requirements.

470  
471 (3) The proposed site has an existing and operational therapeutic cardiac catheterization service  
472 and is meeting its minimum volume requirements pursuant to the CON review standards for cardiac  
473 catheterization services and open heart surgery services.

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

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

481  
482 (5) Non-cardiac MRI diagnostic studies shall not be performed in an MRI-guided EPI unit approved  
483 under this section unless the patient meets one of the following criteria:

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

489  
490 (6) The approved MRI-guided EPI unit shall not be subject to MRI volume requirements.

491  
492 (7) The applicant shall not utilize the procedures performed on the MRI-guided EPI unit to  
493 demonstrate need or to satisfy MRI CON review standards requirements.

494  
495 **Section 11. Requirements for all applicants proposing to initiate, replace, or acquire an MRI**  
496 **simulator that will not be used solely for MRT treatment planning purposes**

497  
498 Sec. 11. MRI simulation is the use of MRI to help simulate (or plan) a patient's MRT treatment and to  
499 incorporate superior delineation of soft tissues for MRT treatment plans. An applicant proposing to  
500 initiate, replace, or acquire an MRI simulator shall demonstrate each of the following, as applicable to the  
501 proposed project.

502  
503 (1) The proposed site has an existing fixed MRI service that has been operational for the previous  
504 36 consecutive months and is meeting its minimum volume requirements.

505  
506 (2) The proposed site has an existing and operational MRT service and is meeting its minimum  
507 volume requirements pursuant to the CON review standards for MRT services/units.

508  
509 (3) MRI diagnostic studies shall not be performed using an MRI simulator approved under this  
510 section unless the patient meets one of the following criteria:

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

514  
515 (4) The approved MRI simulator will not be subject to MRI volume requirements.

516  
517 (5) The applicant shall not utilize the procedures performed on the MRI simulator to demonstrate  
518 need or to satisfy MRI CON review standards requirements.

519  
520

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

523  
524 Sec. 12. An applicant proposing to initiate, expand, replace, or acquire an FDA-approved PET/MRI  
525 scanner hybrid shall demonstrate that it meets all of the following:

526  
527 (1) There is an approved PET CON for the FDA-approved PET/MRI hybrid, and the FDA-approved  
528 PET/MRI scanner hybrid is in compliance with all applicable project delivery requirements as set forth in  
529 the CON review standards for PET.

530  
531 (2) The applicant agrees to operate the FDA-approved PET/MRI scanner hybrid in accordance with  
532 all applicable project delivery requirements set forth in Section 14 of these standards.

533  
534 (3) The approved FDA-approved PET/MRI scanner hybrid shall not be subject to MRI volume  
535 requirements.

536  
537 (4) An FDA-approved PET/MRI scanner hybrid approved under the CON review standards for PET  
538 scanner services and the review standards for MRI scanner services may not utilize MRI procedures  
539 performed on an FDA-approved PET/MRI scanner hybrid to demonstrate need or to satisfy MRI CON  
540 review standards requirements.

541  
542 **Section 13. Requirements for all applicants**

543  
544 Sec. 13. An applicant shall provide verification of Medicaid participation. An applicant that is a new  
545 provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided  
546 to the Department within six (6) months from the offering of services if a CON is approved.

547  
548 **Section 14. Project delivery requirements – terms of approval**

549  
550 Sec. 14. An applicant shall agree that, if approved, MRI services, whether fixed or mobile, shall be  
551 delivered and maintained in compliance with the following:

552  
553 (1) Compliance with these standards.

554  
555 (2) Compliance with the following quality assurance standards:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

607  
608 (3) Compliance with the following access to care requirements:  
609 The applicant, to assure that the MRI unit will be utilized by all segments of the Michigan population, shall

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

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

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

616 (d) The operation of and referral of patients to the MRI unit shall be in conformance with 1978 PA  
617 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

618  
619 (4) Compliance with the following monitoring and reporting requirements:

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

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

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

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

627 (ii) 5,500 MRI adjusted procedures per unit for mobile MRI services.  
628 (iii) 3,500 MRI adjusted procedures per unit for dedicated pediatric MRI units.  
629 (iv) Each mobile host site in a rural or micropolitan statistical area county shall have provided at  
630 least a total of 400 adjusted procedures during its second 12 months of operation, and annually thereafter,  
631 from all mobile units providing services to the site. Each mobile host site not in a rural or micropolitan  
632 statistical area county shall have provided at least a total of 600 adjusted procedures during its second 12  
633 months of operation and annually thereafter, from all mobile units providing services to the site.  
634 (v) In meeting these requirements, an applicant shall not include any MRI adjusted procedures  
635 performed on an MRI unit used exclusively for research and approved pursuant to Section 7 or for an IMRI  
636 unit approved pursuant to Section 9.  
637  
638 (b) The applicant shall participate in a data collection network established and administered by the  
639 Department or its designee. The data may include, but is not limited to, operating schedules,  
640 demographic and diagnostic information, and the volume of care provided to patients from all payor  
641 sources, as well as other data requested by the Department or its designee and approved by the  
642 Commission. The applicant shall provide the required data in a format established by the Department and  
643 in a mutually agreed upon media no later than 30 days following the last day of the quarter for which data  
644 are being reported to the Department. An applicant shall be considered in violation of this term of  
645 approval if the required data are not submitted to the Department within 30 days following the last day of  
646 the quarter for which data are being reported. The Department may elect to verify the data through on-site  
647 review of appropriate records. Data for an MRI unit approved pursuant to Section 7, Section 8, Section 9,  
648 Section 10, or Section 11 shall be reported separately.  
649 For purposes of Section 9, the data reported shall include, at a minimum, how often the IMRI unit is used  
650 and for what type of services, i.e., intra-operative or diagnostic. For purposes of Section 10, the data  
651 reported shall include, at a minimum, how often the MRI-guided EPI unit is used and for what type of  
652 services, i.e., electrophysiology or diagnostic. For purposes of Section 11, the data reported shall include,  
653 at a minimum, how often the MRI simulator is used and for what type of services, i.e., treatment plans or  
654 diagnostic services.  
655 (c) The applicant shall provide the Department with a notice stating the first date on which the MRI  
656 unit became operational, and such notice shall be submitted to the Department consistent with applicable  
657 statute and promulgated rules.  
658 (d) An applicant who is a central service coordinator shall notify the Department of any additions,  
659 deletions, or changes in the host sites of each approved mobile MRI unit within 10 days after the  
660 change(s) in host sites is made.  
661  
662 (5) An applicant for an MRI unit approved under Section 7 shall agree that the services provided by  
663 the MRI unit are delivered in compliance with the following terms.  
664 (a) The capital and operating costs relating to the research use of the MRI unit shall be charged  
665 only to a specific research account(s) and not to any patient or third-party payor.  
666 (b) The MRI unit shall not be used for any purposes other than as approved by the IRB unless the  
667 applicant has obtained CON approval for the MRI unit pursuant to Part 222 and these standards, other  
668 than Section 7.  
669 (c) The dedicated research MRI unit will be used primarily (70% or more of the procedures) for  
670 research purposes only.  
671  
672 (6) The dedicated pediatric MRI unit approved under Section 8 shall include at least 80% of the  
673 MRI procedures that are performed on patients under 18 years of age.  
674  
675 (7) The agreements and assurances required by this section shall be in the form of a certification  
676 agreed to by the applicant or its authorized agent.  
677  
678

679 **Section 15. MRI procedure adjustments**  
680

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

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

685 (i) fMRI means brain activation studies.

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

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

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

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

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

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

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

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

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

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

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

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

706  
707 (2) The Department shall apply not more than one of the adjustment factors set forth in this  
708 subsection, as applicable, to the number of MRI procedures adjusted in accordance with the applicable  
709 provisions of subsection (1) that are performed by an existing MRI service or unit.

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

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

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

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

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

724  
725 (3) The number of MRI adjusted procedures performed by an existing MRI service is the sum of the  
726 results of subsections (1) and (2).

727  
728 **Section 16. Documentation of actual utilization**  
729

730 Sec. 16. Documentation of the number of MRI procedures performed by an MRI unit shall be  
731 substantiated by the Department utilizing data submitted by the applicant in a format and media specified

732 by the Department and as verified for the 12-month period reported on the most recently published "MRI  
733 Service Utilization List" as of the date an application is deemed submitted by the Department. The  
734 number of MRI procedures actually performed shall be documented by procedure records and not by  
735 application of the methodology required in Section 17. The Department may elect to verify the data  
736 through on-site review of appropriate records.  
737

### 738 **Section 17. Methodology for computing the number of available MRI adjusted procedures** 739

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

786 (viii) The result shall be the "Available MRI Adjusted Procedures List."  
787

788 (2) After publication of the "Available MRI Adjusted Procedures List" resulting from (1) above, the  
789 data shall be updated to account for a) doctor commitments of available MRI adjusted procedures in  
790 subsequent MRI CON applications and b) MRI adjusted procedures used in subsequent MRI CON  
791 applications received in which applicants apply for fixed MRI services pursuant to Section 3(2).  
792

### 793 **Section 18. Procedures and requirements for commitments of available MRI adjusted procedures** 794

795 Sec. 18. (1) If one or more host sites on a mobile MRI service are located within the planning area of  
796 the proposed site, the applicant may access available MRI adjusted procedures from the entire mobile  
797 MRI service.  
798

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

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

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

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

812 (c) If the required documentation for the doctor commitments submitted under this subsection is  
813 not submitted with the application on the designated application date, the application will be deemed  
814 submitted on the first applicable designated application date after all required documentation is received  
815 by the Department.  
816

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

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

826 (b) A committing doctor certifies ownership interest, either direct or indirect, in the applicant entity.  
827 Indirect ownership includes ownership in an entity that has ownership interest in the applicant entity. This  
828 requirement shall not apply if the applicant entity is a group practice of which the committing doctor is a  
829 member. Group practice means a group practice as defined pursuant to the provisions of 42 U.S.C.  
830 1395nn (h)(4), commonly known as Stark II, and the Code of Federal Regulations, 42 CFR, Part 411,  
831 published in the Federal Register on August 14, 1995, or its replacement.

832 (c) A committing doctor certifies that he or she has not been provided, or received a promise of  
833 being provided, a financial incentive to commit any of his or her available MRI adjusted procedures to the  
834 application.  
835

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

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

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

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

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

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

853

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

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

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

873

874 (6) The Department shall not consider any data commitment submitted by an applicant after the  
875 date an application is deemed submitted unless an applicant is notified by the Department, pursuant to  
876 subsection (5), that one or more committing doctors submitted data commitments for available MRI  
877 adjusted procedures from the same MRI service. If an applicant is notified that one or more doctors' data  
878 commitments will not be considered by the Department, the Department shall consider data commitments  
879 submitted after the date an application is deemed submitted only to the extent necessary to replace the  
880 data commitments not being considered pursuant to subsection (5).

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

883

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

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

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

888

889 (8) The Department shall consider a withdrawal of a signed data commitment if a committing doctor  
890 submits a written notice to the Department, that specifies the CON application number and the specific  
891 MRI services for which a data commitment is being withdrawn, and if an applicant demonstrates that the  
892 requirements of subsection (7) also have been met.  
893

#### 894 **Section 19. Lists published by the Department** 895

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

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

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

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

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

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

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

907 (ii) The name, address, and license number of each referring doctor, identified in Section  
908 17(1)(c)(v), whose patients received MRI services at that MRI service; and

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

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

917 (d) The Department shall not be required to publish a list that sorts MRI database information by  
918 referring doctor, only by MRI service.  
919

920 (2) When an MRI service begins to operate at a site at which MRI services previously were not  
921 provided, the Department shall include in the MRI database, data beginning with the second full quarter of  
922 operation of the new MRI service. Data from the start-up date to the start of the first full quarter will not be  
923 collected to allow a new MRI service sufficient time to develop its data reporting capability. Data from the  
924 first full quarter of operation will be submitted as test data but will not be reported in the lists published  
925 pursuant to this section.  
926

927 (3) In publishing the lists pursuant to subsections (a) and (b), if an MRI service has not reported  
928 data in compliance with the requirements of Section 14, the Department shall indicate on both lists that the  
929 MRI service is in violation of the requirements set forth in Section 14, and no data will be shown for that  
930 service on either list.  
931

#### 932 **Section 20. Effect on prior CON Review Standards; Comparative reviews** 933

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

937  
938 (2) Projects reviewed under these standards shall not be subject to comparative review.  
939  
940

941 **Section 21. Health Service Areas**

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

944

945 **HSA** **COUNTIES**

946

947

948 1 Livingston Monroe St. Clair  
 949 Macomb Oakland Washtenaw  
 950 Wayne

951

952 2 Clinton Hillsdale Jackson  
 953 Eaton Ingham Lenawee

954

955 3 Barry Calhoun St. Joseph  
 956 Berrien Cass Van Buren  
 957 Branch Kalamazoo

958

959 4 Allegan Mason Newaygo  
 960 Ionia Mecosta Oceana  
 961 Kent Montcalm Osceola  
 962 Lake Muskegon Ottawa

963

964 5 Genesee Lapeer Shiawassee

965

966 6 Arenac Huron Roscommon  
 967 Bay Iosco Saginaw  
 968 Clare Isabella Sanilac  
 969 Gladwin Midland Tuscola  
 970 Gratiot Ogemaw

971

972 7 Alcona Crawford Missaukee  
 973 Alpena Emmet Montmorency  
 974 Antrim Gd Traverse Oscoda  
 975 Benzie Kalkaska Otsego  
 976 Charlevoix Leelanau Presque Isle  
 977 Cheboygan Manistee Wexford

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979 8 Alger Gogebic Mackinac  
 980 Baraga Houghton Marquette  
 981 Chippewa Iron Menominee  
 982 Delta Keweenaw Ontonagon  
 983 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	

1000 Micropolitan statistical area Michigan counties are as follows:

1001			
1002	Allegan	Hillsdale	Mason
1003	Alpena	Houghton	Mecosta
1004	Benzie	Ionia	Menominee
1005	Branch	Isabella	Missaukee
1006	Chippewa	Kalkaska	St. Joseph
1007	Delta	Keweenaw	Shiawassee
1008	Dickinson	Leelanau	Wexford
1009	Grand Traverse	Lenawee	
1010	Gratiot	Marquette	

1011  
1012 Metropolitan statistical area Michigan counties are as follows:

1013			
1014	Barry	Jackson	Muskegon
1015	Bay	Kalamazoo	Oakland
1016	Berrien	Kent	Ottawa
1017	Calhoun	Lapeer	Saginaw
1018	Cass	Livingston	St. Clair
1019	Clinton	Macomb	Van Buren
1020	Eaton	Midland	Washtenaw
1021	Genesee	Monroe	Wayne
1022	Ingham	Montcalm	

1023  
1024 Source:

1025  
1026 75 F.R., p. 37245 (June 28, 2010)  
1027 Statistical Policy Office  
1028 Office of Information and Regulatory Affairs  
1029 United States Office of Management and Budget  
1030