

1 | **MICHIGAN DEPARTMENT OF COMMUNITY HEALTH**  
2  
3 | **CERTIFICATE OF NEED (CON) REVIEW STANDARDS**  
4 | **FOR MAGNETIC RESONANCE IMAGING (MRI) SERVICES**  
5

6 (By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of  
7 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being  
8 sections 333.22215, 24.207, and 24.208 of the Michigan Compiled Laws.)  
9

10 **Section 1. Applicability**  
11

12 Sec. 1. These standards are requirements for the approval of the initiation, expansion, replacement,  
13 relocation, or acquisition of MRI services and the delivery of services under Part 222 of the Code.  
14 Pursuant to Part 222 of the Code, MRI is a covered clinical service. The Department shall use these  
15 standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan  
16 Compiled Laws and Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan  
17 Compiled Laws.  
18

19 **Section 2. Definitions**  
20

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

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

25 (b) "Actual MRI adjusted procedures" or "MRI adjusted procedures," means the number of MRI  
26 procedures, adjusted in accordance with the applicable provisions of Section 13, performed on an  
27 existing MRI unit, or if an MRI service has two or more MRI units at the same site, the average number of  
28 MRI adjusted procedures performed on each unit, for the 12-month period reported on the most recently  
29 published "MRI Service Utilization List," as of the date an application is deemed submitted by the  
30 Department.

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

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

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

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

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

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

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

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

- 54 (j) "Doctor" means an individual licensed under Article 15 of the Code to engage in the practice of  
55 medicine, osteopathic medicine and surgery, chiropractic, dentistry, or podiatry.
- 56 (k) "Existing MRI service" means either the utilization of a CON-approved and operational MRI  
57 unit(s) at one site in the case of a fixed MRI service, and in the case of a mobile MRI service, the  
58 utilization of a CON-approved and operational mobile MRI unit(s) at each host site, on the date an  
59 application is submitted to the Department.
- 60 (l) "Existing MRI unit" means a CON-approved and operational MRI unit used to provide MRI  
61 services.
- 62 (m) "Expand an existing fixed MRI service" means an increase in the number of fixed MRI units to  
63 be operated by the applicant.
- 64 (n) "Expand an existing mobile MRI service" means the addition of a mobile MRI unit that will be  
65 operated by a central service coordinator that is approved to operate one or more mobile MRI units as of  
66 the date an application is submitted to the Department.
- 67 (o) "Group practice" means a group practice as defined pursuant to the provisions of 42 U.S.C.  
68 1395nn (h)(4), commonly known as Stark II, and the Code of Federal Regulations, 42 CFR, Part 411,  
69 published in the Federal Register on August 14, 1995, or its replacement.
- 70 (p) "Health service area" or "HSA" means the geographic areas set forth in Section 19.
- 71 (q) "Host site" means the site at which a mobile MRI unit is authorized by CON to provide MRI  
72 services.
- 73 (r) "Initiate a fixed MRI service" means begin operation of a fixed MRI service at a site that does  
74 not provide or is not CON approved to provide fixed MRI services as of the date an application is  
75 submitted to the Department. The term does not include the acquisition or relocation of an existing fixed  
76 MRI service or the renewal of a lease.
- 77 (s) "Initiate a mobile MRI host site" means the provision of MRI services at a host site that has not  
78 received any MRI services within 12 months from the date an application is submitted to the Department.  
79 The term does not include the renewal of a lease.
- 80 (t) "Initiate a mobile MRI service" means begin operation of a mobile MRI unit that serves two or  
81 more host sites.  
82 The term does not include the acquisition of an existing mobile MRI service or the renewal of a  
83 lease.
- 84 (u) "Inpatient" means an MRI visit involving an individual who has been admitted to the licensed  
85 hospital at the site of the MRI service/unit or in the case of an MRI unit that is not located at that licensed  
86 hospital site, an admitted patient transported from a licensed hospital site by ambulance to the MRI  
87 service.
- 88 (v) "Institutional review board" or "IRB" means an institutional review board as defined by Public  
89 Law 93-348 that is regulated by Title 45 CFR 46.
- 90 (w) "Intra-operative magnetic resonance imaging" or "IMRI" means the integrated use of MRI  
91 technology during surgical and interventional procedures within a licensed operative environment.
- 92 (x) "Licensed hospital site" means the location of the hospital authorized by license and listed on  
93 that licensee's certificate of licensure.
- 94 (y) "Magnetic resonance imaging" or "MRI" means the analysis of the interaction that occurs  
95 between radio frequency energy, atomic nuclei, and strong magnetic fields to produce cross sectional  
96 images similar to those displayed by computed tomography (CT) but without the use of ionizing radiation.
- 97 (z) "MRI adjusted procedure" means an MRI visit, at an existing MRI service, that has been  
98 adjusted in accordance with the applicable provisions of Section 13.
- 99 (aa) "MRI database" means the database, maintained by the Department pursuant to Section 12 of  
100 these standards, that collects information about each MRI visit at MRI services located in Michigan.
- 101 (bb) "MRI procedure" means a procedure conducted by an MRI unit approved pursuant to sections  
102 3, 4, 5, 6, 7, or 9 of these standards which is either a single, billable diagnostic magnetic resonance  
103 procedure or a procedure conducted by an MRI unit at a site participating with an approved diagnostic  
104 radiology residency program, under a research protocol approved by an IRB. The capital and operating  
105 costs related to the research use are charged to a specific research account and not charged to or

106 collected from third-party payors or patients. The term does not include a procedure conducted by an  
107 MRI unit approved pursuant to Section 8(1).

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

111 (dd) "MRI unit" means the magnetic resonance system consisting of an integrated set of machines  
112 and related equipment necessary to produce the images and/or spectroscopic quantitative data from  
113 scans. The term does not include MRI simulators used solely for treatment planning purposes in  
114 conjunction with an MRT unit.

115 (ee) "MRI visit" means a single patient visit to an MRI service/unit that may involve one or more MRI  
116 procedures.

117 (ff) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6  
118 and 1396r-8 to 1396v.

119 (gg) "Metropolitan statistical area county" means a county located in a metropolitan statistical area  
120 as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas"  
121 by the statistical policy office of the office of information and regulatory affairs of the United States office  
122 of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.

123 (hh) "Micropolitan statistical area county" means a county located in a micropolitan statistical area  
124 as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas"  
125 by the statistical policy office of the office of information and regulatory affairs of the United States office  
126 of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.

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

130 (jj) "Ownership interest, direct or indirect" means a direct ownership relationship between a doctor  
131 and an applicant entity or an ownership relationship between a doctor and an entity that has an  
132 ownership relationship with an applicant entity.

133 (kk) "Pediatric patient" means a patient who is 12 years of age or less, except for Section 9.

134 (ll) "Planning area" means

135 (i) in the case of a proposed fixed MRI service or unit, the geographic area within a 20-mile radius  
136 from the proposed site if the proposed site is not in a rural or micropolitan statistical area county and a  
137 75-mile radius from the proposed site if the proposed site is in a rural or micropolitan statistical area  
138 county.

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

143 (iii) in the case of a proposed mobile MRI service or unit meeting the requirement of Section  
144 13(2)(d), the health service area in which all the proposed mobile host sites will be located.

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

149 (nn) "Relocate an existing MRI service and/or MRI unit(s)" means a change in the location of an  
150 existing MRI service and/or MRI unit(s) from the existing site to a different site within the relocation zone.

151 (oo) "Relocation zone" means the geographic area that is within a 10-mile radius of the existing site  
152 of the MRI service or unit to be relocated.

153 (pp) "Renewal of a lease" means extending the effective period of a lease for an existing MRI unit  
154 that does not involve either replacement of the MRI unit, as defined in Section 2(1)(pp)(i), or (ii) a change  
155 in the parties to the lease.

156 (qq) "Replace an existing MRI unit" means (i) any equipment change involving a change in, or  
157 replacement of, the magnet resulting in an applicant operating the same number and type (fixed or  
158 mobile) of MRI units before and after project completion or (ii) an equipment change other than a change

159 in the magnet that involves a capital expenditure of \$750,000 or more in any consecutive 24-month  
160 period or (iii) the renewal of a lease. The term does not include an upgrade of an existing MRI service or  
161 unit, and it does not include a host site that proposes to receive mobile MRI services from a different  
162 central service coordinator if the requirements of Section 3(5) have been met.

163 (rr) "Research scan" means an MRI scan administered under a research protocol approved by the  
164 applicant's IRB.

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

167 (tt) "Rural county" means a county not located in a metropolitan statistical area or micropolitan  
168 statistical areas as those terms are defined under the "standards for defining metropolitan and  
169 micropolitan statistical areas" by the statistical policy office of the office of information regulatory affairs of  
170 the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as  
171 shown in Appendix A.

172 (uu) "Sedated patient" means a patient that meets all of the following:

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

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

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

179 (vv) "Site" means

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

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

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

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

193 (yy) "Unadjusted MRI scan" means an MRI procedure performed on a single anatomical site as  
194 defined by the MRI database and that is not adjusted pursuant to the applicable provisions of Section 13.

195 (zz) "Upgrade an existing MRI unit" means any equipment change that

196 (i) does not involve a change in, or replacement of, the magnet; does not result in an increase in  
197 the number of MRI units; or does not result in a change in the type of MRI unit (e.g., changing a mobile  
198 MRI unit to a fixed MRI unit); and

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

201

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

203

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

205

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

208

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

212  
213 (2) An applicant proposing to initiate a fixed MRI service that meets the following requirements  
214 shall not be required to be in compliance with subsection (1):  
215 (a) The applicant is currently an existing host site.  
216 (b) The applicant has received in aggregate, one of the following:  
217 (i) At least 6,000 MRI adjusted procedures.  
218 (ii) At least 4,000 MRI adjusted procedures and the applicant meets all of the following:  
219 (A) Is located in a county that has no fixed MRI machines that are pending, approved by the  
220 Department, or operational at the time the application is deemed submitted.  
221 (B) The nearest fixed MRI machine is located more than 15 radius miles from the application site.  
222 (iii) At least 3,000 MRI adjusted procedures and the applicant meets all of the following:  
223 (A) The proposed site is a hospital licensed under Part 215 of the Code.  
224 (B) The applicant hospital operates an emergency room that provides 24-hour emergency care  
225 services and at least 20,000 visits within the most recent 12-month period for which data, verifiable by the  
226 Department, is available.  
227 (c) All of the MRI adjusted procedures from the mobile MRI service referenced in Section 3(2)(b)  
228 shall be utilized even if the aggregated data exceeds the minimum requirements.  
229 (d) The applicant shall install the fixed MRI unit at the same site as the existing host site or within  
230 the relocation zone. If applying pursuant to Section 3(2)(b)(iii), the applicant shall install the fixed MRI  
231 unit at the same site as the existing host site.  
232 (e) The applicant shall cease operation as a host site and not become a host site for at least 12  
233 months from the date the fixed service and its unit becomes operational.  
234  
235 (3) An applicant proposing to initiate a mobile MRI service shall demonstrate 5,500 available MRI  
236 adjusted procedures from within the same planning area as the proposed service/unit, and the applicant  
237 shall meet the following:  
238 (a) Identify the proposed route schedule and procedures for handling emergency situations.  
239 (b) Submit copies of all proposed contracts for the proposed host site related to the mobile MRI  
240 service.  
241 (c) Identify a minimum of two (2) host sites for the proposed service.  
242  
243 (4) An applicant, whether the central service coordinator or the host site, proposing to initiate a  
244 host site on a new or existing mobile MRI service shall demonstrate the following, as applicable:  
245 (a) 600 available MRI adjusted procedures, from within the same planning area as the proposed  
246 service/unit, for a proposed host site that is not located in a rural or micropolitan statistical area county, or  
247 (b) 400 available MRI adjusted procedures from within the same planning area for a proposed host  
248 site that is located in a rural or micropolitan statistical area county, and  
249 (c) The proposed host site has not received any mobile MRI service within the most recent 12-  
250 month period as of the date an application is submitted to the Department.  
251  
252 (5) An applicant proposing to add or change service on an existing mobile MRI service that meets  
253 the following requirements shall not be required to be in compliance with subsection (4):  
254 (a) The host site has received mobile MRI services from an existing mobile MRI unit within the  
255 most recent 12-month period as of the date an application is submitted to the Department.  
256 (b) Submit copies of all proposed contracts for the proposed host site related to the mobile MRI  
257 service.  
258  
259 (6) The applicant shall demonstrate that the available MRI adjusted procedures from the "Available  
260 MRI Adjusted Procedures List" or the adjusted procedures from the "MRI Service Utilization List," as  
261 applicable, are from the most recently published MRI lists as of the date an application is deemed  
262 submitted by the Department.  
263

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

265 Sec. 4. An applicant proposing to replace an existing MRI unit shall demonstrate the following  
266 requirements, as applicable:  
267

268 (1) An applicant shall demonstrate that the applicable MRI adjusted procedures are from the most  
269 recently published MRI Service Utilization List as of the date an application is deemed submitted by the  
270 Department:  
271

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

274 (b) Each existing fixed MRI unit at the current site has performed at least an average of 6,000 MRI  
275 adjusted procedures per MRI unit unless the applicant demonstrates compliance with one of the  
276 following:

277 (i) The existing fixed MRI unit initiated pursuant to Section 3(2)(b)(ii) has performed at least 4,000  
278 MRI adjusted procedures and is the only fixed MRI unit at the current site.

279 (ii) The existing fixed MRI unit initiated pursuant to Section 3(2)(b)(iii) has performed at least 3,000  
280 MRI adjusted procedures and is the only fixed MRI unit at the current site.

281 (c) Each existing dedicated pediatric MRI unit at the current site has performed at least an average  
282 of 3,500 MRI adjusted procedures per MRI unit.  
283

284 (2) Equipment that is replaced shall be removed from service and disposed of or rendered  
285 considerably inoperable on or before the date that the replacement equipment becomes operational.  
286

287 (3) The replacement unit shall be located at the same site unless the requirements of the  
288 relocation section have been met.  
289

290 (4) An applicant proposing to replace an existing MRI unit that does not involve a renewal of a  
291 lease shall demonstrate that the MRI unit to be replaced is fully depreciated according to generally  
292 accepted accounting principles; the existing equipment clearly poses a threat to the safety of the public;  
293 or the proposed replacement equipment offers a significant technological improvement which enhances  
294 quality of care, increases efficiency, and reduces operating costs.  
295

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

297 Sec. 5. An applicant proposing to expand an existing MRI service shall demonstrate the following:  
298

299 (1) An applicant shall demonstrate that the applicable MRI adjustable procedures are from the  
300 most recently published MRI Service Utilization List as of the date of an application is deemed submitted  
301 by the Department:  
302

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

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

307 (c) Each existing dedicated pediatric MRI unit at the current site has performed at least an average  
308 of 3,500 MRI adjusted procedures per MRI unit.  
309

310 (2) The additional fixed unit shall be located at the same site unless the requirements of the  
311 relocation section have been met.  
312

313 **Section 6. Requirements to relocate an existing fixed MRI service and/or MRI unit(s)**

314 Sec. 6. (1) An applicant proposing to relocate an existing fixed MRI service and its unit(s) shall  
315 demonstrate the following:  
316

317 (a) The existing MRI service and its unit(s) to be relocated has been in operation for at least 36  
318 months as of the date an application is submitted to the Department.

319 (b) The proposed new site is in the relocation zone.

320 (c) Each existing MRI unit to be relocated performed at least the applicable minimum number of  
321 MRI adjusted procedures set forth in Section 12 based on the most recently published MRI Service  
322 Utilization List as of the date an application is deemed submitted by the Department.

323

324 (2) An applicant proposing to relocate a fixed MRI unit of an existing MRI service shall  
325 demonstrate the following:

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

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

329 (c) The proposed new site is in the relocation zone.

330 (d) Each existing MRI unit at the service from which a unit is to be relocated performed at least the  
331 applicable minimum number of MRI adjusted procedures set forth in Section 12 based on the most  
332 recently published MRI Service Utilization List as of the date an application is deemed submitted by the  
333 Department.

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

336

### 337 **Section 7. Requirements to acquire an existing MRI service or an existing MRI unit(s)**

338

339 Sec 7. (1) An applicant proposing to acquire an existing fixed or mobile MRI service and its unit(s)  
340 shall demonstrate the following:

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

347 (b) For any application proposing to acquire an existing fixed or mobile MRI service and its unit(s),  
348 except the first application approved pursuant to subsection (a), an applicant shall be required to  
349 document that the MRI service and its unit(s) to be acquired is operating in compliance with the volume  
350 requirements set forth in Section 12 of these standards applicable to an existing MRI service on the date  
351 the application is submitted to the Department.

352

353 (2) An applicant proposing to acquire an existing fixed or mobile MRI unit of an existing MRI  
354 service shall demonstrate that the proposed project meets all of the following:

355 (a) The project will not change the number of MRI units at the site of the MRI service being  
356 acquired, subject to the applicable requirements under Section 6(2), unless the applicant demonstrates  
357 that the project is in compliance with the requirements of the initiation or expansion Section, as  
358 applicable.

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

361

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

363

364 Sec. 8. An applicant proposing an MRI unit to be used exclusively for research shall demonstrate the  
365 following:

366

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

370  
371 (2) Submit copies of documentation demonstrating that the MRI unit shall operate under a protocol  
372 approved by the applicant's IRB.  
373

374 (3) An applicant meeting the requirements of this section shall be exempt from meeting the  
375 requirements of sections to initiate and replace.  
376

377 **Section 9. Requirements to establish a dedicated pediatric MRI unit**  
378

379 Sec. 9. (1) An applicant proposing to establish dedicated pediatric MRI shall demonstrate all of the  
380 following:

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

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

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

387 (i) pediatric radiology (at least two)

388 (ii) pediatric anesthesiology

389 (iii) pediatric cardiology

390 (iv) pediatric critical care

391 (v) pediatric gastroenterology

392 (vi) pediatric hematology/oncology

393 (vii) pediatric neurology

394 (viii) pediatric neurosurgery

395 (ix) pediatric orthopedic surgery

396 (x) pediatric pathology

397 (xi) pediatric pulmonology

398 (xii) pediatric surgery

399 (xiii) neonatology

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

401 (i) pediatric bone marrow transplant program

402 (ii) established pediatric sedation program

403 (iii) pediatric open heart program  
404

405 (2) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the  
406 requirements of Section 5 of these standards.  
407

408 **Section 10. ~~Pilot program~~ Requirements for approval—ALL applicants proposing to initiate,**  
409 **replace, or acquire a hospital based IMRI**  
410

411 Sec. 10. ~~As a pilot program, an AN~~ applicant proposing to initiate, replace, or acquire a hospital  
412 based IMRI service shall demonstrate ~~that it meets all~~ EACH of the following, AS APPLICABLE TO THE  
413 PROPOSED PROJECT.  
414

415 (1) The proposed site is a licensed hospital under Part 215 of the Code.  
416

417 (2) The proposed site has an existing fixed MRI service that has been operational for the previous  
418 36 consecutive months and is meeting its minimum volume requirements.  
419

420 (3) The proposed site has an existing and operational surgical service and is meeting its minimum  
421 volume requirements pursuant to the CON Review Standards for Surgical Services.  
422

423 | (4) The applicant ~~shall have experienced~~HAS ACHIEVED one of the following:  
424 | (a) at least 1,500 oncology discharges in the most recent year of operation; or  
425 | (b) at least 1,000 neurological surgeries in the most recent year of operation; or  
426 | (c) at least 7,000 pediatric (<18 years old) discharges (excluding normal newborns) and at least  
427 | 5,000 pediatric (<18 years old) surgeries in the most recent year of operation.

428 |  
429 | (5) The proposed IMRI unit must be located in an operating room or a room adjoining an operating  
430 | room allowing for transfer of the patient between the operating room and this adjoining room.

431 |  
432 | (6) Non-surgical diagnostic studies shall not be performed on an IMRI unit approved under this  
433 | section unless the patient meets one of the following criteria:

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

437 |  
438 | (7) The approved IMRI unit will not be subject to MRI volume requirements.

439 |  
440 | (8) The applicant shall not utilize the procedures performed on the IMRI unit to demonstrate need  
441 | or to satisfy MRI CON review standards requirements.

442 |  
443 | ~~(9) The provisions of Section 10 are part of a pilot program approved by the CON commission and  
444 | shall expire and be of no further force and effect, and shall not be applicable to any application which has  
445 | not been submitted by December 31, 2010.~~

#### 446 | **Section 11. Requirements for all applicants**

447 |  
448 |  
449 | Sec. 11. An applicant shall provide verification of Medicaid participation. An applicant that is a new  
450 | provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided  
451 | to the Department within six (6) months from the offering of services if a CON is approved.

#### 452 | **Section 12. Project delivery requirements – terms of approval**

453 |  
454 |  
455 | Sec. 12. (1) An applicant shall agree that, if approved, MRI services, whether fixed or mobile, shall  
456 | be delivered and maintained in compliance with the following:

457 | (a) Compliance with these standards.  
458 | (b) Compliance with applicable safety and operating standards.  
459 | (c) Compliance with the following quality assurance standards:  
460 | (i) An applicant shall develop and maintain policies and procedures that establish protocols for  
461 | assuring the effectiveness of operation and the safety of the general public, patients, and staff in the MRI  
462 | service.

463 | (ii) An applicant shall establish a schedule for preventive maintenance for the MRI unit.

464 | (iii) An applicant shall provide documentation identifying the specific individuals that form the MRI  
465 | team. At a minimum, the MRI team shall consist of the following professionals:

466 | (A) Physicians who shall be responsible for screening of patients to assure appropriate utilization  
467 | of the MRI service and taking and interpretation of scans. At least one of these physicians shall be a  
468 | board-certified radiologist.

469 | (B) An appropriately trained MRI technician who shall be responsible for taking an MRI scan.

470 | (C) An MRI physicist/engineer available as a team member on a full-time, part-time, or contractual  
471 | basis.

472 | (iv) An applicant shall document that the MRI team members have the following qualifications:

473 | (A) Each physician credentialed to interpret MRI scans meets the requirements of each of the  
474 | following:

475 | (1) The physician is licensed to practice medicine in the State of Michigan.

476 (2) The physician has had at least 60 hours of training in MRI physics, MRI safety, and MRI  
477 instrumentation in a program that is part of an imaging program accredited by the Accreditation Council  
478 for Graduate Medical Education or the American Osteopathic Association, and the physician meets the  
479 requirements of subdivision (i), (ii), or (iii):

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

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

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

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

493 (4) The physician interprets, as the primary interpreting physician, at least 250 unadjusted MRI  
494 scans annually.

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

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

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

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

513 (d) Compliance with the following terms of approval, as applicable:

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

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

517 (1) 4,000 MRI adjusted procedures for the fixed MRI unit initiated pursuant to Section 3(2)(b)(ii)  
518 and is the only fixed MRI unit at the current site,

519 (2) 3,000 MRI adjusted procedures for the fixed MRI unit initiated pursuant to Section 3(2)(b)(iii)  
520 and is the only fixed MRI unit at the hospital site licensed under part 215 of the code,

521 (B) 5,500 MRI adjusted procedures per unit for mobile MRI services.

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

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

527 its second 12 months of operation and annually thereafter, from all mobile units providing services to the  
528 site.

529 (E) In meeting these requirements, an applicant shall not include any MRI adjusted procedures  
530 performed on an MRI unit used exclusively for research and approved pursuant to Section 8(1) or for an  
531 IMRI unit approved pursuant to Section 10.

532 (ii) The applicant, to assure that the MRI unit will be utilized by all segments of the Michigan  
533 population, shall

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

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

538 (iii) The applicant shall participate in a data collection network established and administered by the  
539 Department or its designee. The data may include, but is not limited to, operating schedules,  
540 demographic and diagnostic information, and the volume of care provided to patients from all payor  
541 sources, as well as other data requested by the Department or its designee and approved by the  
542 Commission. The applicant shall provide the required data in a format established by the Department  
543 and in a mutually agreed upon media no later than 30 days following the last day of the quarter for which  
544 data are being reported to the Department. An applicant shall be considered in violation of this term of  
545 approval if the required data are not submitted to the Department within 30 days following the last day of  
546 the quarter for which data are being reported. The Department may elect to verify the data through  
547 on-site review of appropriate records. Data for an MRI unit approved pursuant to Section 8(1), Section 9,  
548 or Section 10 shall be reported separately.

549 For purposes of Section 10, the data reported shall include, at a minimum, how often the IMRI unit is  
550 used and for what type of services, i.e., intra-operative or diagnostic.

551 (iv) The operation of and referral of patients to the MRI unit shall be in conformance with 1978 PA  
552 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

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

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

559  
560 (2) An applicant for an MRI unit approved under Section 8(1) shall agree that the services provided  
561 by the MRI unit are delivered in compliance with the following terms.

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

564 (b) The MRI unit shall not be used for any purposes other than as approved by the IRB unless the  
565 applicant has obtained CON approval for the MRI unit pursuant to Part 222 and these standards, other  
566 than Section 8.

567  
568 (3) The agreements and assurances required by this section shall be in the form of a certification  
569 agreed to by the applicant or its authorized agent.

### 570 571 **Section 13. MRI procedure adjustments**

572  
573 Sec. 13. (1) The Department shall apply the following formula, as applicable, to determine the  
574 number of MRI adjusted procedures that are performed by an existing MRI service or unit:

575 (a) The base value for each MRI procedure is 1.0.

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

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

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

- 580 (e) For each MRI procedure performed on a re-sedated patient, 0.25 shall be added to the base  
581 value.  
582 (f) For each MRI procedure performed on a special needs patient, 0.25 shall be added to the base  
583 value.  
584 (g) For each MRI visit that involves both a clinical and research scan on a single patient in a single  
585 visit, 0.25 shall be added to the base value.  
586 (h) For each contrast MRI procedure performed after use of a contrast agent, and not involving a  
587 procedure before use of a contrast agent, 0.35 shall be added to the base value.  
588 (i) For each contrast MRI procedure involving a procedure before and after use of a contrast  
589 agent, 1.0 shall be added to the base value.  
590 (j) For each MRI procedure performed at a teaching facility, 0.15 shall be added to the base value.  
591 (k) The results of subsections (a) through (j) shall be summed, and that sum shall represent an  
592 MRI adjusted procedure.  
593

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

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

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

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

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

609 (e) Subsection (2) shall not apply to an application proposing a subsequent fixed MRI unit (second,  
610 third, etc.) at the same site.  
611

612 (3) The number of MRI adjusted procedures performed by an existing MRI service is the sum of  
613 the results of subsections (1) and (2).  
614

#### 615 **Section 14. Documentation of actual utilization**

616  
617 Sec. 14. Documentation of the number of MRI procedures performed by an MRI unit shall be  
618 substantiated by the Department utilizing data submitted by the applicant in a format and media specified  
619 by the Department and as verified for the 12-month period reported on the most recently published "MRI  
620 Service Utilization List" as of the date an application is deemed submitted by the Department. The  
621 number of MRI procedures actually performed shall be documented by procedure records and not by  
622 application of the methodology required in Section 15. The Department may elect to verify the data  
623 through on-site review of appropriate records.  
624

#### 625 **Section 15. Methodology for computing the number of available MRI adjusted procedures**

626  
627 Sec. 15. (1) The number of available MRI adjusted procedures required pursuant to Section 3 shall  
628 be computed in accordance with the methodology set forth in this section. In applying the methodology,  
629 the following steps shall be taken in sequence, and data for the 12-month period reported on the most  
630 recently published "Available MRI Adjusted Procedures List," as of the date an application is deemed  
631 submitted by the Department, shall be used:

632 (a) Identify the number of actual MRI adjusted procedures performed by each existing MRI service  
633 as determined pursuant to Section 13.  
634 (i) For purposes of computing actual MRI adjusted procedures, MRI adjusted procedures  
635 performed on MRI units used exclusively for research and approved pursuant to Section 8(1) and  
636 dedicated pediatric MRI approved pursuant to Section 9 shall be excluded.  
637 (ii) For purposes of computing actual MRI adjusted procedures, the MRI adjusted procedures,  
638 from the host site routes utilized to meet the requirements of Section 3(2)(c), shall be excluded beginning  
639 at the time the application is submitted and for three years from the date the fixed MRI unit becomes  
640 operational.  
641 (iii) For purposes of computing actual MRI adjusted procedures, the MRI adjusted procedures  
642 utilized to meet the requirements of Section 5(1) shall be reduced by 8,000 and shall be excluded  
643 beginning at the time the application is submitted and for three years from the date the fixed MRI unit  
644 becomes operational.  
645 (b) Identify the number of available MRI adjusted procedures, if any, for each existing MRI service  
646 as determined pursuant to Section 2(1)(c).  
647 (c) Determine the number of available MRI adjusted procedures that each referring doctor may  
648 commit from each service to an application in accordance with the following:  
649 (i) Divide the number of available MRI adjusted procedures identified in subsection (b) for each  
650 service by the number of actual MRI adjusted procedures identified in subsection (a) for that existing MRI  
651 service.  
652 (ii) For each doctor referring to that existing service, multiply the number of actual MRI adjusted  
653 procedures that the referring doctor made to the existing MRI service by the applicable proportion  
654 obtained by the calculation in subdivision (c)(i).  
655 (A) For each doctor, subtract any available adjusted procedures previously committed. The total  
656 for each doctor cannot be less than zero.  
657 (B) The total number of available adjusted procedures for that service shall be the sum of the  
658 results of (A) above.  
659 (iii) For each MRI service, the available MRI adjusted procedures resulting from the calculation in  
660 (c)(ii) above shall be sorted in descending order by the available MRI adjusted procedures for each  
661 doctor. Then any duplicate values shall be sorted in descending order by the doctors' license numbers  
662 (last 6 digits only).  
663 (iv) Using the data produced in (c)(iii) above, sum the number of available adjusted procedures in  
664 descending order until the summation equals at least 75 percent of the total available adjusted  
665 procedures. This summation shall include the minimum number of doctors necessary to reach the 75  
666 percent level.  
667 (v) For the doctors representing 75 percent of the total available adjusted procedures in (c)(iv)  
668 above, sum the available adjusted procedures.  
669 (vi) For the doctors used in subsection (c)(v) above, divide the total number of available adjusted  
670 procedures identified in (c)(ii)(B) above by the sum of those available adjusted procedures produced in  
671 (c)(v) above.  
672 (vii) For only those doctors identified in (c)(v) above, multiply the result of (c)(vi) above by the  
673 available adjusted procedures calculated in (c)(ii)(A) above.  
674 (viii) The result shall be the "Available MRI Adjusted Procedures List."  
675  
676 (2) After publication of the "Available MRI Adjusted Procedures List" resulting from (1) above, the  
677 data shall be updated to account for a) doctor commitments of available MRI adjusted procedures in  
678 subsequent MRI CON applications and b) MRI adjusted procedures used in subsequent MRI CON  
679 applications received in which applicants apply for fixed MRI services pursuant to Section 3(2).  
680

681 **Section 16. Procedures and requirements for commitments of available MRI adjusted procedures**  
682

683 Sec. 16. (1) If one or more host sites on a mobile MRI service are located within the planning area of  
684 the proposed site, the applicant may access available MRI adjusted procedures from the entire mobile  
685 MRI service.  
686

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

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

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

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

700 (c) If the required documentation for the doctor commitments submitted under this subsection is  
701 not submitted with the application on the designated application date, the application will be deemed  
702 submitted on the first applicable designated application date after all required documentation is received  
703 by the Department.  
704

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

708 (a) A committing doctor certifies that 100% of his or her available MRI adjusted procedures for  
709 each specified MRI service, calculated pursuant to Section 15, is being committed and specifies the CON  
710 application number for the MRI unit to which the data commitment is made. A doctor shall not be  
711 required to commit available MRI adjusted procedures from all MRI services to which his or her patients  
712 are referred for MRI services but only from those MRI services specified by the doctor in the data  
713 commitment form provided by the Department and submitted by the applicant in support of its application.

714 (b) A committing doctor certifies ownership interest, either direct or indirect, in the applicant entity.  
715 Indirect ownership includes ownership in an entity that has ownership interest in the applicant entity. This  
716 requirement shall not apply if the applicant entity is a group practice of which the committing doctor is a  
717 member. Group practice means a group practice as defined pursuant to the provisions of 42 U.S.C.  
718 1395nn (h)(4), commonly known as Stark II, and the Code of Federal Regulations, 42 CFR, Part 411,  
719 published in the Federal Register on August 14, 1995, or its replacement.

720 (c) A committing doctor certifies that he or she has not been provided, or received a promise of  
721 being provided, a financial incentive to commit any of his or her available MRI adjusted procedures to the  
722 application.  
723

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

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

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

732 (b) The Department shall not consider a data commitment from a doctor for available MRI adjusted  
733 procedures from a specific MRI service if the available MRI adjusted procedures from that specific MRI  
734 service were used to support an application for a new fixed or mobile MRI unit or additional mobile MRI

735 unit pursuant to Section 3, for which a final decision to disapprove was issued by the Director of the  
736 Department until either of the following occurs:

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

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

741  
742 (5) The Department shall not consider a data commitment from a committing doctor for available  
743 MRI adjusted procedures from the same MRI service if that doctor has submitted a signed data  
744 commitment, on a form provided by Department, for more than one (1) application for which a final  
745 decision has not been issued by the Department. If the Department determines that a doctor has  
746 submitted a signed data commitment for the same available MRI adjusted procedures from the same MRI  
747 service to more than one CON application pending a final decision for a new fixed or mobile MRI unit or  
748 additional mobile MRI unit pursuant to Section 3, the Department shall,

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

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

762  
763 (6) The Department shall not consider any data commitment submitted by an applicant after the  
764 date an application is deemed submitted unless an applicant is notified by the Department, pursuant to  
765 subsection (5), that one or more committing doctors submitted data commitments for available MRI  
766 adjusted procedures from the same MRI service. If an applicant is notified that one or more doctors' data  
767 commitments will not be considered by the Department, the Department shall consider data commitments  
768 submitted after the date an application is deemed submitted only to the extent necessary to replace the  
769 data commitments not being considered pursuant to subsection (5).

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

772  
773 (7) In accordance with either of the following, the Department shall not consider a withdrawal of a  
774 signed data commitment:

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

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

777  
778 (8) The Department shall consider a withdrawal of a signed data commitment if a committing  
779 doctor submits a written notice to the Department, that specifies the CON application number and the  
780 specific MRI services for which a data commitment is being withdrawn, and if an applicant demonstrates  
781 that the requirements of subsection (7) also have been met.

## 782 **Section 17. Lists published by the Department**

783  
784 Sec. 17. (1) On or before May 1 and November 1 of each year, the Department shall publish the  
785 following lists:  
786

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

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

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

- 795 (i) The number of available MRI adjusted procedures;
- 796 (ii) The name, address, and license number of each referring doctor, identified in Section  
797 15(1)(c)(v), whose patients received MRI services at that MRI service; and
- 798 (iii) The number of available MRI adjusted procedures performed on patients referred by each  
799 referring doctor, identified in Section 15(1)(c)(v), and if any are committed to an MRI service. This  
800 number shall be calculated in accordance with the requirements of Section 15(1). A referring doctor may  
801 have fractional portions of available MRI adjusted procedures.

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

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

808  
809 (2) When an MRI service begins to operate at a site at which MRI services previously were not  
810 provided, the Department shall include in the MRI database, data beginning with the second full quarter  
811 of operation of the new MRI service. Data from the start-up date to the start of the first full quarter will not  
812 be collected to allow a new MRI service sufficient time to develop its data reporting capability. Data from  
813 the first full quarter of operation will be submitted as test data but will not be reported in the lists published  
814 pursuant to this section.

815  
816 (3) In publishing the lists pursuant to subsections (a) and (b), if an MRI service has not reported  
817 data in compliance with the requirements of Section 12, the Department shall indicate on both lists that  
818 the MRI service is in violation of the requirements set forth in Section 12, and no data will be shown for  
819 that service on either list.

## 820 821 **Section 18. Effect on prior CON Review Standards; Comparative reviews**

822  
823 Sec. 18. (1) These CON review standards supersede and replace the CON Review Standards for  
824 MRI Services approved by the CON Commission on ~~September-DECEMBER 1015, 2009-2010~~ and  
825 effective ~~November-MARCH 511, 20092011~~.

826  
827 (2) Projects reviewed under these standards shall not be subject to comparative review.

## 828 829 **Section 19. Health Service Areas**

830  
831 Sec. 19. Counties assigned to each of the health service areas are as follows:

832	833 <b>HSA</b>			834 <b>COUNTIES</b>		
835	836 1	837 Livingston	838 Monroe	839 St. Clair		
		837 Macomb	838 Oakland	839 Washtenaw		
		837 Wayne				

840	2	Clinton	Hillsdale	Jackson
841		Eaton	Ingham	Lenawee
842	3	Barry	Calhoun	St. Joseph
844		Berrien	Cass	Van Buren
845		Branch	Kalamazoo	
846	4	Allegan	Mason	Newaygo
848		Ionia	Mecosta	Oceana
849		Kent	Montcalm	Osceola
850		Lake	Muskegon	Ottawa
851	5	Genesee	Lapeer	Shiawassee
853				
854	6	Arenac	Huron	Roscommon
855		Bay	Iosco	Saginaw
856		Clare	Isabella	Sanilac
857		Gladwin	Midland	Tuscola
858		Gratiot	Ogemaw	
859	7	Alcona	Crawford	Missaukee
861		Alpena	Emmet	Montmorency
862		Antrim	Gd Traverse	Oscoda
863		Benzie	Kalkaska	Otsego
864		Charlevoix	Leelanau	Presque Isle
865		Cheboygan	Manistee	Wexford
866	8	Alger	Gogebic	Mackinac
868		Baraga	Houghton	Marquette
869		Chippewa	Iron	Menominee
870		Delta	Keweenaw	Ontonagon
871		Dickinson	Luce	Schoolcraft

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**CON REVIEW STANDARDS**  
**FOR MRI SERVICES**

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

65 F.R., p. 82238 (December 27, 2000)  
Statistical Policy Office  
Office of Information and Regulatory Affairs  
United States Office of Management and Budget