

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, lease,  
24 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 ~~4315~~, 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 performed  
32 by an existing MRI service in excess of 8,000 per fixed MRI unit and 7,000 per mobile MRI unit. For either  
33 a fixed or mobile MRI service, the number of MRI units used to compute available MRI adjusted  
34 procedures shall include both existing and approved but not yet operational MRI units. In determining the  
35 number of available MRI adjusted procedures, the Department shall use data for the 12-month period  
36 reported on the most recently published list of available MRI adjusted procedures as of the date an  
37 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 for  
43 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 a  
50 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 [4921](#).

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 [4315](#).

99 (aa) "MRI database" means the database, maintained by the Department pursuant to Section [42-14](#)  
100 of these standards, that collects information about each MRI visit at MRI services located in Michigan.

101 [\(BB\) "MRI-GUIDED ELECTROPHYSIOLOGY INTERVENTION" OR "MRI-GUIDED EPI" MEANS](#)  
102 [EQUIPMENT SPECIFICALLY DESIGNED FOR THE INTEGRATED USE OF MRI TECHNOLOGY FOR](#)  
103 [THE PURPOSES OF ELECTROPHYSIOLOGY INTERVENTIONAL PROCEDURES WITHIN A CARDIAC](#)  
104 [CATHETERIZATION LAB.](#)

105 ~~(bbCC)~~ "MRI procedure" means a procedure conducted by an MRI unit approved pursuant to sections  
106 3, 4, 5, 6, 7, or 9 of these standards which is either a single, billable diagnostic magnetic resonance

107 procedure or a procedure conducted by an MRI unit at a site participating with an approved diagnostic  
108 radiology residency program, under a research protocol approved by an IRB. The capital and operating  
109 costs related to the research use are charged to a specific research account and not charged to or  
110 collected from third-party payors or patients. THE TERM INCLUDES FDA-APPROVED POSITRON  
111 EMISSION TOMOGRAPHY (PET)/MRI SCANNER HYBRIDS IF USED FOR MRI ONLY PROCEDURES.  
112 The term does not include a procedure conducted by an MRI unit approved pursuant to Section 8(1).  
113 (eeDD) "MRI services" means either the utilization of an authorized MRI unit(s) at one site in the case of  
114 a fixed MRI service or in the case of a mobile MRI service, the utilization of an authorized mobile MRI unit  
115 at each host site.  
116 (eeEE) "MRI unit" means the magnetic resonance system consisting of an integrated set of machines  
117 and related equipment necessary to produce the images and/or spectroscopic quantitative data from  
118 scans INCLUDING FDA-APPROVED POSITRON EMISSION TOMOGRAPHY (PET)/MRI SCANNER  
119 HYBRIDS IF USED FOR MRI ONLY PROCEDURES. The term does not include MRI simulators used  
120 solely for treatment planning purposes in conjunction with an MRT unit.  
121 (eeFF) "MRI visit" means a single patient visit to an MRI service/unit that may involve one or more MRI  
122 procedures.  
123 (ffGG) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6 TO  
124 and 1396r-8G to AND 1396I TO 1396v1396J.  
125 (ggHH) "Metropolitan statistical area county" means a county located in a metropolitan statistical area  
126 as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by  
127 the statistical policy office of the office of information and regulatory affairs of the United States office of  
128 management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.  
129 (hhII) "Micropolitan statistical area county" means a county located in a micropolitan statistical area as  
130 that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by  
131 the statistical policy office of the office of information and regulatory affairs of the United States office of  
132 management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.  
133 (iiJJ) "Mobile MRI unit" means an MRI unit operating at two or more host sites and that has a central  
134 service coordinator. The mobile MRI unit shall operate under a contractual agreement for the provision of  
135 MRI services at each host site on a regularly scheduled basis.  
136 (jjKK) "Ownership interest, direct or indirect" means a direct ownership relationship between a doctor  
137 and an applicant entity or an ownership relationship between a doctor and an entity that has an ownership  
138 relationship with an applicant entity.  
139 (kkLL) "Pediatric patient" means a patient who is 12 years of age or less, except for Section 9.  
140 (mmMM) "Planning area" means  
141 (i) in the case of a proposed fixed MRI service or unit, the geographic area within a 20-mile radius  
142 from the proposed site if the proposed site is not in a rural or micropolitan statistical area county and a 75-  
143 mile radius from the proposed site if the proposed site is in a rural or micropolitan statistical area county.  
144 (ii) in the case of a proposed mobile MRI service or unit, except as provided in subsection (iii), the  
145 geographic area within a 20-mile radius from each proposed host site if the proposed site is not in a rural  
146 or micropolitan statistical area county and within a 75-mile radius from each proposed host site if the  
147 proposed site is in a rural or micropolitan statistical area county.  
148 (iii) in the case of a proposed mobile MRI service or unit meeting the requirement of Section  
149 4315(2)(d), the health service area in which all the proposed mobile host sites will be located.  
150 (mmNN) "Referring doctor" means the doctor of record who ordered the MRI procedure(s) and either to  
151 whom the primary report of the results of an MRI procedure(s) is sent or in the case of a teaching facility,  
152 the attending doctor who is responsible for the house officer or resident that requested the MRI procedure.  
153 (nnOO) "Relocate an existing MRI service and/or MRI unit(s)" means a change in the location of an  
154 existing MRI service and/or MRI unit(s) from the existing site to a different site within the relocation zone.  
155 (eePP) "Relocation zone" means the geographic area that is within a 10-mile radius of the existing site  
156 of the MRI service or unit to be relocated.  
157 (ppQQ) "Renewal of a lease" means extending the effective period of a lease for an existing MRI unit  
158 that does not involve either replacement of the MRI unit, as defined in Section 2(1)(ppRR)(i), or (ii) a  
159 change in the parties to the lease.

- 160 | (~~qqRR~~) "Replace an existing MRI unit" means (i) any equipment change involving a change in, or  
 161 | replacement of, the magnet resulting in an applicant operating the same number and type (fixed or  
 162 | mobile) of MRI units before and after project completion or (ii) an equipment change other than a change  
 163 | in the magnet that involves a capital expenditure of \$750,000 or more in any consecutive 24-month period  
 164 | or (iii) the renewal of a lease. The term does not include an upgrade of an existing MRI service or unit,  
 165 | and it does not include a host site that proposes to receive mobile MRI services from a different central  
 166 | service coordinator if the requirements of Section 3(5) have been met.
- 167 | (~~rsSS~~) "Research scan" means an MRI scan administered under a research protocol approved by the  
 168 | applicant's IRB.
- 169 | (~~ssTT~~) "Re-sedated patient" means a patient, either pediatric or adult, who fails the initial sedation  
 170 | during the scan time and must be extracted from the unit to rescue the patient with additional sedation.
- 171 | (~~ttUU~~) "Rural county" means a county not located in a metropolitan statistical area or micropolitan  
 172 | statistical areas as those terms are defined under the "standards for defining metropolitan and  
 173 | micropolitan statistical areas" by the statistical policy office of the office of information regulatory affairs of  
 174 | the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as  
 175 | shown in Appendix A.
- 176 | (~~uuVV~~) "Sedated patient" means a patient that meets all of the following:  
 177 | (i) whose level of consciousness is either conscious-sedation or a higher level of sedation, as  
 178 | defined by the American Association of Anesthesiologists, the American Academy of Pediatrics, the Joint  
 179 | Commission on the Accreditation of Health Care Organizations, or an equivalent definition.  
 180 | (ii) who is monitored by mechanical devices while in the magnet.  
 181 | (iii) who requires observation while in the magnet by personnel, other than employees routinely  
 182 | assigned to the MRI unit, who are trained in cardiopulmonary resuscitation (CPR).
- 183 | (~~vvWW~~) "Site" means  
 184 | (i) in the case of a licensed hospital site, a location that is part of the licensed hospital site or a  
 185 | location that is contiguous to the licensed hospital site or  
 186 | (ii) in the case of a location that is not a licensed hospital site, a location at the same address or a  
 187 | location that is contiguous to that address.
- 188 | (~~wwXX~~) "Special needs patient" means a non-sedated patient, either pediatric or adult, with any of the  
 189 | following conditions: down syndrome, autism, attention deficit hyperactivity disorder (ADHD),  
 190 | developmental delay, malformation syndromes, hunter's syndrome, multi-system disorders, psychiatric  
 191 | disorders, and other conditions that make the patient unable to comply with the positional requirements of  
 192 | the exam.
- 193 | (~~xxYY~~) "Teaching facility" means a licensed hospital site, or other location, that provides either fixed or  
 194 | mobile MRI services and at which residents or fellows of a training program in diagnostic radiology, that is  
 195 | approved by the Accreditation Council on Graduate Medical Education or American Osteopathic  
 196 | Association, are assigned.
- 197 | (~~yyZZ~~) "Unadjusted MRI scan" means an MRI procedure performed on a single anatomical site as  
 198 | defined by the MRI database and that is not adjusted pursuant to the applicable provisions of Section  
 199 | ~~4315~~.
- 200 | (~~zzAAA~~) "Upgrade an existing MRI unit" means any equipment change that  
 201 | (i) does not involve a change in, or replacement of, the magnet; does not result in an increase in  
 202 | the number of MRI units; or does not result in a change in the type of MRI unit (e.g., changing a mobile  
 203 | MRI unit to a fixed MRI unit); and  
 204 | (ii) involves a capital expenditure related to the MRI equipment of less than \$750,000 in any  
 205 | consecutive 24-month period.
- 206 |  
 207 | (2) Terms defined in the Code have the same meanings when used in these standards.

209 | **Section 3. Requirements to initiate an MRI service**

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

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

266 applicable, are from the most recently published MRI lists as of the date an application is deemed  
267 submitted by the Department.

268

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

270

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

273

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

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

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

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

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

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

287

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

290

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

293

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

299

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

301

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

303

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

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

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

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

313

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

316

317



318 **Section 6. Requirements to relocate an existing fixed MRI service and/or MRI unit(s)**  
319

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

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

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

325 (c) Each existing MRI unit to be relocated performed at least the applicable minimum number of  
326 MRI adjusted procedures set forth in Section [42-14](#) based on the most recently published MRI Service  
327 Utilization List as of the date an application is deemed submitted by the Department.

328  
329 (2) An applicant proposing to relocate a fixed MRI unit of an existing MRI service shall demonstrate  
330 the following:

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

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

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

335 (d) Each existing MRI unit at the service from which a unit is to be relocated performed at least the  
336 applicable minimum number of MRI adjusted procedures set forth in Section [42-14](#) based on the most  
337 recently published MRI Service Utilization List as of the date an application is deemed submitted by the  
338 Department.

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

341  
342 **Section 7. Requirements to acquire an existing MRI service or an existing MRI unit(s)**  
343

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

346 (a) For the first application proposing to acquire an existing fixed or mobile MRI service on or after  
347 July 1, 1997, the existing MRI service and its unit(s) to be acquired shall not be required to be in  
348 compliance with the volume requirements applicable to a seller/lessor on the date the acquisition occurs.  
349 The MRI service shall be operating at the applicable volume requirements set forth in Section [42-14](#) of  
350 these standards in the second 12 months after the effective date of the acquisition, and annually  
351 thereafter.

352 (b) For any application proposing to acquire an existing fixed or mobile MRI service and its unit(s),  
353 except the first application approved pursuant to subsection (a), an applicant shall be required to  
354 document that the MRI service and its unit(s) to be acquired is operating in compliance with the volume  
355 requirements set forth in Section [42-14](#) of these standards applicable to an existing MRI service on the  
356 date the application is submitted to the Department.

357  
358 (2) An applicant proposing to acquire an existing fixed or mobile MRI unit of an existing MRI service  
359 shall demonstrate that the proposed project meets all of the following:

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

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

365  
366 **Section 8. Requirements to establish a dedicated research MRI unit**  
367

368 Sec. 8. An applicant proposing an MRI unit to be used exclusively for research shall demonstrate the  
369 following:  
370

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

374  
375 (2) Submit copies of documentation demonstrating that the MRI unit shall operate under a protocol  
376 approved by the applicant's IRB.

377  
378 (3) An applicant meeting the requirements of this section shall be exempt from meeting the  
379 requirements of sections to initiate and replace.

### 380 **Section 9. Requirements to establish a dedicated pediatric MRI unit**

381  
382  
383 Sec. 9. (1) An applicant proposing to establish dedicated pediatric MRI shall demonstrate all of the  
384 following:

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

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

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

391 (i) pediatric radiology (at least two)

392 (ii) pediatric anesthesiology

393 (iii) pediatric cardiology

394 (iv) pediatric critical care

395 (v) pediatric gastroenterology

396 (vi) pediatric hematology/oncology

397 (vii) pediatric neurology

398 (viii) pediatric neurosurgery

399 (ix) pediatric orthopedic surgery

400 (x) pediatric pathology

401 (xi) pediatric pulmonology

402 (xii) pediatric surgery

403 (xiii) neonatology

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

405 (i) pediatric bone marrow transplant program

406 (ii) established pediatric sedation program

407 (iii) pediatric open heart program

408  
409 (2) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the  
410 requirements of Section 5 of these standards.

### 411 **Section 10. Requirements for all applicants proposing to initiate, replace, or acquire a hospital** 412 **based IMRI**

413  
414  
415 Sec. 10. An applicant proposing to initiate, replace, or acquire a hospital based IMRI service shall  
416 demonstrate each of the following, as applicable to the proposed project.

417  
418 (1) The proposed site is a licensed hospital under Part 215 of the Code.

419  
420 (2) The proposed site has an existing fixed MRI service that has been operational for the previous  
421 36 consecutive months and is meeting its minimum volume requirements.



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

425  
426 (4) The applicant has achieved one of the following:

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

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

429 (c) at least 7,000 pediatric (<18 years old) discharges (excluding normal newborns) and at least  
430 5,000 pediatric (<18 years old) surgeries in the most recent year of operation.

431  
432 (5) The proposed IMRI unit must be located in an operating room or a room adjoining an operating  
433 room allowing for transfer of the patient between the operating room and this adjoining room.

434  
435 (6) Non-surgical diagnostic studies shall not be performed on an IMRI unit approved under this  
436 section unless the patient meets one of the following criteria:

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

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

440  
441 (7) The approved IMRI unit will not be subject to MRI volume requirements.

442  
443 (8) The applicant shall not utilize the procedures performed on the IMRI unit to demonstrate need  
444 or to satisfy MRI CON review standards requirements.

445  
446 **SECTION 11. REQUIREMENTS FOR ALL APPLICANTS PROPOSING TO INITIATE, REPLACE, OR**  
447 **ACQUIRE A HOSPITAL BASED MRI-GUIDED EPI SERVICE**

448  
449 SEC. 11. AN APPLICANT PROPOSING TO INITIATE, REPLACE, OR ACQUIRE A HOSPITAL  
450 BASED MRI-GUIDED EPI SERVICE SHALL DEMONSTRATE EACH OF THE FOLLOWING, AS  
451 APPLICABLE TO THE PROPOSED PROJECT.

452  
453 (1) THE PROPOSED SITE IS A LICENSED HOSPITAL UNDER PART 215 OF THE CODE.

454  
455 (2) THE PROPOSED SITE HAS AN EXISTING FIXED MRI SERVICE THAT HAS BEEN  
456 OPERATIONAL FOR THE PREVIOUS 36 CONSECUTIVE MONTHS AND IS MEETING ITS MINIMUM  
457 VOLUME REQUIREMENTS.

458  
459 (3) THE PROPOSED SITE HAS AN EXISTING AND OPERATIONAL THERAPEUTIC CARDIAC  
460 CATHETERIZATION SERVICE AND IS MEETING ITS MINIMUM VOLUME REQUIREMENTS  
461 PURSUANT TO THE CON REVIEW STANDARDS FOR CARDIAC CATHETERIZATION SERVICES  
462 AND OPEN HEART SURGERY SERVICES.

463  
464 (4) THE PROPOSED MRI-GUIDED EPI UNIT MUST BE LOCATED IN A CARDIAC  
465 CATHETERIZATION LAB CONTAINING A FLOUROSCOPY UNIT WITH AN ADJOINING ROOM  
466 CONTAINING AN MRI SCANNER. THE ROOMS SHALL CONTAIN A PATIENT TRANSFER SYSTEM  
467 ALLOWING FOR TRANSFER OF THE PATIENT BETWEEN THE CARDIAC CATHETERIZATION LAB  
468 AND THE MRI UNIT, UTILIZING ONE OF THE FOLLOWING:

469 (A) MOVING THE PATIENT TO THE MRI SCANNER, OR

470 (B) INSTALLING THE MRI SCANNER ON A SLIDING GANTRY TO ALLOW THE PATIENT TO  
471 REMAIN STATIONARY.

474 (5) NON-CARDIAC MRI DIAGNOSTIC STUDIES SHALL NOT BE PERFORMED IN AN MRI-  
475 GUIDED EPI UNIT APPROVED UNDER THIS SECTION UNLESS THE PATIENT MEETS ONE OF THE  
476 FOLLOWING CRITERIA:

477 (A) THE PATIENT HAS BEEN ADMITTED TO AN INPATIENT UNIT; OR  
478 (B) THE PATIENT IS HAVING THE STUDY PERFORMED ON AN OUTPATIENT BASIS AS  
479 FOLLOWS:

480 (I) IS IN NEED OF GENERAL ANESTHESIA OR DEEP SEDATION AS DEFINED BY THE  
481 AMERICAN SOCIETY OF ANESTHESIOLOGISTS, OR  
482 (II) HAS AN IMPLANTABLE CARDIAC DEVICE.

483  
484 (6) THE APPROVED MRI-GUIDED EPI UNIT SHALL NOT BE SUBJECT TO MRI VOLUME  
485 REQUIREMENTS.

486  
487 (7) THE APPLICANT SHALL NOT UTILIZE THE PROCEDURES PERFORMED ON THE MRI-  
488 GUIDED EPI UNIT TO DEMONSTRATE NEED OR TO SATISFY MRI CON REVIEW STANDARDS  
489 REQUIREMENTS.

490  
491 **SECTION 12. REQUIREMENTS FOR APPROVAL OF AN FDA-APPROVED PET/MRI SCANNER**  
492 **HYBRID FOR INITIATION, EXPANSION, REPLACEMENT, AND ACQUISITION**

493  
494 SEC. 12. AN APPLICANT PROPOSING TO INITIATE, EXPAND, REPLACE, OR ACQUIRE AN FDA-  
495 APPROVED PET/MRI SCANNER HYBRID SHALL DEMONSTRATE THAT IT MEETS ALL OF THE  
496 FOLLOWING:

497  
498 (1) THERE IS AN APPROVED PET CON FOR THE FDA-APPROVED PET/MRI HYBRID, AND  
499 THE FDA-APPROVED PET/MRI SCANNER HYBRID IS IN COMPLIANCE WITH ALL APPLICABLE  
500 PROJECT DELIVERY REQUIREMENTS AS SET FORTH IN THE CON REVIEW STANDARDS FOR  
501 PET.

502  
503 (2) THE APPLICANT AGREES TO OPERATE THE FDA-APPROVED PET/MRI SCANNER  
504 HYBRID IN ACCORDANCE WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS SET  
505 FORTH IN SECTION 4314 OF THESE STANDARDS.

506  
507 (3) THE APPROVED FDA-APPROVED PET/MRI SCANNER HYBRID SHALL NOT BE SUBJECT  
508 TO MRI VOLUME REQUIREMENTS.

509  
510 (4) AN FDA-APPROVED PET/MRI SCANNER HYBRID APPROVED UNDER THE CON REVIEW  
511 STANDARDS FOR PET SCANNER SERVICES AND THE REVIEW STANDARDS FOR MRI SCANNER  
512 SERVICES MAY NOT UTILIZE MRI PROCEDURES PERFORMED ON AN FDA-APPROVED PET/MRI  
513 SCANNER HYBRID TO DEMONSTRATE NEED OR TO SATISFY MRI CON REVIEW STANDARDS  
514 REQUIREMENTS.

515  
516 **Section 4113. Requirements for all applicants**

517  
518 **Sec. 4113.** An applicant shall provide verification of Medicaid participation. An applicant that is a new  
519 provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided  
520 to the Department within six (6) months from the offering of services if a CON is approved.

521  
522 **Section 4214. Project delivery requirements – terms of approval**

523  
524 **Sec. 4214.** (1) An applicant shall agree that, if approved, MRI services, whether fixed or mobile, shall  
525 be delivered and maintained in compliance with the following:

526 (a) Compliance with these standards.

527 (b) Compliance with applicable safety and operating standards.  
528 (c) Compliance with the following quality assurance standards:  
529 (i) An applicant shall develop and maintain policies and procedures that establish protocols for  
530 assuring the effectiveness of operation and the safety of the general public, patients, and staff in the MRI  
531 service.  
532 (ii) An applicant shall establish a schedule for preventive maintenance for the MRI unit.  
533 (iii) An applicant shall provide documentation identifying the specific individuals that form the MRI  
534 team. At a minimum, the MRI team shall consist of the following professionals:  
535 (A) Physicians who shall be responsible for screening of patients to assure appropriate utilization of  
536 the MRI service and taking and interpretation of scans. At least one of these physicians shall be a  
537 board-certified radiologist.  
538 (B) An appropriately trained MRI technician who shall be responsible for taking an MRI scan.  
539 (C) An MRI physicist/engineer available as a team member on a full-time, part-time, or contractual  
540 basis.  
541 (iv) An applicant shall document that the MRI team members have the following qualifications:  
542 (A) Each physician credentialed to interpret MRI scans meets the requirements of each of the  
543 following:  
544 (1) The physician is licensed to practice medicine in the State of Michigan.  
545 (2) The physician has had at least 60 hours of training in MRI physics, MRI safety, and MRI  
546 instrumentation in a program that is part of an imaging program accredited by the Accreditation Council for  
547 Graduate Medical Education or the American Osteopathic Association, and the physician meets the  
548 requirements of subdivision (i), (ii), or (iii):  
549 (i) Board certification by the American Board of Radiology, the American Osteopathic Board of  
550 Radiology, or the Royal College of Physicians and Surgeons of Canada. If the diagnostic radiology  
551 program completed by a physician in order to become board certified did not include at least two months  
552 of MRI training, that physician shall document that he or she has had the equivalent of two months of  
553 postgraduate training in clinical MRI imaging at an institution which has a radiology program accredited by  
554 the Accreditation Council for Graduate Medical Education or the American Osteopathic Association.  
555 (ii) Formal training by an imaging program(s), accredited by the Accreditation Council for Graduate  
556 Medical Education or the American Osteopathic Association, that included two years of training in cross-  
557 sectional imaging and six months training in organ-specific imaging areas.  
558 (iii) A practice in which at least one-third of total professional time, based on a full-time clinical  
559 practice during the most recent 5-year period, has been the primary interpretation of MR imaging.  
560 (3) The physician has completed and will complete a minimum of 40 hours every two years of  
561 Category in Continuing Medical Education credits in topics directly involving MR imaging.  
562 (4) The physician interprets, as the primary interpreting physician, at least 250 unadjusted MRI  
563 scans annually.  
564 (B) An MRI technologist who is registered by the American Registry of Radiologic Technicians or by  
565 the American Registry of Magnetic Resonance Imaging Technologists (ARMRIT) and has, or will have  
566 within 36 months of the effective date of these standards or the date a technologist is employed by an MRI  
567 service, whichever is later, special certification in MRI. If a technologist does not have special certification  
568 in MRI within either of the 3-year periods of time, all continuing education requirements shall be in the area  
569 of MRI services.  
570 (C) An applicant shall document that an MRI physicist/engineer is appropriately qualified. For  
571 purposes of evaluating this subdivision, the Department shall consider it prima facie evidence as to the  
572 qualifications of the physicist/engineer if the physicist/engineer is certified as a medical physicist by the  
573 American Board of Radiology, the American Board of Medical Physics, or the American Board of Science  
574 in Nuclear Medicine. However, the applicant may submit and the Department may accept other evidence  
575 that an MRI physicist/engineer is qualified appropriately.  
576 (v) The applicant shall have, within the MRI unit/service, equipment and supplies to handle clinical  
577 emergencies that might occur in the unit. MRI service staff will be trained in CPR and other appropriate  
578 emergency interventions. A physician shall be on-site, in, or immediately available to the MRI unit at all  
579 times when patients are undergoing scans.

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

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

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

585 (A) 6,000 MRI adjusted procedures per unit for fixed MRI services unless compliant with (1) or (2),  
586 (1) 4,000 MRI adjusted procedures for the fixed MRI unit initiated pursuant to Section 3(2)(b)(ii) and  
587 is the only fixed MRI unit at the current site,  
588 (2) 3,000 MRI adjusted procedures for the fixed MRI unit initiated pursuant to Section 3(2)(b)(iii)  
589 and is the only fixed MRI unit at the hospital site licensed under part 215 of the code,

590 (B) 5,500 MRI adjusted procedures per unit for mobile MRI services.  
591 (C) 3,500 MRI adjusted procedures per unit for dedicated pediatric MRI units.  
592 (D) Each mobile host site in a rural or micropolitan statistical area county shall have provided at  
593 least a total of 400 adjusted procedures during its second 12 months of operation, and annually thereafter,  
594 from all mobile units providing services to the site. Each mobile host site not in a rural or micropolitan  
595 statistical area county shall have provided at least a total of 600 adjusted procedures during its second 12  
596 months of operation and annually thereafter, from all mobile units providing services to the site.

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

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

602 (A) provide MRI services to all individuals based on the clinical indications of need for the service  
603 and not on ability to pay or source of payment.  
604 (B) maintain information by source of payment to indicate the volume of care from each source  
605 provided annually.

606 (iii) The applicant shall participate in a data collection network established and administered by the  
607 Department or its designee. The data may include, but is not limited to, operating schedules,  
608 demographic and diagnostic information, and the volume of care provided to patients from all payor  
609 sources, as well as other data requested by the Department or its designee and approved by the  
610 Commission. The applicant shall provide the required data in a format established by the Department and  
611 in a mutually agreed upon media no later than 30 days following the last day of the quarter for which data  
612 are being reported to the Department. An applicant shall be considered in violation of this term of  
613 approval if the required data are not submitted to the Department within 30 days following the last day of  
614 the quarter for which data are being reported. The Department may elect to verify the data through on-site  
615 review of appropriate records. Data for an MRI unit approved pursuant to Section 8(1), Section 9, ~~or~~  
616 Section 10, OR SECTION 11 shall be reported separately.  
617 For purposes of Section 10, the data reported shall include, at a minimum, how often the IMRI unit is used  
618 and for what type of services, i.e., intra-operative or diagnostic. FOR PURPOSES OF SECTION 11, THE  
619 DATA REPORTED SHALL INCLUDE, AT A MINIMUM, HOW OFTEN THE MRI-GUIDED EPI UNIT IS  
620 USED AND FOR WHAT TYPE OF SERVICES, I.E., ELECTROPHYSIOLOGY OR DIAGNOSTIC.

621 (iv) The operation of and referral of patients to the MRI unit shall be in conformance with 1978 PA  
622 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

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

626 (f) An applicant who is a central service coordinator shall notify the Department of any additions,  
627 deletions, or changes in the host sites of each approved mobile MRI unit within 10 days after the  
628 change(s) in host sites is made.  
629

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

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

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

637  
638 (3) The agreements and assurances required by this section shall be in the form of a certification  
639 agreed to by the applicant or its authorized agent.

640

641 | **Section 4315. MRI procedure adjustments**

642

643 | Sec. 4315. (1) The Department shall apply the following formula, as applicable, to determine the  
644 number of MRI adjusted procedures that are performed by an existing MRI service or unit:

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

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

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

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

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

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

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

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

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

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

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

662

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

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

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

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

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

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

680

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

683

684 | **Section 4416. Documentation of actual utilization**

685  
686 | Sec. 4416. Documentation of the number of MRI procedures performed by an MRI unit shall be  
687 substantiated by the Department utilizing data submitted by the applicant in a format and media specified  
688 by the Department and as verified for the 12-month period reported on the most recently published "MRI  
689 Service Utilization List" as of the date an application is deemed submitted by the Department. The  
690 number of MRI procedures actually performed shall be documented by procedure records and not by  
691 | application of the methodology required in Section 4517. The Department may elect to verify the data  
692 through on-site review of appropriate records.  
693

694 | **Section 4517. Methodology for computing the number of available MRI adjusted procedures**  
695

696 | Sec. 4517. (1) The number of available MRI adjusted procedures required pursuant to Section 3 shall  
697 be computed in accordance with the methodology set forth in this section. In applying the methodology,  
698 the following steps shall be taken in sequence, and data for the 12-month period reported on the most  
699 recently published "Available MRI Adjusted Procedures List," as of the date an application is deemed  
700 submitted by the Department, shall be used:

701 (a) Identify the number of actual MRI adjusted procedures performed by each existing MRI service  
702 | as determined pursuant to Section 4315.

703 (i) For purposes of computing actual MRI adjusted procedures, MRI adjusted procedures  
704 performed on MRI units used exclusively for research and approved pursuant to Section 8(1) and  
705 dedicated pediatric MRI approved pursuant to Section 9 shall be excluded.

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

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

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

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

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

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

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

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

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

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

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



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

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

742 (viii) The result shall be the "Available MRI Adjusted Procedures List."  
743

744 (2) After publication of the "Available MRI Adjusted Procedures List" resulting from (1) above, the  
745 data shall be updated to account for a) doctor commitments of available MRI adjusted procedures in  
746 subsequent MRI CON applications and b) MRI adjusted procedures used in subsequent MRI CON  
747 applications received in which applicants apply for fixed MRI services pursuant to Section 3(2).  
748

749 | **Section 4618. Procedures and requirements for commitments of available MRI adjusted**  
750 **procedures**

751 |  
752 | Sec. 4618. (1) If one or more host sites on a mobile MRI service are located within the planning area  
753 of the proposed site, the applicant may access available MRI adjusted procedures from the entire mobile  
754 MRI service.  
755

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

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

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

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

769 (c) If the required documentation for the doctor commitments submitted under this subsection is  
770 not submitted with the application on the designated application date, the application will be deemed  
771 submitted on the first applicable designated application date after all required documentation is received  
772 by the Department.  
773

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

777 (a) A committing doctor certifies that 100% of his or her available MRI adjusted procedures for  
778 | each specified MRI service, calculated pursuant to Section 4617, is being committed and specifies the  
779 CON application number for the MRI unit to which the data commitment is made. A doctor shall not be  
780 required to commit available MRI adjusted procedures from all MRI services to which his or her patients  
781 are referred for MRI services but only from those MRI services specified by the doctor in the data  
782 commitment form provided by the Department and submitted by the applicant in support of its application.

783 (b) A committing doctor certifies ownership interest, either direct or indirect, in the applicant entity.  
784 Indirect ownership includes ownership in an entity that has ownership interest in the applicant entity. This  
785 requirement shall not apply if the applicant entity is a group practice of which the committing doctor is a  
786 member. Group practice means a group practice as defined pursuant to the provisions of 42 U.S.C.  
787 1395nn (h)(4), commonly known as Stark II, and the Code of Federal Regulations, 42 CFR, Part 411,  
788 published in the Federal Register on August 14, 1995, or its replacement.

789 (c) A committing doctor certifies that he or she has not been provided, or received a promise of  
790 being provided, a financial incentive to commit any of his or her available MRI adjusted procedures to the  
791 application.  
792

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

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

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

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

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

808 (ii) If an appeal was made, either that appeal is withdrawn by the applicant or the committing doctor  
809 withdraws his or her data commitment pursuant to the requirements of subsection (8).  
810

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

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

824 (b) if the applications were submitted on different designated application dates, consider the data  
825 commitment in the application submitted on the earliest designated application date and shall notify,  
826 simultaneously in writing, all applicants of applications submitted on designated application dates  
827 subsequent to the earliest date that one or more committing doctors have submitted data commitments  
828 for available MRI adjusted procedures from the same MRI service and that the doctors' data shall not be  
829 considered in the review of the application(s) submitted on the subsequent designated application date(s).  
830

831 (6) The Department shall not consider any data commitment submitted by an applicant after the  
832 date an application is deemed submitted unless an applicant is notified by the Department, pursuant to  
833 subsection (5), that one or more committing doctors submitted data commitments for available MRI  
834 adjusted procedures from the same MRI service. If an applicant is notified that one or more doctors' data  
835 commitments will not be considered by the Department, the Department shall consider data commitments  
836 submitted after the date an application is deemed submitted only to the extent necessary to replace the  
837 data commitments not being considered pursuant to subsection (5).

838 (a) The applicant shall have 30 days to submit replacement of doctor commitments as identified by  
839 the Department in this Section.  
840

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

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

845  
846 (8) The Department shall consider a withdrawal of a signed data commitment if a committing doctor  
847 submits a written notice to the Department, that specifies the CON application number and the specific  
848 MRI services for which a data commitment is being withdrawn, and if an applicant demonstrates that the  
849 requirements of subsection (7) also have been met.

### 851 | **Section 4719. Lists published by the Department**

852  
853 | Sec. 4719. (1) On or before May 1 and November 1 of each year, the Department shall publish the  
854 following lists:

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

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

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

- 863 (i) The number of available MRI adjusted procedures;
- 864 (ii) The name, address, and license number of each referring doctor, identified in Section  
865 | [4517\(1\)\(c\)\(v\)](#), whose patients received MRI services at that MRI service; and

866 (iii) The number of available MRI adjusted procedures performed on patients referred by each  
867 | referring doctor, identified in Section [4517\(1\)\(c\)\(v\)](#), and if any are committed to an MRI service. This  
868 | number shall be calculated in accordance with the requirements of Section [4517\(1\)](#). A referring doctor  
869 | may have fractional portions of available MRI adjusted procedures.

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

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

876  
877 (2) When an MRI service begins to operate at a site at which MRI services previously were not  
878 provided, the Department shall include in the MRI database, data beginning with the second full quarter of  
879 operation of the new MRI service. Data from the start-up date to the start of the first full quarter will not be  
880 collected to allow a new MRI service sufficient time to develop its data reporting capability. Data from the  
881 first full quarter of operation will be submitted as test data but will not be reported in the lists published  
882 pursuant to this section.

883  
884 (3) In publishing the lists pursuant to subsections (a) and (b), if an MRI service has not reported  
885 | data in compliance with the requirements of Section [4214](#), the Department shall indicate on both lists that  
886 | the MRI service is in violation of the requirements set forth in Section [4214](#), and no data will be shown for  
887 | that service on either list.

### 888 | **Section 4820. Effect on prior CON Review Standards; Comparative reviews**

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890  
891 | Sec. 4820. (1) These CON review standards supersede and replace the CON Review Standards for  
892 | MRI Services approved by the CON Commission on ~~December 15, 2010~~[September 22, 2011](#) and  
893 | effective ~~March 14~~[November 21](#), 2011.

894

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

896

897 | **Section 4921. Health Service Areas**

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899 | Sec. 4921. Counties assigned to each of the health service areas are as follows:

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901 **HSA**

**COUNTIES**

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904	1	Livingston	Monroe	St. Clair
905		Macomb	Oakland	Washtenaw
906		Wayne		

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908	2	Clinton	Hillsdale	Jackson
909		Eaton	Ingham	Lenawee

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911	3	Barry	Calhoun	St. Joseph
912		Berrien	Cass	Van Buren
913		Branch	Kalamazoo	

914

915	4	Allegan	Mason	Newaygo
916		Ionia	Mecosta	Oceana
917		Kent	Montcalm	Osceola
918		Lake	Muskegon	Ottawa

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920	5	Genesee	Lapeer	Shiawassee
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922	6	Arenac	Huron	Roscommon
923		Bay	Iosco	Saginaw
924		Clare	Isabella	Sanilac
925		Gladwin	Midland	Tuscola
926		Gratiot	Ogemaw	

927

928	7	Alcona	Crawford	Missaukee
929		Alpena	Emmet	Montmorency
930		Antrim	Gd Traverse	Oscoda
931		Benzie	Kalkaska	Otsego
932		Charlevoix	Leelanau	Presque Isle
933		Cheboygan	Manistee	Wexford

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935	8	Alger	Gogebic	Mackinac
936		Baraga	Houghton	Marquette
937		Chippewa	Iron	Menominee
938		Delta	Keweenaw	Ontonagon
939		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