

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 or acquisition of MRI services and the delivery of services under Part 222 of the Code. Pursuant to Part
14 222 of the Code, MRI is a covered clinical service. The Department shall use these standards in applying
15 Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and Section
16 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.
17

18 **Section 2. Definitions**
19

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

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

24 (b) "Actual MRI adjusted procedures" or "MRI adjusted procedures," means the number of MRI
25 procedures, adjusted in accordance with the applicable provisions of Section 15, performed on an existing
26 MRI unit, or if an MRI service has two or more MRI units at the same site, the average number of MRI
27 adjusted procedures performed on each unit, for the 12-month period reported on the most recently
28 published "MRI Service Utilization List," as of the date an application is deemed submitted by the
29 Department.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

133 (kkj) "Ownership interest, direct or indirect" means a direct ownership relationship between a doctor
134 and an applicant entity or an ownership relationship between a doctor and an entity that has an ownership
135 relationship with an applicant entity.

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

137 (mm) "Planning area" means

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

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

145 (iii) in the case of a proposed mobile MRI service or unit meeting the requirement of Section
146 15(2)(d), the health service area in which all the proposed mobile host sites will be located.

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

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

153 (ppnn) "Research scan" means an MRI scan administered under a research protocol approved by the
154 applicant's IRB.

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

157 ~~(rr) "Rural county" means a county not located in a metropolitan statistical area or micropolitan
158 statistical areas as these terms are defined under the "standards for defining metropolitan and~~

159 | ~~micropolitan statistical areas" by the statistical policy office of the office of information regulatory affairs of~~
160 | ~~the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as~~
161 | ~~shown in Appendix A.~~

162 | (~~sspp~~) "Sedated patient" means a patient that meets all of the following:

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

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

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

169 | (~~tgq~~) "Site" means

170 | (i) in the case of a licensed hospital site, a location that is part of the licensed hospital site or a
171 | location that is contiguous to the licensed hospital site or

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

174 | (~~urr~~) "Special needs patient" means a non-sedated patient, either pediatric or adult, with any of the
175 | following conditions: down syndrome, autism, attention deficit hyperactivity disorder (ADHD),
176 | developmental delay, malformation syndromes, hunter's syndrome, multi-system disorders, psychiatric
177 | disorders, and other conditions that make the patient unable to comply with the positional requirements of
178 | the exam.

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

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

185 |
186 | (2) Terms defined in the Code have the same meanings when used in these standards.
187 |

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

189 |
190 | Sec. 3. An applicant proposing to initiate an MRI service or a host site shall demonstrate the following
191 | requirements, as applicable:
192 |

193 | (1) An applicant proposing to initiate a fixed MRI service shall demonstrate 6,000 available MRI
194 | adjusted procedures per proposed fixed MRI unit from within the same planning area as the proposed
195 | service/unit.
196 |

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

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

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

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

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

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

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

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

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

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

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

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

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

218
219 (3) An applicant proposing to initiate a mobile MRI service shall demonstrate 5,500 available MRI
220 adjusted procedures from within the same planning area as the proposed service/unit, and the applicant
221 shall meet the following:

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

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

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

226
227 (4) An applicant, whether the central service coordinator or the host site, proposing to initiate a host
228 site on a new or existing mobile MRI service shall demonstrate the following, as applicable:

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

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

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

235
236 (5) An applicant proposing to add or change service on an existing mobile MRI service that meets
237 the following requirements shall not be required to be in compliance with subsection (4):

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

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

242
243 (6) The applicant shall demonstrate that the available MRI adjusted procedures from the "Available
244 MRI Adjusted Procedures List" or the adjusted procedures from the "MRI Service Utilization List," as
245 applicable, are from the most recently published MRI lists as of the date an application is deemed
246 submitted by the Department.

247 248 **Section 4. Requirements to replace an existing MRI unit**

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

260
261 (1) "Upgrade an existing MRI unit" means any equipment change that

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

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

267

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

272

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

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

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

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

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

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

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

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

292 (c) The replacement unit shall be located at the same site.

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

298

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

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

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

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

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

309 (e) The relocation will not involve a change in the current central service coordinator unless the
310 requirements of Section 3(5) are met.

311

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

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

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

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

320

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

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

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

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

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

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

333

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

335

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

337

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

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

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

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

347

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

350

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

352

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

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

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

365

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

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

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

373

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

375

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

378

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

381

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

385

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

388

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

391

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

393

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

396

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

399

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

402

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

405 (a) pediatric radiology (at least two)

406 (b) pediatric anesthesiology

407 (c) pediatric cardiology

408 (d) pediatric critical care

409 (e) pediatric gastroenterology

410 (f) pediatric hematology/oncology

411 (g) pediatric neurology

412 (h) pediatric neurosurgery

413 (i) pediatric orthopedic surgery

414 (j) pediatric pathology

415 (k) pediatric pulmonology

416 (l) pediatric surgery

417 (m) neonatology

418

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

424 (5) An applicant meeting the requirements of this section shall be exempt from meeting the
425 requirements of Section 5 of these standards.
426

427 **Section 9. Requirements for all applicants proposing to initiate, replace, or acquire a hospital**
428 **based IMRI**
429

430 Sec. 9. An applicant proposing to initiate, replace, or acquire a hospital based IMRI service shall
431 demonstrate each of the following, as applicable to the proposed project.
432

433 (1) The proposed site is a licensed hospital under Part 215 of the Code.
434

435 (2) The proposed site has an existing fixed MRI service that has been operational for the previous
436 36 consecutive months and is meeting its minimum volume requirements.
437

438 (3) The proposed site has an existing and operational surgical service and is meeting its minimum
439 volume requirements pursuant to the CON Review Standards for Surgical Services.
440

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

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

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

444 (c) at least 7,000 pediatric (<18 years old) discharges (excluding normal newborns) and at least
445 5,000 pediatric (<18 years old) surgeries in the most recent year of operation.
446

447 (5) The proposed IMRI unit must be located in an operating room or a room adjoining an operating
448 room allowing for transfer of the patient between the operating room and this adjoining room.
449

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

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

453 (b) the patient is having the study performed on an outpatient basis, but is in need of general
454 anesthesia or deep sedation as defined by the American Society of Anesthesiologists.
455

456 (7) The approved IMRI unit will not be subject to MRI volume requirements.
457

458 (8) The applicant shall not utilize the procedures performed on the IMRI unit to demonstrate need
459 or to satisfy MRI CON review standards requirements.
460

461 **Section 10. Requirements for all applicants proposing to initiate, replace, or acquire a hospital**
462 **based MRI-guided EPI service**
463

464 Sec. 10. An applicant proposing to initiate, replace, or acquire a hospital based MRI-guided EPI
465 service shall demonstrate each of the following, as applicable to the proposed project.
466

467 (1) The proposed site is a licensed hospital under part 215 of the Code.
468

469 (2) The proposed site has an existing fixed MRI service that has been operational for the previous
470 36 consecutive months and is meeting its minimum volume requirements.
471

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

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

- 480 (a) moving the patient to the MRI scanner, or
- 481 (b) installing the MRI scanner on a sliding gantry to allow the patient to remain stationary.
482

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

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

491 (6) The approved MRI-guided EPI unit shall not be subject to MRI volume requirements.
492

493 (7) The applicant shall not utilize the procedures performed on the MRI-guided EPI unit to
494 demonstrate need or to satisfy MRI CON review standards requirements.
495

496 **Section 11. Requirements for all applicants proposing to initiate, replace, or acquire an MRI**
497 **simulator that will not be used solely for MRT treatment planning purposes**
498

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

504 (1) The proposed site has an existing fixed MRI service that has been operational for the previous
505 36 consecutive months and is meeting its minimum volume requirements.
506

507 (2) The proposed site has an existing and operational MRT service and is meeting its minimum
508 volume requirements pursuant to the CON review standards for MRT services/units.
509

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

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

516 (4) The approved MRI simulator will not be subject to MRI volume requirements.
517

518 (5) The applicant shall not utilize the procedures performed on the MRI simulator to demonstrate
519 need or to satisfy MRI CON review standards requirements.
520
521

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

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

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

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

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

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

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

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

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

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

553
554 (1) Compliance with these standards.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

617 (d) The operation of and referral of patients to the MRI unit shall be in conformance with 1978 PA
618 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

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

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

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

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

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

628 (ii) 5,500 MRI adjusted procedures per unit for mobile MRI services.
629 (iii) 3,500 MRI adjusted procedures per unit for dedicated pediatric MRI units.
630 (iv) Each mobile host site in a rural or micropolitan statistical area county shall have provided at
631 least a total of 400 adjusted procedures during its second 12 months of operation, and annually thereafter,
632 from all mobile units providing services to the site. Each mobile host site not in a rural or micropolitan
633 statistical area county shall have provided at least a total of 600 adjusted procedures during its second 12
634 months of operation and annually thereafter, from all mobile units providing services to the site.
635 (v) In meeting these requirements, an applicant shall not include any MRI adjusted procedures
636 performed on an MRI unit used exclusively for research and approved pursuant to Section 7 or for an IMRI
637 unit approved pursuant to Section 9.
638
639 (b) The applicant shall participate in a data collection network established and administered by the
640 Department or its designee. The data may include, but is not limited to, operating schedules,
641 demographic and diagnostic information, and the volume of care provided to patients from all payor
642 sources, as well as other data requested by the Department or its designee and approved by the
643 Commission. The applicant shall provide the required data in a format established by the Department and
644 in a mutually agreed upon media no later than 30 days following the last day of the quarter for which data
645 are being reported to the Department. An applicant shall be considered in violation of this term of
646 approval if the required data are not submitted to the Department within 30 days following the last day of
647 the quarter for which data are being reported. The Department may elect to verify the data through on-site
648 review of appropriate records. Data for an MRI unit approved pursuant to Section 7, Section 8, Section 9,
649 Section 10, or Section 11 shall be reported separately.
650 For purposes of Section 9, the data reported shall include, at a minimum, how often the IMRI unit is used
651 and for what type of services, i.e., intra-operative or diagnostic. For purposes of Section 10, the data
652 reported shall include, at a minimum, how often the MRI-guided EPI unit is used and for what type of
653 services, i.e., electrophysiology or diagnostic. For purposes of Section 11, the data reported shall include,
654 at a minimum, how often the MRI simulator is used and for what type of services, i.e., treatment plans or
655 diagnostic services.
656 (c) The applicant shall provide the Department with a notice stating the first date on which the MRI
657 unit became operational, and such notice shall be submitted to the Department consistent with applicable
658 statute and promulgated rules.
659 (d) An applicant who is a central service coordinator shall notify the Department of any additions,
660 deletions, or changes in the host sites of each approved mobile MRI unit within 10 days after the
661 change(s) in host sites is made.
662
663 (5) An applicant for an MRI unit approved under Section 7 shall agree that the services provided by
664 the MRI unit are delivered in compliance with the following terms.
665 (a) The capital and operating costs relating to the research use of the MRI unit shall be charged
666 only to a specific research account(s) and not to any patient or third-party payor.
667 (b) The MRI unit shall not be used for any purposes other than as approved by the IRB unless the
668 applicant has obtained CON approval for the MRI unit pursuant to Part 222 and these standards, other
669 than Section 7.
670 (c) The dedicated research MRI unit will be used primarily (70% or more of the procedures) for
671 research purposes only.
672
673 (6) The dedicated pediatric MRI unit approved under Section 8 shall include at least 80% of the
674 MRI procedures that are performed on patients under 18 years of age.
675
676 (7) The agreements and assurances required by this section shall be in the form of a certification
677 agreed to by the applicant or its authorized agent.
678
679

680 **Section 15. MRI procedure adjustments**

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

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

686 (i) fMRI means brain activation studies.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

733 by the Department and as verified for the 12-month period reported on the most recently published "MRI
734 Service Utilization List" as of the date an application is deemed submitted by the Department. The
735 number of MRI procedures actually performed shall be documented by procedure records and not by
736 application of the methodology required in Section 17. The Department may elect to verify the data
737 through on-site review of appropriate records.
738

739 **Section 17. Methodology for computing the number of available MRI adjusted procedures** 740

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

787 (viii) The result shall be the "Available MRI Adjusted Procedures List."
788

789 (2) After publication of the "Available MRI Adjusted Procedures List" resulting from (1) above, the
790 data shall be updated to account for a) doctor commitments of available MRI adjusted procedures in
791 subsequent MRI CON applications and b) MRI adjusted procedures used in subsequent MRI CON
792 applications received in which applicants apply for fixed MRI services pursuant to Section 3(2).
793

794 **Section 18. Procedures and requirements for commitments of available MRI adjusted procedures** 795

796 Sec. 18. (1) If one or more host sites on a mobile MRI service are located within the planning area of
797 the proposed site, the applicant may access available MRI adjusted procedures from the entire mobile
798 MRI service.
799

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

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

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

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

813 (c) If the required documentation for the doctor commitments submitted under this subsection is
814 not submitted with the application on the designated application date, the application will be deemed
815 submitted on the first applicable designated application date after all required documentation is received
816 by the Department.
817

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

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

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

833 (c) A committing doctor certifies that he or she has not been provided, or received a promise of
834 being provided, a financial incentive to commit any of his or her available MRI adjusted procedures to the
835 application.
836

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

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

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

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

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

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

854

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

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

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

874

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

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

884

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

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

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

889

890 (8) The Department shall consider a withdrawal of a signed data commitment if a committing doctor
891 submits a written notice to the Department, that specifies the CON application number and the specific
892 MRI services for which a data commitment is being withdrawn, and if an applicant demonstrates that the
893 requirements of subsection (7) also have been met.
894

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

896

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

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

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

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

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

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

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

908 (ii) The name, address, and license number of each referring doctor, identified in Section
909 17(1)(c)(v), whose patients received MRI services at that MRI service; and

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

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

918 (d) The Department shall not be required to publish a list that sorts MRI database information by
919 referring doctor, only by MRI service.
920

921 (2) When an MRI service begins to operate at a site at which MRI services previously were not
922 provided, the Department shall include in the MRI database, data beginning with the second full quarter of
923 operation of the new MRI service. Data from the start-up date to the start of the first full quarter will not be
924 collected to allow a new MRI service sufficient time to develop its data reporting capability. Data from the
925 first full quarter of operation will be submitted as test data but will not be reported in the lists published
926 pursuant to this section.
927

928 (3) In publishing the lists pursuant to subsections (a) and (b), if an MRI service has not reported
929 data in compliance with the requirements of Section 14, the Department shall indicate on both lists that the
930 MRI service is in violation of the requirements set forth in Section 14, and no data will be shown for that
931 service on either list.
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933 **Section 20. Effect on prior CON Review Standards; Comparative reviews**

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935 Sec. 20. (1) These CON review standards supersede and replace the CON Review Standards for
936 MRI Services approved by the CON Commission on June ~~4413~~, ~~2012-2013~~ and effective September
937 ~~2818~~, ~~2012-2013~~.

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939 (2) Projects reviewed under these standards shall not be subject to comparative review.
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942 **Section 21. Health Service Areas**

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

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946 **HSA** **COUNTIES**

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

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953 2 Clinton Hillsdale Jackson
 954 Eaton Ingham Lenawee

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

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

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965 5 Genesee Lapeer Shiawassee

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

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

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980 8 Alger Gogebic Mackinac
 981 Baraga Houghton Marquette
 982 Chippewa Iron Menominee
 983 Delta Keweenaw Ontonagon
 984 Dickinson Luce Schoolcraft

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CON REVIEW STANDARDS
FOR MRI SERVICES

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

Allegan	<u>HILLSDALE</u>	<u>MASON</u>
Alpena	Houghton	Mecosta
Benzie	<u>IONIA</u>	Menominee
Branch	Isabella	Midland
Chippewa	Kalkaska	Missaukee
Delta	Keweenaw	St. Joseph
Dickinson	Leelanau	Shiawassee
Grand Traverse	Lenawee	Wexford
Gratiot	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry	onia	<u>MONTCALM</u> Newaygo
Bay	Jackson	Muskegon
Berrien	Kalamazoo	Oakland
Calhoun	Kent	Ottawa
Cass	Lapeer	Saginaw
Clinton	Livingston	St. Clair
Eaton	Macomb	Van Buren
Genesee	<u>MIDLAND</u>	Washtenaw
Ingham	Monroe	Wayne

Source:

65-75 F.R., p. 82238-37245 (~~December 27~~JUNE 28, 2000~~2010~~)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget