

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,
23 lease, 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
26 existing MRI unit, or if an MRI service has two or more MRI units at the same site, the average number of
27 MRI 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
31 performed by an existing MRI service in excess of 8,000 per fixed MRI unit and 7,000 per mobile MRI
32 unit. For either a fixed or mobile MRI service, the number of MRI units used to compute available MRI
33 adjusted procedures shall include both existing and approved but not yet operational MRI units. In
34 determining the number of available MRI adjusted procedures, the Department shall use data for the 12-
35 month period reported on the most recently published list of available MRI adjusted procedures as of the
36 date an 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
42 for 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
49 a 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
109 MRI unit approved pursuant to Section 7.

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

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

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

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

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

125 (ii) "Ownership interest, direct or indirect" means a direct ownership relationship between a doctor
126 and an applicant entity or an ownership relationship between a doctor and an entity that has an
127 ownership relationship with an applicant entity.

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

129 (kk) "Planning area" means

130 (i) in the case of a proposed fixed MRI service or unit, the geographic area within a 20-mile radius
131 from the proposed site if the proposed site is not in a rural or micropolitan statistical area county and a
132 75-mile radius from the proposed site if the proposed site is in a rural or micropolitan statistical area
133 county.

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

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

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

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

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

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

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

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

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

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

158 (qq) "Site" means

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

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

163 (rr) "Special needs patient" means a non-sedated patient, either pediatric or adult, with any of the
164 following conditions: down syndrome, autism, attention deficit hyperactivity disorder (ADHD),
165 developmental delay, malformation syndromes, hunter's syndrome, multi-system disorders, psychiatric
166 disorders, IMPLANTABLE CARDIAC DEVICES (ICDS), and other conditions that make the patient
167 unable to comply with the positional requirements of the exam OR IS UNABLE TO COMPLY WITH THE
168 MOTIONLESS REQUIREMENTS AND WHOSE RESULTING MOVEMENTS RESULT IN NON-
169 DIAGNOSTIC QUALITY IMAGES THEREFORE REQUIRING THE TECHNOLOGIST TO REPEAT THE
170 SAME SEQUENCE IN AN ATTEMPT TO OBTAIN A DIAGNOSTIC QUALITY IMAGE.

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

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

177
178 (2) Terms defined in the Code have the same meanings when used in these standards.
179

180 **Section 3. Requirements to initiate an MRI service**

181
182 Sec. 3. An applicant proposing to initiate an MRI service or a host site shall demonstrate the
183 following requirements, as applicable:
184

185 (1) An applicant proposing to initiate a fixed MRI service shall demonstrate 6,000 available MRI
186 adjusted procedures per proposed fixed MRI unit from within the same planning area as the proposed
187 service/unit.
188

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

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

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

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

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

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

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

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

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

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

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

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

208 (e) The applicant shall cease operation as a host site and not become a host site for at least 12
209 months from the date the fixed service and its unit becomes operational.
210

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

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

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

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

218

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

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

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

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

227

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

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

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

234

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

239

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

241

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

252

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

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

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

259

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

264
265 (3) An applicant proposing to replace an existing MRI unit shall demonstrate the following
266 requirements, ~~as applicable:~~

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

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

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

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

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

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

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

285 ~~(eb)~~ The replacement unit shall be located at the same site.

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

291
292 (4) An applicant proposing to replace an existing mobile MRI host site to a new location shall
293 demonstrate the following:

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

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

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

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

302 ~~(ed)~~ The relocation will not involve a change in the current central service coordinator unless the
303 requirements of Section 3(5) are met.

304
305 (5) An applicant proposing to replace an existing fixed MRI service and its unit(s) to a new site
306 shall demonstrate the following:

307 (a) The existing MRI service and its unit(s) to be replaced has been in operation for at least 36
308 months as of the date an application is submitted to the Department UNLESS THE APPLICANT MEETS
309 THE REQUIREMENT IN SUBSECTION (c)(i) OR (ii).

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

311 (c) Each existing MRI unit to be relocated performed at least the applicable minimum number of
312 MRI adjusted procedures set forth in Section 14 based on the most recently published MRI Service
313 Utilization List as of the date an application is deemed submitted by the Department, UNLESS ONE OF
314 THE FOLLOWING REQUIRMENTS ARE MET-:

315 (i) THE OWNER OF THE BUILDING WHERE THE SITE IS LOCATED HAS INCURRED A
316 FILING FOR BANKRUPTCY UNDER CHAPTER SEVEN (7) WITHIN THE LAST THREE YEARS;

317 (ii) THE OWNERSHIP OF THE BUILDING WHERE THE SITE IS LOCATED HAS CHANGED
318 WITHIN 24 MONTHS OF THE DATE OF THE SERVICE BEING OPERATIONAL; OR
319 (iii) THE MRI SERVICE BEING REPLACED IS PART OF THE REPLACEMENT OF AN ENTIRE
320 HOSPITAL TO A NEW GEOGRAPHIC SITE AND HAS ONLY ONE (1) MRI UNIT.

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

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

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

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

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

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

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
339 most recently published MRI Service Utilization List as of the date of an application is deemed submitted
340 by the Department:

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

343 (b) Each existing fixed MRI unit at the current site has performed at least an average of 11,000
344 MRI 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 **Section 6. Requirements to acquire an existing MRI service or an existing MRI unit(s)**

351
352 Sec. 6. ~~(1)~~ An applicant proposing to acquire an existing fixed or mobile MRI service and its unit(s)
353 shall demonstrate the following:

354 ~~(a1)~~ For the first application proposing to acquire an existing fixed or mobile MRI service on or after
355 July 1, 1997, the existing MRI service and its unit(s) to be acquired shall not be required to be in
356 compliance with the volume requirements applicable to a seller/lessor on the date the acquisition occurs.
357 The MRI service shall be operating at the applicable volume requirements set forth in Section 14 of
358 these standards in the second 12 months after the effective date of the acquisition, and annually
359 thereafter.

360
361 ~~(b2)~~ For any application proposing to acquire an existing fixed or mobile MRI service and its unit(s),
362 except the first application approved pursuant to subsection (a), an applicant shall be required to
363 document that the MRI service and its unit(s) to be acquired is operating in compliance with the volume
364 requirements set forth in Section 14 of these standards applicable to an existing MRI service on the date
365 the application is submitted to the Department.
366
367
368

369 (23) An applicant proposing to acquire an existing fixed or mobile MRI unit of an existing MRI
370 service shall demonstrate that the proposed project meets all of the following, AS APPLICABLE:

371 (a) AN APPLICANT SHALL DEMONSTRATE THAT THE APPLICABLE MRI ADJUSTABLE
372 PROCEDURES ARE FROM THE MOST RECENTLY PUBLISHED MRI SERVICE UTILIZATION LIST
373 AS OF THE DATE OF AN APPLICATION IS DEEMED SUBMITTED BY THE DEPARTMENT:

374 (i)- THE FIXED MRI UNIT(S) TO BE ACQUIRED PERFORMED AT LEAST 6,000 MRI ADJUSTED
375 PROCEDURES PER FIXED MRI UNIT.

376 (ii) THE MOBILE MRI UNIT(S) TO BE ACQUIRED PERFORMED AT LEAST 5,500 MRI
377 ADJUSTED PROCEDURES PER MOBILE MRI UNIT.

378 (b) The project will not change the number of MRI units at the site ~~of the MRI service~~ FROM
379 WHICH THE NUMBER OF UNITS ARE being acquired, subject to the applicable requirements under
380 Section 4(6), unless the applicant demonstrates that the project is in compliance with the requirements of
381 the initiation or expansion Section, as applicable.

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

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

385
386
387 Sec. 7. An applicant proposing an MRI unit to be used exclusively for research shall demonstrate the
388 following:

389
390 (1) The applicant agrees that the dedicated research MRI unit will be used primarily (70% or more
391 of the procedures) for research purposes only.

392
393 (2) Submit copies of documentation demonstrating that the applicant operates a diagnostic
394 radiology residency program approved by the Accreditation Council for Graduate Medical Education, the
395 American Osteopathic Association, or an equivalent organization.

396
397 (3) Submit copies of documentation demonstrating that the MRI unit shall operate under a protocol
398 approved by the applicant's IRB.

399
400 (4) An applicant meeting the requirements of this section shall be exempt from meeting the
401 requirements of sections to initiate and replace.

402
403 (5) THE DEDICATED RESEARCH MRI UNIT APPROVED UNDER THIS SECTION MAY NOT
404 UTILIZE MRI ADJUSTED PROCEDURES PERFORMED ON THE DEDICATED MRI UNIT TO
405 DEMONSTRATE NEED OR TO SATISFY MRI CON REVIEW STANDARDS REQUIREMENTS.

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

407
408
409 Sec. 8. An applicant proposing to establish dedicated pediatric MRI shall demonstrate all of the
410 following:

411
412 (1) The applicant shall have experienced at least 7,000 pediatric (< 18 years old) discharges
413 (excluding normal newborns) in the most recent year of operation.

414
415 (2) The applicant shall have performed at least 5,000 pediatric (< 18 years old) surgeries in the
416 most recent year of operation.

417
418 (3) The applicant shall have an active medical staff that includes, but is not limited to, physicians
419 who are fellowship-trained in the following pediatric specialties:

420 (a) pediatric radiology (at least two)

421 (b) pediatric anesthesiology

- 422 (c) pediatric cardiology
- 423 (d) pediatric critical care
- 424 (e) pediatric gastroenterology
- 425 (f) pediatric hematology/oncology
- 426 (g) pediatric neurology
- 427 (h) pediatric neurosurgery
- 428 (i) pediatric orthopedic surgery
- 429 (j) pediatric pathology
- 430 (k) pediatric pulmonology
- 431 (l) pediatric surgery
- 432 (m) neonatology

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

- 435 (a) pediatric bone marrow transplant program
- 436 (b) established pediatric sedation program
- 437 (c) pediatric open heart program

438 (5) An applicant meeting the requirements of this section shall be exempt from meeting the
439 requirements of Section 5 of these standards.

440
441 **Section 9. Requirements for all applicants proposing to initiate, replace, or acquire a hospital**
442 **based IMRI**

443
444 Sec. 9. An applicant proposing to initiate, replace, or acquire a hospital based IMRI service shall
445 demonstrate each of the following, as applicable to the proposed project.

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

447 (2) The proposed site has an existing fixed MRI service that has been operational for the previous
448 36 consecutive months and is meeting its minimum volume requirements.

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

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

- 452 (a) at least 1,500 oncology discharges in the most recent year of operation; or
- 453 (b) at least 1,000 neurological surgeries in the most recent year of operation; or
- 454 (c) at least 7,000 pediatric (<18 years old) discharges (excluding normal newborns) and at least
455 5,000 pediatric (<18 years old) surgeries in the most recent year of operation.

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

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

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

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

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

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

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

- (1) The proposed site is a licensed hospital under part 215 of the Code.
- (2) The proposed site has an existing fixed MRI service that has been operational for the previous 36 consecutive months and is meeting its minimum volume requirements.
- (3) The proposed site has an existing and operational therapeutic cardiac catheterization service and is meeting its minimum volume requirements pursuant to the CON review standards for cardiac catheterization services and open heart surgery services.
- (4) The proposed MRI-guided EPI unit must be located in a cardiac catheterization lab containing a flouroscopy unit with an adjoining room containing an MRI scanner. The rooms shall contain a patient transfer system allowing for transfer of the patient between the cardiac catheterization lab and the MRI unit, utilizing one of the following:
 - (a) moving the patient to the MRI scanner, or
 - (b) installing the MRI scanner on a sliding gantry to allow the patient to remain stationary.
- (5) Non-cardiac MRI diagnostic studies shall not be performed in an MRI-guided EPI unit approved under this section unless the patient meets one of the following criteria:
 - (a) The patient has been admitted to an inpatient unit; or
 - (b) The patient is having the study performed on an outpatient basis as follows:
 - (i) is in need of general anesthesia or deep sedation as defined by the American Society of Anesthesiologists, or
 - (ii) has an implantable cardiac device.
- (6) The approved MRI-guided EPI unit shall not be subject to MRI volume requirements.
- (7) The applicant shall not utilize the procedures performed on the MRI-guided EPI unit to demonstrate need or to satisfy MRI CON review standards requirements.

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

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

- (1) The proposed site has an existing fixed MRI service that has been operational for the previous 36 consecutive months and is meeting its minimum volume requirements.
- (2) The proposed site has an existing and operational MRT service and is meeting its minimum volume requirements pursuant to the CON review standards for MRT services/units.
- (3) MRI diagnostic studies shall not be performed using an MRI simulator approved under this section unless the patient meets one of the following criteria:
 - (a) The patient has been admitted to an inpatient unit; or

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

530

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

532

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

535

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

538

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

541

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

545

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

548

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

551

552 (4) An FDA-approved PET/MRI scanner hybrid approved under the CON review standards for PET
553 scanner services and the review standards for MRI scanner services may not utilize MRI procedures
554 performed on an FDA-approved PET/MRI scanner hybrid to demonstrate need or to satisfy MRI CON
555 review standards requirements.

556

557 **Section 13. Requirements for all applicants**

558

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

562

563 **Section 14. Project delivery requirements – terms of approval**

564

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

567

568 (1) Compliance with these standards.

569

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

571

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

574

575 (b) An applicant shall establish a schedule for preventive maintenance for the MRI unit.
576 (c) An applicant shall provide documentation identifying the specific individuals that form the MRI
577 team. At a minimum, the MRI team shall consist of the following professionals:

577

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

580

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

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

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

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

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

587 (B) The physician has had at least 60 hours of training in MRI physics, MRI safety, and MRI
588 instrumentation in a program that is part of an imaging program accredited by the Accreditation Council
589 for Graduate Medical Education or the American Osteopathic Association, and the physician meets the
590 requirements of subdivision (1), (2), or (3):

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

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

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

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

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

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

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

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

622

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

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

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

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

631 (d) The operation of and referral of patients to the MRI unit shall be in conformance with 1978 PA
632 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

633

634 (4) Compliance with the following monitoring and reporting requirements:
635 (a) MRI units shall be operating at a minimum average annual utilization during the second 12
636 months of operation, and annually thereafter, as applicable:
637 (i) 6,000 MRI adjusted procedures per unit for fixed MRI services unless compliant with (4A) or
638 (2B),
639 (A) 4,000 MRI adjusted procedures for the fixed MRI unit initiated pursuant to Section 3(2)(b)(ii)
640 and is the only fixed MRI unit at the current site,
641 (B) 3,000 MRI adjusted procedures for the fixed MRI unit initiated pursuant to Section 3(2)(b)(iii)
642 and is the only fixed MRI unit at the hospital site licensed under part 215 of the code,
643 (ii) 5,500 MRI adjusted procedures per unit for mobile MRI services.
644 (iii) 3,500 MRI adjusted procedures per unit for dedicated pediatric MRI units.
645 (iv) Each mobile host site in a rural or micropolitan statistical area county shall have provided at
646 least a total of 400 adjusted procedures during its second 12 months of operation, and annually
647 thereafter, from all mobile units providing services to the site. Each mobile host site not in a rural or
648 micropolitan statistical area county shall have provided at least a total of 600 adjusted procedures during
649 its second 12 months of operation and annually thereafter, from all mobile units providing services to the
650 site.
651 (v) In meeting these requirements, an applicant shall not include any MRI adjusted procedures
652 performed on an MRI unit used exclusively for research and approved pursuant to Section 7 or for an
653 IMRI unit approved pursuant to Section 9.
654
655 (b) The applicant shall participate in a data collection network established and administered by the
656 Department or its designee. The data may include, but is not limited to, operating schedules,
657 demographic and diagnostic information, and the volume of care provided to patients from all payor
658 sources, as well as other data requested by the Department or its designee and approved by the
659 Commission. The applicant shall provide the required data in a format established by the Department
660 and in a mutually agreed upon media no later than 30 days following the last day of the quarter for which
661 data are being reported to the Department. An applicant shall be considered in violation of this term of
662 approval if the required data are not submitted to the Department within 30 days following the last day of
663 the quarter for which data are being reported. The Department may elect to verify the data through
664 on-site review of appropriate records. Data for an MRI unit approved pursuant to Section 7, Section 8,
665 Section 9, Section 10, or Section 11 shall be reported separately.
666 For purposes of Section 9, the data reported shall include, at a minimum, how often the IMRI unit is used
667 and for what type of services, i.e., intra-operative or diagnostic. For purposes of Section 10, the data
668 reported shall include, at a minimum, how often the MRI-guided EPI unit is used and for what type of
669 services, i.e., electrophysiology or diagnostic. For purposes of Section 11, the data reported shall
670 include, at a minimum, how often the MRI simulator is used and for what type of services, i.e., treatment
671 plans or diagnostic services.
672 (c) The applicant shall provide the Department with a notice stating the first date on which the MRI
673 unit became operational, and such notice shall be submitted to the Department consistent with applicable
674 statute and promulgated rules.
675 (d) An applicant who is a central service coordinator shall notify the Department of any additions,
676 deletions, or changes in the host sites of each approved mobile MRI unit ~~within 10 days~~ after the
677 change(s) in host sites is made.
678
679 (5) An applicant for an MRI unit approved under Section 7 shall agree that the services provided
680 by the MRI unit are delivered in compliance with the following terms.
681 (a) The capital and operating costs relating to the research use of the MRI unit shall be charged
682 only to a specific research account(s) and not to any patient or third-party payor.
683 (b) The MRI unit shall not be used for any purposes other than as approved by the IRB unless the
684 applicant has obtained CON approval for the MRI unit pursuant to Part 222 and these standards, other
685 than Section 7.

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

688
689 (6) The dedicated pediatric MRI unit approved under Section 8 shall include at least 80% of the
690 MRI procedures that are performed on patients under 18 years of age.

691
692 (7) The agreements and assurances required by this section shall be in the form of a certification
693 agreed to by the applicant or its authorized agent.

694

695 **Section 15. MRI procedure adjustments**

696

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

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

701 (i) fMRI means brain activation studies.

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

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

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

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

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

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

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

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

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

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

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

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

723

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

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

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

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

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

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

741
742 (3) The number of MRI adjusted procedures performed by an existing MRI service is the sum of
743 the results of subsections (1) and (2).

744
745 **Section 16. Documentation of actual utilization**

746
747 Sec. 16. Documentation of the number of MRI procedures performed by an MRI unit shall be
748 substantiated by the Department utilizing data submitted by the applicant in a format and media specified
749 by the Department and as verified for the 12-month period reported on the most recently published "MRI
750 Service Utilization List" as of the date an application is deemed submitted by the Department. The
751 number of MRI procedures actually performed shall be documented by procedure records and not by
752 application of the methodology required in Section 17. The Department may elect to verify the data
753 through on-site review of appropriate records.

754
755 **Section 17. Methodology for computing the number of available MRI adjusted procedures**

756
757 Sec. 17. (1) The number of available MRI adjusted procedures required pursuant to Section 3 shall
758 be computed in accordance with the methodology set forth in this section. In applying the methodology,
759 the following steps shall be taken in sequence, and data for the 12-month period reported on the most
760 recently published "Available MRI Adjusted Procedures List," as of the date an application is deemed
761 submitted by the Department, shall be used:

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

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

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

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

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

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

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

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

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

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

789 (iii) For each MRI service, the available MRI adjusted procedures resulting from the calculation in
790 (c)(ii) above shall be sorted in descending order by the available MRI adjusted procedures for each

791 doctor. Then any duplicate values shall be sorted in descending order by the doctors' license numbers
792 (last 6 digits only).

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

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

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

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

804 (viii) The result shall be the "Available MRI Adjusted Procedures List."
805

806 (2) After publication of the "Available MRI Adjusted Procedures List" resulting from (1) above, the
807 data shall be updated to account for a) doctor commitments of available MRI adjusted procedures in
808 subsequent MRI CON applications and b) MRI adjusted procedures used in subsequent MRI CON
809 applications received in which applicants apply for fixed MRI services pursuant to Section 3(2).
810

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

812
813 Sec. 18. (1) If one or more host sites on a mobile MRI service are located within the planning area of
814 the proposed site, the applicant may access available MRI adjusted procedures from the entire mobile
815 MRI service.
816

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

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

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

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

830 (c) If the required documentation for the doctor commitments submitted under this subsection is
831 not submitted with the application on the designated application date, the application will be deemed
832 submitted on the first applicable designated application date after all required documentation is received
833 by the Department.
834

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

838 (a) A committing doctor certifies that 100% of his or her available MRI adjusted procedures for
839 each specified MRI service, calculated pursuant to Section 17, is being committed and specifies the CON
840 application number for the MRI unit to which the data commitment is made. A doctor shall not be
841 required to commit available MRI adjusted procedures from all MRI services to which his or her patients

842 are referred for MRI services but only from those MRI services specified by the doctor in the data
843 commitment form provided by the Department and submitted by the applicant in support of its application.

844 (b) A committing doctor certifies ownership interest, either direct or indirect, in the applicant entity.
845 Indirect ownership includes ownership in an entity that has ownership interest in the applicant entity. This
846 requirement shall not apply if the applicant entity is a group practice of which the committing doctor is a
847 member. Group practice means a group practice as defined pursuant to the provisions of 42 U.S.C.
848 1395nn (h)(4), commonly known as Stark II, and the Code of Federal Regulations, 42 CFR, Part 411,
849 published in the Federal Register on August 14, 1995, or its replacement.

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

853
854 (4)(a) The Department shall not consider a data commitment from a doctor for available MRI adjusted
855 procedures from a specific MRI service if the available MRI adjusted procedures from that specific MRI
856 service were used to support approval of an application for a new ~~or additional~~ MRI unit, pursuant to
857 Section 3, for which a final decision to approve has been issued by the Director of the Department until
858 either of the following occurs:

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

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

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

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

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

871
872 (5) The Department shall not consider a data commitment from a committing doctor for available
873 MRI adjusted procedures from the same MRI service if that doctor has submitted a signed data
874 commitment, on a form provided by Department, for more than one (1) application for which a final
875 decision has not been issued by the Department. If the Department determines that a doctor has
876 submitted a signed data commitment for the same available MRI adjusted procedures from the same MRI
877 service to more than one CON application pending a final decision for a new fixed or mobile MRI unit or
878 additional mobile MRI unit pursuant to Section 3, the Department shall,

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

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

892
893 (6) The Department shall not consider any data commitment submitted by an applicant after the
894 date an application is deemed submitted unless an applicant is notified by the Department, pursuant to

895 subsection (5), that one or more committing doctors submitted data commitments for available MRI
896 adjusted procedures from the same MRI service. If an applicant is notified that one or more doctors' data
897 commitments will not be considered by the Department, the Department shall consider data commitments
898 submitted after the date an application is deemed submitted only to the extent necessary to replace the
899 data commitments not being considered pursuant to subsection (5).

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

902
903 (7) ~~In accordance with either of the following, t~~The Department shall not consider a withdrawal of a
904 signed data commitment:

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

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

907
908 (8) The Department shall consider a withdrawal of a signed data commitment if a committing
909 doctor submits a written notice to the Department **BEFORE THE APPLICATION IS DEEMED**
910 **SUBMITTED**, that specifies the CON application number and the specific MRI services for which a data
911 commitment is being withdrawn, ~~and if an applicant demonstrates that the requirements of subsection (7)~~
912 ~~also have been met.~~

913 914 **Section 19. Lists published by the Department**

915
916 Sec. 19. (1) On or before May 1 and November 1 of each year, the Department shall publish the
917 following lists:

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

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

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

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

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

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

927 (ii) The name, address, and license number of each referring doctor, identified in Section
928 17(1)(c)(v), whose patients received MRI services at that MRI service; and

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

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

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

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

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

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

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954 Sec. 20. (1) These CON review standards supersede and replace the CON Review Standards for
955 MRI Services approved by the CON Commission on ~~June 13, 2013~~September 25, 2014 and effective
956 ~~September 18, 2013~~December 22, 2014.

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

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961 **Section 21. Health Service Areas**

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

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965 **HSA**

COUNTIES

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968	1	Livingston	Monroe	St. Clair
969		Macomb	Oakland	Washtenaw
970		Wayne		

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972	2	Clinton	Hillsdale	Jackson
973		Eaton	Ingham	Lenawee

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975	3	Barry	Calhoun	St. Joseph
976		Berrien	Cass	Van Buren
977		Branch	Kalamazoo	

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979	4	Allegan	Mason	Newaygo
980		Ionia	Mecosta	Oceana
981		Kent	Montcalm	Osceola
982		Lake	Muskegon	Ottawa

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984	5	Genesee	Lapeer	Shiawassee
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986	6	Arenac	Huron	Roscommon
987		Bay	Iosco	Saginaw
988		Clare	Isabella	Sanilac
989		Gladwin	Midland	Tuscola
990		Gratiot	Ogemaw	

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992	7	Alcona	Crawford	Missaukee
993		Alpena	Emmet	Montmorency
994		Antrim	Gd Traverse	Oscoda
995		Benzie	Kalkaska	Otsego
996		Charlevoix	Leelanau	Presque Isle
997		Cheboygan	Manistee	Wexford

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999	8	Alger	Gogebic	Mackinac
1000		Baraga	Houghton	Marquette
1001		Chippewa	Iron	Menominee
1002		Delta	Keweenaw	Ontonagon
1003		Dickinson	Luce	Schoolcraft

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Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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