

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

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

10 **Section 1. Applicability**
11

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

19 **Section 2. Definitions**
20

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

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

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

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

38 ~~—In the case of an MRI service that operates, or has a valid CON to operate, more than one fixed MRI~~
39 ~~unit at the same site, the term means the number of MRI adjusted procedures in excess of 8,000~~
40 ~~multiplied by the number of fixed MRI units at the same site. For example, if an MRI service operates, or~~
41 ~~has a valid CON to operate, two fixed MRI units at the same site, the available number of MRI adjusted~~
42 ~~procedures is the number that is in excess of 16,000 (8,000 x 2) MRI adjusted procedures. [Please note~~
43 ~~that this needs to be removed as it is no longer applicable with the ala carte language.]~~

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

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

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

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

- 54 (g) "Contrast MRI procedure" means an MRI procedure involving either of the following: (i) a
55 procedure following use of a contrast agent or (ii) procedures performed both before and after the use of
56 a contrast agent.
- 57 (h) "Dedicated pediatric MRI" means an MRI unit on which at least 80% of the MRI procedures are
58 performed on patients under 18 years of age
- 59 (i) "Department" means the Michigan Department of Community Health (MDCH).
- 60 (j) "Doctor" means an individual licensed under Article 15 of the Code to engage in the practice of
61 medicine, osteopathic medicine and surgery, chiropractic, dentistry, or podiatry.
- 62 (k) "Existing MRI service" means either the utilization of a CON-approved and operational MRI
63 unit(s) at one site in the case of a fixed MRI service, and in the case of a mobile MRI service, the
64 utilization of a CON-approved and operational mobile MRI unit(s) at each host site, on the date an
65 application is submitted to the Department.
- 66 (l) "Existing MRI unit" means a CON-approved and operational MRI unit used to provide MRI
67 services.
- 68 (m) "Expand an existing fixed MRI service" means an increase in the number of fixed MRI units to
69 be operated by the applicant.
- 70 (n) "Expand an existing mobile MRI service" means the addition of a mobile MRI unit that will be
71 operated by a central service coordinator that is approved to operate one or more mobile MRI units as of
72 the date an application is submitted to the Department.
- 73 (o) "Group practice" means a group practice as defined pursuant to the provisions of 42 U.S.C.
74 1395nn (h)(4), commonly known as Stark II, and the Code of Federal Regulations, 42 CFR, Part 411,
75 published in the Federal Register on August 14, 1995, or its replacement.
- 76 (p) "Health service area" or "HSA" means the geographic areas set forth in Section 19.
- 77 (q) "Host site" means the site at which a mobile MRI unit is authorized by CON to provide MRI
78 services.
- 79 (r) "Initiate a fixed MRI service" means begin operation of a fixed MRI service at a site that does
80 not provide or is not CON approved to provide fixed MRI services as of the date an application is
81 submitted to the Department. The term does not include the acquisition or relocation of an existing fixed
82 MRI service or the renewal of a lease.
- 83 (s) "Initiate a mobile MRI host site" means the provision of MRI services at a host site that has not
84 received any MRI services within 12 months from the date an application is submitted to the Department.
85 The term does not include the renewal of a lease.
- 86 (t) "Initiate a mobile MRI service" means begin operation of a mobile MRI unit that serves two or
87 more host sites.
88 The term does not include the acquisition of an existing mobile MRI service or the renewal of a
89 lease.
- 90 (u) "Inpatient" means an MRI visit involving an individual who has been admitted to the licensed
91 hospital at the site of the MRI service/unit or in the case of an MRI unit that is not located at that licensed
92 hospital site, an admitted patient transported from a licensed hospital site by ambulance to the MRI
93 service.
- 94 (v) "Institutional review board" or "IRB" means an institutional review board as defined by Public
95 Law 93-348 that is regulated by Title 45 CFR 46.
- 96 (w) "Intra-operative magnetic resonance imaging" or "IMRI" means the integrated use of MRI
97 technology during surgical and interventional procedures within a licensed operative environment.
- 98 (x) "Licensed hospital site" means the location of the hospital authorized by license and listed on
99 that licensee's certificate of licensure.
- 100 (y) "Magnetic resonance imaging" or "MRI" means the analysis of the interaction that occurs
101 between radio frequency energy, atomic nuclei, and strong magnetic fields to produce cross sectional
102 images similar to those displayed by computed tomography (CT) but without the use of ionizing radiation.
- 103 (z) "MRI adjusted procedure" means an MRI visit, at an existing MRI service, that has been
104 adjusted in accordance with the applicable provisions of Section 13.
- 105 (aa) "MRI database" means the database, maintained by the Department pursuant to Section 12 of
106 these standards, that collects information about each MRI visit at MRI services located in Michigan.

107 (bb) "MRI procedure" means a procedure conducted by an MRI unit approved pursuant to sections
108 3, 4, 5, 6, 7, or 9 of these standards which is either a single, billable diagnostic magnetic resonance
109 procedure or a procedure conducted by an MRI unit at a site participating with an approved diagnostic
110 radiology residency program, under a research protocol approved by an IRB. The capital and operating
111 costs related to the research use are charged to a specific research account and not charged to or
112 collected from third-party payors or patients. The term does not include a procedure conducted by an
113 MRI unit approved pursuant to Section 8(1).

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

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

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

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

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

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

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

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

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

140 (ll) "Planning area" means

141 (i) in the case of a proposed fixed MRI service or unit, the geographic area within a 20-mile radius
142 from the proposed site if the proposed site is not in a rural or micropolitan statistical area county and a
143 75-mile radius from the proposed site if the proposed site is in a rural or micropolitan statistical area
144 county.

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

149 (iii) in the case of a proposed mobile MRI service or unit meeting the requirement of Section
150 13(2)(d), the health service area in which all the proposed mobile host sites will be located.

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

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

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

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

162 (qq) "Replace an existing MRI unit" means (i) any equipment change involving a change in, or
163 replacement of, the magnet resulting in an applicant operating the same number and type (fixed or
164 mobile) of MRI units before and after project completion or (ii) an equipment change other than a change
165 in the magnet that involves a capital expenditure of \$750,000 or more in any consecutive 24-month
166 period or (iii) the renewal of a lease. The term does not include an upgrade of an existing MRI service or
167 unit, and it does not include a host site that proposes to receive mobile MRI services from a different
168 central service coordinator if the requirements of Section 3(5) have been met.

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

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

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

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

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

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

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

185 (vv) "Site" means

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

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

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

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

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

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

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

205 (ii) involves a capital expenditure **RELATED TO THE MRI EQUIPMENT** of less than \$750,000 in
206 any consecutive 24-month period.

207
208 (2) Terms defined in the Code have the same meanings when used in these standards.
209

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

212 Sec. 3. An applicant proposing to initiate an MRI service or a host site shall demonstrate the
213 following requirements, as applicable:
214

215 (1) An applicant proposing to initiate a fixed MRI service shall demonstrate 6,000 available MRI
216 adjusted procedures per proposed fixed MRI unit from within the same planning area as the proposed
217 service/unit.
218

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

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

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

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

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

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

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

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

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

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

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

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

238 (e) The applicant shall cease operation as a host site and not become a host site for at least 12
239 months from the date the fixed service and its unit becomes operational.
240

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

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

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

247 (c) Identify a minimum of two (2) host sites for the proposed service.
248

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

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

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

255 (c) The proposed host site has not received any mobile MRI service within the most recent 12-
256 month period as of the date an application is submitted to the Department.
257

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

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

262 (b) Submit copies of all proposed contracts for the proposed host site related to the mobile MRI
263 service.
264

265 (6) The applicant shall demonstrate that the available MRI adjusted procedures **FROM THE**
266 **AVAILABLE MRI ADJUSTED PROCEDURES LIST OR THE ADJUSTED PROCEDURES FROM THE**
267 **MRI SERVICE UTILIZATION LIST, AS APPLICABLE,** are from the most recently published available MRI
268 ~~adjusted procedures list~~**LISTS** as of the date an application is deemed submitted by the Department.
269

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

271
272 Sec. 4. An applicant proposing to replace an existing MRI unit shall demonstrate the following
273 requirements, as applicable:
274

275 (1) 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 AND MEETS ONE OF THE FOLLOWING:**

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

280 (b) Each existing fixed MRI unit at the current site has performed at least an average of 6,000 MRI
281 adjusted procedures per MRI unit **UNLESS THE APPLICANT DEMONSTRATES COMPLIANCE WITH**
282 **ONE OF THE FOLLOWING-:**

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

285 **(I) THE EXISTING FIXED MRI UNIT INITIATED PURSUANT TO SECTION 3(2)(B)(II) HAS**
286 **PERFORMED AT LEAST 4,000 MRI ADJUSTED PROCEDURES AND IS THE ONLY FIXED MRI UNIT**
287 **AT THE CURRENT SITE.**

288 **(II) THE EXISTING FIXED MRI UNIT INITIATED PURSUANT TO SECTION 3(2)(B)(III) HAS**
289 **PERFORMED AT LEAST 3,000 MRI ADJUSTED PROCEDURES AND IS THE ONLY FIXED MRI UNIT**
290 **AT THE CURRENT SITE.**

291 **(C) EACH EXISTING DEDICATED PEDIATRIC MRI UNIT AT THE CURRENT SITE HAS**
292 **PERFORMED AT LEAST AN AVERAGE OF 3,500 MRI ADJUSTED PROCEDURES PER MRI UNIT.**
293

294 (2) Equipment that is replaced shall be removed from service and disposed of or rendered
295 considerably inoperable on or before the date that the replacement equipment becomes operational.
296

297 (3) The replacement unit shall be located at the same site unless the requirements of the
298 relocation section have been met.
299

300 (4) An applicant proposing to replace an existing MRI unit that does not involve a renewal of a
301 lease shall demonstrate that the MRI unit to be replaced is fully depreciated according to generally
302 accepted accounting principles; the existing equipment clearly poses a threat to the safety of the public;
303 or the proposed replacement equipment offers a significant technological improvement which enhances
304 quality of care, increases efficiency, and reduces operating costs.
305

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

307
308 Sec. 5. An applicant proposing to expand an existing MRI service shall demonstrate the following:
309

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

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

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

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

319
320 (2) The additional fixed unit shall be located at the same site unless the requirements of the
321 relocation section have been met.
322

323 **Section 6. Requirements to relocate an existing fixed MRI service and/or MRI unit(s)**
324

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

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

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

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

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

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

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

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

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

344 (e) For volume purposes, the new site shall remain associated to the original site for a minimum of
345 three years.
346

347 **Section 7. Requirements to acquire an existing MRI service or an existing MRI unit(s)**
348

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

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

357 (b) For any application proposing to acquire an existing fixed or mobile MRI service and its unit(s),
358 except the first application approved pursuant to subsection (a), an applicant shall be required to
359 document that the MRI service and its unit(s) to be acquired is operating in compliance with the volume
360 requirements set forth in Section 12 of these standards applicable to an existing MRI service on the date
361 the application is submitted to the Department.
362

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

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

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

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

373
374 Sec. 8. An applicant proposing an MRI unit to be used exclusively for research shall demonstrate the
375 following:

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

379
380 (2) Submit copies of documentation demonstrating that the MRI unit shall operate under a protocol
381 approved by the applicant's IRB.

382
383 (3) An applicant meeting the requirements of this section shall be exempt from meeting the
384 requirements of sections to initiate and replace.

385
386 **Section 9. Requirements to establish a dedicated pediatric MRI unit**

387
388 Sec. 9. (1) An applicant proposing to establish dedicated pediatric MRI shall demonstrate all of the
389 following:

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

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

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

396 (i) pediatric radiology (at least two)

397 (ii) pediatric anesthesiology

398 (iii) pediatric cardiology

399 (iv) pediatric critical care

400 (v) pediatric gastroenterology

401 (vi) pediatric hematology/oncology

402 (vii) pediatric neurology

403 (viii) pediatric neurosurgery

404 (ix) pediatric orthopedic surgery

405 (x) pediatric pathology

406 (xi) pediatric pulmonology

407 (xii) pediatric surgery

408 (xiii) neonatology

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

410 (i) pediatric bone marrow transplant program

411 (ii) established pediatric sedation program

412 (iii) pediatric open heart program

413
414 (2) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the
415 requirements of Section 5 of these standards.

416
417 **Section 10. Pilot program requirements for approval – applicants proposing to initiate, replace, or**
418 **acquire a hospital based IMRI**

419
420 Sec. 10. As a pilot program, an applicant proposing to initiate, replace, or acquire a hospital based IMRI
421 service shall demonstrate that it meets all of the following:

422
423 (1) The proposed site is a licensed hospital under Part 215 of the Code.

424
425 (2) The proposed site has an existing fixed MRI service that has been operational for the previous
426 36 consecutive months and is meeting its minimum volume requirements.

427
428 (3) The proposed site has an existing and operational surgical service and is meeting its minimum
429 volume requirements pursuant to the CON Review Standards for Surgical Services.

430
431 (4) The applicant shall have experienced one of the following:
432 (a) at least 1,500 oncology discharges in the most recent year of operation; or
433 (b) at least 1,000 neurological surgeries in the most recent year of operation; or
434 (c) at least 7,000 pediatric (<18 years old) discharges (excluding normal newborns) and at least
435 5,000 pediatric (<18 years old) surgeries in the most recent year of operation.

436
437 (5) The proposed IMRI unit must be located in an operating room or a room adjoining an operating
438 room allowing for transfer of the patient between the operating room and this adjoining room.

439
440 (6) Non-surgical diagnostic studies shall not be performed on an IMRI unit approved under this
441 section unless the patient meets one of the following criteria:
442 (a) the patient has been admitted to an inpatient unit; or
443 (b) the patient is having the study performed on an outpatient basis, but is in need of general
444 anesthesia or deep sedation as defined by the American Society of Anesthesiologists.

445
446 (7) The approved IMRI unit will not be subject to MRI volume requirements.

447
448 (8) The applicant shall not utilize the procedures performed on the IMRI unit to demonstrate need
449 or to satisfy MRI CON review standards requirements.

450
451 (9) The provisions of Section 10 are part of a pilot program approved by the CON commission and
452 shall expire and be of no further force and effect, and shall not be applicable to any application which has
453 not been submitted by December 31, 2010.

454
455 **Section 11. Requirements for all applicants**

456
457 Sec. 11. An applicant shall provide verification of Medicaid participation. An applicant that is a new
458 provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided
459 to the Department within six (6) months from the offering of services if a CON is approved.

460
461 **Section 12. Project delivery requirements – terms of approval**

462
463 Sec. 12. (1) An applicant shall agree that, if approved, MRI services, whether fixed or mobile, shall
464 be delivered and maintained in compliance with the following:

465 (a) Compliance with these standards.
466 (b) Compliance with applicable safety and operating standards.
467 (c) Compliance with the following quality assurance standards:
468 (i) An applicant shall develop and maintain policies and procedures that establish protocols for
469 assuring the effectiveness of operation and the safety of the general public, patients, and staff in the MRI
470 service.

471 (ii) An applicant shall establish a schedule for preventive maintenance for the MRI unit.
472 (iii) An applicant shall provide documentation identifying the specific individuals that form the MRI
473 team. At a minimum, the MRI team shall consist of the following professionals:

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

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

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

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

481 (A) Each physician credentialed to interpret MRI scans meets the requirements of each of the
482 following:

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

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

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

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

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

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

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

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

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

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

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

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

522 (i) MRI units shall be operating at a minimum average annual ~~level of utilization during the second~~
523 12 months of operation, and annually thereafter, ~~AS APPLICABLE of:~~

524 ~~(A) 6,000 actual MRI adjusted procedures per unit for fixed MRI services UNLESS COMPLIANT~~
525 ~~WITH (1) OR (2).~~

526 ~~(1) 4,000 MRI ADJUSTED PROCEDURES FOR THE FIXED UNIT INITIATED PURSUANT TO~~
527 ~~SECTION 3(2)(B)(II) AND IS THE ONLY FIXED MRI UNIT AT THE CURRENT SITE.~~

528 ~~(2) 3,000 MRI ADJUSTED PROCEDURES FOR THE FIXED MRI UNIT INITIATED PURSUANT~~
529 ~~TO SECTION 3(2)(B)(III) AND IS THE ONLY FIXED MRI UNIT AT THE HOSPITAL SITE LICENSED~~
530 ~~UNDER PART 215 OF THE CODE.~~

531 ~~(B) 5,500 actual MRI adjusted procedures per unit for mobile MRI services.~~

532 ~~(C) 4,000 ADJUSTED PROCEDURES PER UNIT FOR FIXED MRI SERVICES APPROVED~~
533 ~~PURSUANT TO SECTION 3(2)(B)(II), 3,000 ADJUSTED PROCEDURES PER UNIT FOR FIXED MRI~~

534 | ~~SERVICES APPROVED PURSUANT TO SECTION 3(2)(B)(III), and a total of 3,500 MRI adjusted~~
535 | ~~procedures per unit for dedicated pediatric MRI UNITS.~~

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

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

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

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

549 | (B) maintain information by source of payment to indicate the volume of care from each source
550 | provided annually.

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

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

564 | (iv) The operation of and referral of patients to the MRI unit shall be in conformance with 1978 PA
565 | 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

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

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

572 |
573 | (2) An applicant for an MRI unit approved under Section 8(1) shall agree that the services provided
574 | by the MRI unit are delivered in compliance with the following terms.

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

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

580 |
581 | (3) The agreements and assurances required by this section shall be in the form of a certification
582 | agreed to by the applicant or its authorized agent.

583 | **Section 13. MRI procedure adjustments**

584 |
585 |
586 | Sec. 13. (1) The Department shall apply the following formula, as applicable, to determine the
587 | number of MRI adjusted procedures that are performed by an existing MRI service or unit:

- 588 (a) The base value for each MRI procedure is 1.0.
589 (b) For each MRI visit involving a pediatric patient, 0.25 shall be added to the base value.
590 (c) For each MRI visit involving an inpatient, 0.50 shall be added to the base value.
591 (d) For each MRI procedure performed on a sedated patient, 0.75 shall be added to the base
592 value.
593 (e) For each MRI procedure performed on a re-sedated patient, 0.25 shall be added to the base
594 value.
595 (f) For each MRI procedure performed on a special needs patient, 0.25 shall be added to the base
596 value.
597 (g) For each MRI visit that involves both a clinical and research scan on a single patient in a single
598 visit, 0.25 shall be added to the base value.
599 (h) For each contrast MRI procedure performed after use of a contrast agent, and not involving a
600 procedure before use of a contrast agent, 0.35 shall be added to the base value.
601 (i) For each contrast MRI procedure involving a procedure before and after use of a contrast
602 agent, 1.0 shall be added to the base value.
603 (j) For each MRI procedure performed at a teaching facility, 0.15 shall be added to the base value.
604 (k) The results of subsections (a) through (j) shall be summed, and that sum shall represent an
605 MRI adjusted procedure.

606
607 (2) The Department shall apply not more than one of the adjustment factors set forth in this
608 subsection, as applicable, to the number of MRI procedures adjusted in accordance with the applicable
609 provisions of subsection (1) that are performed by an existing MRI service or unit.

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

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

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

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

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

624
625 (3) The number of MRI adjusted procedures performed by an existing MRI service is the sum of
626 the results of subsections (1) and (2).

627 **Section 14. Documentation of actual utilization**

628
629
630 Sec. 14. Documentation of the number of MRI procedures performed by an MRI unit shall be
631 substantiated by the Department utilizing data submitted by the applicant in a format and media specified
632 by the Department and as verified for the 12-month period reported on the most recently published "MRI
633 Service Utilization List" as of the date an application is deemed complete SUBMITTED by the
634 Department. The number of MRI procedures actually performed shall be documented by procedure
635 records and not by application of the methodology required in Section 15. The Department may elect to
636 verify the data through on-site review of appropriate records.

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

638
639
640 Sec. 15. (1) The number of available MRI adjusted procedures required pursuant to Section 3 shall
641 be computed in accordance with the methodology set forth in this section. In applying the methodology,

642 the following steps shall be taken in sequence, and data for the 12-month period reported on the most
643 recently published "Available MRI Adjusted Procedures List," as of the date an application is deemed
644 complete SUBMITTED by the Department, shall be used:

645 (a) Identify the number of actual MRI adjusted procedures performed by each existing MRI service
646 as determined pursuant to Section 13.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

688

689 (2) After publication of the "Available MRI Adjusted Procedures List" resulting from (1) above, the
690 data shall be updated to account for a) doctor commitments of available MRI adjusted procedures in
691 subsequent MRI CON applications and b) MRI adjusted procedures used in subsequent MRI CON
692 applications received in which applicants apply for fixed MRI services pursuant to Section 3(2).
693

693

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

695
696 Sec. 16. (1) If one or more host sites on a mobile MRI service are located within the planning area of
697 the proposed site, the applicant may access available MRI adjusted procedures from the entire mobile
698 MRI service.
699

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

704 (b) An applicant also shall submit, at the time the application is **SUBMITTED TO** ~~filed with the~~
705 Department, a computer file that lists, for each MRI service from which data are being committed to the
706 same application, the name and license number of each doctor for whom a signed and dated data
707 commitment form is submitted.

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

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

713 (c) If the required documentation for the doctor commitments submitted under this subsection is
714 **not submitted with the application on the designated application date, the application will be deemed filed**
715 **SUBMITTED** on the first applicable designated application date after all required documentation is
716 received by the Department.

717
718 (3) The Department shall consider a signed and dated data commitment on a form provided by the
719 Department in response to the applicant's letter of intent that meets the requirements of each of the
720 following, as applicable:

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

727 (b) A committing doctor certifies ownership interest, either direct or indirect, in the applicant entity.
728 Indirect ownership includes ownership in an entity that has ownership interest in the applicant entity. This
729 requirement shall not apply if the applicant entity is a group practice of which the committing doctor is a
730 member. Group practice means a group practice as defined pursuant to the provisions of 42 U.S.C.
731 1395nn (h)(4), commonly known as Stark II, and the Code of Federal Regulations, 42 CFR, Part 411,
732 published in the Federal Register on August 14, 1995, or its replacement.

733 (c) A committing doctor certifies that he or she has not been provided, or received a promise of
734 being provided, a financial incentive to commit any of his or her available MRI adjusted procedures to the
735 application.
736

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

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

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

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

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

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

752 (ii) If an appeal was made, either that appeal is withdrawn by the applicant or the committing
753 doctor withdraws his or her data commitment pursuant to the requirements of subsection (8).
754

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

762 (a) if the applications were ~~filed~~ **SUBMITTED** on the same designated application date, notify all
763 applicants, simultaneously and in writing, that one or more doctors have submitted data commitments for
764 available MRI adjusted procedures from the same MRI service and that the doctors' data from the same
765 MRI service shall not be considered in the review of any of the pending applications **SUBMITTED** ~~filed~~ on
766 the same designated application date until the doctor notifies the Department, in writing, of the one (1)
767 application for which the data commitment shall be considered.

768 (b) if the applications were ~~filed~~ **SUBMITTED** on different designated application dates, consider
769 the data commitment ~~submitted~~ in the application **SUBMITTED** ~~filed~~ on the earliest designated application
770 date and shall notify, simultaneously in writing, all applicants of applications **SUBMITTED** ~~filed~~ on
771 designated application dates subsequent to the earliest date that one or more committing doctors have
772 submitted data commitments for available MRI adjusted procedures from the same MRI service and that
773 the doctors' data shall not be considered in the review of the application(s) **SUBMITTED** ~~filed~~ on the
774 subsequent designated application date(s).
775

776 (6) The Department shall not consider any data commitment submitted by an applicant after the
777 date an application is deemed ~~complete~~ **SUBMITTED** unless an applicant is notified by the Department,
778 pursuant to subsection (5), that one or more committing doctors submitted data commitments for
779 available MRI adjusted procedures from the same MRI service. If an applicant is notified that one or
780 more doctors' data commitments will not be considered by the Department, the Department shall
781 consider data commitments submitted after the date an application is deemed ~~complete~~ **SUBMITTED**
782 **only to the extent** necessary to replace the data commitments not being considered pursuant to
783 subsection (5).

784 (a) The applicant shall have 30 days to submit replacement of doctor commitments as identified by
785 the Department in this Section.
786

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

789 (a) **ON OR AFTER THE DATE AN APPLICATION IS DEEMED SUBMITTED BY THE**
790 **DEPARTMENT** ~~during the 120-day period following the date on which the Department's review of an~~
791 ~~application commences.~~

792 (b) after a proposed decision to approve an application has been issued by the Department.
793

794 (8) The Department shall consider a withdrawal of a signed data commitment if a committing
795 doctor submits a written notice to the Department, that specifies the CON application number and the
796 specific MRI services for which a data commitment is being withdrawn, and if an applicant demonstrates
797 that the requirements of subsection (7) also have been met.
798

799 **Section 17. Lists published by the Department**

800

801 Sec. 17. (1) On or before May 1 and November 1 of each year, the Department shall publish the
 802 following lists:
 803 (a) A list, known as the "MRI Service Utilization List," of all MRI services in Michigan that includes
 804 at least the following for each MRI service:
 805 (i) The number of actual MRI adjusted procedures;
 806 (ii) The number of available MRI adjusted procedures, if any; and
 807 (iii) The number of MRI units, including whether each unit is a clinical, research, or dedicated
 808 pediatric.
 809 (b) A list, known as the "Available MRI Adjusted Procedures List," that identifies each MRI service
 810 that has available MRI adjusted procedures and includes at least the following:
 811 (i) The number of available MRI adjusted procedures;
 812 (ii) The name, address, and license number of each referring doctor, identified in Section
 813 15(1)(c)(v), whose patients received MRI services at that MRI service; and
 814 (iii) The number of available MRI adjusted procedures performed on patients referred by each
 815 referring doctor, identified in Section 15(1)(c)(v), and if any are committed to an MRI service. This
 816 number shall be calculated in accordance with the requirements of Section 15(1). A referring doctor may
 817 have fractional portions of available MRI adjusted procedures.
 818 (c) For the lists published pursuant to subsections (a) or (b), the May 1 list will report 12 months of
 819 data from the previous January 1 through December 31 reporting period, and the November 1 list will
 820 report 12 months of data from the previous July 1 through June 30 reporting period. Copies of both lists
 821 shall be available upon request.
 822 (d) The Department shall not be required to publish a list that sorts MRI database information by
 823 referring doctor, only by MRI service.

824
 825 (2) When an MRI service begins to operate at a site at which MRI services previously were not
 826 provided, the Department shall include in the MRI database, data beginning with the second full quarter
 827 of operation of the new MRI service. Data from the start-up date to the start of the first full quarter will not
 828 be collected to allow a new MRI service sufficient time to develop its data reporting capability. Data from
 829 the first full quarter of operation will be submitted as test data but will not be reported in the lists published
 830 pursuant to this section.

831
 832 (3) In publishing the lists pursuant to subsections (a) and (b), if an MRI service has not reported
 833 data in compliance with the requirements of Section 12, the Department shall indicate on both lists that
 834 the MRI service is in violation of the requirements set forth in Section 12, and no data will be shown for
 835 that service on either list.

836
 837 **Section 18. Effect on prior CON Review Standards; Comparative reviews**

838
 839 Sec. 18. (1) These CON review standards supersede and replace the CON Review Standards for
 840 **Magnetic Resonance ImagingMRI Services approved by the CON Commission on September 16¹⁰,**
 841 **2008-2009 and effective November 13⁵, 20082009.**

842
 843 (2) Projects reviewed under these standards shall not be subject to comparative review.
 844

845 **Section 19. Health Service Areas**

846
 847 Sec. 19. Counties assigned to each of the health service areas are as follows:
 848

HSA	COUNTIES		
1	Livingston Macomb Wayne	Monroe Oakland	St. Clair Washtenaw

855				
856	2	Clinton	Hillsdale	Jackson
857		Eaton	Ingham	Lenawee
858				
859	3	Barry	Calhoun	St. Joseph
860		Berrien	Cass	Van Buren
861		Branch	Kalamazoo	
862				
863	4	Allegan	Mason	Newaygo
864		Ionia	Mecosta	Oceana
865		Kent	Montcalm	Osceola
866		Lake	Muskegon	Ottawa
867				
868	5	Genesee	Lapeer	Shiawassee
869				
870	6	Arenac	Huron	Roscommon
871		Bay	Iosco	Saginaw
872		Clare	Isabella	Sanilac
873		Gladwin	Midland	Tuscola
874		Gratiot	Ogemaw	
875				
876	7	Alcona	Crawford	Missaukee
877		Alpena	Emmet	Montmorency
878		Antrim	Gd Traverse	Oscoda
879		Benzie	Kalkaska	Otsego
880		Charlevoix	Leelanau	Presque Isle
881		Cheboygan	Manistee	Wexford
882				
883	8	Alger	Gogebic	Mackinac
884		Baraga	Houghton	Marquette
885		Chippewa	Iron	Menominee
886		Delta	Keweenaw	Ontonagon
887		Dickinson	Luce	Schoolcraft

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CON REVIEW STANDARDS
FOR MRI SERVICES

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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