

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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

139 (ll) "Planning area" means

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

184 (vv) "Site" means

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

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

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

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

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

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

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

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

206
207 (2) Terms defined in the Code have the same meanings when used in these standards.
208

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

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

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

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

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

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

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

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

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

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

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

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

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

232 (IV) AT LEAST 2,000 MRI ADJUSTED PROCEDURES AND THE APPLICANT MEETS ALL OF
233 THE FOLLOWING:

234 (A) AT LEAST 25% OF THE MRI ADJUSTED PROCEDURES HAVE A PAYER SOURCE OF
235 MEDICAID AND/OR NO CHARGE.

236 (B) THE APPLICANT IS A FOR-PROFIT, FREESTANDING FACILITY.

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

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

242 (e) The applicant shall cease operation as a host site and not become a host site for at least 12
243 months from the date the fixed service and its unit becomes operational.
244

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

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

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

251 (c) Identify a minimum of two (2) host sites for the proposed service.
252

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

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

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

259 (c) The proposed host site has not received any mobile MRI service within the most recent 12-
260 month period as of the date an application is submitted to the Department.
261

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

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

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

268
269 (6) The applicant shall demonstrate that the available MRI adjusted procedures FROM THE
270 AVAILABLE MRI ADJUSTED PROCEDURES LIST AND THE ADJUSTED PROCEDURES FROM THE
271 MRI SERVICE UTILIZATION LIST, AS APPLICABLE, are from the most recently published available MRI
272 adjusted procedures list as of the date an application is deemed submitted by the Department.

273 274 **Section 4. Requirements to replace an existing MRI unit**

275
276 Sec. 4. An applicant proposing to replace an existing MRI unit shall demonstrate the following
277 requirements, as applicable:

278
279 (1) An applicant shall demonstrate that the applicable MRI adjusted procedures are from the most
280 recently published MRI Service Utilization List as of the date an application is deemed submitted by the
281 Department:

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

284 (b) Each existing fixed MRI unit at the current site has performed at least an average of 6,000 MRI
285 adjusted procedures per MRI unit.

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

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

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

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

300 301 **Section 5. Requirements to expand an existing MRI service**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

340
341 **Section 7. Requirements to acquire an existing MRI service or an existing MRI unit(s)**
342

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

345 (a) For the first application proposing to acquire an existing fixed or mobile MRI service on or after
346 July 1, 1997, the existing MRI service and its unit(s) to be acquired shall not be required to be in
347 compliance with the volume requirements applicable to a seller/lessor on the date the acquisition occurs.

348 The MRI service shall be operating at the applicable volume requirements set forth in Section 12 of
349 these standards in the second 12 months after the effective date of the acquisition, and annually
350 thereafter.

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

356
357 (2) An applicant proposing to acquire an existing fixed or mobile MRI unit of an existing MRI
358 service shall demonstrate that the proposed project meets all of the following:

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

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

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

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

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

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

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

379
380 **Section 9. Requirements to establish a dedicated pediatric MRI unit**

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

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

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

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

390 (i) pediatric radiology (at least two)

391 (ii) pediatric anesthesiology

392 (iii) pediatric cardiology

393 (iv) pediatric critical care

394 (v) pediatric gastroenterology

395 (vi) pediatric hematology/oncology

396 (vii) pediatric neurology

397 (viii) pediatric neurosurgery

398 (ix) pediatric orthopedic surgery

399 (x) pediatric pathology

400 (xi) pediatric pulmonology

401 (xii) pediatric surgery

402 (xiii) neonatology

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

404 (i) pediatric bone marrow transplant program

405 (ii) established pediatric sedation program

406 (iii) pediatric open heart program

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

410
411 **Section 10. Pilot program requirements for approval – applicants proposing to initiate, replace, or**
412 **acquire a hospital based IMRI**

413
414 Sec. 10. As a pilot program, an applicant proposing to initiate, replace, or acquire a hospital based IMRI
415 service shall demonstrate that it meets all of the following:

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

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

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

- 424
425 (4) The applicant shall have experienced one of the following:
426 (a) at least 1,500 oncology discharges in the most recent year of operation; or
427 (b) at least 1,000 neurological surgeries in the most recent year of operation; or
428 (c) at least 7,000 pediatric (<18 years old) discharges (excluding normal newborns) and at least
429 5,000 pediatric (<18 years old) surgeries in the most recent year of operation.
430
431 (5) The proposed IMRI unit must be located in an operating room or a room adjoining an operating
432 room allowing for transfer of the patient between the operating room and this adjoining room.
433
434 (6) Non-surgical diagnostic studies shall not be performed on an IMRI unit approved under this
435 section unless the patient meets one of the following criteria:
436 (a) the patient has been admitted to an inpatient unit; or
437 (b) the patient is having the study performed on an outpatient basis, but is in need of general
438 anesthesia or deep sedation as defined by the American Society of Anesthesiologists.
439
440 (7) The approved IMRI unit will not be subject to MRI volume requirements.
441
442 (8) The applicant shall not utilize the procedures performed on the IMRI unit to demonstrate need
443 or to satisfy MRI CON review standards requirements.
444
445 (9) The provisions of Section 10 are part of a pilot program approved by the CON commission and
446 shall expire and be of no further force and effect, and shall not be applicable to any application which has
447 not been submitted by December 31, 2010.
448

449 **Section 11. Requirements for all applicants**

450
451 Sec. 11. An applicant shall provide verification of Medicaid participation. An applicant that is a new
452 provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided
453 to the Department within six (6) months from the offering of services if a CON is approved.
454

455 **Section 12. Project delivery requirements – terms of approval**

456
457 Sec. 12. (1) An applicant shall agree that, if approved, MRI services, whether fixed or mobile, shall
458 be delivered and maintained in compliance with the following:
459 (a) Compliance with these standards.
460 (b) Compliance with applicable safety and operating standards.
461 (c) Compliance with the following quality assurance standards:
462 (i) An applicant shall develop and maintain policies and procedures that establish protocols for
463 assuring the effectiveness of operation and the safety of the general public, patients, and staff in the MRI
464 service.
465 (ii) An applicant shall establish a schedule for preventive maintenance for the MRI unit.
466 (iii) An applicant shall provide documentation identifying the specific individuals that form the MRI
467 team. At a minimum, the MRI team shall consist of the following professionals:
468 (A) Physicians who shall be responsible for screening of patients to assure appropriate utilization
469 of the MRI service and taking and interpretation of scans. At least one of these physicians shall be a
470 board-certified radiologist.
471 (B) An appropriately trained MRI technician who shall be responsible for taking an MRI scan.
472 (C) An MRI physicist/engineer available as a team member on a full-time, part-time, or contractual
473 basis.
474 (iv) An applicant shall document that the MRI team members have the following qualifications:
475 (A) Each physician credentialed to interpret MRI scans meets the requirements of each of the
476 following:
477 (1) The physician is licensed to practice medicine in the State of Michigan.

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

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

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

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

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

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

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

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

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

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

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

516 (i) MRI units shall be operating at a minimum average annual level of utilization during the second
517 12 months of operation, and annually thereafter, of 6,000 actual MRI adjusted procedures per unit for
518 fixed MRI services, 5,500 actual MRI adjusted procedures per unit for mobile MRI services, and a total of
519 3,500 MRI adjusted procedures per unit for dedicated pediatric MRI. Each mobile host site in a rural or
520 micropolitan statistical area county shall have provided at least a total of 400 adjusted procedures during
521 its second 12 months of operation, and annually thereafter, from all mobile units providing services to the
522 site. Each mobile host site not in a rural or micropolitan statistical area county shall have provided at
523 least a total of 600 adjusted procedures during its second 12 months of operation and annually thereafter,
524 from all mobile units providing services to the site. In meeting these requirements, an applicant shall not
525 include any MRI adjusted procedures performed on an MRI unit used exclusively for research and
526 approved pursuant to Section 8(1) or for an IMRI unit approved pursuant to Section 10.

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

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

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

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

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

546 (iv) The operation of and referral of patients to the MRI unit shall be in conformance with 1978 PA
547 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

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

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

554
555 (2) An applicant for an MRI unit approved under Section 8(1) shall agree that the services provided
556 by the MRI unit are delivered in compliance with the following terms.

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

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

562
563 (3) AN APPLICANT FOR AN MRI UNIT APPROVED UNDER SECTION 3(2)(B)(IV) SHALL
564 AGREE TO CONTINUE TO PROVIDE AT LEAST 25% OF THE MRI VISITS WITH A PAYER SOURCE
565 OF MEDICAID AND/OR NO CHARGE DURING THE FIRST 12 MONTHS OF OPERATION AND
566 ANNUALLY THEREAFTER FOR AT LEAST 10 YEARS.

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

570

571 **Section 13. MRI procedure adjustments**

572

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

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

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

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

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

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

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

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

- 593
- 594 (2) The Department shall apply not more than one of the adjustment factors set forth in this
595 subsection, as applicable, to the number of MRI procedures adjusted in accordance with the applicable
596 provisions of subsection (1) that are performed by an existing MRI service or unit.
- 597 (a) For a site located in a rural or micropolitan statistical area county, the number of MRI adjusted
598 procedures shall be multiplied by a factor of 1.4.
- 599 (b) For a mobile MRI unit that serves hospitals and other host sites located in rural, micropolitan
600 statistical area, and metropolitan statistical area counties, the number of MRI adjusted procedures for a
601 site located in a rural or micropolitan statistical area county, shall be multiplied by a factor of 1.4 and for a
602 site located in a metropolitan statistical area county, the number of MRI adjusted procedures shall be
603 multiplied by a factor of 1.0.
- 604 (c) For a mobile MRI unit that serves only sites located in rural or micropolitan statistical area
605 counties, the number of MRI adjusted procedures shall be multiplied by a factor of 2.0.
- 606 (d) For a mobile MRI unit that serves only sites located in a health service area with one or fewer
607 fixed MRI units and one or fewer mobile MRI units, the number of MRI adjusted procedures shall be
608 multiplied by a factor of 3.5.
- 609 (e) Subsection (2) shall not apply to an application proposing a subsequent fixed MRI unit (second,
610 third, etc.) at the same site.
- 611
- 612 (3) The number of MRI adjusted procedures performed by an existing MRI service is the sum of
613 the results of subsections (1) and (2).

614

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

616

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

624

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

626

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

674 (viii) The result shall be the "Available MRI Adjusted Procedures List."
675

676 (2) After publication of the "Available MRI Adjusted Procedures List" resulting from (1) above, the
677 data shall be updated to account for a) doctor commitments of available MRI adjusted procedures in
678 subsequent MRI CON applications and b) MRI adjusted procedures used in subsequent MRI CON
679 applications received in which applicants apply for fixed MRI services pursuant to Section 3(2).
680

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

682
683 Sec. 16. (1) If one or more host sites on a mobile MRI service are located within the planning area of
684 the proposed site, the applicant may access available MRI adjusted procedures from the entire mobile
685 MRI service.
686

687 (2)(a) At the time the application is submitted to the Department, the applicant shall submit a signed
688 data commitment, on a form provided by the Department in response to the applicant's letter of intent for

689 each doctor committing available MRI adjusted procedures to that application for a new MRI unit that
690 requires doctor commitments.

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

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

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

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

704
705 (3) The Department shall consider a signed and dated data commitment on a form provided by the
706 Department in response to the applicant's letter of intent that meets the requirements of each of the
707 following, as applicable:

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

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

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

723
724 (4)(a) The Department shall not consider a data commitment from a doctor for available MRI adjusted
725 procedures from a specific MRI service if the available MRI adjusted procedures from that specific MRI
726 service were used to support approval of an application for a new or additional MRI unit, pursuant to
727 Section 3, for which a final decision to approve has been issued by the Director of the Department until
728 either of the following occurs:

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

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

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

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

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

741

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

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

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

761
762 (6) The Department shall not consider any data commitment submitted by an applicant after the
763 date an application is deemed ~~complete~~ SUBMITTED unless an applicant is notified by the Department,
764 pursuant to subsection (5), that one or more committing doctors submitted data commitments for
765 available MRI adjusted procedures from the same MRI service. If an applicant is notified that one or
766 more doctors' data commitments will not be considered by the Department, the Department shall
767 consider data commitments submitted after the date an application is deemed ~~complete~~ SUBMITTED
768 only to the extent necessary to replace the data commitments not being considered pursuant to
769 subsection (5).

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

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

775 (a) during the 120-day period following the date on which the Department's review of an
776 application commences.

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

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

783 784 **Section 17. Lists published by the Department**

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

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

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

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

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

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

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

797 (ii) The name, address, and license number of each referring doctor, identified in Section
798 15(1)(c)(v), whose patients received MRI services at that MRI service; and

799 (iii) The number of available MRI adjusted procedures performed on patients referred by each
800 referring doctor, identified in Section 15(1)(c)(v), and if any are committed to an MRI service. This
801 number shall be calculated in accordance with the requirements of Section 15(1). A referring doctor may
802 have fractional portions of available MRI adjusted procedures.

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

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

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

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

821

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

823

824 Sec. 18. (1) These CON review standards supersede and replace the CON Review Standards for
825 Magnetic Resonance Imaging Services approved by the CON Commission on ~~September 16, 2008~~
826 SEPTEMBER 10, 2009 and effective ~~November 13, 2008~~ NOVEMBER 5, 2009.

827

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

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Section 19. Health Service Areas

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

HSA	COUNTIES		
1	Livingston Macomb Wayne	Monroe Oakland	St. Clair Washtenaw
2	Clinton Eaton	Hillsdale Ingham	Jackson Lenawee
3	Barry Berrien Branch	Calhoun Cass Kalamazoo	St. Joseph Van Buren
4	Allegan Ionia Kent Lake	Mason Mecosta Montcalm Muskegon	Newaygo Oceana Osceola Ottawa
5	Genesee	Lapeer	Shiawassee
6	Arenac Bay Clare Gladwin Gratiot	Huron Iosco Isabella Midland Ogemaw	Roscommon Saginaw Sanilac Tuscola
7	Alcona Alpena Antrim Benzie Charlevoix Cheboygan	Crawford Emmet Gd Traverse Kalkaska Leelanau Manistee	Missaukee Montmorency Oscoda Otsego Presque Isle Wexford
8	Alger Baraga Chippewa Delta Dickinson	Gogebic Houghton Iron Keweenaw Luce	Mackinac Marquette Menominee Ontonagon 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