

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

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

10 **Section 1. Applicability**
11

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

19 **Section 2. Definitions**
20

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

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

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

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

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

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

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

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

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

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

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

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

108 costs related to the research use are charged to a specific research account and not charged to or
109 collected from third-party payors or patients. The term does not include a procedure conducted by an MRI
110 unit approved pursuant to Section ~~8(4)7~~.

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

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

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

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

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

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

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

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

137 (ll) "Pediatric patient" means a patient who is 12 years of age or less, except for Section 98.

138 (mm) "Planning area" means

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

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

146 (iii) in the case of a proposed mobile MRI service or unit meeting the requirement of Section
147 15(2)(d), the health service area in which all the proposed mobile host sites will be located.

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

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

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

155 ~~(qq) "Renewal of a lease" means extending the effective period of a lease for an existing MRI unit~~
156 ~~that does not involve either replacement of the MRI unit, as defined in Section 2(1)(rr)(i)4, or (ii) a change~~
157 ~~in the parties to the lease.~~

158 ~~(rr)PP "Replace an existing MRI unit" means (i) any equipment change involving a change in, or~~
159 ~~replacement of, the magnet resulting in an applicant operating the same number and type (fixed or~~
160 ~~mobile) of MRI units before and after project completion or (ii) an equipment change other than a change~~
161 ~~in the magnet that involves a capital expenditure of \$750,000 or more in any consecutive 24-month period~~

162 | ~~or (iii) the renewal of a lease. The term does not include an upgrade of an existing MRI service or unit,~~
163 | ~~and it does not include a host site that proposes to receive mobile MRI services from a different central~~
164 | ~~service coordinator if the requirements of Section 3(5) have been met.~~

165 | ~~(ss)~~ "Research scan" means an MRI scan administered under a research protocol approved by the
166 | applicant's IRB.

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

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

174 | (vvSS) "Sedated patient" means a patient that meets all of the following:

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

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

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

181 | (wwTT) "Site" means

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

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

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

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

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

197 | (aaaXX) "Upgrade an existing MRI unit" means any equipment change that

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

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

203 |
204 | (2) Terms defined in the Code have the same meanings when used in these standards.
205 |

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

207 |
208 | Sec. 3. An applicant proposing to initiate an MRI service or a host site shall demonstrate the following
209 | requirements, as applicable:
210 |

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

215 (2) An applicant proposing to initiate a fixed MRI service that meets the following requirements shall
216 not be required to be in compliance with subsection (1):
217 (a) The applicant is currently an existing host site.
218 (b) The applicant has received in aggregate, one of the following:
219 (i) At least 6,000 MRI adjusted procedures.
220 (ii) At least 4,000 MRI adjusted procedures and the applicant meets all of the following:
221 (A) Is located in a county that has no fixed MRI machines that are pending, approved by the
222 Department, or operational at the time the application is deemed submitted.
223 (B) The nearest fixed MRI machine is located more than 15 radius miles from the application site.
224 (iii) At least 3,000 MRI adjusted procedures and the applicant meets all of the following:
225 (A) The proposed site is a hospital licensed under Part 215 of the Code.
226 (B) The applicant hospital operates an emergency room that provides 24-hour emergency care
227 services and at least 20,000 visits within the most recent 12-month period for which data, verifiable by the
228 Department, is available.
229 (c) All of the MRI adjusted procedures from the mobile MRI service referenced in Section 3(2)(b)
230 shall be utilized even if the aggregated data exceeds the minimum requirements.
231 (d) The applicant shall install the fixed MRI unit at the same site as the existing host site or within
232 the relocation zone. If applying pursuant to Section 3(2)(b)(iii), the applicant shall install the fixed MRI unit
233 at the same site as the existing host site.
234 (e) The applicant shall cease operation as a host site and not become a host site for at least 12
235 months from the date the fixed service and its unit becomes operational.
236
237 (3) An applicant proposing to initiate a mobile MRI service shall demonstrate 5,500 available MRI
238 adjusted procedures from within the same planning area as the proposed service/unit, and the applicant
239 shall meet the following:
240 (a) Identify the proposed route schedule and procedures for handling emergency situations.
241 (b) Submit copies of all proposed contracts for the proposed host site related to the mobile MRI
242 service.
243 (c) Identify a minimum of two (2) host sites for the proposed service.
244
245 (4) An applicant, whether the central service coordinator or the host site, proposing to initiate a host
246 site on a new or existing mobile MRI service shall demonstrate the following, as applicable:
247 (a) 600 available MRI adjusted procedures, from within the same planning area as the proposed
248 service/unit, for a proposed host site that is not located in a rural or micropolitan statistical area county, or
249 (b) 400 available MRI adjusted procedures from within the same planning area for a proposed host
250 site that is located in a rural or micropolitan statistical area county, and
251 (c) The proposed host site has not received any mobile MRI service within the most recent 12-
252 month period as of the date an application is submitted to the Department.
253
254 (5) An applicant proposing to add or change service on an existing mobile MRI service that meets
255 the following requirements shall not be required to be in compliance with subsection (4):
256 (a) The host site has received mobile MRI services from an existing mobile MRI unit within the
257 most recent 12-month period as of the date an application is submitted to the Department.
258 (b) Submit copies of all proposed contracts for the proposed host site related to the mobile MRI
259 service.
260
261 (6) The applicant shall demonstrate that the available MRI adjusted procedures from the "Available
262 MRI Adjusted Procedures List" or the adjusted procedures from the "MRI Service Utilization List," as
263 applicable, are from the most recently published MRI lists as of the date an application is deemed
264 submitted by the Department.
265
266 |

267 **Section 4. Requirements to replace an existing MRI unit**
268

269 Sec. 4. Replace an existing MRI unit means (i) any equipment change involving a change in, or
270 replacement of, the ENTIRE MRI UNIT resulting in an applicant operating the same number and type
271 (fixed or mobile) of MRI units before and after project completion or (ii) an equipment change, other than a
272 change in the magnet, that involves a capital expenditure of \$750,000 or more in any consecutive 24-
273 month period or (iii) the renewal of a lease. REPLACEMENT ALSO MEANS THE RELOCATION OF AN
274 MRI SERVICE OR UNIT TO A NEW SITE. THE TERM DOES NOT INCLUDE THE REPLACEMENT OF
275 COMPONENTS OF THE MRI SYSTEM, INCLUDING THE MAGNET, UNDER AN EXISTING SERVICE
276 CONTRACT OR REQUIRED MAINTENANCE TO MAINTAIN THE SYSTEM TO OPERATE WITHIN
277 MANUFACTURER SPECIFICATIONS. The term does not include an upgrade TO AN EXISTING MRI
278 UNIT OR REPAIR of an existing MRI service or unit, and it does not include a host site that proposes to
279 receive mobile MRI services from a different central service coordinator if the requirements of Section 3(5)
280 have been met.

281
282 (1) "Upgrade an existing MRI unit" means any equipment change that
283 (i) does not involve a change in, or replacement of, the magnet; ENTIRE MRI UNIT, does not
284 result in an increase in the number of MRI units; or does not result in a change in the type of MRI unit
285 (e.g., changing a mobile MRI unit to a fixed MRI unit); and
286 (ii) involves a capital expenditure related to the MRI equipment of less than \$750,000 in any
287 consecutive 24-month period.

288
289 (2) "REPAIR AN EXISTING MRI UNIT" MEANS RESTORING THE ABILITY OF THE SYSTEM TO
290 OPERATE WITHIN THE MANUFACTURER'S SPECIFICATIONS BY REPLACING OR REPAIRING THE
291 EXISTING COMPONENTS OR PARTS OF THE SYSTEM, INCLUDING THE MAGNET, PURSUANT TO
292 THE TERMS OF AN EXISTING MAINTENANCE AGREEMENT THAT DOES NOT RESULT IN A
293 CHANGE IN THE STRENGTH OF THE MRI UNIT.

294
295 (3) An applicant proposing to replace an existing MRI unit shall demonstrate the following
296 requirements, as applicable:

297
298 ~~(4a)~~ An applicant shall demonstrate that the applicable MRI adjusted procedures are from the most
299 recently published MRI Service Utilization List as of the date an application is deemed submitted by the
300 Department. AN APPLICANT PROPOSING TO REPLACE AN EXISTING MRI UNIT THAT IS BELOW 1
301 TESLA WITH AN MRI UNIT THAT IS A 1 TESLA OR HIGHER, SHALL BE EXEMPT ONCE, AS OF
302 (INSERT EFFECTIVE DATE OF THE STANDARDS), FROM THE MINIMUM VOLUME REQUIREMENTS
303 FOR REPLACEMENT:

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

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

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

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

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

317
318 (3c) The replacement unit shall be located at the same site ~~unless the requirements of the relocation~~
319 ~~section have been met.~~

321 (4d) An applicant proposing to replace an existing MRI unit that does not involve a renewal of a lease
322 shall demonstrate that the MRI unit to be replaced is fully depreciated according to generally accepted
323 accounting principles; the existing equipment clearly poses a threat to the safety of the public; or the
324 proposed replacement equipment offers a significant technological improvement which enhances quality
325 of care, increases efficiency, and reduces operating costs.

326
327 (4) AN APPLICANT PROPOSING TO REPLACE AN EXISTING MOBILE MRI HOST SITE TO A
328 NEW LOCATION SHALL DEMONSTRATE THE FOLLOWING:

329 (a) THE APPLICANT CURRENTLY OPERATES THE MRI MOBILE HOST SITE TO BE
330 RELOCATED.

331 (b) THE MRI MOBILE HOST SITE TO BE RELOCATED HAS BEEN IN OPERATION FOR AT
332 LEAST 36 MONTHS AS OF THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT.

333 (c) THE PROPOSED NEW SITE IS WITHIN A 5-MILE RADIUS OF THE EXISTING SITE FOR A
334 METROPOLITAN STATISTICAL AREA COUNTY OR WITHIN A 10-MILE RADIUS FOR A RURAL OR
335 MICROPOLITAN STATISTICAL AREA COUNTY.

336 (d) THE MOBILE MRI HOST SITE TO BE RELOCATED PERFORMED AT LEAST THE
337 APPLICABLE MINIMUM NUMBER OF MRI ADJUSTED PROCEDURES SET FORTH IN SECTION 14
338 BASED ON THE MOST RECENTLY PUBLISHED MRI SERVICE UTILIZATION LIST AS OF THE DATE
339 AN APPLICATION IS DEEMED SUBMITTED BY THE DEPARTMENT.

340 (e) THE RELOCATION WILL NOT INVOLVE A CHANGE IN THE CURRENT CENTRAL SERVICE
341 COORDINATOR UNLESS THE REQUIREMENTS OF SECTION 3(5) ARE MET.

342
343 (5) An applicant proposing to ~~relocate~~REPLACE an existing fixed MRI service and its unit(s) to a
344 new site shall demonstrate the following:

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

347 (b) The proposed new site is ~~in the relocation zone~~ within a 10-mile radius of the existing site.

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

351
352 (6) An applicant proposing to ~~relocate~~REPLACE a fixed MRI unit of an existing MRI service TO A
353 NEW SITE shall demonstrate the following:

354 (a) The applicant currently operates the MRI ~~service~~UNIT from which the unit will TO be relocated.

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

357 (c) The proposed new site is ~~in the relocation zone~~ within a 10-mile radius of the existing site.

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

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

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

365
366
367 Sec. 5. An applicant proposing to expand an existing MRI service shall demonstrate the following:

368
369 (1) An applicant shall demonstrate that the applicable MRI adjustable procedures are from the most
370 recently published MRI Service Utilization List as of the date of an application is deemed submitted by the
371 Department:

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

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

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

378
379 (2) The additional fixed unit shall be located at the same site unless the requirements of the
380 relocation section have been met.

381
382 **Section 6. Requirements to relocate an existing fixed MRI service and/or MRI unit(s)**

383
384 ~~Sec. 6. (1) An applicant proposing to relocate an existing fixed MRI service and its unit(s) shall
385 demonstrate the following:~~

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

388 ~~— (b) The proposed new site is in the relocation zone.~~

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

392
393 ~~(2) An applicant proposing to relocate a fixed MRI unit of an existing MRI service shall demonstrate
394 the following:~~

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

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

398 ~~— (c) The proposed new site is in the relocation zone.~~

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

403 ~~— (e) For volume purposes, the new site shall remain associated to the original site for a minimum of
404 three years.~~

405
406 **Section 76. Requirements to acquire an existing MRI service or an existing MRI unit(s)**

407
408 ~~Sec 76. (1) An applicant proposing to acquire an existing fixed or mobile MRI service and its unit(s)
409 shall demonstrate the following:~~

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

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

420
421 (2) An applicant proposing to acquire an existing fixed or mobile MRI unit of an existing MRI service
422 shall demonstrate that the proposed project meets all of the following:

423 (a) The project will not change the number of MRI units at the site of the MRI service being
424 acquired, subject to the applicable requirements under Section 64(26), unless the applicant demonstrates
425 that the project is in compliance with the requirements of the initiation or expansion Section, as applicable.

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

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Section 87. Requirements to establish a dedicated research MRI unit

Sec. 87. An applicant proposing an MRI unit to be used exclusively for research shall demonstrate the following:

(1) THE APPLICANT AGREES THAT THE DEDICATED RESEARCH MRI UNIT WILL BE USED PRIMARILY (70% OR MORE OF THE PROCEDURES) FOR RESEARCH PURPOSES ONLY.

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

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

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

Section 98. Requirements to establish a dedicated pediatric MRI unit

Sec. 98. ~~(1)~~—An applicant proposing to establish dedicated pediatric MRI shall demonstrate all of the following:

(a1) The applicant shall have experienced at least 7,000 pediatric (< 18 years old) discharges (excluding normal newborns) in the most recent year of operation.

(b2) The applicant shall have performed at least 5,000 pediatric (< 18 years old) surgeries in the most recent year of operation.

(e3) The applicant shall have an active medical staff that includes, but is not limited to, physicians who are fellowship-trained in the following pediatric specialties:

- (ia) pediatric radiology (at least two)
- (ib) pediatric anesthesiology
- (iic) pediatric cardiology
- (ivd) pediatric critical care
- (ve) pediatric gastroenterology
- (vif) pediatric hematology/oncology
- (viig) pediatric neurology
- (viiih) pediatric neurosurgery
- (ixi) pediatric orthopedic surgery
- (xj) pediatric pathology
- (xik) pediatric pulmonology
- (xiii) pediatric surgery
- (xiiim) neonatology

(d4) The applicant shall have in operation the following pediatric specialty programs:

- (ia) pediatric bone marrow transplant program
- (ib) established pediatric sedation program
- (iic) pediatric open heart program

(25) An applicant meeting the requirements of ~~subsection-THIS section (1)~~ shall be exempt from meeting the requirements of Section 5 of these standards.

482 | **Section 409. Requirements for all applicants proposing to initiate, replace, or acquire a hospital**
483 **based IMRI**

485 | Sec. 409. An applicant proposing to initiate, replace, or acquire a hospital based IMRI service shall
486 demonstrate each of the following, as applicable to the proposed project.

- 487
- 488 (1) The proposed site is a licensed hospital under Part 215 of the Code.
- 489
- 490 (2) The proposed site has an existing fixed MRI service that has been operational for the previous
491 36 consecutive months and is meeting its minimum volume requirements.
- 492
- 493 (3) The proposed site has an existing and operational surgical service and is meeting its minimum
494 volume requirements pursuant to the CON Review Standards for Surgical Services.
- 495
- 496 (4) The applicant has achieved one of the following:
- 497 (a) at least 1,500 oncology discharges in the most recent year of operation; or
- 498 (b) at least 1,000 neurological surgeries in the most recent year of operation; or
- 499 (c) at least 7,000 pediatric (<18 years old) discharges (excluding normal newborns) and at least
500 5,000 pediatric (<18 years old) surgeries in the most recent year of operation.
- 501
- 502 (5) The proposed IMRI unit must be located in an operating room or a room adjoining an operating
503 room allowing for transfer of the patient between the operating room and this adjoining room.
- 504
- 505 (6) Non-surgical diagnostic studies shall not be performed on an IMRI unit approved under this
506 section unless the patient meets one of the following criteria:
- 507 (a) the patient has been admitted to an inpatient unit; or
- 508 (b) the patient is having the study performed on an outpatient basis, but is in need of general
509 anesthesia or deep sedation as defined by the American Society of Anesthesiologists.
- 510
- 511 (7) The approved IMRI unit will not be subject to MRI volume requirements.
- 512
- 513 (8) The applicant shall not utilize the procedures performed on the IMRI unit to demonstrate need
514 or to satisfy MRI CON review standards requirements.
- 515

516 | **Section 4410. Requirements for all applicants proposing to initiate, replace, or acquire a hospital**
517 **based MRI-guided EPI service**

519 | Sec. 4410. An applicant proposing to initiate, replace, or acquire a hospital based MRI-guided EPI
520 service shall demonstrate each of the following, as applicable to the proposed project.

- 521
- 522 (1) The proposed site is a licensed hospital under part 215 of the Code.
- 523
- 524 (2) The proposed site has an existing fixed MRI service that has been operational for the previous
525 36 consecutive months and is meeting its minimum volume requirements.
- 526
- 527 (3) The proposed site has an existing and operational therapeutic cardiac catheterization service
528 and is meeting its minimum volume requirements pursuant to the CON review standards for cardiac
529 catheterization services and open heart surgery services.
- 530
- 531 (4) The proposed MRI-guided EPI unit must be located in a cardiac catheterization lab containing a
532 flouroscopy unit with an adjoining room containing an MRI scanner. The rooms shall contain a patient
533 transfer system allowing for transfer of the patient between the cardiac catheterization lab and the MRI
534 unit, utilizing one of the following:
- 535 (a) moving the patient to the MRI scanner, or

- 536 (b) installing the MRI scanner on a sliding gantry to allow the patient to remain stationary.
537
538 (5) Non-cardiac MRI diagnostic studies shall not be performed in an MRI-guided EPI unit approved
539 under this section unless the patient meets one of the following criteria:
540 (a) The patient has been admitted to an inpatient unit; or
541 (b) The patient is having the study performed on an outpatient basis as follows:
542 (i) is in need of general anesthesia or deep sedation as defined by the American Society of
543 Anesthesiologists, or
544 (ii) has an implantable cardiac device.
545
546 (6) The approved MRI-guided EPI unit shall not be subject to MRI volume requirements.
547
548 (7) The applicant shall not utilize the procedures performed on the MRI-guided EPI unit to
549 demonstrate need or to satisfy MRI CON review standards requirements.
550

551 **Section 11. Requirements for all applicants proposing to initiate, replace, or acquire an MRI**
552 **SIMULATOR THAT WILL NOT BE USED SOLELY FOR MRT TREATMENT PLANNING PURPOSES**
553

554 Sec. 11. MRI SIMULATION IS THE USE OF MRI TO HELP SIMULATE (OR PLAN) A PATIENT'S
555 MRT TREATMENT AND TO INCORPORATE SUPERIOR DELINEATION OF SOFT TISSUES FOR MRT
556 TREATMENT PLANS. AN APPLICANT PROPOSING TO INITIATE, REPLACE, OR ACQUIRE AN MRI
557 SIMULATOR SHALL DEMONSTRATE EACH OF THE FOLLOWING, AS APPLICABLE TO THE
558 PROPOSED PROJECT.
559

560 (1) THE PROPOSED SITE HAS AN EXISTING FIXED MRI SERVICE THAT HAS BEEN
561 OPERATIONAL FOR THE PREVIOUS 36 CONSECUTIVE MONTHS AND IS MEETING ITS MINIMUM
562 VOLUME REQUIREMENTS.
563

564 (2) THE PROPOSED SITE HAS AN EXISTING AND OPERATIONAL MRT SERVICE AND IS
565 MEETING ITS MINIMUM VOLUME REQUIREMENTS PURSUANT TO THE CON REVIEW STANDARDS
566 FOR MRT SERVICES/UNITS.
567

568 (3) MRI DIAGNOSTIC STUDIES SHALL NOT BE PERFORMED USING AN MRI SIMULATOR
569 APPROVED UNDER THIS SECTION UNLESS THE PATIENT MEETS ONE OF THE FOLLOWING
570 CRITERIA:

571 (A) THE PATIENT HAS BEEN ADMITTED TO AN INPATIENT UNIT; OR
572 (B) THE PATIENT IS HAVING THE STUDY PERFORMED ON AN OUTPATIENT BASIS, BUT IS
573 IN NEED OF GENERAL ANESTHESIA OR DEEP SEDATION AS DEFINED BY THE AMERICAN
574 SOCIETY OF ANESTHESIOLOGISTS.
575

576 (4) THE APPROVED MRI SIMULATOR WILL NOT BE SUBJECT TO MRI VOLUME
577 REQUIREMENTS.
578

579 (5) THE APPLICANT SHALL NOT UTILIZE THE PROCEDURES PERFORMED ON THE MRI
580 SIMULATOR TO DEMONSTRATE NEED OR TO SATISFY MRI CON REVIEW STANDARDS
581 REQUIREMENTS.
582

583 **Section 12. Requirements for approval of an FDA-approved PET/MRI scanner hybrid for initiation,**
584 **expansion, replacement, and acquisition**
585

586 Sec. 12. An applicant proposing to initiate, expand, replace, or acquire an FDA-approved PET/MRI
587 scanner hybrid shall demonstrate that it meets all of the following:
588

- 589 (1) There is an approved PET CON for the FDA-approved PET/MRI hybrid, and the FDA-approved

590 PET/MRI scanner hybrid is in compliance with all applicable project delivery requirements as set forth in
591 the CON review standards for PET.

592
593 (2) The applicant agrees to operate the FDA-approved PET/MRI scanner hybrid in accordance with
594 all applicable project delivery requirements set forth in Section 14 of these standards.

595
596 (3) The approved FDA-approved PET/MRI scanner hybrid shall not be subject to MRI volume
597 requirements.

598
599 (4) An FDA-approved PET/MRI scanner hybrid approved under the CON review standards for PET
600 scanner services and the review standards for MRI scanner services may not utilize MRI procedures
601 performed on an FDA-approved PET/MRI scanner hybrid to demonstrate need or to satisfy MRI CON
602 review standards requirements.

603

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

605

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

609

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

611

612 | Sec. 14. ~~(1)~~ An applicant shall agree that, if approved, MRI services, whether fixed or mobile, shall be
613 delivered and maintained in compliance with the following:

614 | ~~(a1)~~ Compliance with these standards.

615 | ~~(b) Compliance with applicable safety and operating standards.~~

616 | ~~(e2)~~ Compliance with the following quality assurance standards:

617 | ~~(ia)~~ An applicant shall develop and maintain policies and procedures that establish protocols for
618 assuring the effectiveness of operation and the safety of the general public, patients, and staff in the MRI
619 service.

620 | ~~(#b)~~ An applicant shall establish a schedule for preventive maintenance for the MRI unit.

621 | ~~(#c)~~ An applicant shall provide documentation identifying the specific individuals that form the MRI
622 team. At a minimum, the MRI team shall consist of the following professionals:

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

626 | ~~(Bii)~~ An appropriately trained MRI technician who shall be responsible for taking an MRI scan.

627 | ~~(Ciii)~~ An MRI physicist/engineer available as a team member on a full-time, part-time, or contractual
628 basis.

629 | ~~(ivd)~~ An applicant shall document that the MRI team members have the following qualifications:

630 | ~~(A)~~ Each physician credentialed to interpret MRI scans meets the requirements of each of the
631 following:

632 | ~~(4A)~~ The physician is licensed to practice medicine in the State of Michigan.

633 | ~~(2B)~~ The physician has had at least 60 hours of training in MRI physics, MRI safety, and MRI
634 instrumentation in a program that is part of an imaging program accredited by the Accreditation Council for
635 Graduate Medical Education or the American Osteopathic Association, and the physician meets the
636 requirements of subdivision ~~(i1)~~, ~~(#2)~~, or ~~(#3)~~:

637 | ~~(i1)~~ Board certification by the American Board of Radiology, the American Osteopathic Board of
638 Radiology, or the Royal College of Physicians and Surgeons of Canada. If the diagnostic radiology
639 program completed by a physician in order to become board certified did not include at least two months
640 of MRI training, that physician shall document that he or she has had the equivalent of two months of
641 postgraduate training in clinical MRI imaging at an institution which has a radiology program accredited by
642 the Accreditation Council for Graduate Medical Education or the American Osteopathic Association.

643 | (~~#2~~) Formal training by an imaging program(s), accredited by the Accreditation Council for Graduate
644 | Medical Education or the American Osteopathic Association, that included two years of training in cross-
645 | sectional imaging and six months training in organ-specific imaging areas.

646 | (~~#3~~) A practice in which at least one-third of total professional time, based on a full-time clinical
647 | practice during the most recent 5-year period, has been the primary interpretation of MR imaging.

648 | (~~3C~~) The physician has completed and will complete a minimum of 40 hours every two years of
649 | Category in Continuing Medical Education credits in topics directly involving MR imaging.

650 | (~~4D~~) The physician ~~interprets, as the primary interpreting physician, at least 250 unadjusted MRI~~
651 | ~~scans annually~~ COMPLIES WITH THE "AMERICAN COLLEGE OF RADIOLOGY (ACR) PRACTICE
652 | GUIDELINE FOR PERFORMING AND INTERPRETING MAGNETIC RESONANCE IMAGING (MRI)."

653 | (~~Bii~~) An MRI technologist who is registered by the American Registry of Radiologic Technicians or by
654 | the American Registry of Magnetic Resonance Imaging Technologists (ARMRIT) and has, or will have
655 | within 36 months of the effective date of these standards or the date a technologist is employed by an MRI
656 | service, whichever is later, special certification in MRI. If a technologist does not have special certification
657 | in MRI within either of the 3-year periods of time, all continuing education requirements shall be in the area
658 | of MRI services.

659 | (~~Ciii~~) An applicant shall document that an MRI physicist/engineer is appropriately qualified. For
660 | purposes of evaluating this subdivision, the Department shall consider it prima facie evidence as to the
661 | qualifications of the physicist/engineer if the physicist/engineer is certified as a medical physicist by the
662 | American Board of Radiology, the American Board of Medical Physics, or the American Board of Science
663 | in Nuclear Medicine. However, the applicant may submit and the Department may accept other evidence
664 | that an MRI physicist/engineer is qualified appropriately.

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

669 | (3) COMPLIANCE WITH THE FOLLOWING ACCESS TO CARE REQUIREMENTS:

671 | The applicant, to assure that the MRI unit will be utilized by all segments of the Michigan population, shall

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

674 | (b) maintain information by source of payment to indicate the volume of care from each source
675 | provided annually.

676 | (~~wc~~) An applicant shall participate in Medicaid at least 12 consecutive months within the first two
677 | years of operation and continue to participate annually thereafter.

678 | (d) The operation of and referral of patients to the MRI unit shall be in conformance with 1978 PA
679 | 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

680 | (d4) Compliance with the following ~~terms of approval, as applicable~~ MONITORING AND
682 | REPORTING REQUIREMENTS:

683 | (~~ia~~) MRI units shall be operating at a minimum average annual utilization during the second 12
684 | months of operation, and annually thereafter, as applicable:

685 | (~~Ai~~) 6,000 MRI adjusted procedures per unit for fixed MRI services unless compliant with (1) or (2),

686 | (~~1A~~) 4,000 MRI adjusted procedures for the fixed MRI unit initiated pursuant to Section 3(2)(b)(ii) and
687 | is the only fixed MRI unit at the current site,

688 | (~~2B~~) 3,000 MRI adjusted procedures for the fixed MRI unit initiated pursuant to Section 3(2)(b)(iii)
689 | and is the only fixed MRI unit at the hospital site licensed under part 215 of the code,

690 | (~~Bii~~) 5,500 MRI adjusted procedures per unit for mobile MRI services.

691 | (~~Ciii~~) 3,500 MRI adjusted procedures per unit for dedicated pediatric MRI units.

692 | (~~Div~~) Each mobile host site in a rural or micropolitan statistical area county shall have provided at
693 | least a total of 400 adjusted procedures during its second 12 months of operation, and annually thereafter,
694 | from all mobile units providing services to the site. Each mobile host site not in a rural or micropolitan
695 | statistical area county shall have provided at least a total of 600 adjusted procedures during its second 12
696 | months of operation and annually thereafter, from all mobile units providing services to the site.

697 (Ev) In meeting these requirements, an applicant shall not include any MRI adjusted procedures
698 performed on an MRI unit used exclusively for research and approved pursuant to Section ~~87(4)~~ or for an
699 IMRI unit approved pursuant to Section 409.

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

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

704 ~~(B) maintain information by source of payment to indicate the volume of care from each source
705 provided annually.~~

706 (iii) The applicant shall participate in a data collection network established and administered by the
707 Department or its designee. The data may include, but is not limited to, operating schedules,
708 demographic and diagnostic information, and the volume of care provided to patients from all payor
709 sources, as well as other data requested by the Department or its designee and approved by the
710 Commission. The applicant shall provide the required data in a format established by the Department and
711 in a mutually agreed upon media no later than 30 days following the last day of the quarter for which data
712 are being reported to the Department. An applicant shall be considered in violation of this term of
713 approval if the required data are not submitted to the Department within 30 days following the last day of
714 the quarter for which data are being reported. The Department may elect to verify the data through on-site
715 review of appropriate records. Data for an MRI unit approved pursuant to SECTION 7, Section 8(4),
716 Section 9, Section 10, or Section 11 shall be reported separately.

717 For purposes of Section 409, the data reported shall include, at a minimum, how often the IMRI unit is
718 used and for what type of services, i.e., intra-operative or diagnostic. For purposes of Section 4410, the
719 data reported shall include, at a minimum, how often the MRI-guided EPI unit is used and for what type of
720 services, i.e., electrophysiology or diagnostic. FOR PURPOSES OF SECTION 11, THE DATA
721 REPORTED SHALL INCLUDE, AT A MINIMUM, HOW OFTEN THE MRI SIMULATOR IS USED AND
722 FOR WHAT TYPE OF SERVICES, I.E., TREATMENT PLANS OR DIAGNOSTIC SERVICES.

723 ~~(iv) The operation of and referral of patients to the MRI unit shall be in conformance with 1978 PA~~
724 ~~368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).~~

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

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

731
732 (25) An applicant for an MRI unit approved under Section ~~87(4)~~ shall agree that the services
733 provided by the MRI unit are delivered in compliance with the following terms.

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

736 (b) The MRI unit shall not be used for any purposes other than as approved by the IRB unless the
737 applicant has obtained CON approval for the MRI unit pursuant to Part 222 and these standards, other
738 than Section 87.

739 (C) THE DEDICATED RESEARCH MRI UNIT WILL BE USED PRIMARILY (70% OR MORE OF
740 THE PROCEDURES) FOR RESEARCH PURPOSES ONLY.

741
742 (6) THE DEDICATED PEDIATRIC MRI UNIT APPROVED UNDER SECTION 8 SHALL INCLUDE
743 AT LEAST 80% OF THE MRI PROCEDURES THAT ARE PERFORMED ON PATIENTS UNDER 18
744 YEARS OF AGE.

745
746 (73) The agreements and assurances required by this section shall be in the form of a certification
747 agreed to by the applicant or its authorized agent.

748
749 **Section 15. MRI procedure adjustments**

750

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

753 (a) The base value for each MRI procedure is 1.0. FOR FUNCTIONAL MRI (fMRI)
754 PROCEDURES, MRI-GUIDED INTERVENTIONS, AND CARDIAC MRI PROCEDURES, THE BASE
755 VALUE IS 2.0.

756 (i) fMRI MEANS BRAIN ACTIVATION STUDIES.

757 (ii) MRI-GUIDED INTERVENTIONS MEANS ANY INVASIVE PROCEDURE PERFORMED
758 REQUIRING MRI GUIDANCE PERFORMED IN THE MRI SCANNER.

759 (iii) CARDIAC MRI PROCEDURE MEANS DEDICATED MRI PERFORMED OF THE HEART
760 DONE FOR THE SOLE PURPOSE OF EVALUATION OF CARDIAC FUNCTION, PHYSIOLOGY, OR
761 VIABILITY.

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

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

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

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

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

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

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

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

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

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

778
779 (2) The Department shall apply not more than one of the adjustment factors set forth in this
780 subsection, as applicable, to the number of MRI procedures adjusted in accordance with the applicable
781 provisions of subsection (1) that are performed by an existing MRI service or unit.

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

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

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

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

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

796
797 (3) The number of MRI adjusted procedures performed by an existing MRI service is the sum of the
798 results of subsections (1) and (2).

800 **Section 16. Documentation of actual utilization**

801
802 Sec. 16. Documentation of the number of MRI procedures performed by an MRI unit shall be
803 substantiated by the Department utilizing data submitted by the applicant in a format and media specified
804 by the Department and as verified for the 12-month period reported on the most recently published "MRI

805 Service Utilization List" as of the date an application is deemed submitted by the Department. The
806 number of MRI procedures actually performed shall be documented by procedure records and not by
807 application of the methodology required in Section 17. The Department may elect to verify the data
808 through on-site review of appropriate records.
809

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

811

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

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

819 (i) For purposes of computing actual MRI adjusted procedures, MRI adjusted procedures
820 performed on MRI units used exclusively for research and approved pursuant to Section ~~8(4)7~~ and
821 dedicated pediatric MRI approved pursuant to Section ~~9-8~~ shall be excluded.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- 913 (i) The approved CON is withdrawn or expires.
- 914 (ii) The MRI service or unit to which the data were committed has been in operation for at least 36
915 continuous months.
- 916 (b) The Department shall not consider a data commitment from a doctor for available MRI adjusted
917 procedures from a specific MRI service if the available MRI adjusted procedures from that specific MRI
918 service were used to support an application for a new fixed or mobile MRI unit or additional mobile MRI
919 unit pursuant to Section 3, for which a final decision to disapprove was issued by the Director of the
920 Department until either of the following occurs:
- 921 (i) A final decision to disapprove an application is issued by the Director and the applicant does not
922 appeal that disapproval or
- 923 (ii) If an appeal was made, either that appeal is withdrawn by the applicant or the committing doctor
924 withdraws his or her data commitment pursuant to the requirements of subsection (8).
925
- 926 (5) The Department shall not consider a data commitment from a committing doctor for available
927 MRI adjusted procedures from the same MRI service if that doctor has submitted a signed data
928 commitment, on a form provided by Department, for more than one (1) application for which a final
929 decision has not been issued by the Department. If the Department determines that a doctor has
930 submitted a signed data commitment for the same available MRI adjusted procedures from the same MRI
931 service to more than one CON application pending a final decision for a new fixed or mobile MRI unit or
932 additional mobile MRI unit pursuant to Section 3, the Department shall,
- 933 (a) if the applications were submitted on the same designated application date, notify all applicants,
934 simultaneously and in writing, that one or more doctors have submitted data commitments for available
935 MRI adjusted procedures from the same MRI service and that the doctors' data from the same MRI
936 service shall not be considered in the review of any of the pending applications submitted on the same
937 designated application date until the doctor notifies the Department, in writing, of the one (1) application
938 for which the data commitment shall be considered.
- 939 (b) if the applications were submitted on different designated application dates, consider the data
940 commitment in the application submitted on the earliest designated application date and shall notify,
941 simultaneously in writing, all applicants of applications submitted on designated application dates
942 subsequent to the earliest date that one or more committing doctors have submitted data commitments
943 for available MRI adjusted procedures from the same MRI service and that the doctors' data shall not be
944 considered in the review of the application(s) submitted on the subsequent designated application date(s).
945
- 946 (6) The Department shall not consider any data commitment submitted by an applicant after the
947 date an application is deemed submitted unless an applicant is notified by the Department, pursuant to
948 subsection (5), that one or more committing doctors submitted data commitments for available MRI
949 adjusted procedures from the same MRI service. If an applicant is notified that one or more doctors' data
950 commitments will not be considered by the Department, the Department shall consider data commitments
951 submitted after the date an application is deemed submitted only to the extent necessary to replace the
952 data commitments not being considered pursuant to subsection (5).
- 953 (a) The applicant shall have 30 days to submit replacement of doctor commitments as identified by
954 the Department in this Section.
955
- 956 (7) In accordance with either of the following, the Department shall not consider a withdrawal of a
957 signed data commitment:
- 958 (a) on or after the date an application is deemed submitted by the Department.
- 959 (b) after a proposed decision to approve an application has been issued by the Department.
960
- 961 (8) The Department shall consider a withdrawal of a signed data commitment if a committing doctor
962 submits a written notice to the Department, that specifies the CON application number and the specific
963 MRI services for which a data commitment is being withdrawn, and if an applicant demonstrates that the
964 requirements of subsection (7) also have been met.
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966 **Section 19. Lists published by the Department**

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

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

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

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

- (i) The number of available MRI adjusted procedures;
- (ii) The name, address, and license number of each referring doctor, identified in Section 17(1)(c)(v), whose patients received MRI services at that MRI service; and
- (iii) The number of available MRI adjusted procedures performed on patients referred by each referring doctor, identified in Section 17(1)(c)(v), and if any are committed to an MRI service. This number shall be calculated in accordance with the requirements of Section 17(1). A referring doctor may have fractional portions of available MRI adjusted procedures.

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

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

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

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

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

Sec. 20. (1) These CON review standards supersede and replace the CON Review Standards for MRI Services approved by the CON Commission on ~~September 22, 2011~~ JUNE 14, 2012 and effective ~~November 21, 2011~~ SEPTEMBER 28, 2012.

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

Section 21. Health Service Areas

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

HSA	COUNTIES		
1	Livingston Macomb	Monroe Oakland	St. Clair Washtenaw

1021		Wayne		
1022				
1023	2	Clinton	Hillsdale	Jackson
1024		Eaton	Ingham	Lenawee
1025				
1026	3	Barry	Calhoun	St. Joseph
1027		Berrien	Cass	Van Buren
1028		Branch	Kalamazoo	
1029				
1030	4	Allegan	Mason	Newaygo
1031		Ionia	Mecosta	Oceana
1032		Kent	Montcalm	Osceola
1033		Lake	Muskegon	Ottawa
1034				
1035	5	Genesee	Lapeer	Shiawassee
1036				
1037	6	Arenac	Huron	Roscommon
1038		Bay	Iosco	Saginaw
1039		Clare	Isabella	Sanilac
1040		Gladwin	Midland	Tuscola
1041		Gratiot	Ogemaw	
1042				
1043	7	Alcona	Crawford	Missaukee
1044		Alpena	Emmet	Montmorency
1045		Antrim	Gd Traverse	Oscoda
1046		Benzie	Kalkaska	Otsego
1047		Charlevoix	Leelanau	Presque Isle
1048		Cheboygan	Manistee	Wexford
1049				
1050	8	Alger	Gogebic	Mackinac
1051		Baraga	Houghton	Marquette
1052		Chippewa	Iron	Menominee
1053		Delta	Keweenaw	Ontonagon
1054		Dickinson	Luce	Schoolcraft

CON REVIEW STANDARDS
FOR MRI SERVICES

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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