

**Certificate of Need MRI Standards Workgroup
Draft Language for Agenda Item IV.**

Section 4

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

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

(b) The MRI mobile host site to be relocated has been in operation for at least ~~36~~ **24** months as of the date an application is submitted to the Department.

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

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

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

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

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

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

(c) Each existing MRI unit to be relocated performed at least the applicable minimum number of MRI adjusted procedures set forth in Section 14 based on the most recently published MRI Service Utilization List as of the date an application is deemed submitted by the Department, **unless one of the following requirements are met:**

(i) The owner of the building where the site is located has incurred a filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application; or

(ii) The MRI service being replaced as part of the replacement of an entire hospital to a new geographic site.

Certificate of Need MRI Standards Workgroup
Draft Language for Agenda Item IV.

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

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

(a) **THE APPLICANT** shall not be required to be in compliance with the volume requirements applicable to a seller/lessor on the date the acquisition occurs **IF THE PROPOSED PROJECT MEETS ONE OF THE FOLLOWING:**

(1) For the first application proposing to acquire an existing fixed or mobile MRI service on or after July 1, 1997, the existing MRI service and its unit(s) to be acquired.

(2) THE EXISTING FIXED OR MOBILE MRI SERVICE IS OWNED BY, IS UNDER COMMON CONTROL OF, OR HAS COMMON OWNERSHIP AS THE EXISTING FIXED OR MOBILE SERVICE.

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

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

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

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

(3) THE MRI SERVICE SHALL BE OPERATING AT THE APPLICABLE VOLUME REQUIREMENTS SET FORTH IN SECTION 14 OF THESE STANDARDS IN THE SECOND 12 MONTHS AFTER THE EFFECTIVE DATE OF THE ACQUISITION AND ANNUALLY THEREAFTER.

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

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

10 **Section 1. Applicability**
11

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

18 **Section 2. Definitions**
19

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

129 (kk) "Planning area" means

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

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

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

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

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

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

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

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

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

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

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

158 (qq) "Site" means

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

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

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

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

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

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

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

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

184
185 (1) An applicant proposing to initiate a fixed MRI service shall demonstrate 6,000 available MRI
186 adjusted procedures per proposed fixed MRI unit from within the same planning area as the proposed
187 service/unit.
188

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

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

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

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

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

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

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

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

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

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

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

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

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

210
211 (3) An applicant proposing to initiate a mobile MRI service shall demonstrate 5,500 available MRI
212 adjusted procedures from within the same planning area as the proposed service/unit, and the applicant
213 shall meet the following:

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

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

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

218
219 (4) An applicant, whether the central service coordinator or the host site, proposing to initiate a
220 host site on a new or existing mobile MRI service shall demonstrate the following, as applicable:

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

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

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

227
228 (5) An applicant proposing to add or change service on an existing mobile MRI service that meets
229 the following requirements shall not be required to be in compliance with subsection (4):

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

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

234
235 (6) The applicant shall demonstrate that the available MRI adjusted procedures from the "Available
236 MRI Adjusted Procedures List" or the adjusted procedures from the "MRI Service Utilization List," as
237 applicable, are from the most recently published MRI lists as of the date an application is deemed
238 submitted by the Department.

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

240
241
242 Sec. 4. Replace an existing MRI unit means (i) any equipment change involving a change in, or
243 replacement of, the entire MRI unit resulting in an applicant operating the same number and type (fixed or
244 mobile) of MRI units before and after project completion or (ii) an equipment change that involves a
245 capital expenditure of \$750,000 or more in any consecutive 24-month period or (iii) the renewal of a
246 lease. Replacement also means the relocation of an MRI service or unit to a new site. The term does
247 not include the replacement of components of the MRI system, including the magnet, under an existing
248 service contract or required maintenance to maintain the system to operate within manufacturer
249 specifications. The term does not include an upgrade to an existing MRI unit or repair of an existing MRI
250 service or unit, and it does not include a host site that proposes to receive mobile MRI services from a
251 different central service coordinator if the requirements of Section 3(5) have been met.

252
253 (1) "Upgrade an existing MRI unit" means any equipment change that

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

313
314 (6) An applicant proposing to replace a fixed MRI unit of an existing MRI service to a new site shall
315 demonstrate the following:

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

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

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

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

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

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

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328
329 Sec. 5. An applicant proposing to expand an existing MRI service shall demonstrate the following:

330
331 (1) An applicant shall demonstrate that the applicable MRI adjustable procedures are from the
332 most recently published MRI Service Utilization List as of the date of an application is deemed submitted
333 by the Department:

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

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

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

340
341 (2) The additional fixed unit shall be located at the same site unless the requirements of the
342 replacement section have been met.

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

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345
346 Sec. 6. ~~(1)~~ An applicant proposing to acquire an existing fixed or mobile MRI service and its unit(s)
347 shall demonstrate the following:

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

354
355 ~~(b2)~~ For any application proposing to acquire an existing fixed or mobile MRI service and its unit(s),
356 except the first application approved pursuant to subsection (a), an applicant shall be required to
357 document that the MRI service and its unit(s) to be acquired is operating in compliance with the volume
358 requirements set forth in Section 14 of these standards applicable to an existing MRI service on the date
359 the application is submitted to the Department.

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

363 (a) THE FIXED MRI UNIT(S) TO BE ACQUIRED PERFORMED AT LEAST 6,000 MRI ADJUSTED
364 PROCEDURES PER FIXED MRI UNIT IN THE MOST RECENT 12-MONTH PERIOD FOR WHICH THE
365 DEPARTMENT HAS VERIFIABLE DATA.

366 (b) THE MOBILE MRI UNIT(S) TO BE ACQUIRED PERFORMED AT LEAST 5,500 MRI
367 ADJUSTED PROCEDURES PER MOBILE MRI UNIT IN THE MOST RECENT 12-MONTH PERIOD FOR
368 WHICH THE DEPARTMENT HAS VERIFIABLE DATA.

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

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

375 Section 7. Requirements to establish a dedicated research MRI unit

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

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

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

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

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

393
394 (5) THE DEDICATED RESEARCH MRI UNIT APPROVED UNDER THIS SECTION MAY NOT
395 UTILIZE MRI ADJUSTED PROCEDURES PERFORMED ON THE DEDICATED MRI UNIT TO
396 DEMONSTRATE NEED OR TO SATISFY MRI CON REVIEW STANDARDS REQUIREMENTS.

397 Section 8. Requirements to establish a dedicated pediatric MRI unit

398
399
400 Sec. 8. An applicant proposing to establish dedicated pediatric MRI shall demonstrate all of the
401 following:

402
403 (1) The applicant shall have experienced at least 7,000 pediatric (< 18 years old) discharges
404 (excluding normal newborns) in the most recent year of operation.

405
406 (2) The applicant shall have performed at least 5,000 pediatric (< 18 years old) surgeries in the
407 most recent year of operation.

408
409 (3) The applicant shall have an active medical staff that includes, but is not limited to, physicians
410 who are fellowship-trained in the following pediatric specialties:

411 (a) pediatric radiology (at least two)

412 (b) pediatric anesthesiology

- 413 (c) pediatric cardiology
- 414 (d) pediatric critical care
- 415 (e) pediatric gastroenterology
- 416 (f) pediatric hematology/oncology
- 417 (g) pediatric neurology
- 418 (h) pediatric neurosurgery
- 419 (i) pediatric orthopedic surgery
- 420 (j) pediatric pathology
- 421 (k) pediatric pulmonology
- 422 (l) pediatric surgery
- 423 (m) neonatology

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

- 426 (a) pediatric bone marrow transplant program
- 427 (b) established pediatric sedation program
- 428 (c) pediatric open heart program

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

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

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

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

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

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

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

- 438 (a) at least 1,500 oncology discharges in the most recent year of operation; or
- 439 (b) at least 1,000 neurological surgeries in the most recent year of operation; or
- 440 (c) at least 7,000 pediatric (<18 years old) discharges (excluding normal newborns) and at least 441 5,000 pediatric (<18 years old) surgeries in the most recent year of operation.

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

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

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

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

463

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

466
467 **Section 10. Requirements for all applicants proposing to initiate, replace, or acquire a hospital**
468 **based MRI-guided EPI service**

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

471
472 (1) The proposed site is a licensed hospital under part 215 of the Code.

473
474 (2) The proposed site has an existing fixed MRI service that has been operational for the previous
475 36 consecutive months and is meeting its minimum volume requirements.

476
477 (3) The proposed site has an existing and operational therapeutic cardiac catheterization service
478 and is meeting its minimum volume requirements pursuant to the CON review standards for cardiac
479 catheterization services and open heart surgery services.

480
481 (4) The proposed MRI-guided EPI unit must be located in a cardiac catheterization lab containing a
482 fluoroscopy unit with an adjoining room containing an MRI scanner. The rooms shall contain a patient
483 transfer system allowing for transfer of the patient between the cardiac catheterization lab and the MRI
484 unit, utilizing one of the following:

485 (a) moving the patient to the MRI scanner, or

486 (b) installing the MRI scanner on a sliding gantry to allow the patient to remain stationary.

487
488 (5) Non-cardiac MRI diagnostic studies shall not be performed in an MRI-guided EPI unit approved
489 under this section unless the patient meets one of the following criteria:

490 (a) The patient has been admitted to an inpatient unit; or

491 (b) The patient is having the study performed on an outpatient basis as follows:

492 (i) is in need of general anesthesia or deep sedation as defined by the American Society of
493 Anesthesiologists, or

494 (ii) has an implantable cardiac device.

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

496
497 (7) The applicant shall not utilize the procedures performed on the MRI-guided EPI unit to
498 demonstrate need or to satisfy MRI CON review standards requirements.

501
502 **Section 11. Requirements for all applicants proposing to initiate, replace, or acquire an MRI**
503 **simulator that will not be used solely for MRT treatment planning purposes**

504
505 Sec. 11. MRI simulation is the use of MRI to help simulate (or plan) a patient's MRT treatment and to
506 incorporate superior delineation of soft tissues for MRT treatment plans. An applicant proposing to
507 initiate, replace, or acquire an MRI simulator shall demonstrate each of the following, as applicable to the
508 proposed project.

509
510 (1) The proposed site has an existing fixed MRI service that has been operational for the previous
511 36 consecutive months and is meeting its minimum volume requirements.

512
513 (2) The proposed site has an existing and operational MRT service and is meeting its minimum
514 volume requirements pursuant to the CON review standards for MRT services/units.

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

518 (a) The patient has been admitted to an inpatient unit; or

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

521

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

523

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

526

527

528 **Section 12. Requirements for approval of an FDA-approved PET/MRI scanner hybrid for initiation,**
529 **expansion, replacement, and acquisition**
530

531 Sec. 12. An applicant proposing to initiate, expand, replace, or acquire an FDA-approved PET/MRI
532 scanner hybrid shall demonstrate that it meets all of the following:
533

534 (1) There is an approved PET CON for the FDA-approved PET/MRI hybrid, and the FDA-approved
535 PET/MRI scanner hybrid is in compliance with all applicable project delivery requirements as set forth in
536 the CON review standards for PET.
537

538 (2) The applicant agrees to operate the FDA-approved PET/MRI scanner hybrid in accordance
539 with all applicable project delivery requirements set forth in Section 14 of these standards.
540

541 (3) The approved FDA-approved PET/MRI scanner hybrid shall not be subject to MRI volume
542 requirements.
543

544 (4) An FDA-approved PET/MRI scanner hybrid approved under the CON review standards for PET
545 scanner services and the review standards for MRI scanner services may not utilize MRI procedures
546 performed on an FDA-approved PET/MRI scanner hybrid to demonstrate need or to satisfy MRI CON
547 review standards requirements.
548

549 **Section 13. Requirements for all applicants**
550

551 Sec. 13. An applicant shall provide verification of Medicaid participation. An applicant that is a new
552 provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided
553 to the Department within six (6) months from the offering of services if a CON is approved.
554

555 **Section 14. Project delivery requirements – terms of approval**
556

557 Sec. 14. An applicant shall agree that, if approved, MRI services, whether fixed or mobile, shall be
558 delivered and maintained in compliance with the following:
559

560 (1) Compliance with these standards.
561

562 (2) Compliance with the following quality assurance standards:
563

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

622 (d) The operation of and referral of patients to the MRI unit shall be in conformance with 1978 PA
623 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

624 (4) Compliance with the following monitoring and reporting requirements:
625

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

628 (i) 6,000 MRI adjusted procedures per unit for fixed MRI services unless compliant with (4A) or
629 (2B),
630

631 (A) 4,000 MRI adjusted procedures for the fixed MRI unit initiated pursuant to Section 3(2)(b)(ii)
632 and is the only fixed MRI unit at the current site,
633 (B) 3,000 MRI adjusted procedures for the fixed MRI unit initiated pursuant to Section 3(2)(b)(iii)
634 and is the only fixed MRI unit at the hospital site licensed under part 215 of the code,
635 (ii) 5,500 MRI adjusted procedures per unit for mobile MRI services.
636 (iii) 3,500 MRI adjusted procedures per unit for dedicated pediatric MRI units.
637 (iv) Each mobile host site in a rural or micropolitan statistical area county shall have provided at
638 least a total of 400 adjusted procedures during its second 12 months of operation, and annually
639 thereafter, from all mobile units providing services to the site. Each mobile host site not in a rural or
640 micropolitan statistical area county shall have provided at least a total of 600 adjusted procedures during
641 its second 12 months of operation and annually thereafter, from all mobile units providing services to the
642 site.
643 (v) In meeting these requirements, an applicant shall not include any MRI adjusted procedures
644 performed on an MRI unit used exclusively for research and approved pursuant to Section 7 or for an
645 IMRI unit approved pursuant to Section 9.
646
647 (b) The applicant shall participate in a data collection network established and administered by the
648 Department or its designee. The data may include, but is not limited to, operating schedules,
649 demographic and diagnostic information, and the volume of care provided to patients from all payor
650 sources, as well as other data requested by the Department or its designee and approved by the
651 Commission. The applicant shall provide the required data in a format established by the Department
652 and in a mutually agreed upon media no later than 30 days following the last day of the quarter for which
653 data are being reported to the Department. An applicant shall be considered in violation of this term of
654 approval if the required data are not submitted to the Department within 30 days following the last day of
655 the quarter for which data are being reported. The Department may elect to verify the data through
656 on-site review of appropriate records. Data for an MRI unit approved pursuant to Section 7, Section 8,
657 Section 9, Section 10, or Section 11 shall be reported separately.
658 For purposes of Section 9, the data reported shall include, at a minimum, how often the IMRI unit is used
659 and for what type of services, i.e., intra-operative or diagnostic. For purposes of Section 10, the data
660 reported shall include, at a minimum, how often the MRI-guided EPI unit is used and for what type of
661 services, i.e., electrophysiology or diagnostic. For purposes of Section 11, the data reported shall
662 include, at a minimum, how often the MRI simulator is used and for what type of services, i.e., treatment
663 plans or diagnostic services.
664 (c) The applicant shall provide the Department with a notice stating the first date on which the MRI
665 unit became operational, and such notice shall be submitted to the Department consistent with applicable
666 statute and promulgated rules.
667 (d) An applicant who is a central service coordinator shall notify the Department of any additions,
668 deletions, or changes in the host sites of each approved mobile MRI unit ~~within 10 days~~ after the
669 change(s) in host sites is made.
670
671 (5) An applicant for an MRI unit approved under Section 7 shall agree that the services provided
672 by the MRI unit are delivered in compliance with the following terms.
673 (a) The capital and operating costs relating to the research use of the MRI unit shall be charged
674 only to a specific research account(s) and not to any patient or third-party payor.
675 (b) The MRI unit shall not be used for any purposes other than as approved by the IRB unless the
676 applicant has obtained CON approval for the MRI unit pursuant to Part 222 and these standards, other
677 than Section 7.
678 (c) The dedicated research MRI unit will be used primarily (70% or more of the procedures) for
679 research purposes only.
680

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

683
684 (7) The agreements and assurances required by this section shall be in the form of a certification
685 agreed to by the applicant or its authorized agent.

686
687 **Section 15. MRI procedure adjustments**

688
689 Sec. 15. (1) The Department shall apply the following formula, as applicable, to determine the
690 number of MRI adjusted procedures that are performed by an existing MRI service or unit:

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

693 (i) fMRI means brain activation studies.

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

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

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

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

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

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

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

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

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

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

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

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

715
716 (2) The Department shall apply not more than one of the adjustment factors set forth in this
717 subsection, as applicable, to the number of MRI procedures adjusted in accordance with the applicable
718 provisions of subsection (1) that are performed by an existing MRI service or unit.

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

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

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

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

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

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

Section 16. Documentation of actual utilization

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

796 (viii) The result shall be the "Available MRI Adjusted Procedures List."
797

798 (2) After publication of the "Available MRI Adjusted Procedures List" resulting from (1) above, the
799 data shall be updated to account for a) doctor commitments of available MRI adjusted procedures in
800 subsequent MRI CON applications and b) MRI adjusted procedures used in subsequent MRI CON
801 applications received in which applicants apply for fixed MRI services pursuant to Section 3(2).
802

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

804
805 Sec. 18. (1) If one or more host sites on a mobile MRI service are located within the planning area of
806 the proposed site, the applicant may access available MRI adjusted procedures from the entire mobile
807 MRI service.
808

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

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

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

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

822 (c) If the required documentation for the doctor commitments submitted under this subsection is
823 not submitted with the application on the designated application date, the application will be deemed
824 submitted on the first applicable designated application date after all required documentation is received
825 by the Department.
826

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

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

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

836 (b) A committing doctor certifies ownership interest, either direct or indirect, in the applicant entity.
837 Indirect ownership includes ownership in an entity that has ownership interest in the applicant entity. This
838 requirement shall not apply if the applicant entity is a group practice of which the committing doctor is a
839 member. Group practice means a group practice as defined pursuant to the provisions of 42 U.S.C.
840 1395nn (h)(4), commonly known as Stark II, and the Code of Federal Regulations, 42 CFR, Part 411,
841 published in the Federal Register on August 14, 1995, or its replacement.

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

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

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

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

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

859 ~~(i) A final decision to disapprove an application is issued by the Director, and the applicant does~~
860 ~~not appeal that disapproval or~~

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

863
864 (5) The Department shall not consider a data commitment from a committing doctor for available
865 MRI adjusted procedures from the same MRI service if that doctor has submitted a signed data
866 commitment, on a form provided by Department, for more than one (1) application for which a final
867 decision has not been issued by the Department. If the Department determines that a doctor has
868 submitted a signed data commitment for the same available MRI adjusted procedures from the same MRI
869 service to more than one CON application pending a final decision for a new fixed or mobile MRI unit or
870 additional mobile MRI unit pursuant to Section 3, the Department shall,

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

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

884

885 (6) The Department shall not consider any data commitment submitted by an applicant after the
886 date an application is deemed submitted unless an applicant is notified by the Department, pursuant to
887 subsection (5), that one or more committing doctors submitted data commitments for available MRI
888 adjusted procedures from the same MRI service. If an applicant is notified that one or more doctors' data
889 commitments will not be considered by the Department, the Department shall consider data commitments
890 submitted after the date an application is deemed submitted only to the extent necessary to replace the
891 data commitments not being considered pursuant to subsection (5).

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

894
895 (7) ~~In accordance with either of the following, t~~The Department shall not consider a withdrawal of a
896 signed data commitment:

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

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

899
900 (8) The Department shall consider a withdrawal of a signed data commitment if a committing
901 doctor submits a written notice to the Department, that specifies the CON application number and the
902 specific MRI services for which a data commitment is being withdrawn, and if an applicant demonstrates
903 that the requirements of subsection (7) also have been met.

904

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

906

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

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

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

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

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

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

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

918 (ii) The name, address, and license number of each referring doctor, identified in Section

919 17(1)(c)(v), whose patients received MRI services at that MRI service; and

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

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

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

930

931 (2) When an MRI service begins to operate at a site at which MRI services previously were not
932 provided, the Department shall include in the MRI database, data beginning with the second full quarter
933 of operation of the new MRI service. Data from the start-up date to the start of the first full quarter will not
934 be collected to allow a new MRI service sufficient time to develop its data reporting capability. Data from

935 the first full quarter of operation will be submitted as test data but will not be reported in the lists published
936 pursuant to this section.

937

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

942

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

944

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

948

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

950

951

952 **Section 21. Health Service Areas**

953

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

955

956 **HSA**

COUNTIES

957

958

959 1 Livingston Monroe St. Clair
 960 Macomb Oakland Washtenaw
 961 Wayne

962

963 2 Clinton Hillsdale Jackson
 964 Eaton Ingham Lenawee

965

966 3 Barry Calhoun St. Joseph
 967 Berrien Cass Van Buren
 968 Branch Kalamazoo

969

970 4 Allegan Mason Newaygo
 971 Ionia Mecosta Oceana
 972 Kent Montcalm Osceola
 973 Lake Muskegon Ottawa

974

975 5 Genesee Lapeer Shiawassee

976

977 6 Arenac Huron Roscommon
 978 Bay Iosco Saginaw
 979 Clare Isabella Sanilac
 980 Gladwin Midland Tuscola
 981 Gratiot Ogemaw

982

983 7 Alcona Crawford Missaukee
 984 Alpena Emmet Montmorency
 985 Antrim Gd Traverse Oscoda
 986 Benzie Kalkaska Otsego
 987 Charlevoix Leelanau Presque Isle
 988 Cheboygan Manistee Wexford

989

990 8 Alger Gogebic Mackinac
 991 Baraga Houghton Marquette
 992 Chippewa Iron Menominee
 993 Delta Keweenaw Ontonagon
 994 Dickinson Luce Schoolcraft

995
996
997 Rural Michigan counties are as follows:
998

999	Alcona	Gogebic	Ogemaw
1000	Alger	Huron	Ontonagon
1001	Antrim	Iosco	Osceola
1002	Arenac	Iron	Oscoda
1003	Baraga	Lake	Otsego
1004	Charlevoix	Luce	Presque Isle
1005	Cheboygan	Mackinac	Roscommon
1006	Clare	Manistee	Sanilac
1007	Crawford	Montmorency	Schoolcraft
1008	Emmet	Newaygo	Tuscola
1009	Gladwin	Oceana	

1010
1011 Micropolitan statistical area Michigan counties are as follows:
1012

1013	Allegan	Hillsdale	Mason
1014	Alpena	Houghton	Mecosta
1015	Benzie	Ionia	Menominee
1016	Branch	Isabella	Missaukee
1017	Chippewa	Kalkaska	St. Joseph
1018	Delta	Keweenaw	Shiawassee
1019	Dickinson	Leelanau	Wexford
1020	Grand Traverse	Lenawee	
1021	Gratiot	Marquette	

1022
1023 Metropolitan statistical area Michigan counties are as follows:
1024

1025	Barry	Jackson	Muskegon
1026	Bay	Kalamazoo	Oakland
1027	Berrien	Kent	Ottawa
1028	Calhoun	Lapeer	Saginaw
1029	Cass	Livingston	St. Clair
1030	Clinton	Macomb	Van Buren
1031	Eaton	Midland	Washtenaw
1032	Genesee	Monroe	Wayne
1033	Ingham	Montcalm	

1034
1035 Source:
1036

1037 75 F.R., p. 37245 (June 28, 2010)
1038 Statistical Policy Office
1039 Office of Information and Regulatory Affairs
1040 United States Office of Management and Budget
1041