

1 MICHIGAN DEPARTMENT OF **COMMUNITY HEALTH AND HUMAN SERVICES**

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**

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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**

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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 AND HUMAN SERVICES**
53 **(MDCHMDHHS).**

- 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 replacement of an existing
76 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
110 MRI unit approved pursuant to Section 7.

111 (dd) "MRI services" means either the utilization of an authorized MRI unit(s) at one site in the case
112 of a fixed MRI service or in the case of a mobile MRI service, the utilization of an authorized mobile MRI
113 unit 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 a 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) "Mobile MRI unit" means an MRI unit operating at two or more host sites and that has a central
124 service coordinator. The mobile MRI unit shall operate under a contractual agreement for the provision of
125 MRI services at each host site on a regularly scheduled basis.

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

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

130 (kk) "Planning area" means

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

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

139 (iii) in the case of a proposed mobile MRI service or unit meeting the requirement of Section
140 15(2)(d), the health service area in which all the proposed mobile host sites will be located.

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

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

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

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

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

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

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

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

159 (qq) "Site" means

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

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

164 (rr) "Special needs patient" means a non-sedated patient, either pediatric or adult, with any of the
165 following conditions: down syndrome, autism, attention deficit hyperactivity disorder (ADHD),
166 developmental delay, malformation syndromes, hunter's syndrome, multi-system disorders, psychiatric
167 disorders, implantable cardiac devices (ICDS), and other conditions that make the patient unable to
168 comply with the positional requirements of the exam or is unable to comply with the motionless
169 requirements and whose resulting movements result in non-diagnostic quality images therefore requiring
170 the technologist to repeat the same sequence in an attempt to obtain a diagnostic quality image.

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

175 (tt) "Unadjusted MRI scan" means an MRI procedure performed on a single anatomical site as
176 defined by the MRI database and that is not adjusted pursuant to the applicable provisions of Section 15.
177

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

218

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

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

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

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

227

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

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

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

234

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

239

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

241

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

252

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

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

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

259

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

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(3) An applicant proposing to replace an existing MRI unit shall demonstrate the following requirements:

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

(b) The replacement unit shall be located at the same site.

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

(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 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 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 unless the applicant meets the requirement in subsection (c)(i) or (ii).

(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 under chapter 7 within the last three years;

(ii) the ownership of the building where the site is located has changed within 24 months of the date of the service being operational; or

(iii) the MRI service being replaced is part of the replacement of an entire hospital to a new geographic site and has only one (1) MRI unit.

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

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

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

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

(d) Each existing MRI unit at the service from which a unit is 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) For volume purposes, the new site shall remain associated to the original site for a minimum of three years.

Section 5. Requirements to expand an existing MRI service

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318 Sec. 5. An applicant proposing to expand an existing MRI service shall demonstrate the following:
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320 (1) An applicant shall demonstrate that the applicable MRI adjustable procedures are from the
321 most recently published MRI Service Utilization List as of the date of an application is deemed submitted
322 by the Department:

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

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

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

329
330 (2) The additional fixed unit shall be located at the same site unless the requirements of the
331 replacement section have been met.

332
333 **Section 6. Requirements to acquire an existing MRI service or an existing MRI unit(s)**
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335 Sec. 6. An applicant proposing to acquire an existing fixed or mobile MRI service and its unit(s) shall
336 demonstrate the following:
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338 (1) ~~For the first application proposing to acquire an existing fixed or mobile MRI service on or after~~
339 ~~July 1, 1997, the existing MRI service and its unit(s) to be acquired~~THE APPLICANT shall not be required
340 to be in compliance with the volume requirements applicable to a seller/lessor on the date the acquisition
341 occurs IF THE PROPOSED PROJECT MEETS ONE OF THE FOLLOWING:

342 (a) ~~For IT IS the first application proposing to acquire an~~THE existing fixed or mobile MRI service
343 AND ITS UNIT(S) on or after July 1, 1997, ~~the existing MRI service and its unit(s) to be acquired.~~

344 (b) THE EXISTING FIXED OR MOBILE MRI SERVICE IS OWNED BY, IS UNDER COMMON
345 CONTROL OF, OR HAS A COMMON PARENT AS THE APPLICANT, AND THE MRI SERVICE AND
346 ITS UNIT(S) SHALL REMAIN AT THE SAME SITE. ~~The MRI service shall be operating at the applicable~~
347 ~~volume requirements set forth in Section 14 of these standards in the second 12 months after the~~
348 ~~effective date of the acquisition, and annually thereafter.~~

349
350 (2) For any application proposing to acquire an existing fixed or mobile MRI service and its unit(s),
351 except ~~the first~~AN application approved pursuant to subsection (a1), an applicant shall be required to
352 document that the MRI service and its unit(s) to be acquired is operating in compliance with the volume
353 requirements set forth in Section 14 of these standards applicable to an existing MRI service on the date
354 the application is submitted to the Department.

355
356 (3) An applicant proposing to acquire an existing fixed or mobile MRI unit of an existing MRI
357 service shall demonstrate that the proposed project meets all of the following, as applicable:

358 (a) An applicant shall demonstrate that the applicable MRI adjustable procedures are from the
359 most recently published MRI service utilization list as of the date of an application is deemed submitted
360 by the Department:

361 (i) The fixed MRI unit(s) to be acquired performed at least 6,000 MRI adjusted procedures per
362 fixed MRI unit.

363 (ii) The mobile MRI unit(s) to be acquired performed at least 5,500 MRI adjusted procedures per
364 mobile MRI unit.

365 (b) The project will not change the number of MRI units at the site from which the number of units
366 are being acquired, subject to the applicable requirements under Section 4(6), unless the applicant
367 demonstrates that the project is in compliance with the requirements of the initiation or expansion
368 Section, as applicable.

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

371
372 (4) The MRI service AND ITS UNIT(S) shall be operating at the applicable volume requirements
373 set forth in Section 14 of these standards in the second 12 months after the effective date of the
374 acquisition, and annually thereafter.

375 376 **Section 7. Requirements to establish a dedicated research MRI unit**

377
378 Sec. 7. An applicant proposing an MRI unit to be used exclusively for research shall demonstrate the
379 following:

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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 utilize MRI adjusted
395 procedures performed on the dedicated MRI unit to demonstrate need or to satisfy MRI CON review
396 standards requirements.

397 398 **Section 8. Requirements to establish a dedicated pediatric MRI unit**

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
- 425 (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
- 430 (5) An applicant meeting the requirements of this section shall be exempt from meeting the
- 431 requirements of Section 5 of these standards.
- 432

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

434 **based IMRI**

435

436 Sec. 9. An applicant proposing to initiate, replace, or acquire a hospital based IMRI service shall

437 demonstrate each of the following, as applicable to the proposed project.

438

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

440

441 (2) The proposed site has an existing fixed MRI service that has been operational for the previous

442 36 consecutive months and is meeting its minimum volume requirements.

443

444 (3) The proposed site has an existing and operational surgical service and is meeting its minimum

445 volume requirements pursuant to the CON Review Standards for Surgical Services.

446

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

448 (a) at least 1,500 oncology discharges in the most recent year of operation; or

449 (b) at least 1,000 neurological surgeries in the most recent year of operation; or

450 (c) at least 7,000 pediatric (<18 years old) discharges (excluding normal newborns) and at least

451 5,000 pediatric (<18 years old) surgeries in the most recent year of operation.

452

453 (5) The proposed IMRI unit must be located in an operating room or a room adjoining an operating

454 room allowing for transfer of the patient between the operating room and this adjoining room.

455

456 (6) Non-surgical diagnostic studies shall not be performed on an IMRI unit approved under this

457 section unless the patient meets one of the following criteria:

458 (a) the patient has been admitted to an inpatient unit; or

459 (b) the patient is having the study performed on an outpatient basis, but is in need of general

460 anesthesia or deep sedation as defined by the American Society of Anesthesiologists.

461

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

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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

470 Sec. 10. An applicant proposing to initiate, replace, or acquire a hospital based MRI-guided EPI

471 service shall demonstrate each of the following, as applicable to the proposed project.

472

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

474

475 (2) The proposed site has an existing fixed MRI service that has been operational for the previous
476 36 consecutive months and is meeting its minimum volume requirements.

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

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

- 486 (a) moving the patient to the MRI scanner, or
- 487 (b) installing the MRI scanner on a sliding gantry to allow the patient to remain stationary.

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

- 491 (a) The patient has been admitted to an inpatient unit; or
- 492 (b) The patient is having the study performed on an outpatient basis as follows:
 - 493 (i) is in need of general anesthesia or deep sedation as defined by the American Society of
494 Anesthesiologists, or
 - 495 (ii) has an implantable cardiac device.

496
497 (6) The approved MRI-guided EPI unit shall not be subject to MRI volume requirements.

498
499 (7) The applicant shall not utilize the procedures performed on the MRI-guided EPI unit to
500 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.

515
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 **Section 12. Requirements for approval of an FDA-approved PET/MRI scanner hybrid for initiation,**

528 **expansion, replacement, and acquisition**

529

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

532

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

536

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

539

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

542

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

547

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

549

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

553

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

555

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

558

559 (1) Compliance with these standards.

560

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

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

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

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

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

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

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

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

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

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

578 (B) The physician has had at least 60 hours of training in MRI physics, MRI safety, and MRI
579 instrumentation in a program that is part of an imaging program accredited by the Accreditation Council

580 for Graduate Medical Education or the American Osteopathic Association, and the physician meets the
581 requirements of subdivision (1), (2), or (3):

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

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

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

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

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

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

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

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

613
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
625 (4) Compliance with the following monitoring and reporting requirements:

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 (A) or (B),

629 (A) 4,000 MRI adjusted procedures for the fixed MRI unit initiated pursuant to Section 3(2)(b)(ii)
630 and is the only fixed MRI unit at the current site,

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

633 (ii) 5,500 MRI adjusted procedures per unit for mobile MRI services.
634 (iii) 3,500 MRI adjusted procedures per unit for dedicated pediatric MRI units.
635 (iv) Each mobile host site in a rural or micropolitan statistical area county shall have provided at
636 least a total of 400 adjusted procedures during its second 12 months of operation, and annually
637 thereafter, from all mobile units providing services to the site. Each mobile host site not in a rural or
638 micropolitan statistical area county shall have provided at least a total of 600 adjusted procedures during
639 its second 12 months of operation and annually thereafter, from all mobile units providing services to the
640 site.
641 (v) In meeting these requirements, an applicant shall not include any MRI adjusted procedures
642 performed on an MRI unit used exclusively for research and approved pursuant to Section 7 or for an
643 IMRI unit approved pursuant to Section 9.
644
645 (b) The applicant shall participate in a data collection network established and administered by the
646 Department or its designee. The data may include, but is not limited to, operating schedules,
647 demographic and diagnostic information, and the volume of care provided to patients from all payor
648 sources, as well as other data requested by the Department or its designee and approved by the
649 Commission. The applicant shall provide the required data in a format established by the Department
650 and in a mutually agreed upon media no later than 30 days following the last day of the quarter for which
651 data are being reported to the Department. An applicant shall be considered in violation of this term of
652 approval if the required data are not submitted to the Department within 30 days following the last day of
653 the quarter for which data are being reported. The Department may elect to verify the data through
654 on-site review of appropriate records. Data for an MRI unit approved pursuant to Section 7, Section 8,
655 Section 9, Section 10, or Section 11 shall be reported separately.
656 For purposes of Section 9, the data reported shall include, at a minimum, how often the IMRI unit is used
657 and for what type of services, i.e., intra-operative or diagnostic. For purposes of Section 10, the data
658 reported shall include, at a minimum, how often the MRI-guided EPI unit is used and for what type of
659 services, i.e., electrophysiology or diagnostic. For purposes of Section 11, the data reported shall
660 include, at a minimum, how often the MRI simulator is used and for what type of services, i.e., treatment
661 plans or diagnostic services.
662 (c) The applicant shall provide the Department with a notice stating the first date on which the MRI
663 unit became operational, and such notice shall be submitted to the Department consistent with applicable
664 statute and promulgated rules.
665 (d) An applicant who is a central service coordinator shall notify the Department of any additions,
666 deletions, or changes in the host sites of each approved mobile MRI unit after the change(s) in host sites
667 is made.
668
669 (5) An applicant for an MRI unit approved under Section 7 shall agree that the services provided
670 by the MRI unit are delivered in compliance with the following terms.
671 (a) The capital and operating costs relating to the research use of the MRI unit shall be charged
672 only to a specific research account(s) and not to any patient or third-party payor.
673 (b) The MRI unit shall not be used for any purposes other than as approved by the IRB unless the
674 applicant has obtained CON approval for the MRI unit pursuant to Part 222 and these standards, other
675 than Section 7.
676 (c) The dedicated research MRI unit will be used primarily (70% or more of the procedures) for
677 research purposes only.
678
679 (6) The dedicated pediatric MRI unit approved under Section 8 shall include at least 80% of the
680 MRI procedures that are performed on patients under 18 years of age.
681
682 (7) The agreements and assurances required by this section shall be in the form of a certification
683 agreed to by the applicant or its authorized agent.
684

685 **Section 15. MRI procedure adjustments**

686

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

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

691 (i) fMRI means brain activation studies.

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

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

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

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

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

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

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

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

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

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

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

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

713

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

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

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

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

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

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

731

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

734

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

736

737 Sec. 16. Documentation of the number of MRI procedures performed by an MRI unit shall be
738 substantiated by the Department utilizing data submitted by the applicant in a format and media specified
739 by the Department and as verified for the 12-month period reported on the most recently published "MRI
740 Service Utilization List" as of the date an application is deemed submitted by the Department. The
741 number of MRI procedures actually performed shall be documented by procedure records and not by
742 application of the methodology required in Section 17. The Department may elect to verify the data
743 through on-site review of appropriate records.
744

745 **Section 17. Methodology for computing the number of available MRI adjusted procedures**
746

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

794 (viii) The result shall be the "Available MRI Adjusted Procedures List."
795

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

801 **Section 18. Procedures and requirements for commitments of available MRI adjusted procedures** 802

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

859 (ii) If an appeal was made, the appeal is withdrawn by the applicant.

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

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

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

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

888 (a) The applicant shall have 30 days to submit replacement of doctor commitments as identified by
889 the Department in this Section.
890

891 (7) The Department shall not consider a withdrawal of a signed data commitment on or after the
892 date an application is deemed submitted by the Department.
893

894 (8) The Department shall consider a withdrawal of a signed data commitment if a committing
895 doctor submits a written notice to the Department before the application is deemed submitted, that
896 specifies the CON application number and the specific MRI services for which a data commitment is
897 being withdrawn.
898

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

900

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

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

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

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

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

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

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

912 (ii) The name, address, and license number of each referring doctor, identified in Section
913 17(1)(c)(v), whose patients received MRI services at that MRI service; and

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

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

922 (d) The Department shall not be required to publish a list that sorts MRI database information by
923 referring doctor, only by MRI service.
924

925 (2) When an MRI service begins to operate at a site at which MRI services previously were not
926 provided, the Department shall include in the MRI database, data beginning with the second full quarter
927 of operation of the new MRI service. Data from the start-up date to the start of the first full quarter will not
928 be collected to allow a new MRI service sufficient time to develop its data reporting capability. Data from
929 the first full quarter of operation will be submitted as test data but will not be reported in the lists published
930 pursuant to this section.
931

932 (3) In publishing the lists pursuant to subsections (a) and (b), if an MRI service has not reported
933 data in compliance with the requirements of Section 14, the Department shall indicate on both lists that
934 the MRI service is in violation of the requirements set forth in Section 14, and no data will be shown for
935 that service on either list.
936

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

938

939 Sec. 20. (1) These CON review standards supersede and replace the CON Review Standards for
940 MRI Services approved by the CON Commission on ~~September 25, 2014~~MARCH 16, 2016 and effective
941 ~~December 22, 2014~~MAY 27, 2016.
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943 (2) Projects reviewed under these standards shall not be subject to comparative review.

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946 **Section 21. Health Service Areas**

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

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950	HSA	COUNTIES		
951				
952				
953	1	Livingston	Monroe	St. Clair
954		Macomb	Oakland	Washtenaw
955		Wayne		
956				
957	2	Clinton	Hillsdale	Jackson
958		Eaton	Ingham	Lenawee
959				
960	3	Barry	Calhoun	St. Joseph
961		Berrien	Cass	Van Buren
962		Branch	Kalamazoo	
963				
964	4	Allegan	Mason	Newaygo
965		Ionia	Mecosta	Oceana
966		Kent	Montcalm	Osceola
967		Lake	Muskegon	Ottawa
968				
969	5	Genesee	Lapeer	Shiawassee
970				
971	6	Arenac	Huron	Roscommon
972		Bay	Iosco	Saginaw
973		Clare	Isabella	Sanilac
974		Gladwin	Midland	Tuscola
975		Gratiot	Ogemaw	
976				
977	7	Alcona	Crawford	Missaukee
978		Alpena	Emmet	Montmorency
979		Antrim	Gd Traverse	Oscoda
980		Benzie	Kalkaska	Otsego
981		Charlevoix	Leelanau	Presque Isle
982		Cheboygan	Manistee	Wexford
983				
984	8	Alger	Gogebic	Mackinac
985		Baraga	Houghton	Marquette
986		Chippewa	Iron	Menominee
987		Delta	Keweenaw	Ontonagon
988		Dickinson	Luce	Schoolcraft

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Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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