

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

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

25 (b) "Actual MRI adjusted procedures" or "MRI adjusted procedures," means the number of MRI
26 procedures, adjusted in accordance with the applicable provisions of Section ~~1315~~, performed on an
27 existing MRI unit, or if an MRI service has two or more MRI units at the same site, the average number of
28 MRI adjusted procedures performed on each unit, for the 12-month period reported on the most recently
29 published "MRI Service Utilization List," as of the date an application is deemed submitted by the
30 Department.

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

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

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

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

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

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

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

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

54 (j) "Doctor" means an individual licensed under Article 15 of the Code to engage in the practice of
55 medicine, osteopathic medicine and surgery, chiropractic, dentistry, or podiatry.

56 (k) "Existing MRI service" means either the utilization of a CON-approved and operational MRI
57 unit(s) at one site in the case of a fixed MRI service, and in the case of a mobile MRI service, the
58 utilization of a CON-approved and operational mobile MRI unit(s) at each host site, on the date an
59 application is submitted to the Department.

60 (l) "Existing MRI unit" means a CON-approved and operational MRI unit used to provide MRI
61 services.

62 (m) "Expand an existing fixed MRI service" means an increase in the number of fixed MRI units to
63 be operated by the applicant.

64 (n) "Expand an existing mobile MRI service" means the addition of a mobile MRI unit that will be
65 operated by a central service coordinator that is approved to operate one or more mobile MRI units as of
66 the date an application is submitted to the Department.

67 (o) "Group practice" means a group practice as defined pursuant to the provisions of 42 U.S.C.
68 1395nn (h)(4), commonly known as Stark II, and the Code of Federal Regulations, 42 CFR, Part 411,
69 published in the Federal Register on August 14, 1995, or its replacement.

70 (p) "Health service area" or "HSA" means the geographic areas set forth in Section 4921.

71 (q) "Host site" means the site at which a mobile MRI unit is authorized by CON to provide MRI
72 services.

73 (r) "Initiate a fixed MRI service" means begin operation of a fixed MRI service at a site that does
74 not provide or is not CON approved to provide fixed MRI services as of the date an application is
75 submitted to the Department. The term does not include the acquisition or relocation of an existing fixed
76 MRI service 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 4315.

99 (aa) "MRI database" means the database, maintained by the Department pursuant to Section 42-14
100 of 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
102 EQUIPMENT SPECIFICALLY DESIGNED FOR THE INTEGRATED USE OF MRI TECHNOLOGY FOR
103 THE PURPOSES OF ELECTROPHYSIOLOGY INTERVENTIONAL PROCEDURES WITHIN A
104 CARDIAC CATHETERIZATION LAB.

105 (bbcc) "MRI procedure" means a procedure conducted by an MRI unit approved pursuant to sections
106 3, 4, 5, 6, 7, or 9 of these standards which is either a single, billable diagnostic magnetic resonance

107 procedure or a procedure conducted by an MRI unit at a site participating with an approved diagnostic
108 radiology residency program, under a research protocol approved by an IRB. The capital and operating
109 costs related to the research use are charged to a specific research account and not charged to or
110 collected from third-party payors or patients. **THE TERM INCLUDES FDA-APPROVED POSITRON
111 EMISSION TOMOGRAPHY (PET)/MRI SCANNER HYBRIDS IF USED FOR MRI ONLY PROCEDURES.**
112 The term does not include a procedure conducted by an MRI unit approved pursuant to Section 8(1).
113 **(eeDD)** "MRI services" means either the utilization of an authorized MRI unit(s) at one site in the case
114 of a fixed MRI service or in the case of a mobile MRI service, the utilization of an authorized mobile MRI
115 unit at each host site.
116 **(eeEE)** "MRI unit" means the magnetic resonance system consisting of an integrated set of machines
117 and related equipment necessary to produce the images and/or spectroscopic quantitative data from
118 scans. The term does not include MRI simulators used solely for treatment planning purposes in
119 conjunction with an MRT unit.
120 **(eeFF)** "MRI visit" means a single patient visit to an MRI service/unit that may involve one or more MRI
121 procedures.
122 **(#GG)** "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6
123 and 1396r-8 to 1396v.
124 **(ggHH)** "Metropolitan statistical area county" means a county located in a metropolitan statistical area
125 as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas"
126 by the statistical policy office of the office of information and regulatory affairs of the United States office
127 of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.
128 **(hhII)** "Micropolitan statistical area county" means a county located in a micropolitan statistical area
129 as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas"
130 by the statistical policy office of the office of information and regulatory affairs of the United States office
131 of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.
132 **(#JJ)** "Mobile MRI unit" means an MRI unit operating at two or more host sites and that has a central
133 service coordinator. The mobile MRI unit shall operate under a contractual agreement for the provision of
134 MRI services at each host site on a regularly scheduled basis.
135 **(#KK)** "Ownership interest, direct or indirect" means a direct ownership relationship between a doctor
136 and an applicant entity or an ownership relationship between a doctor and an entity that has an
137 ownership relationship with an applicant entity.
138 **(kkLL)** "Pediatric patient" means a patient who is 12 years of age or less, except for Section 9.
139 **(#MM)** "Planning area" means
140 (i) in the case of a proposed fixed MRI service or unit, the geographic area within a 20-mile radius
141 from the proposed site if the proposed site is not in a rural or micropolitan statistical area county and a
142 75-mile radius from the proposed site if the proposed site is in a rural or micropolitan statistical area
143 county.
144 (ii) in the case of a proposed mobile MRI service or unit, except as provided in subsection (iii), the
145 geographic area within a 20-mile radius from each proposed host site if the proposed site is not in a rural
146 or micropolitan statistical area county and within a 75-mile radius from each proposed host site if the
147 proposed site is in a rural or micropolitan statistical area county.
148 (iii) in the case of a proposed mobile MRI service or unit meeting the requirement of Section
149 **1315(2)(d)**, the health service area in which all the proposed mobile host sites will be located.
150 **(mmNN)** "Referring doctor" means the doctor of record who ordered the MRI procedure(s) and either to
151 whom the primary report of the results of an MRI procedure(s) is sent or in the case of a teaching facility,
152 the attending doctor who is responsible for the house officer or resident that requested the MRI
153 procedure.
154 **(mmOO)** "Relocate an existing MRI service and/or MRI unit(s)" means a change in the location of an
155 existing MRI service and/or MRI unit(s) from the existing site to a different site within the relocation zone.
156 **(eePP)** "Relocation zone" means the geographic area that is within a 10-mile radius of the existing site
157 of the MRI service or unit to be relocated.

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

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

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

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

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

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

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

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

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

184 | (~~vv~~WW) "Site" means

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

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

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

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

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

200 | ~~1315.~~

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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265 (6) The applicant shall demonstrate that the available MRI adjusted procedures from the "Available
266 MRI Adjusted Procedures List" or the adjusted procedures from the "MRI Service Utilization List," as
267 applicable, are from the most recently published MRI lists as of the date an application is deemed
268 submitted by the Department.
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270 **Section 4. Requirements to replace an existing MRI unit**

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272 Sec. 4. An applicant proposing to replace an existing MRI unit shall demonstrate the following
273 requirements, as applicable:
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275 (1) An applicant shall demonstrate that the applicable MRI adjusted procedures are from the most
276 recently published MRI Service Utilization List as of the date an application is deemed submitted by the
277 Department:

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

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

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

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

287 (c) Each existing dedicated pediatric MRI unit at the current site has performed at least an average
288 of 3,500 MRI adjusted procedures per MRI unit.
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290 (2) Equipment that is replaced shall be removed from service and disposed of or rendered
291 considerably inoperable on or before the date that the replacement equipment becomes operational.
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293 (3) The replacement unit shall be located at the same site unless the requirements of the
294 relocation section have been met.
295

296 (4) An applicant proposing to replace an existing MRI unit that does not involve a renewal of a
297 lease shall demonstrate that the MRI unit to be replaced is fully depreciated according to generally
298 accepted accounting principles; the existing equipment clearly poses a threat to the safety of the public;
299 or the proposed replacement equipment offers a significant technological improvement which enhances
300 quality of care, increases efficiency, and reduces operating costs.
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302 **Section 5. Requirements to expand an existing MRI service**

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

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

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

313 (c) Each existing dedicated pediatric MRI unit at the current site has performed at least an average
314 of 3,500 MRI adjusted procedures per MRI unit.
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316 (2) The additional fixed unit shall be located at the same site unless the requirements of the
317 relocation section have been met.
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320 **Section 6. Requirements to relocate an existing fixed MRI service and/or MRI unit(s)**
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322 Sec. 6. (1) An applicant proposing to relocate an existing fixed MRI service and its unit(s) shall
323 demonstrate the following:

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

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

327 (c) Each existing MRI unit to be relocated performed at least the applicable minimum number of
328 MRI adjusted procedures set forth in Section ~~42-14~~ based on the most recently published MRI Service
329 Utilization List as of the date an application is deemed submitted by the Department.

330
331 (2) An applicant proposing to relocate a fixed MRI unit of an existing MRI service shall
332 demonstrate the following:

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

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

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

337 (d) Each existing MRI unit at the service from which a unit is to be relocated performed at least the
338 applicable minimum number of MRI adjusted procedures set forth in Section ~~42-14~~ based on the most
339 recently published MRI Service Utilization List as of the date an application is deemed submitted by the
340 Department.

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

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344 **Section 7. Requirements to acquire an existing MRI service or an existing MRI unit(s)**
345

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

348 (a) 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 ~~42-14~~ of
352 these standards in the second 12 months after the effective date of the acquisition, and annually
353 thereafter.

354 (b) For any application proposing to acquire an existing fixed or mobile MRI service and its unit(s),
355 except the first application approved pursuant to subsection (a), an applicant shall be required to
356 document that the MRI service and its unit(s) to be acquired is operating in compliance with the volume
357 requirements set forth in Section ~~42-14~~ of these standards applicable to an existing MRI service on the
358 date the application is submitted to the Department.

359
360 (2) An applicant proposing to acquire an existing fixed or mobile MRI unit of an existing MRI
361 service shall demonstrate that the proposed project meets all of the following:

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

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

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369 **Section 8. Requirements to establish a dedicated research MRI unit**
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371 Sec. 8. An applicant proposing an MRI unit to be used exclusively for research shall demonstrate the
372 following:

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

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

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

Section 9. Requirements to establish a dedicated pediatric MRI unit

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

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

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

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

- (i) pediatric radiology (at least two)
- (ii) pediatric anesthesiology
- (iii) pediatric cardiology
- (iv) pediatric critical care
- (v) pediatric gastroenterology
- (vi) pediatric hematology/oncology
- (vii) pediatric neurology
- (viii) pediatric neurosurgery
- (ix) pediatric orthopedic surgery
- (x) pediatric pathology
- (xi) pediatric pulmonology
- (xii) pediatric surgery
- (xiii) neonatology

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

- (i) pediatric bone marrow transplant program
- (ii) established pediatric sedation program
- (iii) pediatric open heart program

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

Section 10. Requirements for all applicants proposing to initiate, replace, or acquire a hospital based IMRI

Sec. 10. 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.

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

(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.

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

428
429 (4) The applicant has achieved one of the following:

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

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

432 (c) at least 7,000 pediatric (<18 years old) discharges (excluding normal newborns) and at least
433 5,000 pediatric (<18 years old) surgeries in the most recent year of operation.

434
435 (5) The proposed IMRI unit must be located in an operating room or a room adjoining an operating
436 room allowing for transfer of the patient between the operating room and this adjoining room.

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

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

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

443
444 (7) The approved IMRI unit will not be subject to MRI volume requirements.

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

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449 **SECTION 11. REQUIREMENTS FOR ALL APPLICANTS PROPOSING TO INITIATE, REPLACE, OR**
450 **ACQUIRE A HOSPITAL BASED MRI-GUIDED EPI SERVICE**

451
452 **SEC. 11. AN APPLICANT PROPOSING TO INITIATE, REPLACE, OR ACQUIRE A HOSPITAL**
453 **BASED MRI-GUIDED EPI SERVICE SHALL DEMONSTRATE EACH OF THE FOLLOWING, AS**
454 **APPLICABLE TO THE PROPOSED PROJECT.**

455
456 **(1) THE PROPOSED SITE IS A LICENSED HOSPITAL UNDER PART 215 OF THE CODE.**

457
458 **(2) THE PROPOSED SITE HAS AN EXISTING FIXED MRI SERVICE THAT HAS BEEN**
459 **OPERATIONAL FOR THE PREVIOUS 36 CONSECUTIVE MONTHS AND IS MEETING ITS MINIMUM**
460 **VOLUME REQUIREMENTS.**

461
462 **(3) THE PROPOSED SITE HAS AN EXISTING AND OPERATIONAL THERAPEUTIC CARDIAC**
463 **CATHETERIZATION SERVICE AND IS MEETING ITS MINIMUM VOLUME REQUIREMENTS**
464 **PURSUANT TO THE CON REVIEW STANDARDS FOR CARDIAC CATHETERIZATION SERVICES**
465 **AND OPEN HEART SURGERY SERVICES.**

466
467 **(4) THE PROPOSED MRI-GUIDED EPI UNIT MUST BE LOCATED IN A CARDIAC**
468 **CATHETERIZATION LAB CONTAINING A FLOUROSCOPY UNIT WITH AN ADJOINING ROOM**
469 **CONTAINING AN MRI SCANNER. THE ROOMS SHALL CONTAIN A PATIENT TRANSFER SYSTEM**
470 **ALLOWING FOR TRANSFER OF THE PATIENT BETWEEN THE CARDIAC CATHETERIZATION LAB**
471 **AND THE MRI UNIT, UTILIZING ONE OF THE FOLLOWING:**

472 **(A) MOVING THE PATIENT TO THE MRI SCANNER, OR**

473 **(B) INSTALLING THE MRI SCANNER ON A SLIDING GANTRY TO ALLOW THE PATIENT TO**
474 **REMAIN STATIONARY.**

477 (5) NON-CARDIAC MRI DIAGNOSTIC STUDIES SHALL NOT BE PERFORMED IN AN MRI-
478 GUIDED EPI UNIT APPROVED UNDER THIS SECTION UNLESS THE PATIENT MEETS ONE OF THE
479 FOLLOWING CRITERIA:

480 (A) THE PATIENT HAS BEEN ADMITTED TO AN INPATIENT UNIT; OR
481 (B) THE PATIENT IS HAVING THE STUDY PERFORMED ON AN OUTPATIENT BASIS AS
482 FOLLOWS:

483 (I) IS IN NEED OF GENERAL ANESTHESIA OR DEEP SEDATION AS DEFINED BY THE
484 AMERICAN SOCIETY OF ANESTHESIOLOGISTS, OR
485 (II) HAS AN IMPLANTABLE CARDIAC DEVICE.

486
487 (6) THE APPROVED MRI-GUIDED EPI UNIT SHALL NOT BE SUBJECT TO MRI VOLUME
488 REQUIREMENTS.

489
490 (7) THE APPLICANT SHALL NOT UTILIZE THE PROCEDURES PERFORMED ON THE MRI-
491 GUIDED EPI UNIT TO DEMONSTRATE NEED OR TO SATISFY MRI CON REVIEW STANDARDS
492 REQUIREMENTS.

493
494 **SECTION 12. REQUIREMENTS FOR APPROVAL OF AN FDA-APPROVED PET/MRI SCANNER**
495 **HYBRID FOR INITIATION, EXPANSION, REPLACEMENT, AND ACQUISITION**

496
497 **SEC. 12. AN APPLICANT PROPOSING TO INITIATE, EXPAND, REPLACE, OR ACQUIRE AN FDA-**
498 **APPROVED PET/MRI SCANNER HYBRID SHALL DEMONSTRATE THAT IT MEETS ALL OF THE**
499 **FOLLOWING:**

500
501 (1) THERE IS AN APPROVED PET CON FOR THE FDA-APPROVED PET/MRI HYBRID, AND
502 THE FDA-APPROVED PET/MRI SCANNER HYBRID IS IN COMPLIANCE WITH ALL APPLICABLE
503 PROJECT DELIVERY REQUIREMENTS AS SET FORTH IN THE CON REVIEW STANDARDS FOR
504 PET.

505
506 (2) THE APPLICANT AGREES TO OPERATE THE FDA-APPROVED PET/MRI SCANNER
507 HYBRID IN ACCORDANCE WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS SET
508 FORTH IN SECTION 4314 OF THESE STANDARDS.

509
510 (3) THE APPROVED FDA-APPROVED PET/MRI SCANNER HYBRID SHALL NOT BE SUBJECT
511 TO MRI VOLUME REQUIREMENTS.

512
513 (4) AN FDA-APPROVED PET/MRI SCANNER HYBRID APPROVED UNDER THE CON REVIEW
514 STANDARDS FOR PET SCANNER SERVICES AND THE REVIEW STANDARDS FOR MRI SCANNER
515 SERVICES MAY NOT UTILIZE MRI PROCEDURES PERFORMED ON AN FDA-APPROVED PET/MRI
516 SCANNER HYBRID TO DEMONSTRATE NEED OR TO SATISFY MRI CON REVIEW STANDARDS
517 REQUIREMENTS.

518
519 **Section 4413. Requirements for all applicants**

520
521 Sec. 4413. An applicant shall provide verification of Medicaid participation. An applicant that is a new
522 provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided
523 to the Department within six (6) months from the offering of services if a CON is approved.

524
525 **Section 4214. Project delivery requirements – terms of approval**

526
527 Sec. 4214. (1) An applicant shall agree that, if approved, MRI services, whether fixed or mobile, shall
528 be delivered and maintained in compliance with the following:

529 (a) Compliance with these standards.

530 (b) Compliance with applicable safety and operating standards.
531 (c) Compliance with the following quality assurance standards:
532 (i) An applicant shall develop and maintain policies and procedures that establish protocols for
533 assuring the effectiveness of operation and the safety of the general public, patients, and staff in the MRI
534 service.
535 (ii) An applicant shall establish a schedule for preventive maintenance for the MRI unit.
536 (iii) An applicant shall provide documentation identifying the specific individuals that form the MRI
537 team. At a minimum, the MRI team shall consist of the following professionals:
538 (A) Physicians who shall be responsible for screening of patients to assure appropriate utilization
539 of the MRI service and taking and interpretation of scans. At least one of these physicians shall be a
540 board-certified radiologist.
541 (B) An appropriately trained MRI technician who shall be responsible for taking an MRI scan.
542 (C) An MRI physicist/engineer available as a team member on a full-time, part-time, or contractual
543 basis.
544 (iv) An applicant shall document that the MRI team members have the following qualifications:
545 (A) Each physician credentialed to interpret MRI scans meets the requirements of each of the
546 following:
547 (1) The physician is licensed to practice medicine in the State of Michigan.
548 (2) The physician has had at least 60 hours of training in MRI physics, MRI safety, and MRI
549 instrumentation in a program that is part of an imaging program accredited by the Accreditation Council
550 for Graduate Medical Education or the American Osteopathic Association, and the physician meets the
551 requirements of subdivision (i), (ii), or (iii):
552 (i) Board certification by the American Board of Radiology, the American Osteopathic Board of
553 Radiology, or the Royal College of Physicians and Surgeons of Canada. If the diagnostic radiology
554 program completed by a physician in order to become board certified did not include at least two months
555 of MRI training, that physician shall document that he or she has had the equivalent of two months of
556 postgraduate training in clinical MRI imaging at an institution which has a radiology program accredited
557 by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association.
558 (ii) Formal training by an imaging program(s), accredited by the Accreditation Council for Graduate
559 Medical Education or the American Osteopathic Association, that included two years of training in cross-
560 sectional imaging and six months training in organ-specific imaging areas.
561 (iii) A practice in which at least one-third of total professional time, based on a full-time clinical
562 practice during the most recent 5-year period, has been the primary interpretation of MR imaging.
563 (3) The physician has completed and will complete a minimum of 40 hours every two years of
564 Category in Continuing Medical Education credits in topics directly involving MR imaging.
565 (4) The physician interprets, as the primary interpreting physician, at least 250 unadjusted MRI
566 scans annually.
567 (B) An MRI technologist who is registered by the American Registry of Radiologic Technicians or
568 by the American Registry of Magnetic Resonance Imaging Technologists (ARMRIT) and has, or will have
569 within 36 months of the effective date of these standards or the date a technologist is employed by an
570 MRI service, whichever is later, special certification in MRI. If a technologist does not have special
571 certification in MRI within either of the 3-year periods of time, all continuing education requirements shall
572 be in the area of MRI services.
573 (C) An applicant shall document that an MRI physicist/engineer is appropriately qualified. For
574 purposes of evaluating this subdivision, the Department shall consider it prima facie evidence as to the
575 qualifications of the physicist/engineer if the physicist/engineer is certified as a medical physicist by the
576 American Board of Radiology, the American Board of Medical Physics, or the American Board of Science
577 in Nuclear Medicine. However, the applicant may submit and the Department may accept other evidence
578 that an MRI physicist/engineer is qualified appropriately.
579 (v) The applicant shall have, within the MRI unit/service, equipment and supplies to handle clinical
580 emergencies that might occur in the unit. MRI service staff will be trained in CPR and other appropriate
581 emergency interventions. A physician shall be on-site, in, or immediately available to the MRI unit at all
582 times when patients are undergoing scans.

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

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

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

588 (A) 6,000 MRI adjusted procedures per unit for fixed MRI services unless compliant with (1) or (2),
589 (1) 4,000 MRI adjusted procedures for the fixed MRI unit initiated pursuant to Section 3(2)(b)(ii)
590 and is the only fixed MRI unit at the current site,
591 (2) 3,000 MRI adjusted procedures for the fixed MRI unit initiated pursuant to Section 3(2)(b)(iii)
592 and is the only fixed MRI unit at the hospital site licensed under part 215 of the code,
593 (B) 5,500 MRI adjusted procedures per unit for mobile MRI services.
594 (C) 3,500 MRI adjusted procedures per unit for dedicated pediatric MRI units.
595 (D) Each mobile host site in a rural or micropolitan statistical area county shall have provided at
596 least a total of 400 adjusted procedures during its second 12 months of operation, and annually
597 thereafter, from all mobile units providing services to the site. Each mobile host site not in a rural or
598 micropolitan statistical area county shall have provided at least a total of 600 adjusted procedures during
599 its second 12 months of operation and annually thereafter, from all mobile units providing services to the
600 site.

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

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

606 (A) provide MRI services to all individuals based on the clinical indications of need for the service
607 and not on ability to pay or source of payment.
608 (B) maintain information by source of payment to indicate the volume of care from each source
609 provided annually.

610 (iii) The applicant shall participate in a data collection network established and administered by the
611 Department or its designee. The data may include, but is not limited to, operating schedules,
612 demographic and diagnostic information, and the volume of care provided to patients from all payor
613 sources, as well as other data requested by the Department or its designee and approved by the
614 Commission. The applicant shall provide the required data in a format established by the Department
615 and in a mutually agreed upon media no later than 30 days following the last day of the quarter for which
616 data are being reported to the Department. An applicant shall be considered in violation of this term of
617 approval if the required data are not submitted to the Department within 30 days following the last day of
618 the quarter for which data are being reported. The Department may elect to verify the data through
619 on-site review of appropriate records. Data for an MRI unit approved pursuant to Section 8(1), Section 9,
620 ~~or Section 10, OR SECTION 11~~ shall be reported separately.

621 For purposes of Section 10, the data reported shall include, at a minimum, how often the IMRI unit is
622 used and for what type of services, i.e., intra-operative or diagnostic. **FOR PURPOSES OF SECTION**
623 **11, THE DATA REPORTED SHALL INCLUDE, AT A MINIMUM, HOW OFTEN THE MRI-GUIDED EPI**
624 **UNIT IS USED AND FOR WHAT TYPE OF SERVICES, I.E., ELECTROPHYSIOLOGY OR**
625 **DIAGNOSTIC.**

626 (iv) The operation of and referral of patients to the MRI unit shall be in conformance with 1978 PA
627 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

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

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

634

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

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

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

642

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

645

646 | **Section 1315. MRI procedure adjustments**

647

648 | Sec. 1315. (1) The Department shall apply the following formula, as applicable, to determine the
649 number of MRI adjusted procedures that are performed by an existing MRI service or unit:

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

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

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

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

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

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

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

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

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

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

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

668

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

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

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

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

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

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

686

687 (3) The number of MRI adjusted procedures performed by an existing MRI service is the sum of
688 the results of subsections (1) and (2).
689

690 | **Section 1416. Documentation of actual utilization**
691

692 | Sec. 1416. Documentation of the number of MRI procedures performed by an MRI unit shall be
693 substantiated by the Department utilizing data submitted by the applicant in a format and media specified
694 by the Department and as verified for the 12-month period reported on the most recently published "MRI
695 Service Utilization List" as of the date an application is deemed submitted by the Department. The
696 number of MRI procedures actually performed shall be documented by procedure records and not by
697 | application of the methodology required in Section 1517. The Department may elect to verify the data
698 through on-site review of appropriate records.
699

700 | **Section 1517. Methodology for computing the number of available MRI adjusted procedures**
701

702 | Sec. 1517. (1) The number of available MRI adjusted procedures required pursuant to Section 3
703 shall be computed in accordance with the methodology set forth in this section. In applying the
704 methodology, the following steps shall be taken in sequence, and data for the 12-month period reported
705 on the most recently published "Available MRI Adjusted Procedures List," as of the date an application is
706 deemed submitted by the Department, shall be used:

707 (a) Identify the number of actual MRI adjusted procedures performed by each existing MRI service
708 | as determined pursuant to Section 1315.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

749 (viii) The result shall be the "Available MRI Adjusted Procedures List."
750

751 (2) After publication of the "Available MRI Adjusted Procedures List" resulting from (1) above, the
752 data shall be updated to account for a) doctor commitments of available MRI adjusted procedures in
753 subsequent MRI CON applications and b) MRI adjusted procedures used in subsequent MRI CON
754 applications received in which applicants apply for fixed MRI services pursuant to Section 3(2).
755

756 | **Section 4618. Procedures and requirements for commitments of available MRI adjusted**
757 **procedures**

759 | Sec. 4618. (1) If one or more host sites on a mobile MRI service are located within the planning area
760 of the proposed site, the applicant may access available MRI adjusted procedures from the entire mobile
761 MRI service.
762

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

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

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

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

776 (c) If the required documentation for the doctor commitments submitted under this subsection is
777 not submitted with the application on the designated application date, the application will be deemed
778 submitted on the first applicable designated application date after all required documentation is received
779 by the Department.
780

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

784 (a) A committing doctor certifies that 100% of his or her available MRI adjusted procedures for
785 | each specified MRI service, calculated pursuant to Section 4517, is being committed and specifies the
786 CON application number for the MRI unit to which the data commitment is made. A doctor shall not be
787 required to commit available MRI adjusted procedures from all MRI services to which his or her patients
788 are referred for MRI services but only from those MRI services specified by the doctor in the data
789 commitment form provided by the Department and submitted by the applicant in support of its application.

790 (b) A committing doctor certifies ownership interest, either direct or indirect, in the applicant entity.
791 Indirect ownership includes ownership in an entity that has ownership interest in the applicant entity. This
792 requirement shall not apply if the applicant entity is a group practice of which the committing doctor is a
793 member. Group practice means a group practice as defined pursuant to the provisions of 42 U.S.C.
794 1395nn (h)(4), commonly known as Stark II, and the Code of Federal Regulations, 42 CFR, Part 411,
795 published in the Federal Register on August 14, 1995, or its replacement.

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

799
800 (4)(a) The Department shall not consider a data commitment from a doctor for available MRI adjusted
801 procedures from a specific MRI service if the available MRI adjusted procedures from that specific MRI
802 service were used to support approval of an application for a new or additional MRI unit, pursuant to
803 Section 3, for which a final decision to approve has been issued by the Director of the Department until
804 either of the following occurs:

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

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

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

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

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

817
818 (5) The Department shall not consider a data commitment from a committing doctor for available
819 MRI adjusted procedures from the same MRI service if that doctor has submitted a signed data
820 commitment, on a form provided by Department, for more than one (1) application for which a final
821 decision has not been issued by the Department. If the Department determines that a doctor has
822 submitted a signed data commitment for the same available MRI adjusted procedures from the same MRI
823 service to more than one CON application pending a final decision for a new fixed or mobile MRI unit or
824 additional mobile MRI unit pursuant to Section 3, the Department shall,

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

831 (b) if the applications were submitted on different designated application dates, consider the data
832 commitment in the application submitted on the earliest designated application date and shall notify,
833 simultaneously in writing, all applicants of applications submitted on designated application dates
834 subsequent to the earliest date that one or more committing doctors have submitted data commitments
835 for available MRI adjusted procedures from the same MRI service and that the doctors' data shall not be
836 considered in the review of the application(s) submitted on the subsequent designated application
837 date(s).

838
839 (6) The Department shall not consider any data commitment submitted by an applicant after the
840 date an application is deemed submitted unless an applicant is notified by the Department, pursuant to
841 subsection (5), that one or more committing doctors submitted data commitments for available MRI
842 adjusted procedures from the same MRI service. If an applicant is notified that one or more doctors' data

843 commitments will not be considered by the Department, the Department shall consider data commitments
844 submitted after the date an application is deemed submitted only to the extent necessary to replace the
845 data commitments not being considered pursuant to subsection (5).

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

848
849 (7) In accordance with either of the following, the Department shall not consider a withdrawal of a
850 signed data commitment:

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

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

853

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

858

859 | **Section 4719. Lists published by the Department**

860

861 | Sec. 4719. (1) On or before May 1 and November 1 of each year, the Department shall publish the
862 following lists:

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

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

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

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

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

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

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

873 | 4517(1)(c)(v), whose patients received MRI services at that MRI service; and

874 (iii) The number of available MRI adjusted procedures performed on patients referred by each
875 | referring doctor, identified in Section 4517(1)(c)(v), and if any are committed to an MRI service. This
876 | number shall be calculated in accordance with the requirements of Section 4517(1). A referring doctor
877 | may have fractional portions of available MRI adjusted procedures.

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

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

884

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

891

892 (3) In publishing the lists pursuant to subsections (a) and (b), if an MRI service has not reported
893 | data in compliance with the requirements of Section 4214, the Department shall indicate on both lists that

894 | the MRI service is in violation of the requirements set forth in Section 1214, and no data will be shown for
895 | that service on either list.

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897 | **Section 1820. Effect on prior CON Review Standards; Comparative reviews**

898

899 | Sec. 1820. (1) These CON review standards supersede and replace the CON Review Standards for
900 | MRI Services approved by the CON Commission on ~~December 15, 2010~~ September 22, 2011 and
901 | effective ~~March 11~~ November 21, 2011.

902

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

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905 | **Section 1921. Health Service Areas**

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907 | Sec. 1921. Counties assigned to each of the health service areas are as follows:

908

909 | **HSA**

COUNTIES

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912 | 1 | Livingston | Monroe | St. Clair
913 | | Macomb | Oakland | Washtenaw
914 | | Wayne | |

915

916 | 2 | Clinton | Hillsdale | Jackson
917 | | Eaton | Ingham | Lenawee

918

919 | 3 | Barry | Calhoun | St. Joseph
920 | | Berrien | Cass | Van Buren
921 | | Branch | Kalamazoo |

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923 | 4 | Allegan | Mason | Newaygo
924 | | Ionia | Mecosta | Oceana
925 | | Kent | Montcalm | Osceola
926 | | Lake | Muskegon | Ottawa

927

928 | 5 | Genesee | Lapeer | Shiawassee

929

930 | 6 | Arenac | Huron | Roscommon
931 | | Bay | Iosco | Saginaw
932 | | Clare | Isabella | Sanilac
933 | | Gladwin | Midland | Tuscola
934 | | Gratiot | Ogemaw |

935

936 | 7 | Alcona | Crawford | Missaukee
937 | | Alpena | Emmet | Montmorency
938 | | Antrim | Gd Traverse | Oscoda
939 | | Benzie | Kalkaska | Otsego
940 | | Charlevoix | Leelanau | Presque Isle
941 | | Cheboygan | Manistee | Wexford

942

943 | 8 | Alger | Gogebic | Mackinac
944 | | Baraga | Houghton | Marquette
945 | | Chippewa | Iron | Menominee
946 | | Delta | Keweenaw | Ontonagon

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CON REVIEW STANDARDS
FOR MRI SERVICES

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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