

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

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

10 | **Section 1. Applicability**
11 |

12 | ~~— Sec. 1. (1) These standards are requirements for the approval of the initiation, expansion,~~
13 | ~~replacement, relocation, or acquisition of MRI services and the delivery of services for all projects~~
14 | ~~approved and Certificates of Need issued under Part 222 of the Code that involve magnetic resonance~~
15 | ~~imaging services.~~
16 |

17 | ~~— (2) Magnetic resonance imaging is a covered clinical service for purposes of Part 222 of the Code.~~
18 | ~~An MRI unit approved pursuant to Section 9(1) seeking approval to operate pursuant to sections 3, 4, 5,~~
19 | ~~6, 7, or 8 shall be considered as a person requesting CON approval to initiate, expand, replace, relocate,~~
20 | ~~or acquire a covered clinical service, as applicable.~~
21 |

22 | ~~— (3) The Department shall use sections 3, 4, 5, 6, 7, 8, 9, 10, 13, 14, 15, 16, 17, and 18 as~~
23 | ~~applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan~~
24 | ~~Compiled Laws.~~
25 |

26 | ~~— (4) The Department shall use Section 13, as applicable, in applying Section 22225(2)(c) of the~~
27 | ~~Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.~~
28 |

29 | SEC. 1 THESE STANDARDS ARE REQUIREMENTS FOR THE APPROVAL OF THE
30 | INITIATION, EXPANSION, REPLACEMENT, RELOCATION, OR ACQUISITION OF MRI SERVICES
31 | AND THE DELIVERY OF SERVICES UNDER PART 222 OF THE CODE. PURSUANT TO PART 222
32 | OF THE CODE, MRI IS A COVERED CLINICAL SERVICE. THE DEPARTMENT SHALL USE THESE
33 | STANDARDS IN APPLYING SECTION 22225(1) OF THE CODE, BEING SECTION 333.22225(1) OF
34 | THE MICHIGAN COMPILED LAWS AND SECTION 22225(2)(C) OF THE CODE, BEING SECTION
35 | 333.22225(2)(C) OF THE MICHIGAN COMPILED LAWS.
36 |

37 | **Section 2. Definitions**
38 |

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

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

43 | (b) "Actual MRI adjusted procedures," for purposes of sections 16 and 17, means the number of
44 | MRI procedures, adjusted in accordance with the applicable provisions of Section 14, performed on an
45 | existing MRI unit, or if an MRI service has two or more MRI units at the same site, the average number of
46 | MRI adjusted procedures performed on each unit, for the 12-month period reported on the most recently
47 | published "~~Available MRI Adjusted Procedures~~MRI SERVICE UTILIZATION List," as of the date an
48 | application is deemed complete by the Department.

49 | (c) "Available MRI adjusted procedures," ~~for purposes of Section 16,~~ means the number of MRI
50 | adjusted procedures performed by an existing MRI service in excess of 8,000 per fixed MRI unit and
51 | 7,000 per mobile MRI unit. For either a fixed or mobile MRI service, the number of MRI units used to
52 | compute available MRI adjusted procedures shall include both existing and approved but not yet
53 | operational MRI units. In determining the number of available MRI adjusted procedures, the Department

54 shall use data for the 12-month period reported on the most recently published list of available MRI
55 adjusted procedures as of the date an application is deemed complete by the Department.

56 In the case of an MRI service that operates, or has a valid CON to operate, more than one fixed MRI
57 unit at the same site, the term means the number of MRI adjusted procedures in excess of 8,000
58 multiplied by the number of fixed MRI units at the same site. For example, if an MRI service operates, or
59 has a valid CON to operate, two fixed MRI units at the same site, the available number of MRI adjusted
60 procedures is the number that is in excess of 16,000 (8,000 x 2) MRI adjusted procedures.

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

65 (d) "Central service coordinator" means the organizational unit that has operational responsibility
66 for a mobile MRI unit(s). ~~It shall be a legal entity authorized to do business in the State of Michigan.~~

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

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

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

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

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

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

79 (k) ~~"Existing magnetic resonance imaging service" or "existing EXISTING MRI service"~~ means
80 either the utilization of a CON-approved and operational MRI unit(s) at one site in the case of a fixed MRI
81 service, and in the case of a mobile MRI service, the utilization of a CON-approved and operational
82 mobile MRI unit(s) at each host site, on the date an application is submitted to the Department.

83 (l) ~~"Existing magnetic resonance imaging unit" or "existing EXISTING MRI unit"~~ means a CON-
84 approved and operational MRI unit used to provide MRI services.

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

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

90 (o) "Group practice," ~~for purposes of Section 17(3)(b),~~ means a group practice as defined pursuant
91 to the provisions of 42 U.S.C. 1395nn (h)(4), commonly known as Stark II, and the Code of Federal
92 Regulations, 42 CFR, Part 411, published in the Federal Register on August 14, 1995, or its replacement.

93 (p) "Health service area" or "HSA" means the geographic areas set forth in Section 19.

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

96 (r) "Initiate a fixed MRI service" means begin operation of a fixed MRI service at a site that does
97 not provide or is not CON approved to provide fixed MRI services as of the date an application is
98 submitted to the Department. The term does not include the acquisition or relocation of an existing fixed
99 MRI service or the renewal of a lease.

100 (s) "Initiate a mobile MRI host site" means the provision of MRI services at a host site that has not
101 received any MRI services within 12 months from the date an application is submitted to the Department.

102 The term does not include the renewal of a lease.

103 (t) "Initiate a mobile MRI service" means begin operation of a mobile MRI unit that serves two or
104 more host sites.

105 The term does not include the acquisition of an existing mobile MRI service or the renewal of a
106 lease.

- 107 | (u) "Inpatient," ~~for purposes of Section 14 of these standards,~~ means an MRI visit involving an
108 | individual who has been admitted to the licensed hospital at the site of the MRI service/unit or in the case
109 | of an MRI unit that is not located at that licensed hospital site, an admitted patient transported from a
110 | licensed hospital site by ambulance to the MRI service.
- 111 | (v) ~~"IRB" or "institutional-INSTITUTIONAL review board"~~ OR "IRB" means an institutional review
112 | board as defined by Public Law 93-348 that is regulated by Title 45 CFR 46.
- 113 | (w) "Intra-operative magnetic resonance imaging" or "IMRI" means the integrated use of MRI
114 | technology during surgical and interventional procedures within a licensed operative environment.
- 115 | (x) "Licensed hospital site" means a ~~health facility licensed under Part 215 of the Code. In the~~
116 | ~~case of a single site hospital, it is~~ the location of the facility-HOSPITAL authorized by license and listed on
117 | that licensee's certificate of licensure ~~or in the case of a hospital with multiple sites, the location of each~~
118 | ~~separate and distinct inpatient unit of the health facility as authorized by the licensee's certificate of~~
119 | ~~licensure.~~
- 120 | (y) "Magnetic resonance IMAGING" or "MRI" means the analysis of the interaction that occurs
121 | between radio frequency energy, atomic nuclei, and strong magnetic fields to produce cross sectional
122 | images similar to those displayed by computed tomography (CT) but without the use of ionizing radiation.
- 123 | (z) ~~"Magnetic resonance imaging adjusted procedure" or~~ "MRI adjusted procedure" means an MRI
124 | visit, at an existing MRI service, that has been adjusted in accordance with the applicable provisions of
125 | Section 14.
- 126 | (aa) ~~"Magnetic resonance imaging database" or~~ "MRI database" means the database, maintained
127 | by the Department pursuant to Section 13 of these standards, that collects information about each MRI
128 | visit at MRI services located in Michigan.
- 129 | (bb) ~~"Magnetic resonance imaging procedure" or~~ "MRI procedure" means a procedure conducted by
130 | an MRI unit approved pursuant to sections 3, 4, 5, 6, 7, 8 or 10 of these standards which is either a
131 | single, billable diagnostic magnetic resonance procedure or a procedure conducted by an MRI unit at a
132 | site participating with an approved diagnostic radiology residency program, under a research protocol
133 | approved by an ~~institutional review board- IRB~~. The capital and operating costs related to the research
134 | use are charged to a specific research account and not charged to or collected from third-party payors or
135 | patients. The term does not include a procedure conducted by an MRI unit approved pursuant to Section
136 | 9(1).
- 137 | (cc) ~~"Magnetic resonance imaging services" or~~ "MRI services" means either the utilization of an
138 | authorized MRI unit(s) at one site in the case of a fixed MRI service or in the case of a mobile MRI
139 | service, the utilization of an authorized mobile MRI unit at each host site.
- 140 | (dd) ~~"Magnetic resonance imaging unit" or~~ "MRI unit" means the magnetic resonance system
141 | consisting of an integrated set of machines and related equipment necessary to produce the images
142 | and/or spectroscopic quantitative data from scans.
- 143 | (ee) ~~"Magnetic resonance imaging visit" or~~ "MRI visit" means a single patient visit to an MRI
144 | service/unit that may involve one or more MRI procedures.
- 145 | (ff) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6
146 | and 1396r-8 to 1396v.
- 147 | (gg) "Metropolitan statistical area county" means a county located in a metropolitan statistical area
148 | as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas"
149 | by the statistical policy office of the office of information and regulatory affairs of the United States office
150 | of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.
- 151 | (hh) "Micropolitan statistical area county" means a county located in a micropolitan statistical area
152 | as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas"
153 | by the statistical policy office of the office of information and regulatory affairs of the United States office
154 | of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.
- 155 | (ii) "Mobile MRI unit" means an MRI unit operating at two or more host sites and that has a central
156 | service coordinator. The mobile MRI unit shall operate under a contractual agreement for the provision of
157 | MRI services at each host site on a regularly scheduled basis.

- 158 | (jj) "Ownership interest, direct or indirect," ~~for purposes of these standards,~~ means a direct
159 | ownership relationship between a doctor and an applicant entity or an ownership relationship between a
160 | doctor and an entity that has an ownership relationship with an applicant entity.
- 161 | (kk) "Pediatric patient," ~~for purposes of these standards, except for Section 10,~~ means a patient
162 | who is 12 years of age or less, ~~EXCEPT FOR SECTION 9.~~
- 163 | (ll) "Planning area," ~~for purposes of these standards,~~ means
164 | (i) in the case of a proposed fixed MRI service or unit, the geographic area within a 20-mile radius
165 | from the proposed site if the proposed site is not in a rural or micropolitan statistical area county and a
166 | 75-mile radius from the proposed site if the proposed site is in a rural or micropolitan statistical area
167 | county. For purposes of Section ~~76~~(3) of these standards, the planning area shall be measured from the
168 | original site at which the MRI service was first initiated.
- 169 | (ii) in the case of a proposed mobile MRI service or unit, except as provided in subsection (iii), the
170 | geographic area within a 20-mile radius from each proposed host site if the proposed site is not in a rural
171 | or micropolitan statistical area county and within a 75-mile radius from each proposed host site if the
172 | proposed site is in a rural or micropolitan statistical area county.
- 173 | (iii) in the case of a proposed mobile MRI service or unit meeting the requirement of Section
174 | 14(2)(d), the health service area in which all the proposed mobile host sites will be located.
- 175 | (mm) "Referring doctor," ~~for purposes of these standards,~~ means the doctor of record who ordered
176 | the MRI procedure(s) and either to whom the primary report of the results of an MRI procedure(s) is sent
177 | or in the case of a teaching facility, the attending doctor who is responsible for the house officer or
178 | resident that requested the MRI procedure.
- 179 | (nn) "Relocate an existing MRI service and/or MRI unit(s)" means a change in the location of an
180 | existing MRI service and/or MRI unit(s) from the existing site to a different site within the relocation zone.
- 181 | (oo) "Relocation zone," ~~for purposes of these standards,~~ means the geographic area that is within a
182 | 10-mile radius of the existing site of the MRI service or unit to be relocated.
- 183 | (pp) "Renewal of a lease" means extending the effective period of a lease for an existing MRI unit
184 | that does not involve either replacement of the MRI unit, as defined in Section 2(1)(pp)(i), or (ii) a change
185 | in the parties to the lease.
- 186 | (qq) "Replace an existing MRI unit" means (i) any equipment change involving a change in, or
187 | replacement of, the magnet resulting in an applicant operating the same number and type (fixed or
188 | mobile) of MRI units before and after project completion or (ii) an equipment change other than a change
189 | in the magnet that involves a capital expenditure of \$750,000 or more in any consecutive 24-month
190 | period or (iii) the renewal of a lease. The term does not include an upgrade of an existing MRI service or
191 | unit, and it does not include a host site that proposes to receive mobile MRI services from a different
192 | central service coordinator if the requirements of Section 3(5)(a)-(e), as applicable, have been met.
- 193 | (rr) "Research scan" means an MRI scan administered under a research protocol approved by the
194 | applicant's ~~institutional review board IRB.~~
- 195 | (ss) "Re-sedated patient" means a patient, either pediatric or adult, who fails the initial sedation
196 | during the scan time and must be extracted from the unit to rescue the patient with additional sedation.
- 197 | (tt) "Rural county" means a county not located in a metropolitan statistical area or micropolitan
198 | statistical areas as those terms are defined under the "standards for defining metropolitan and
199 | micropolitan statistical areas" by the statistical policy office of the office of information regulatory affairs of
200 | the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as
201 | shown in Appendix A.
- 202 | (uu) "Sedated patient" means a patient that meets all of the following:
203 | (i) whose level of consciousness is either conscious-sedation or a higher level of sedation, as
204 | defined by the American Association of Anesthesiologists, the American Academy of Pediatrics, the Joint
205 | Commission on the Accreditation of Health Care Organizations, or an equivalent definition.
206 | (ii) who is monitored by mechanical devices while in the magnet.
207 | (iii) who requires observation while in the magnet by personnel, other than employees routinely
208 | assigned to the MRI unit, who are trained in cardiopulmonary resuscitation (CPR).
- 209 | (vv) "Site," ~~for purposes of these standards,~~ means

- 210 (i) in the case of a licensed hospital site, a location that is part of the licensed hospital site or a
211 location that is contiguous to the licensed hospital site or
212 (ii) in the case of a location that is not a licensed hospital site, a location at the same address or a
213 location that is contiguous to that address.
214 (ww) "Special needs patient" means a non-sedated patient, either pediatric or adult, with any of the
215 following conditions: down syndrome, autism, attention deficit hyperactivity disorder (ADHD),
216 developmental delay, malformation syndromes, hunter's syndrome, multi-system disorders, psychiatric
217 disorders, and other conditions that make the patient unable to comply with the positional requirements of
218 the exam.
219 (xx) "Teaching facility," ~~for purposes of these standards,~~ means a licensed hospital site, or other
220 location, that provides either fixed or mobile MRI services and at which residents or fellows of a training
221 program in diagnostic radiology, that is approved by the Accreditation Council on Graduate Medical
222 Education or American Osteopathic Association, are assigned.
223 (yy) "Unadjusted MRI scan" means an MRI procedure performed on a single anatomical site as
224 defined by the MRI database and that is not adjusted pursuant to the applicable provisions of Section 14.
225 (zz) "Upgrade an existing MRI unit" means any equipment change that
226 (i) does not involve a change in, or replacement of, the magnet; does not result in an increase in
227 the number of MRI units; or does not result in a change in the type of MRI unit (e.g., changing a mobile
228 MRI unit to a fixed MRI unit); and
229 (ii) involves a capital expenditure of less than \$750,000 in any consecutive 24-month period.
230
231 (2) Terms defined in the Code have the same meanings when used in these standards.
232

233 **Section 3. Requirements ~~for approval of applicants proposing to initiate an MRI service or mobile~~**
234 **~~MRI host site~~**

235
236 SEC 3. AN APPLICANT PROPOSING TO INITIATE AN MRI SERVICE OR A HOST SITE SHALL
237 DEMONSTRATE THE FOLLOWING REQUIREMENTS, AS APPLICABLE:
238

239 ~~Sec. 3.~~ (1) An applicant proposing to initiate a fixed MRI service shall demonstrate that 6,000
240 available MRI adjusted procedures, PER PROPOSED FIXED MRI UNIT from within the same planning
241 area as the proposed service/unit, ~~per proposed unit result from application of the methodology in Section~~
242 ~~16 of these standards.~~
243

244 (2) AN APPLICANT PROPOSING TO INITIATE A FIXED MRI SERVICE THAT MEETS THE
245 FOLLOWING REQUIREMENTS SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH
246 SUBSECTION (1):

247 (A) THE APPLICANT IS CURRENTLY AN EXISTING HOST SITE.

248 (B) THE APPLICANT HAS RECEIVED IN AGGREGATE:

249 (I) AT LEAST 6,000 MRI ADJUSTED PROCEDURES, OR

250 (II) AT LEAST 4,000 MRI ADJUSTED PROCEDURES AND THE APPLICANT MEETS ALL OF
251 THE FOLLOWING:

252 (A) IS LOCATED IN A COUNTY THAT HAS NO FIXED MRI MACHINES THAT ARE PENDING,
253 APPROVED BY THE DEPARTMENT, OR OPERATIONAL AT THE TIME THE APPLICATION IS
254 DEEMED SUBMITTED,

255 (B) THE NEAREST FIXED MRI MACHINE IS LOCATED MORE THAN 15 RADIUS MILES
256 FROM THE APPLICATION SITE,

257 (C) ALL OF THE MRI ADJUSTED PROCEDURES FROM THE MOBILE MRI SERVICE
258 REFERENCED IN (B) SHALL BE UTILIZED EVEN IF THE AGGREGATED DATA EXCEEDS THE
259 MINIMUM REQUIREMENTS.

260 (D) THE APPLICANT SHALL INSTALL THE FIXED MRI UNIT AT THE SAME SITE AS THE
261 EXISTING HOST SITE OR WITHIN THE RELOCATION ZONE.

262 (E) THE APPLICANT SHALL CEASE OPERATION AS A HOST SITE AND NOT BECOME A
263 HOST SITE FOR AT LEAST 12 MONTHS FROM THE DATE THE FIXED SERVICE AND ITS UNIT
264 BECOMES OPERATIONAL.

266 ~~(23)(a) An applicant proposing to initiate a mobile MRI service that involves beginning operation of a~~
267 ~~mobile MRI unit shall demonstrate that a minimum of 5,500 available MRI adjusted procedures, from~~
268 ~~within the same planning area as the proposed service/unit AND, per proposed unit result from~~
269 ~~application of the methodology in Section 16 of these standards.~~

270 (A) IDENTIFY THE PROPOSED ROUTE SCHEDULE AND PROCEDURES FOR HANDLING
271 EMERGENCY SITUATIONS.

272 (B) SUBMIT COPIES OF ALL PROPOSED CONTRACTS FOR THE PROPOSED HOST SITE
273 RELATED TO THE MOBILE MRI SERVICE.

274 (C) IDENTIFY A MINIMUM OF TWO (2) HOST SITES FOR THE PROPOSED SERVICE.

277 ~~(b4) The AN applicant, whether the central service coordinator or the host site, PROPOSING TO~~
278 ~~INITIATE A HOST SITE ON A NEW OR EXISTING MOBILE MRI SERVICE SHALL must demonstrate:~~
279 ~~that a minimum of 600 available MRI adjusted procedures, from within the same planning area as the~~
280 ~~proposed service/unit, result from the application of the methodology in Section 16 of these standards, for~~
281 ~~each proposed host site that~~

282 (A) 600 AVAILABLE MRI ADJUSTED PROCEDURES, FROM WITHIN THE SAME PLANNING
283 AREA AS THE PROPOSED SERVICE/UNIT, FOR A PROPOSED HOST SITE THAT IS NOT LOCATED
284 IN A RURAL OR MICROPOLITAN STATISTICAL AREA COUNTY, OR

285 (B) 400 AVAILABLE MRI ADJUSTED PROCEDURES FROM WITHIN THE SAME PLANNING
286 AREA FOR A PROPOSED HOST SITE THAT IS LOCATED IN A RURAL OR MICROPOLITAN
287 STATISTICAL AREA COUNTY, AND

288 ~~(i) is not located in a rural or micropolitan statistical area county and~~

289 ~~(ii) THE PROPOSED HOST SITE has not received any mobile MRI service within the most recent~~
290 ~~12-month period as of the date an application is submitted to the Department.~~

291 ~~(c) The applicant, whether the central service coordinator or the host site, must demonstrate that a~~
292 ~~minimum of 400 available MRI adjusted procedures, from within the same planning area as the proposed~~
293 ~~service/unit, result from the application of the methodology in Section 16 of these standards for each~~
294 ~~proposed host site that~~

295 ~~(i) is located in a rural or micropolitan statistical area county and~~

296 ~~(ii) has not received any mobile MRI service within the most recent 12-month period as of the date~~
297 ~~an application is submitted to the Department.~~

299 ~~(3)(a) An applicant, whether the central service coordinator or a proposed host site, proposing to~~
300 ~~initiate a mobile MRI host site not in a rural or micropolitan statistical area county, that is to be part of an~~
301 ~~existing mobile MRI service, must demonstrate that at least 600 available MRI adjusted procedures, from~~
302 ~~within the same planning area as the proposed service/unit, result from the application of the~~
303 ~~methodology in Section 16 of these standards for that host site.~~

304 ~~(b) An applicant, whether the central service coordinator or a proposed host site, proposing to~~
305 ~~initiate a mobile MRI host site in a rural or micropolitan statistical area county, that is to be part of an~~
306 ~~existing mobile MRI service, must demonstrate that at least 400 available MRI adjusted procedures, from~~
307 ~~within the same planning area as the proposed service/unit, result from the application of the~~
308 ~~methodology in Section 16 of these standards for that host site.~~

309 ~~(4) An applicant that meets all of the following requirements shall not be required to be in~~
310 ~~compliance with subsection (1):~~

311 ~~(a) The applicant is proposing to initiate a fixed MRI service.~~

312 ~~(b) The applicant is currently a host site being served by one or more mobile MRI units.~~

313 ~~(c) The applicant has received, in aggregate, the following:~~

315 ~~—— (i) at least 6,000 MRI adjusted procedures within the most recent 12-month period for which data,~~
316 ~~verifiable by the Department, are available or~~
317 ~~—— (ii) at least 4,000 MRI adjusted procedures within the most recent 12-month period for which data,~~
318 ~~verifiable by the Department, are available, and the applicant meets all of the following:~~
319 ~~—— (A) is located in a county that has no fixed MRI machines that are pending, approved by the~~
320 ~~Department, or operational at the time the application is deemed submitted;~~
321 ~~—— (B) the nearest fixed MRI machine is located more than 15 radius miles from the application site;~~
322 ~~—— (C) the applicant is a nonprofit licensed hospital site;~~
323 ~~—— (D) the applicant certifies in its CON application, by providing a governing body resolution, that the~~
324 ~~board of trustees of the facility has performed a due diligence investigation and has determined that the~~
325 ~~fixed MRI service will be economically viable to ensure provision of safe and appropriate patient access~~
326 ~~within the community hospital setting.~~
327 ~~—— (d) All of the MRI adjusted procedures provided at the applicant's approved site in the most recent~~
328 ~~12-month period, referenced in (c) above, by each mobile MRI service/units from which any of the MRI~~
329 ~~adjusted procedures are being utilized to meet the minimum 6,000 or 4,000 MRI adjusted procedures~~
330 ~~shall be utilized to meet the requirements of (c). [For example: If mobile network 19 provided 4,000~~
331 ~~adjusted procedures, network 21 provided 2,100, and network 18 provided 1,000, all of the adjusted~~
332 ~~procedures from network 19 and 21 must be used (i.e., 6,100) but the 1,000 adjusted procedures from~~
333 ~~network 18 do not need to be used to meet the 6,000 minimum.]~~
334 ~~—— (e) The applicant shall install the fixed MRI unit at the same site as the existing approved host site~~
335 ~~or at the applicant's licensed hospital site as defined in these standards.~~

336
337 (5) ~~Initiation of a mobile MRI host site does not include the provision of mobile MRI services at a~~
338 ~~host site if the applicant, whether the host site or the central service coordinator, demonstrates or~~
339 ~~provides each of the following, as applicable: AN APPLICANT PROPOSING TO ADD OR CHANGE~~
340 ~~SERVICE ON AN EXISTING MOBILE MRI SERVICE THAT MEETS THE FOLLOWING~~
341 ~~REQUIREMENTS SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH SUBSECTION (4) AND~~
342 ~~SHALL MEET EACH OF THE FOLLOWING:~~

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

345 ~~(B) SUBMIT COPIES OF ALL PROPOSED CONTRACTS FOR THE PROPOSED HOST SITE~~
346 ~~RELATED TO THE MOBILE MRI SERVICE.~~

347 ~~—— (b) The addition of a host site to a mobile MRI unit will not increase the number of MRI units~~
348 ~~operated by the central service coordinator or by any other person.~~

349 ~~—— (c) Notification to the Department of the addition of a host site prior to the provision of MRI~~
350 ~~services by that mobile MRI unit in accordance with (d).~~

351 ~~—— (d) A signed certification, on a form provided by the Department, whereby each host site for each~~
352 ~~mobile MRI unit has agreed and assured that it will provide MRI services in accordance with the terms for~~
353 ~~approval set forth in Section 13 of these standards, as applicable. The central service coordinator also~~
354 ~~shall identify all current host sites, on this form, that are served by the mobile route as of the date of the~~
355 ~~signed certification or are committed in writing to be served by the mobile route.~~

356 ~~—— (e) The central service coordinator requires, as a condition of any contract with a host site,~~
357 ~~compliance with the requirements of these standards by that host site, and the central service coordinator~~
358 ~~assures compliance, by that host site, as a condition of the CON issued to the central service coordinator.~~

359
360 ~~(6) THE APPLICANT SHALL DEMONSTRATE THAT THE AVAILABLE MRI ADJUSTED~~
361 ~~PROCEDURES ARE FROM THE MOST RECENTLY PUBLISHED AVAILABLE MRI ADJUSTED~~
362 ~~PROCEDURES LIST AS OF THE DATE AN APPLICATION IS DEEMED SUBMITTED BY THE~~
363 ~~DEPARTMENT.~~

364
365 ~~SECTION 4. REQUIREMENTS TO REPLACE AN EXISTING MRI UNIT.~~

367 SEC 4 AN APPLICANT PROPOSING TO REPLACE AN EXISTING MRI UNIT SHALL
368 DEMONSTRATE THE FOLLOWING REQUIREMENTS, AS APPLICABLE:

369
370 (1) AN APPLICANT SHALL DEMONSTRATE THAT THE APPLICABLE MRI ADJUSTED
371 PROCEDURES ARE FROM THE MOST RECENTLY PUBLISHED MRI SERVICE UTILIZATION LIST
372 AS OF THE DATE AN APPLICATION IS DEEMED SUBMITTED BY THE DEPARTMENT:

373 (A) EACH EXISTING MOBILE MRI UNIT ON THE NETWORK HAS PERFORMED AT LEAST AN
374 AVERAGE OF 5,500 MRI ADJUSTED PROCEDURES PER MRI UNIT.

375 (B) EACH EXISTING FIXED MRI UNIT AT THE CURRENT SITE HAS PERFORMED AT LEAST
376 AN AVERAGE OF 6,000 MRI ADJUSTED PROCEDURES PER MRI UNIT.

377 (C) EACH EXISTING DEDICATED PEDIATRIC MRI UNIT AT THE CURRENT SITE HAS
378 PERFORMED AT LEAST AN AVERAGE OF 3,500 MRI ADJUSTED PROCEDURES PER MRI UNIT.

379
380 (2) EQUIPMENT THAT IS REPLACED SHALL BE REMOVED FROM SERVICE AND DISPOSED
381 OF OR RENDERED CONSIDERABLY INOPERABLE ON OR BEFORE THE DATE THAT THE
382 REPLACEMENT EQUIPMENT BECOMES OPERATIONAL.

383
384 (3) THE REPLACEMENT UNIT SHALL BE LOCATED AT THE SAME SITE UNLESS THE
385 REQUIREMENTS OF THE RELOCATION SECTION HAVE BEEN MET.

386
387 (4) AN APPLICANT PROPOSING TO REPLACE AN EXISTING MRI UNIT THAT DOES NOT
388 INVOLVE A RENEWAL OF A LEASE SHALL DEMONSTRATE THAT THE MRI UNIT TO BE
389 REPLACED IS FULLY DEPRECIATED ACCORDING TO GENERALLY ACCEPTED ACCOUNTING
390 PRINCIPLES; THE EXISTING EQUIPMENT CLEARLY POSES A THREAT TO THE SAFETY OF THE
391 PUBLIC; OR THE PROPOSED REPLACEMENT EQUIPMENT OFFERS A SIGNIFICANT
392 TECHNOLOGICAL IMPROVEMENT WHICH ENHANCES QUALITY OF CARE, INCREASES
393 EFFICIENCY, AND REDUCES OPERATING COSTS.

394
395 **Section 45. Requirements for approval of an application proposing to expand an existing MRI**
396 **service**

397
398 ~~— Sec. 4. (1) An applicant proposing to expand an existing fixed MRI service shall demonstrate that its~~
399 ~~existing fixed MRI units (excluding MRI units approved pursuant to Section 10) have performed at least~~
400 ~~an average of 11,000 adjusted procedures for each fixed unit based on the application of the~~
401 ~~methodology in Section 14 and as documented in accordance with Section 15 of these standards.~~

402 ~~— (a) The additional unit shall be located at the same site unless the requirements of Section 7(2)~~
403 ~~have been met.~~

404
405 ~~— (2) An applicant proposing to expand an existing fixed MRI service approved pursuant to Section~~
406 ~~10 shall demonstrate that its existing fixed MRI units have performed at least an average of 3,500~~
407 ~~adjusted procedures for each fixed unit, based on the application of the methodology in Section 14 and~~
408 ~~as documented in accordance with Section 15 of these standards.~~

409 ~~— (a) The additional unit shall be located at the same site unless the requirements of Section 7(2)~~
410 ~~have been met.~~

411
412 ~~— (3) An applicant proposing to expand an existing mobile MRI service shall demonstrate that 4,000~~
413 ~~available MRI adjusted procedures, from within the same planning area as the proposed unit, per~~
414 ~~proposed additional unit result from application of the methodology in Section 16 of these standards.~~

415
416 ~~— (4) An applicant proposing to expand an existing mobile MRI service must provide a copy of the~~
417 ~~existing or revised contracts between the central service coordinator and each host site(s) that includes~~
418 ~~the same stipulations as specified in Section 6(2).~~

420 SEC 5. AN APPLICANT PROPOSING TO EXPAND AN EXISTING MRI SERVICE SHALL
421 DEMONSTRATE THE FOLLOWING:

422
423 (1) AN APPLICANT SHALL DEMONSTRATE THAT THE APPLICABLE MRI ADJUSTABLE
424 PROCEDURES ARE FROM THE MOST RECENTLY PUBLISHED MRI SERVICE UTILIZATION LIST
425 AS OF THE DATE OF AN APPLICATION IS DEEMED SUBMITTED BY THE DEPARTMENT:

426 (A) EACH EXISTING MRI UNIT ON THE NETWORK HAS PERFORMED AT LEAST AN
427 AVERAGE OF 9,000 MRI ADJUSTED PROCEDURES PER MRI UNIT.

428 (B) EACH EXISTING FIXED MRI UNIT AT THE CURRENT SITE HAS PERFORMED AT
429 LEAST AN AVERAGE OF 11,000 MRI ADJUSTED PROCEDURES PER MRI UNIT.

430 (C) EACH EXISTING DEDICATED PEDIATRIC MRI UNIT AT THE CURRENT SITE HAS
431 PERFORMED AT LEAST AN AVERAGE OF 3,500 MRI ADJUSTED PROCEDURES PER MRI UNIT.

432
433 (2) THE ADDITIONAL FIXED UNIT SHALL BE LOCATED AT THE SAME SITE UNLESS
434 THE REQUIREMENTS OF THE RELOCATION SECTION HAVE BEEN MET.

435
436 **Section 5. Requirements for approval of an applicant proposing to replace an existing MRI unit**

437
438 ~~— Sec. 5. An applicant proposing to replace an existing MRI unit shall demonstrate that the proposed~~
439 ~~project meets each of the following requirements:~~

440
441 ~~— (1) Within the most recent 12-month period for which data, verifiable by the Department, are~~
442 ~~available, at least the applicable minimum number of MRI adjusted procedures set forth in subdivision (a),~~
443 ~~(b), or (c) has been performed. In meeting this requirement, an applicant shall not include any~~
444 ~~procedures conducted by an MRI unit approved pursuant to Section 9(1).~~

445 ~~— (a) Each existing mobile MRI unit on the network has performed in excess of an average of 5,500~~
446 ~~MRI adjusted procedures per MRI unit.~~

447 ~~— (b) Each existing fixed MRI unit at the current site has performed in excess of an average of 6,000~~
448 ~~MRI adjusted procedures per MRI unit.~~

449 ~~— (c) Each existing dedicated pediatric MRI unit at the current site has performed in excess of 3,500~~
450 ~~MRI adjusted procedures per MRI unit.~~

451
452 ~~— (2) An applicant proposing to replace an existing MRI unit that does not involve a renewal of a~~
453 ~~lease shall demonstrate that the MRI unit to be replaced is fully depreciated according to generally~~
454 ~~accepted accounting principles; the existing equipment clearly poses a threat to the safety of the public;~~
455 ~~or the proposed replacement equipment offers a significant technological improvement which enhances~~
456 ~~quality of care, increases efficiency, and reduces operating costs.~~

457
458 ~~— (3) Equipment that is replaced shall be removed from service and disposed of or rendered~~
459 ~~considerably inoperable on or before the date that the replacement equipment becomes operational.~~

460
461 ~~— (4) An applicant proposing to replace an existing mobile MRI unit must provide a copy of the~~
462 ~~existing or revised contracts between the central service coordinator and each host site(s) that includes~~
463 ~~the same stipulations as specified in Section 6(2).~~

464
465 ~~— (5) The replacement unit shall be located at the same site unless the requirements of Section 7(2)~~
466 ~~have been met.~~

467
468 **Section 6. Additional requirements for approval of an applicant proposing to initiate a mobile MRI**
469 **service**

471 ~~— Sec. 6. (1) An applicant proposing to initiate a mobile MRI service that involves beginning operation~~
472 ~~of a mobile MRI unit shall identify the proposed regular route schedule and the procedures for handling~~
473 ~~emergency situations.~~

474 ~~— (2) An applicant proposing a mobile MRI service shall submit copies of all proposed contracts~~
475 ~~related to the mobile MRI service in the CON application submitted by the central service coordinator.~~
476 ~~The contract shall include at least the following:~~

477 ~~— (a) A signed certification, on a form provided by the Department, whereby each host site has~~
478 ~~agreed and assured that it will provide MRI services for each mobile MRI unit in accordance with the~~
479 ~~terms of approval set forth in Section 13 of these standards, as applicable. The central service~~
480 ~~coordinator also shall identify all current host sites, on this form, as of the date of the signed certification.~~

481 ~~— (b) A statement that requires compliance with the requirements of these standards by that host site~~
482 ~~and assures compliance, by that host site, as a condition of the CON issued to the central service~~
483 ~~coordinator.~~

484 ~~— (c) A signed agreement between the central service coordinator and the host site(s) that states~~
485 ~~that for any host site applying, at any time in the future, for a fixed MRI unit under Section 3(4), that the~~
486 ~~mobile services at the host site will not cease until the fixed unit is in operation or upon the request of the~~
487 ~~host site. Further, the applicant applying for the fixed MRI unit must stipulate in the application at the time~~
488 ~~it is submitted to the Department that it has notified all affected host sites as well as the central service~~
489 ~~coordinator at least six months prior to beginning operation of the fixed MRI unit.~~

491 **Section 76. Requirements for approval of an applicant proposing to relocate an existing FIXED**
492 **MRI service and/or MRI unit(s)**

493
494 Sec 76. (1) An applicant proposing to relocate an existing fixed MRI service and its unit(s) shall
495 demonstrate ~~that the proposed project meets all of~~ the following:

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

498 (b) The proposed new site ~~of the existing MRI service and its unit(s) to be relocated~~ is in the
499 relocation zone.

500 ~~— (c) The proposed project will not result in the replacement of the existing MRI unit(s) to be~~
501 ~~relocated unless the applicant demonstrates that the requirements of Section 5, as applicable, have been~~
502 ~~met.~~

503 ~~— (d) The proposed project will not result in an increase of the number of MRI units operated by the~~
504 ~~existing MRI service at the proposed site unless the applicant demonstrates that the requirements of~~
505 ~~Section 4, as applicable, have been met.~~

506 (eC) Each existing MRI unit to be relocated performed at least the applicable minimum number of
507 MRI adjusted procedures set forth in Section ~~12 13(1)(d)(i) of these standards~~ based on the most ~~recent~~
508 ~~12-month period for which the Department has verifiable data~~ RECENTLY PUBLISHED MRI SERVICE
509 UTILIZATION LIST AS OF THE DATE AN APPLICATION IS DEEMED SUBMITTED BY THE
510 DEPARTMENT.

511 ~~— (f) The applicant agrees to operate the MRI service and its unit(s) in accordance with all~~
512 ~~applicable project delivery requirements set forth in Section 13 of these standards.~~

513
514 (2) An applicant proposing to relocate a fixed MRI unit of an existing MRI service shall
515 demonstrate ~~that the proposed project meets all of~~ the following:

516 (A) THE APPLICANT CURRENTLY OPERATES THE MRI SERVICE FROM WHICH THE UNIT
517 WILL BE RELOCATED.

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

520 (bC) The proposed new site ~~for the MRI unit(s) to be relocated~~ is in the relocation zone.

521 ~~— (c) The proposed project will not result in the replacement of the MRI unit(s) to be relocated unless~~
522 ~~the applicant demonstrates that the requirements of Section 5, as applicable, have been met.~~

523 ~~— (d) The proposed project will not result in an increase of the number of MRI units operated by an~~
524 ~~existing MRI service at the proposed site unless the applicant demonstrates that the requirements of~~
525 ~~Section 4, as applicable, have been met.~~

526 ~~(eD) Each existing MRI unit at the service from which a unit is to be relocated performed at least the~~
527 ~~applicable minimum number of MRI adjusted procedures set forth in Section 12 13(1)(d)(i) of these~~
528 ~~standards based on the most recent 12-month period for which the Department has verifiable data~~
529 ~~RECENTLY PUBLISHED MRI SERVICE UTILIZATION LIST AS OF THE DATE AN APPLICATION IS~~
530 ~~DEEMED SUBMITTED BY THE DEPARTMENT.~~

531 ~~— (f) The applicant agrees to operate the MRI unit(s) at the proposed site in accordance with all~~
532 ~~applicable project delivery requirements set forth in Section 13 of these standards.~~

533 ~~(gE) For volume purposes, the new site shall remain associated to the original site for a minimum of~~
534 ~~three years.~~

535
536 ~~— (3) An applicant that meets all of the following requirements shall be exempt from relocating within~~
537 ~~the relocation zone:~~

538 ~~— (a) The licensed hospital site to which the MRI service is to be relocated and the MRI service at~~
539 ~~the site from which the MRI service is to be relocated are owned by the same person as defined in~~
540 ~~Section 1106 of this public act or the same governmental entity.~~

541 ~~— (b) The licensed hospital site to which the MRI service is to be relocated is located within the~~
542 ~~planning area.~~

543 ~~— (c) As evidenced in the governing body resolution required in (e), the MRI service to be relocated~~
544 ~~shall cease at its current location within 24 months after the date the application receives a final decision~~
545 ~~of approval from the Department or upon the date the service becomes operational at the relocation site,~~
546 ~~whichever occurs first.~~

547 ~~— (d) The MRI service shall be relocated and shall be operational within 24 months after the date the~~
548 ~~application receives a final decision of approval from the Department or the CON to relocate the MRI~~
549 ~~service shall expire.~~

550 ~~— (e) The CON application includes a resolution of the applicant's governing body that commits to~~
551 ~~the provisions of (c) and (d).~~

552 ~~— (f) The relocation of the MRI service shall not result in the licensed hospital site having more than~~
553 ~~one fixed MRI unit.~~

554
555 **Section 87. Requirements for approval of an applicant proposing to acquire an existing MRI**
556 **service or an existing MRI unit(s)**

557
558 SEC 7. (1) An applicant proposing to acquire an existing fixed or mobile MRI service and its unit(s)
559 shall demonstrate ~~that the proposed project meets all of the following:~~

560 ~~— (a) The project will not change the number of MRI units at the site of the MRI service being~~
561 ~~acquired unless the applicant demonstrates that the project is in compliance with the requirements of~~
562 ~~Section 3 or 4, as applicable.~~

563 ~~— (b) The project will not result in the replacement of an MRI unit at the MRI service to be acquired~~
564 ~~unless the applicant demonstrates that the requirements of Section 5 have been met.~~

565 ~~— (c) The applicant agrees to operate the MRI service and its unit(s) in accordance with all~~
566 ~~applicable project delivery requirements set forth in Section 13 of these standards.~~

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

570 The MRI service shall be operating at the applicable volume requirements set forth in Section 12
571 ~~13(1)(d)(i)~~ of these standards in the second 12 months after the effective date of the acquisition, and
572 annually thereafter.

573 (e) For any application proposing to acquire an existing fixed or mobile MRI service and its unit(s),
574 except the first application approved pursuant to subsection (dA), an applicant shall be required to
575 document that the MRI service and its unit(s) to be acquired is operating in compliance with the volume

576 | requirements set forth in Section ~~12 13(1)(d)(i)~~ of these standards applicable to an existing MRI service
577 | on the date the application is submitted to the Department.

578 |
579 | (2) An applicant proposing to acquire an existing fixed or mobile MRI unit of an existing MRI
580 | service shall demonstrate that the proposed project meets all of the following:

581 | (a) The project will not change the number of MRI units at the site of the MRI service being
582 | acquired, subject to the applicable requirements under Section ~~76~~(2), unless the applicant demonstrates
583 | that the project is in compliance with the requirements of THE INITIATION OR EXPANSION Section ~~3 or~~
584 | 4, as applicable.

585 | (b) The project will not result in the replacement of an MRI unit at the MRI service to be acquired
586 | unless the applicant demonstrates that the requirements OF THE REPLACEMENT SECTION of Section
587 | 5 have been met.

588 | ~~—(c) The applicant agrees to operate the MRI unit(s) in accordance with all applicable project~~
589 | ~~delivery requirements set forth in Section 13 of these standards.~~

590 |
591 | **Section 98. Requirements for approval of an applicant proposing an MRI unit to be used**
592 | **exclusively for research TO ESTABLISH A DEDICATED RESEARCH MRI UNIT**

593 |
594 | Sec. ~~98. (1)~~—An applicant proposing an MRI unit to be used exclusively for research shall
595 | demonstrate ~~each of~~ the following:

596 | (a1) SUBMIT COPIES OF DOCUMENTATION DEMONSTRATING THAT The-~~THE~~ applicant
597 | operates a diagnostic radiology residency program approved by the Accreditation Council for Graduate
598 | Medical Education, the American Osteopathic Association, or an equivalent organization.

599 |
600 | (b2) SUBMIT COPIES OF DOCUMENTATION DEMONSTRATING THAT The-~~THE~~ MRI unit shall
601 | operate under a protocol approved by the applicant's ~~institutional review board IRB~~.

602 | ~~—(c) The applicant agrees to operate the unit in accordance with the terms of approval in Section~~
603 | ~~13(2).~~

604 |
605 | (23) An applicant meeting the requirements of ~~subsection (1)-THIS SECTION~~ shall be exempt from
606 | meeting the requirements ~~and terms~~ of sections ~~3, 4, 5, 6, 7, 8, 13 [with the exception of 13(1)(d)(iii)], 15,~~
607 | ~~and 16 of these standards~~ TO INITIATE AND REPLACE.

608 |
609 | **Section 109. Requirements for approval of an applicant proposing to establish A dedicated**
610 | **pediatric MRI UNIT**

611 |
612 | Sec. ~~109. (1)~~ An applicant proposing to establish dedicated pediatric MRI shall demonstrate all of the
613 | following:

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

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

618 | (c) The applicant shall have an active medical staff, ~~at the time the application is submitted to the~~
619 | ~~Department,~~ that includes, but is not limited to, physicians who are fellowship-trained in the following
620 | pediatric specialties:

621 | (i) pediatric radiology (at least two)

622 | (ii) pediatric anesthesiology

623 | (iii) pediatric cardiology

624 | (iv) pediatric critical care

625 | (v) pediatric gastroenterology

626 | (vi) pediatric hematology/oncology

627 | (vii) pediatric neurology

628 | (viii) pediatric neurosurgery

- 629 (ix) pediatric orthopedic surgery
- 630 (x) pediatric pathology
- 631 (xi) pediatric pulmonology
- 632 (xii) pediatric surgery
- 633 (xiii) neonatology
- 634 (d) The applicant shall have in operation the following pediatric specialty programs ~~at the time the~~
- 635 ~~application is submitted to the Department:~~
- 636 (i) pediatric bone marrow transplant program
- 637 (ii) established pediatric sedation program
- 638 (iii) pediatric open heart program

639

640 (2) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the

641 requirements of Section 4, of these standards.

642

643 **Section 4410. Pilot program requirements for approval – applicants proposing to initiate, replace,**

644 **or acquire a hospital based IMRI**

645

646 Sec. 4410. As a pilot program, an applicant proposing to initiate, replace, or acquire a hospital based

647 IMRI service shall demonstrate that it meets all of the following:

648

- 649 (1) The proposed site is a licensed hospital under Part 215 of the Code.
- 650
- 651 (2) The proposed site has an existing fixed MRI service that has been operational for the previous
- 652 36 consecutive months and is meeting its minimum volume requirements.
- 653
- 654 (3) The proposed site has an existing and operational surgical service and is meeting its minimum
- 655 volume requirements pursuant to the CON Review Standards for Surgical Services.
- 656
- 657 (4) The applicant shall have experienced one of the following:
- 658 (a) at least 1,500 oncology discharges in the most recent year of operation; or
- 659 (b) at least 1,000 neurological surgeries in the most recent year of operation; or
- 660 (c) at least 7,000 pediatric (<18 years old) discharges (excluding normal newborns) and at least
- 661 5,000 pediatric (<18 years old) surgeries in the most recent year of operation.
- 662
- 663 (5) The proposed IMRI unit must be located in an operating room or a room adjoining an operating
- 664 room allowing for transfer of the patient between the operating room and this adjoining room.
- 665
- 666 (6) Non-surgical diagnostic studies shall not be performed on an IMRI unit approved under this
- 667 section unless the patient meets one of the following criteria:
- 668 (a) the patient has been admitted to an inpatient unit; or
- 669 (b) the patient is having the study performed on an outpatient basis, but is in need of general
- 670 anesthesia or deep sedation as defined by the American Society of Anesthesiologists.
- 671
- 672 (7) The approved IMRI unit will not be subject to MRI volume requirements.
- 673
- 674 (8) The applicant shall not utilize the procedures performed on the IMRI unit to demonstrate need
- 675 or to satisfy MRI CON review standards requirements.
- 676

677 ~~— (9) The applicant agrees to operate the IMRI unit in accordance with all applicable project delivery~~

678 ~~requirements set forth in Section 13 of these standards.~~

679

680 | (409) The provisions of Section ~~44-10~~ are part of a pilot program approved by the CON commission
681 | and shall expire and be of no further force and effect, and shall not be applicable to any application which
682 | has not been submitted by December 31, 2010.

683 |
684 | **Section ~~4211~~. Requirements for ~~approval~~—all applicants**
685 |

686 | Sec. ~~4211~~. An applicant shall provide verification of Medicaid participation. An applicant that is a new
687 | provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided
688 | to the Department within six (6) months from the offering of services if a CON is approved.

689 |
690 | **Section ~~4312~~. Project delivery requirements – terms of approval**
691 |

692 | Sec. ~~4312~~. (1) An applicant shall agree that, if approved, MRI services, whether fixed or mobile, shall
693 | be delivered and maintained in compliance with the following ~~terms of CON approval for each~~
694 | ~~geographical location where the applicant operates an MRI unit:~~

- 695 | (a) Compliance with these standards.
696 | (b) Compliance with applicable safety and operating standards ~~for the specific MRI unit approved.~~
697 | (c) Compliance with the following quality assurance standards:
698 | ~~(i) An applicant shall develop and maintain policies and procedures that establish protocols for the~~
699 | ~~following system performance measures. The protocols shall establish the required benchmarks; identify~~
700 | ~~the testing interval, which shall be at least quarterly; and identify the MRI staff person responsible for~~
701 | ~~testing the system performance measures.~~
702 | ~~(A) Signal-to-noise ratio.~~
703 | ~~(B) Spatial resolution.~~
704 | ~~(C) Slice thickness, location, and separation.~~
705 | ~~(D) Spatial linearity.~~
706 | ~~(E) Field homogeneity and drift.~~
707 | ~~(F) System calibration and stability.~~
708 | ~~(G) Cryogen level and boiloff rate.~~
709 | ~~(H) Radio frequency power monitor.~~
710 | ~~(I) Hard copy image quality.~~
711 | ~~In addition to the designated staff person, the system performance measures in subdivisions (A)~~
712 | ~~through (F) and (H) also shall be evaluated by an appropriately trained MRI physicist or engineer. The~~
713 | ~~physicist/engineer shall conduct tests of these system performance measures when the MRI unit begins~~
714 | ~~to operate, and annually thereafter. The purpose of the physicist/engineer test shall be to certify to the~~
715 | ~~Department that the MRI unit meets or exceeds all of the system performance specifications of the~~
716 | ~~manufacturer of the MRI unit in effect for that MRI unit at the time of installation or most recent upgrade.~~
717 | ~~The physicist/engineer shall make available for review the periodic system performance measures test~~
718 | ~~data established in this subsection.~~
719 | ~~(ii) An applicant shall develop and maintain policies, procedures, and protocols for assuring the~~
720 | ~~functionality of each of the following MRI accessories. The protocols shall establish the required~~
721 | ~~benchmarks, identify the testing interval for each accessory, and identify the staff person responsible for~~
722 | ~~testing the system performance measures.~~
723 | ~~(A) All surface coils.~~
724 | ~~(B) Positioning devices.~~
725 | ~~(C) Physiologic triggering/monitoring equipment.~~
726 | ~~(D) Patient communication devices.~~
727 | ~~(E) Scan table position indicator and drives.~~
728 | ~~(F) Data network including storage and retrieval.~~
729 | ~~(G) Emergency rundown/shutdown units.~~
730 | ~~(H) Hard copy devices.~~
731 | (iii) An applicant shall develop and maintain policies and procedures that establish protocols for
732 | assuring the effectiveness of operation and the safety of the general public, patients, and staff in the MRI

733 service. Each of the following must be included and the staff person responsible for development and
734 enforcement of these policies shall be indicated.

735 ~~— (A) Access to the MRI service.~~
736 ~~— (B) Access to the MRI scan room.~~
737 ~~— (C) Patient safety clearance before imaging and safety during imaging.~~
738 ~~— (D) Adverse bioeffects, including~~
739 ~~— (1) acoustic hazard.~~
740 ~~— (2) radio frequency burn hazard.~~
741 ~~— (3) specific absorption rates.~~
742 ~~— (4) peripheral nerve stimulation.~~
743 ~~— (5) pregnancy.~~
744 ~~— (6) magnet quench hazard.~~
745 ~~— (E) Sedation.~~
746 ~~— (F) Contrast administration.~~
747 ~~— (G) Treatment of adverse reactions to contrast.~~
748 ~~— (H) Patient monitoring for sedation, anesthesia, and unstable patients.~~
749 ~~— (I) Patient resuscitation, management of emergencies, maintenance of cardiopulmonary~~
750 ~~resuscitation equipment, and certification requirements for personnel for either basic or advanced~~
751 ~~cardiopulmonary resuscitation.~~
752 ~~— (J) Screening for metallic implants, pacemakers, and metallic foreign bodies, as well as a list of~~
753 ~~contraindications.~~
754 ~~— (K) Mechanism for consultation regarding difficult cases.~~
755 ~~— (L) Pulse sequence protocols for specific indications.~~
756 ~~— (M) Institutional review board IRB policies relating to non-FDA approved pulse sequences or~~
757 ~~investigational procedures.~~
758 ~~— (N) Staff inservice regarding subdivisions (A) through (M).~~

759 (ivII) An applicant shall establish a schedule for preventive maintenance for the MRI unit.
760 ~~— (v) An applicant shall maintain records of the results of the periodic test data required by~~
761 ~~subdivisions (i) and (ii), including the results of the tests performed by the MRI physicist/engineer required~~
762 ~~in subdivision (i). An applicant, upon request, shall submit annually to the Department a report of the test~~
763 ~~data results and evidence of compliance with the applicable project delivery requirements.~~

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

766 ~~— (A) An MRI team leader who shall be responsible for~~
767 ~~— (1) developing criteria for procedure performance.~~
768 ~~— (2) developing protocols for procedure performance.~~
769 ~~— (3) developing a clinical data base for utilization review and quality assurance purposes.~~
770 ~~— (4) transmitting requested data to the Department.~~
771 ~~— (5) screening of patients to assure appropriate utilization of the MRI service.~~
772 ~~— (6) taking and interpretation of scans.~~
773 ~~— (7) coordinating MRI activity at MRI host sites for a mobile MRI unit.~~
774 ~~— (8) identifying and correcting MRI image quality deficiencies.~~

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

778 (CB) An appropriately trained MRI technician who shall be responsible for taking an MRI scan.
779 (DC) An MRI physicist/engineer available as a team member on a full-time, part-time, or contractual
780 basis. An MRI physicist/engineer shall be responsible for at least the following:
781 ~~— (1) providing technical specifications for new equipment and assistance in equipment procurement.~~
782 ~~— (2) performing or validating technical performance for system acceptance.~~
783 ~~— (3) establishing preventive maintenance schedules and quality assurance test procedures and~~
784 ~~recording and reviewing preventive maintenance and quality assurance data.~~
785 ~~— (4) facilitating the repair of acute system malfunctions.~~

786 | ~~— (5) training personnel in the MRI service with respect to the technical aspects of MRI scanning and~~
787 | ~~patient and staff safety.~~
788 | ~~— (6) assisting in designing and optimizing clinical imaging procedures.~~
789 | ~~— (E) System maintenance personnel who shall be responsible for calibrating the MRI system and~~
790 | ~~preventive maintenance at regularly scheduled intervals and who shall compile and submit quality control~~
791 | ~~data to the MRI team leader.~~
792 | (viiV) An applicant shall document that the MRI team members have the following qualifications:
793 | ~~— (A) The MRI team leader is a board-certified or board-eligible radiologist, or other physician trained~~
794 | ~~in MRI, who spends greater than 75 percent of his or her professional time in multiple anatomic site~~
795 | ~~medical imaging. The MRI team leader also shall demonstrate that he or she meets the requirements set~~
796 | ~~forth in subsection (B) for a physician who interprets MRI images.~~
797 | (BA) Each physician credentialed to interpret MRI scans meets the requirements of each of the
798 | following:
799 | (1) The physician is licensed to practice medicine in the State of Michigan.
800 | (2) The physician has had at least 60 hours of training in MRI physics, MRI safety, and MRI
801 | instrumentation in a program that is part of an imaging program accredited by the Accreditation Council
802 | for Graduate Medical Education or the American Osteopathic Association, and the physician meets the
803 | requirements of subdivision (i), (ii), or (iii):
804 | (i) Board certification by the American Board of Radiology, the American Osteopathic Board of
805 | Radiology, or the Royal College of Physicians and Surgeons of Canada. If the diagnostic radiology
806 | program completed by a physician in order to become board certified did not include at least two months
807 | of MRI training, that physician shall document that he or she has had the equivalent of two months of
808 | postgraduate training in clinical MRI imaging at an institution which has a radiology program accredited
809 | by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association.
810 | (ii) Formal training by an imaging program(s), accredited by the Accreditation Council for Graduate
811 | Medical Education or the American Osteopathic Association, that included two years of training in cross-
812 | sectional imaging and six months training in organ-specific imaging areas.
813 | (iii) A practice in which at least one-third of total professional time, based on a full-time clinical
814 | practice during the most recent 5-year period, has been the primary interpretation of MR imaging.
815 | (3) The physician has completed and will complete a minimum of 40 hours every two years of
816 | Category in Continuing Medical Education credits in topics directly involving MR imaging.
817 | (4) The physician interprets, as the primary interpreting physician, at least 250 unadjusted MRI
818 | scans annually.
819 | (CB) An MRI technologist who is registered by the American Registry of Radiologic Technicians or
820 | by the American Registry of Magnetic Resonance Imaging Technologists (ARMRIT) and has, or will have
821 | within 36 months of the effective date of these standards or the date a technologist is employed by an
822 | MRI service, whichever is later, special certification in MRI. If a technologist does not have special
823 | certification in MRI within either of the 3-year periods of time, all continuing education requirements shall
824 | be in the area of MRI services.
825 | (DC) An applicant shall document that an MRI physicist/engineer is appropriately qualified. For
826 | purposes of evaluating this subdivision, the Department shall consider it prima facie evidence as to the
827 | qualifications of the physicist/engineer if the physicist/engineer is certified as a medical physicist by the
828 | American Board of Radiology, the American Board of Medical Physics, or the American Board of Science
829 | in Nuclear Medicine. However, the applicant may submit and the Department may accept other evidence
830 | that an MRI physicist/engineer is qualified appropriately.
831 | ~~— (E) An applicant shall document that system maintenance personnel are qualified on the basis of~~
832 | ~~training and experience to perform the calibration, preventive maintenance, and quality control functions~~
833 | ~~on the specific MRI unit approved.~~
834 | (viiiV) The applicant shall have, within the MRI unit/service, equipment and supplies to handle clinical
835 | emergencies that might occur in the unit. MRI service staff will be trained in CPR and other appropriate
836 | emergency interventions. A physician shall be on-site, in, or immediately available to the MRI unit at all
837 | times when patients are undergoing scans.

838 | ~~— (ix) In addition to all other applicable terms of approval, each mobile MRI unit shall have an~~
839 | ~~operations committee with members representing each host site, the central service coordinator, and the~~
840 | ~~medical director. This committee shall oversee the effective and efficient use of the MRI unit, establish~~
841 | ~~the normal route schedule, identify the process by which changes shall be made to the schedule, develop~~
842 | ~~procedures for handling emergency situations, and review the ongoing operations of the mobile MRI unit~~
843 | ~~on at least a quarterly basis.~~

844 | (XVI) An applicant shall participate in Medicaid at least 12 consecutive months within the first two
845 | years of operation and continue to participate annually thereafter.

846 | (eC) Compliance with the following terms of approval, as applicable:

847 | (i) MRI units shall be operating at a minimum average annual level of utilization during the second
848 | 12 months of operation, and annually thereafter, of 6,000 actual MRI adjusted procedures per unit for
849 | fixed MRI services, 5,500 actual MRI adjusted procedures per unit for mobile MRI services, and a total of
850 | 3,500 MRI adjusted procedures per unit for dedicated pediatric MRI. Each mobile host site in a rural or
851 | micropolitan statistical area county shall have provided at least a total of 400 adjusted procedures during
852 | its second 12 months of operation, and annually thereafter, from all mobile units providing services to the
853 | site. Each mobile host site not in a rural or micropolitan statistical area county shall have provided at
854 | least a total of 600 adjusted procedures during its second 12 months of operation and annually thereafter,
855 | from all mobile units providing services to the site. In meeting these requirements, an applicant shall not
856 | include any MRI adjusted procedures performed on an MRI unit used exclusively for research and
857 | approved pursuant to Section 9(1) or for an IMRI unit approved pursuant to Section 11.

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

860 | (A) provide ~~magnetic resonance MRI~~ services to all individuals based on the clinical indications of
861 | need for the service and not on ability to pay or source of payment.

862 | (B) maintain information by source of payment to indicate the volume of care from each source
863 | provided annually.

864 | ~~Compliance with selective contracting requirements shall not be construed as a violation of this term.~~

865 | (iii) The applicant shall participate in a data collection network established and administered by the
866 | Department or its designee. The data may include, but is not limited to, ~~annual budget and cost~~
867 | ~~information~~, operating schedules, ~~throughout schedules~~, demographic and diagnostic information, and
868 | the volume of care provided to patients from all payor sources, as well as other data requested by the
869 | Department or its designee and approved by the Commission. The applicant shall provide the required
870 | data in a format established by the Department and in a mutually agreed upon media no later than 30
871 | days following the last day of the quarter for which data are being reported to the Department. An
872 | applicant shall be considered in violation of this term of approval if the required data are not submitted to
873 | the Department within 30 days following the last day of the quarter for which data are being reported.

874 | ~~However, the Department shall allow an applicant up to an additional 60 days to submit the required data~~
875 | ~~if reasonable efforts are made by an applicant to provide the required data.~~—The Department may elect to
876 | verify the data through on-site review of appropriate records. Data for an MRI unit approved pursuant to
877 | Section 9(1), Section 10, or Section 11 shall be reported separately.

878 | ~~(a)~~ For purposes of Section 11, the data reported shall include, at a minimum, how often the IMRI
879 | unit is used and for what type of services, i.e., intra-operative or diagnostic.

880 | (iv) The operation of and referral of patients to the MRI unit shall be in conformance with 1978 PA
881 | 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

882 | (eD)(i) The applicant shall provide the Department with a notice stating the first date on which the MRI
883 | unit became operational, and such notice shall be submitted to the Department consistent with applicable
884 | statute and promulgated rules.

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

888

889 (2) An applicant for an MRI unit APPROVED under Section 9(1) shall agree that the services
890 provided by the MRI unit ~~approved pursuant to Section 9(1) shall be IS~~ delivered in compliance with the
891 following terms ~~of CON approval:~~

892 (a) The capital and operating costs relating to the research use of the MRI unit ~~approved pursuant~~
893 ~~to Section 9(1)~~ shall be charged only to a specific research account(s) and not to any patient or third-
894 party payor.

895 (b) The MRI unit ~~approved pursuant to Section 9(1)~~ shall not be used for any purposes other than
896 as approved by the ~~institutional review board IRB~~ unless the applicant has obtained CON approval for
897 the MRI unit pursuant to Part 222 and these standards, other than Section 9.

898
899 (3) The agreements and assurances required by this section shall be in the form of a certification
900 agreed to by the applicant or its authorized agent.

901
902 ~~— (4) An applicant approved to initiate a fixed MRI service pursuant to Section 3(4) of these~~
903 ~~standards shall cease operation as a host site and not become a host site for at least 12 months from the~~
904 ~~date the fixed service and its unit becomes operational.~~

905 906 **Section 1413. MRI procedure adjustments**

907
908 **Sec. 1413.** (1) The Department shall apply the following formula, as applicable, to determine the
909 number of MRI adjusted procedures that are performed by an existing MRI service or unit:

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

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

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

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

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

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

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

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

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

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

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

928
929 (2) The Department shall apply not more than one of the adjustment factors set forth in this
930 subsection, as applicable, to the number of MRI procedures adjusted in accordance with the applicable
931 provisions of subsection (1) that are performed by an existing MRI service or unit.

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

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

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

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

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

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

948

949 | **Section ~~4514~~. Documentation of actual utilization**

950

951 | Sec. ~~4514~~. Documentation of the number of MRI procedures performed by an MRI unit shall be
952 substantiated by the Department utilizing data submitted by the applicant in a format and media specified
953 by the Department and as verified for the 12-month period reported on the most recently published
954 | "~~Available MRI Adjusted Procedures~~ MRI SERVICE UTILIZATION List" as of the date an application is
955 deemed complete by the Department. The number of MRI procedures actually performed shall be
956 | documented by procedure records and not by application of the methodology required in Section ~~4615~~.
957 The Department may elect to verify the data through on-site review of appropriate records.

958

959 | **Section ~~4615~~. Methodology for computing the number of available MRI adjusted procedures**

960

961 | Sec. ~~4615~~. (1) The number of available MRI adjusted procedures required pursuant to Section 3-~~or~~
962 ~~4(2) of these standards~~ shall be computed in accordance with the methodology set forth in this section.
963 In applying the methodology, the following steps shall be taken in sequence, and data for the 12-month
964 period reported on the most recently published "Available MRI Adjusted Procedures List," as of the date
965 an application is deemed complete by the Department, shall be used:

966 (a) Identify the number of actual MRI adjusted procedures performed by each existing MRI service
967 | as determined pursuant to Section ~~4413~~.

968 (i) For purposes of computing actual MRI adjusted procedures, MRI adjusted procedures
969 | performed on MRI units used exclusively for research and approved pursuant to Section ~~98~~(1) and
970 | dedicated pediatric MRI approved pursuant to Section ~~10-9~~ shall be excluded.

971 (ii) For purposes of computing actual MRI adjusted procedures, the MRI adjusted procedures,
972 | from the host site routes utilized to meet the requirements of Section 3(~~42~~)(~~eC~~), shall be excluded
973 beginning at the time the application is submitted and for three years from the date the fixed MRI unit
974 becomes operational.

975 (iii) For purposes of computing actual MRI adjusted procedures, the MRI adjusted procedures
976 | utilized to meet the requirements of Section ~~45~~(1) shall be reduced by 8,000 and shall be excluded
977 beginning at the time the application is submitted and for three years from the date the fixed MRI unit
978 becomes operational.

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

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

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

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

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

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

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

997 (iv) Using the data produced in iii above, sum the number of available adjusted procedures in
998 descending order until the summation equals at least 75 percent of the total available adjusted
999 procedures. This summation shall include the minimum number of doctors necessary to reach the 75
1000 percent level.

1001 (v) For the doctors representing 75 percent of the total available adjusted procedures in (iv) above,
1002 sum the available adjusted procedures.

1003 (vi) For the doctors used in subsection (v) above, divide the total number of available adjusted
1004 procedures identified in (B) above by the sum of those available adjusted procedures produced in (v)
1005 above.

1006 (vii) For only those doctors identified in (v) above, multiply the result of (vi) above by the available
1007 adjusted procedures calculated in (c)(ii)(A) above.

1008 (viii) The result shall be the "Available MRI Adjusted Procedures List."
1009

1010 (2) After publication of the "Available MRI Adjusted Procedures List" resulting from (1) above, the
1011 data shall be updated to account for a) doctor commitments of available MRI adjusted procedures in
1012 subsequent MRI CON applications and b) MRI adjusted procedures used in subsequent MRI CON
1013 applications received in which applicants apply for fixed MRI services pursuant to Section 3(42).
1014

1015 **Section 4716. Procedures and requirements for commitments of available MRI adjusted** 1016 **procedures**

1017
1018 Sec. 4716. (1) If one or more host sites on a mobile MRI service are located within the planning area
1019 of the proposed site, the applicant may access available MRI adjusted procedures from the entire mobile
1020 MRI service.

1021 (2)(a) At the time the application is submitted to the Department, the applicant shall submit a signed
1022 data commitment, on a form provided by the Department in response to the applicant's letter of intent ~~or~~
1023 ~~at the applicant's discretion, on a more current form subsequently provided by the Department,~~ for each
1024 doctor committing available MRI adjusted procedures to that application for a new ~~or additional~~ MRI unit
1025 THAT REQUIRES DOCTOR COMMITMENT pursuant to Section 3 or Section 4(2), respectively.

1026 (b) An applicant also shall submit, at the time the application is filed with the Department, a
1027 computer file that lists, for each MRI service from which data are being committed to the same
1028 application, the name and license number of each doctor for whom a signed and dated data commitment
1029 form is submitted.

1030 (i) The computer file shall be provided to the Department on mutually agreed upon media and in a
1031 format prescribed by the Department.

1032 (ii) If the doctor commitments submitted on the Departmental forms do not agree with the data on
1033 the computer file, the applicant shall be allowed to correct only the computer file data which includes
1034 adding physician commitments that were submitted at the time of application.

1035 (c) If the required documentation for the doctor commitments submitted under this subsection is
1036 not submitted with the application on the designated application date, the application will be deemed filed
1037 on the first applicable designated application date after all required documentation is received by the
1038 Department.
1039

1040 (3) The Department shall consider a SIGNED AND DATED data commitment, on a form provided
1041 by the Department in response to the applicant's letter of intent ~~or at the applicant's discretion, on a more~~
1042 ~~current form subsequently provided by the Department, submitted by the applicant in support of its~~
1043 ~~application,~~ that meets the requirements of each of the following, as applicable:

1044 (a) A committing doctor certifies that 100% of his or her available MRI adjusted procedures for
1045 each specified MRI service, calculated pursuant to Section 4615, is being committed and specifies the

1046 CON application ~~number~~, for the ~~new fixed or mobile MRI unit or for the additional mobile MRI unit~~
1047 ~~proposed to be located within the planning area~~, to which the data commitment is made. A doctor shall
1048 not be required to commit available MRI adjusted procedures from all MRI services to which his or her
1049 patients are referred for MRI services but only from those MRI services specified by the doctor in the data
1050 commitment form provided by the Department and submitted by the applicant in support of its application.

1051 (b) A committing doctor certifies ~~that he or she does not have an~~ ownership interest, either direct
1052 or indirect, in the applicant entity, INDIRECT OWNERSHIP INCLUDES OWNERSHIP IN AN ENTITY
1053 THAT HAS OWNERSHIP INTEREST IN THE APPLICANT ENTITY. ~~except that this~~ THIS requirement
1054 shall not apply if the applicant entity is a group practice of which the committing doctor is a member.
1055 GROUP PRACTICE MEANS A GROUP PRACTICE AS DEFINED PURSUANT TO THE PROVISIONS
1056 OF 42 U.S.C. 1395NN (H)(4), COMMONLY KNOWN AS STARK II, AND THE CODE OF FEDERAL
1057 REGULATIONS, 42 CFR, PART 411, PUBLISHED IN THE FEDERAL REGISTER ON AUGUST 14,
1058 1995, OR IT'S REPLACEMENT.

1059 (c) A committing doctor certifies that he or she has not been provided, or received a promise of
1060 being provided, a financial incentive to commit any of his or her available MRI adjusted procedures to the
1061 application.

1062 (4)(a) The Department shall not consider a data commitment from a doctor for available MRI adjusted
1063 procedures from a specific MRI service if the available MRI adjusted procedures from that specific MRI
1064 service were used to support approval of an application for a new or additional MRI unit, pursuant to
1065 Section 3 ~~or 4(2), respectively~~, for which a final decision to approve has been issued by the Director of
1066 the Department until either of the following occurs:

1067 (i) The approved CON is withdrawn or expires.

1068 (ii) The MRI service or unit to which the data were committed has been in operation for at least 36
1069 continuous months.

1070 (b) The Department shall not consider a data commitment from a doctor for available MRI adjusted
1071 procedures from a specific MRI service if the available MRI adjusted procedures from that specific MRI
1072 service were used to support an application for a new fixed or mobile MRI unit or additional mobile MRI
1073 unit pursuant to Section 3 ~~or 4(2), respectively~~, for which a final decision to disapprove was issued by the
1074 Director of the Department until either of the following occurs:

1075 (i) A final decision to disapprove an application is issued by the Director and the applicant does
1076 not appeal that disapproval or

1077 (ii) If an appeal was made, either that appeal is withdrawn by the applicant or the committing
1078 doctor withdraws his or her data commitment pursuant to the requirements of subsection (8).

1079
1080 (5) The Department shall not consider a data commitment from a committing doctor for available
1081 MRI adjusted procedures from the same MRI service if that doctor has submitted a signed data
1082 commitment, on a form provided by Department, for more than one (1) application for which a final
1083 decision has not been issued by the Department. If the Department determines that a doctor has
1084 submitted a signed data commitment for the same available MRI adjusted procedures from the same MRI
1085 service to more than one CON application pending a final decision for a new fixed or mobile MRI unit or
1086 additional mobile MRI unit pursuant to Section 3 ~~or 4(2), respectively~~, the Department shall,

1087 (a) if the applications were filed on the same designated application date, notify all applicants,
1088 simultaneously and in writing, that one or more doctors have submitted data commitments for available
1089 MRI adjusted procedures from the same MRI service and that the doctors' data from the same MRI
1090 service shall not be considered in the review of any of the pending applications filed on the same
1091 designated application date until the doctor notifies the Department, in writing, of the one (1) application
1092 for which the data commitment shall be considered.

1093 (b) if the applications were filed on different designated application dates, consider the data
1094 commitment submitted in the application filed on the earliest designated application date and shall notify,
1095 simultaneously in writing, all applicants of applications filed on designated application dates subsequent
1096 to the earliest date that one or more committing doctors have submitted data commitments for available
1097 MRI adjusted procedures from the same MRI service and that the doctors' data shall not be considered in
1098 the review of the application(s) filed on the subsequent designated application date(s).

1099
1100 (6) The Department shall not consider any data commitment submitted by an applicant after the
1101 date an application is deemed complete unless an applicant is notified by the Department, pursuant to
1102 subsection (5), that one or more committing doctors submitted data commitments for available MRI
1103 adjusted procedures from the same MRI service. If an applicant is notified that one or more doctors' data
1104 commitments will not be considered by the Department, the Department shall consider data commitments
1105 submitted after the date an application is deemed complete only to the extent necessary to replace the
1106 data commitments not being considered pursuant to subsection (5).

1107 (A) THE APPLICANT WILL HAVE 30 DAYS TO SUBMIT REPLACEMENT OF DOCTOR
1108 COMMITMENTS AS IDENTIFIED BY THE DEPARTMENT IN THIS SECTION.

1109
1110 (7) In accordance with either of the following, the Department shall not consider a withdrawal of a
1111 signed data commitment

1112 (a) during the 120-day period following the date on which the Department's review of an
1113 application commences.

1114 (b) after a proposed decision to approve an application has been issued by the Department.
1115

1116 (8) The Department shall consider a withdrawal of a signed data commitment if a committing
1117 doctor submits a written notice to the Department, that specifies the CON application number and the
1118 specific MRI services for which a data commitment is being withdrawn, and if an applicant demonstrates
1119 that the requirements of subsection (7) also have been met.
1120

1121 **Section 4817. Lists of MRI adjusted procedures published by the Department**
1122

1123 Sec. 4817. (1) ~~At a minimum, on~~ ON or before May 1 and November 1 of each year, the Department
1124 shall publish the following lists:

1125 (a) A list, known as the "MRI Service Utilization List," of all MRI services in Michigan that includes
1126 at least the following for each MRI service:

1127 (i) The number of actual MRI adjusted procedures;

1128 (ii) The number of available MRI adjusted procedures, if any; and

1129 (iii) The number of MRI units, including whether each unit is a clinical, ~~unit or an MRI unit used~~
1130 ~~exclusively for research~~ RESEARCH, OR DEDICATED PEDIATRIC.

1131 (b) A list, known as the "Available MRI Adjusted Procedures List," that identifies each MRI service
1132 that has available MRI adjusted procedures and includes at least the following:

1133 (i) The number of available MRI adjusted procedures;

1134 (ii) The name, address, and license number of each referring doctor, identified in Section

1135 ~~4615~~(1)(c)(v), whose patients received MRI services at that MRI service; and

1136 (iii) The number of available MRI adjusted procedures performed on patients referred by each
1137 referring doctor, identified in Section ~~4615~~(1)(c)(v), and if any are committed to an MRI service. This
1138 number shall be calculated in accordance with the requirements of Section ~~4615~~(1). A referring doctor
1139 may have fractional portions of available MRI adjusted procedures.

1140 (c) For the lists published pursuant to subsections (a) or (b), the May 1 list will report 12 months of
1141 data from the previous January 1 through December 31 reporting period, and the November 1 list will
1142 report 12 months of data from the previous July 1 through June 30 reporting period. Copies of both lists
1143 shall be available upon request.

1144 (d) The Department shall not be required to publish a list that sorts MRI database information by
1145 referring doctor, only by MRI service.
1146

1147 (2) When an MRI service begins to operate at a site at which MRI services previously were not
1148 provided, the Department shall include in the MRI database, data beginning with the second full quarter
1149 of operation of the new MRI service. Data from the start-up date to the start of the first full quarter will not
1150 be collected to allow a new MRI service sufficient time to develop its data reporting capability. Data from

1151 the first full quarter of operation will be submitted as test data but will not be reported in the lists published
1152 pursuant to this section.

1153
1154 (3) In publishing the lists pursuant to subsections (a) and (b), if an MRI service has not reported
1155 data in compliance with the requirements of Section ~~13(1)(d)(iii)12~~, the Department shall indicate on both
1156 lists that the MRI service is in violation of the requirements set forth in Section ~~13(1)(d)(iii)12~~, and no data
1157 will be shown for that service on either list.

1158
1159 ~~— (4) In the case of an MRI service at which MRI services previously were not provided, the~~
1160 ~~Department may use annualized data from at least a consecutive six-month period in publishing the lists~~
1161 ~~pursuant to subsections (a) and (b).~~

1162
1163 **Section ~~4918~~. Effect on prior CON Review Standards; Comparative reviews**

1164
1165 Sec. ~~4918~~. (1) These CON review standards supersede and replace the CON Review Standards for
1166 Magnetic Resonance Imaging Services approved by the CON Commission on ~~September 18, 2007~~
1167 ~~SEPTEMBER 16, 2008~~ and effective ~~November 13, 2007~~ NOVEMBER 13, 2008.

1168
1169 (2) Projects reviewed under these standards shall not be subject to comparative review.

1170

1171 **Section 20. Health Service Areas**

1172

1173 Sec. 20. Counties assigned to each of the health service areas are as follows:

1174

1175 **HSA** **COUNTIES**

1176

1177

1178 1 Livingston Monroe St. Clair
 1179 Macomb Oakland Washtenaw
 1180 Wayne

1181

1182 2 Clinton Hillsdale Jackson
 1183 Eaton Ingham Lenawee

1184

1185 3 Barry Calhoun St. Joseph
 1186 Berrien Cass Van Buren
 1187 Branch Kalamazoo

1188

1189 4 Allegan Mason Newaygo
 1190 Ionia Mecosta Oceana
 1191 Kent Montcalm Osceola
 1192 Lake Muskegon Ottawa

1193

1194 5 Genesee Lapeer Shiawassee

1195

1196 6 Arenac Huron Roscommon
 1197 Bay Iosco Saginaw
 1198 Clare Isabella Sanilac
 1199 Gladwin Midland Tuscola
 1200 Gratiot Ogemaw

1201

1202 7 Alcona Crawford Missaukee
 1203 Alpena Emmet Montmorency
 1204 Antrim Gd Traverse Oscoda
 1205 Benzie Kalkaska Otsego
 1206 Charlevoix Leelanau Presque Isle
 1207 Cheboygan Manistee Wexford

1208

1209 8 Alger Gogebic Mackinac
 1210 Baraga Houghton Marquette
 1211 Chippewa Iron Menominee
 1212 Delta Keweenaw Ontonagon
 1213 Dickinson Luce Schoolcraft

CON REVIEW STANDARDS
FOR MRI SERVICES

1214
1215
1216
1217
1218
1219
1220
1221
1222
1223
1224
1225
1226
1227
1228
1229
1230
1231
1232
1233
1234
1235
1236
1237
1238
1239
1240
1241
1242
1243
1244
1245
1246
1247
1248
1249
1250
1251
1252
1253
1254
1255
1256
1257
1258
1259
1260
1261
1262
1263

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