

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. THE TERM DOES NOT INCLUDE MRI  
143 | SIMULATORS USED SOLEY FOR TREATMENT PLANNING PURPOSES IN CONJUNCTION WITH AN  
144 | MRT UNIT.
- 145 | (ee) ~~"Magnetic resonance imaging visit" or~~ "MRI visit" means a single patient visit to an MRI  
146 | service/unit that may involve one or more MRI procedures.
- 147 | (ff) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6  
148 | and 1396r-8 to 1396v.
- 149 | (gg) "Metropolitan statistical area county" means a county located in a metropolitan statistical area  
150 | as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas"  
151 | by the statistical policy office of the office of information and regulatory affairs of the United States office  
152 | of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.
- 153 | (hh) "Micropolitan statistical area county" means a county located in a micropolitan statistical area  
154 | as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas"  
155 | by the statistical policy office of the office of information and regulatory affairs of the United States office  
156 | of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.
- 157 | (ii) "Mobile MRI unit" means an MRI unit operating at two or more host sites and that has a central  
158 | service coordinator. The mobile MRI unit shall operate under a contractual agreement for the provision of  
159 | MRI services at each host site on a regularly scheduled basis.

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

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

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

221 (xx) "Teaching facility," ~~for purposes of these standards,~~ means a licensed hospital site, or other  
222 location, that provides either fixed or mobile MRI services and at which residents or fellows of a training  
223 program in diagnostic radiology, that is approved by the Accreditation Council on Graduate Medical  
224 Education or American Osteopathic Association, are assigned.

225 (yy) "Unadjusted MRI scan" means an MRI procedure performed on a single anatomical site as  
226 defined by the MRI database and that is not adjusted pursuant to the applicable provisions of Section 14.

227 (zz) "Upgrade an existing MRI unit" means any equipment change that

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

231 (ii) involves a capital expenditure of less than \$750,000 in any consecutive 24-month period.

232  
233 (2) Terms defined in the Code have the same meanings when used in these standards.  
234

### 235 **Section 3. Requirements ~~for approval of applicants proposing to initiate an MRI service or mobile~~** 236 **~~MRI host site~~**

#### 237 SEC 3. AN APPLICANT PROPOSING TO INITIATE AN MRI SERVICE OR A HOST SITE SHALL 238 DEMONSTRATE THE FOLLOWING REQUIREMENTS, AS APPLICABLE: 239

240  
241 ~~Sec. 3.~~ (1) An applicant proposing to initiate a fixed MRI service shall demonstrate that 6,000  
242 available MRI adjusted procedures, PER PROPOSED FIXED MRI UNIT from within the same planning  
243 area as the proposed service/unit, ~~per proposed unit result from application of the methodology in Section~~  
244 ~~16 of these standards.~~

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

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

250 (B) THE APPLICANT HAS RECEIVED IN AGGREGATE, ONE OF THE FOLLOWING:

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

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

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

257 (B) THE NEAREST FIXED MRI MACHINE IS LOCATED MORE THAN 15 RADIUS MILES  
258 FROM THE APPLICATION SITE.

259 (III) AT LEAST 3,000 MRI ADJUSTED PROCEDURES AND THE APPLICANT MEETS ALL OF  
260 THE FOLLOWING:

261 (A) THE PROPOSED SITE IS A HOSPITAL LICENSED UNDER PART 215 OF THE CODE.

262 (B) THE APPLICANT HOSPITAL OPERATES AN EMERGENCY ROOM THAT PROVIDES 24-  
263 HOUR EMERGENCY CARE SERVICES AND AT LEAST 20,000 VISITS WITHIN THE MOST RECENT  
264 12-MONTH PERIOD FOR WHICH DATA, VERIFIABLE BY THE DEPARTMENT, IS AVAILABLE.

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

268 (D) THE APPLICANT SHALL INSTALL THE FIXED MRI UNIT AT THE SAME SITE AS THE  
269 EXISTING HOST SITE OR WITHIN THE RELOCATION ZONE. **IF APPLYING PURSUANT TO**  
270 **SECTION 3(2)(B)(III), THE APPLICANT SHALL INSTALL THE FIXED MRI UNIT AT THE SAME SITE**  
271 **AS THE EXISTING HOST SITE.**

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

275  
276 ~~(23)(a) An applicant proposing to initiate a mobile MRI service that involves beginning operation of a~~  
277 ~~mobile MRI unit shall demonstrate that a minimum of 5,500 available MRI adjusted procedures, from~~  
278 ~~within the same planning area as the proposed service/unit, AND THE APPLICANT SHALL MEET THE~~  
279 ~~FOLLOWING: per proposed unit result from application of the methodology in Section 16 of these~~  
280 ~~standards.~~

281 (A) IDENTIFY THE PROPOSED ROUTE SCHEDULE AND PROCEDURES FOR HANDLING  
282 EMERGENCY SITUATIONS.

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

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

286  
287 ~~(b4) The AN applicant, whether the central service coordinator or the host site, PROPOSING TO~~  
288 ~~INITIATE A HOST SITE ON A NEW OR EXISTING MOBILE MRI SERVICE SHALL must demonstrate~~  
289 ~~THE FOLLOWING, AS APPLICABLE: that a minimum of 600 available MRI adjusted procedures, from~~  
290 ~~within the same planning area as the proposed service/unit, result from the application of the~~  
291 ~~methodology in Section 16 of these standards, for each proposed host site that~~

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

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

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

299 (ii) THE PROPOSED HOST SITE has not received any mobile MRI service within the most recent  
300 12-month period as of the date an application is submitted to the Department.

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

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

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

308  
309 ~~(3)(a) An applicant, whether the central service coordinator or a proposed host site, proposing to~~  
310 ~~initiate a mobile MRI host site not in a rural or micropolitan statistical area county, that is to be part of an~~  
311 ~~existing mobile MRI service, must demonstrate that at least 600 available MRI adjusted procedures, from~~  
312 ~~within the same planning area as the proposed service/unit, result from the application of the~~  
313 ~~methodology in Section 16 of these standards for that host site.~~

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

320 ~~— (4) An applicant that meets all of the following requirements shall not be required to be in~~  
321 ~~compliance with subsection (1):~~  
322 ~~— (a) The applicant is proposing to initiate a fixed MRI service.~~  
323 ~~— (b) The applicant is currently a host site being served by one or more mobile MRI units.~~  
324 ~~— (c) The applicant has received, in aggregate, the following:~~  
325 ~~— (i) at least 6,000 MRI adjusted procedures within the most recent 12-month period for which data,~~  
326 ~~verifiable by the Department, are available or~~  
327 ~~— (ii) at least 4,000 MRI adjusted procedures within the most recent 12-month period for which data,~~  
328 ~~verifiable by the Department, are available, and the applicant meets all of the following:~~  
329 ~~— (A) is located in a county that has no fixed MRI machines that are pending, approved by the~~  
330 ~~Department, or operational at the time the application is deemed submitted;~~  
331 ~~— (B) the nearest fixed MRI machine is located more than 15 radius miles from the application site;~~  
332 ~~— (C) the applicant is a nonprofit licensed hospital site;~~  
333 ~~— (D) the applicant certifies in its CON application, by providing a governing body resolution, that the~~  
334 ~~board of trustees of the facility has performed a due diligence investigation and has determined that the~~  
335 ~~fixed MRI service will be economically viable to ensure provision of safe and appropriate patient access~~  
336 ~~within the community hospital setting.~~  
337 ~~— (d) All of the MRI adjusted procedures provided at the applicant's approved site in the most recent~~  
338 ~~12-month period, referenced in (c) above, by each mobile MRI service/units from which any of the MRI~~  
339 ~~adjusted procedures are being utilized to meet the minimum 6,000 or 4,000 MRI adjusted procedures~~  
340 ~~shall be utilized to meet the requirements of (c). [For example: If mobile network 19 provided 4,000~~  
341 ~~adjusted procedures, network 21 provided 2,100, and network 18 provided 1,000, all of the adjusted~~  
342 ~~procedures from network 19 and 21 must be used (i.e., 6,100) but the 1,000 adjusted procedures from~~  
343 ~~network 18 do not need to be used to meet the 6,000 minimum.]~~  
344 ~~— (e) The applicant shall install the fixed MRI unit at the same site as the existing approved host site~~  
345 ~~or at the applicant's licensed hospital site as defined in these standards.~~

346  
347 ~~(5) Initiation of a mobile MRI host site does not include the provision of mobile MRI services at a~~  
348 ~~host site if the applicant, whether the host site or the central service coordinator, demonstrates or~~  
349 ~~provides each of the following, as applicable: AN APPLICANT PROPOSING TO ADD OR CHANGE~~  
350 ~~SERVICE ON AN EXISTING MOBILE MRI SERVICE THAT MEETS THE FOLLOWING~~  
351 ~~REQUIREMENTS SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH SUBSECTION (4) AND~~  
352 ~~SHALL MEET EACH OF THE FOLLOWING:~~

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

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

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

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

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

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

369  
370 ~~(6) THE APPLICANT SHALL DEMONSTRATE THAT THE AVAILABLE MRI ADJUSTED~~  
371 ~~PROCEDURES ARE FROM THE MOST RECENTLY PUBLISHED AVAILABLE MRI ADJUSTED~~  
372 ~~PROCEDURES LIST AS OF THE DATE AN APPLICATION IS DEEMED SUBMITTED BY THE~~  
373 ~~DEPARTMENT.~~

374  
375 **SECTION 4. REQUIREMENTS TO REPLACE AN EXISTING MRI UNIT.**  
376

377 SEC 4 AN APPLICANT PROPOSING TO REPLACE AN EXISTING MRI UNIT SHALL  
378 DEMONSTRATE THE FOLLOWING REQUIREMENTS, AS APPLICABLE:  
379

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

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

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

387 (C) EACH EXISTING DEDICATED PEDIATRIC MRI UNIT AT THE CURRENT SITE HAS  
388 PERFORMED AT LEAST AN AVERAGE OF 3,500 MRI ADJUSTED PROCEDURES PER MRI UNIT.  
389

390 (2) EQUIPMENT THAT IS REPLACED SHALL BE REMOVED FROM SERVICE AND DISPOSED  
391 OF OR RENDERED CONSIDERABLY INOPERABLE ON OR BEFORE THE DATE THAT THE  
392 REPLACEMENT EQUIPMENT BECOMES OPERATIONAL.  
393

394 (3) THE REPLACEMENT UNIT SHALL BE LOCATED AT THE SAME SITE UNLESS THE  
395 REQUIREMENTS OF THE RELOCATION SECTION HAVE BEEN MET.  
396

397 (4) AN APPLICANT PROPOSING TO REPLACE AN EXISTING MRI UNIT THAT DOES NOT  
398 INVOLVE A RENEWAL OF A LEASE SHALL DEMONSTRATE THAT THE MRI UNIT TO BE  
399 REPLACED IS FULLY DEPRECIATED ACCORDING TO GENERALLY ACCEPTED ACCOUNTING  
400 PRINCIPLES; THE EXISTING EQUIPMENT CLEARLY POSES A THREAT TO THE SAFETY OF THE  
401 PUBLIC; OR THE PROPOSED REPLACEMENT EQUIPMENT OFFERS A SIGNIFICANT  
402 TECHNOLOGICAL IMPROVEMENT WHICH ENHANCES QUALITY OF CARE, INCREASES  
403 EFFICIENCY, AND REDUCES OPERATING COSTS.  
404

405 **Section 45. Requirements for approval of an application proposing to expand an existing MRI**  
406 **service**  
407

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

412 ~~— (a) The additional unit shall be located at the same site unless the requirements of Section 7(2)~~  
413 ~~have been met.~~  
414

415 ~~— (2) An applicant proposing to expand an existing fixed MRI service approved pursuant to Section~~  
416 ~~10 shall demonstrate that its existing fixed MRI units have performed at least an average of 3,500~~  
417 ~~adjusted procedures for each fixed unit, based on the application of the methodology in Section 14 and~~  
418 ~~as documented in accordance with Section 15 of these standards.~~

419 ~~— (a) The additional unit shall be located at the same site unless the requirements of Section 7(2)~~  
420 ~~have been met.~~  
421

422 ~~— (3) An applicant proposing to expand an existing mobile MRI service shall demonstrate that 4,000~~  
423 ~~available MRI adjusted procedures, from within the same planning area as the proposed unit, per~~  
424 ~~proposed additional unit result from application of the methodology in Section 16 of these standards.~~  
425



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

429  
430 SEC 5. AN APPLICANT PROPOSING TO EXPAND AN EXISTING MRI SERVICE SHALL  
431 DEMONSTRATE THE FOLLOWING:

432  
433 (1) AN APPLICANT SHALL DEMONSTRATE THAT THE APPLICABLE MRI ADJUSTABLE  
434 PROCEDURES ARE FROM THE MOST RECENTLY PUBLISHED MRI SERVICE UTILIZATION LIST  
435 AS OF THE DATE OF AN APPLICATION IS DEEMED SUBMITTED BY THE DEPARTMENT:

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

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

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

442  
443 (2) THE ADDITIONAL FIXED UNIT SHALL BE LOCATED AT THE SAME SITE UNLESS  
444 THE REQUIREMENTS OF THE RELOCATION SECTION HAVE BEEN MET.

445  
446 **Section 5. Requirements for approval of an applicant proposing to replace an existing MRI unit**

447  
448 ~~— Sec. 5. An applicant proposing to replace an existing MRI unit shall demonstrate that the proposed~~  
449 ~~project meets each of the following requirements:~~

450  
451 ~~— (1) Within the most recent 12-month period for which data, verifiable by the Department, are~~  
452 ~~available, at least the applicable minimum number of MRI adjusted procedures set forth in subdivision (a),~~  
453 ~~(b), or (c) has been performed. In meeting this requirement, an applicant shall not include any~~  
454 ~~procedures conducted by an MRI unit approved pursuant to Section 9(1).~~

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

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

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

461  
462 ~~— (2) An applicant proposing to replace an existing MRI unit that does not involve a renewal of a~~  
463 ~~lease shall demonstrate that the MRI unit to be replaced is fully depreciated according to generally~~  
464 ~~accepted accounting principles; the existing equipment clearly poses a threat to the safety of the public;~~  
465 ~~or the proposed replacement equipment offers a significant technological improvement which enhances~~  
466 ~~quality of care, increases efficiency, and reduces operating costs.~~

467  
468 ~~— (3) Equipment that is replaced shall be removed from service and disposed of or rendered~~  
469 ~~considerably inoperable on or before the date that the replacement equipment becomes operational.~~

470  
471 ~~— (4) An applicant proposing to replace an existing mobile MRI unit must provide a copy of the~~  
472 ~~existing or revised contracts between the central service coordinator and each host site(s) that includes~~  
473 ~~the same stipulations as specified in Section 6(2).~~

474  
475 ~~— (5) The replacement unit shall be located at the same site unless the requirements of Section 7(2)~~  
476 ~~have been met.~~

478 **Section 6. Additional requirements for approval of an applicant proposing to initiate a mobile MRI**  
479 **service**

480  
481 ~~— Sec. 6. (1) An applicant proposing to initiate a mobile MRI service that involves beginning operation~~  
482 ~~of a mobile MRI unit shall identify the proposed regular route schedule and the procedures for handling~~  
483 ~~emergency situations.~~

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

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

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

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

500  
501 **Section 76. Requirements for approval of an applicant proposing to relocate an existing FIXED**  
502 **MRI service and/or MRI unit(s)**

503  
504 Sec 76. (1) An applicant proposing to relocate an existing fixed MRI service and its unit(s) shall  
505 demonstrate ~~that the proposed project meets all of~~ the following:

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

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

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

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

516 (eC) Each existing MRI unit to be relocated performed at least the applicable minimum number of  
517 MRI adjusted procedures set forth in Section ~~12 13(1)(d)(i) of these standards~~ based on the most ~~recent~~  
518 ~~12-month period for which the Department has verifiable data~~ RECENTLY PUBLISHED MRI SERVICE  
519 UTILIZATION LIST AS OF THE DATE AN APPLICATION IS DEEMED SUBMITTED BY THE  
520 DEPARTMENT.

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

523  
524 (2) An applicant proposing to relocate a fixed MRI unit of an existing MRI service shall  
525 demonstrate ~~that the proposed project meets all of~~ the following:

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

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

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

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

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

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

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

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

545  
546 ~~— (3) An applicant that meets all of the following requirements shall be exempt from relocating within~~  
547 ~~the relocation zone:~~

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

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

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

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

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

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

564  
565 **Section 87. Requirements for approval of an applicant proposing to acquire an existing MRI**  
566 **service or an existing MRI unit(s)**

567  
568 SEC 7. (1) An applicant proposing to acquire an existing fixed or mobile MRI service and its unit(s)  
569 shall demonstrate ~~that the proposed project meets all of the following:~~

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

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

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

577 ~~(dA) For the first application proposing to acquire an existing fixed or mobile MRI service on or after~~  
578 ~~July 1, 1997, the existing MRI service and its unit(s) to be acquired shall not be required to be in~~  
579 ~~compliance with the volume requirements applicable to a seller/lessor on the date the acquisition occurs.~~  
580 ~~The MRI service shall be operating at the applicable volume requirements set forth in Section 12~~  
581 ~~13(1)(d)(i) of these standards in the second 12 months after the effective date of the acquisition, and~~  
582 ~~annually thereafter.~~

583 ~~(e) For any application proposing to acquire an existing fixed or mobile MRI service and its unit(s),~~  
584 ~~except the first application approved pursuant to subsection (dA), an applicant shall be required to~~

585 document that the MRI service and its unit(s) to be acquired is operating in compliance with the volume  
586 requirements set forth in Section ~~12 13(1)(d)(i)~~ of these standards applicable to an existing MRI service  
587 on the date the application is submitted to the Department.  
588

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

591 (a) The project will not change the number of MRI units at the site of the MRI service being  
592 acquired, subject to the applicable requirements under Section ~~76~~(2), unless the applicant demonstrates  
593 that the project is in compliance with the requirements of THE INITIATION OR EXPANSION Section-~~3 or~~  
594 4, as applicable.

595 (b) The project will not result in the replacement of an MRI unit at the MRI service to be acquired  
596 unless the applicant demonstrates that the requirements OF THE REPLACEMENT SECTION of Section  
597 5 have been met.

598 ~~—(c) The applicant agrees to operate the MRI unit(s) in accordance with all applicable project~~  
599 ~~delivery requirements set forth in Section 13 of these standards.~~  
600

601 **Section 98. Requirements for approval of an applicant proposing an MRI unit to be used**  
602 **exclusively for research TO ESTABLISH A DEDICATED RESEARCH MRI UNIT**  
603

604 Sec. ~~98. (1)~~ An applicant proposing an MRI unit to be used exclusively for research shall  
605 demonstrate ~~each of~~ the following:

606 (a1) SUBMIT COPIES OF DOCUMENTATION DEMONSTRATING THAT The-~~THE~~ applicant  
607 operates a diagnostic radiology residency program approved by the Accreditation Council for Graduate  
608 Medical Education, the American Osteopathic Association, or an equivalent organization.  
609

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

612 ~~—(c) The applicant agrees to operate the unit in accordance with the terms of approval in Section~~  
613 ~~13(2).~~  
614

615 (23) An applicant meeting the requirements of ~~subsection (1)-~~THIS SECTION shall be exempt from  
616 meeting the requirements ~~and terms~~ of sections ~~3, 4, 5, 6, 7, 8, 13 [with the exception of 13(1)(d)(iii)], 15,~~  
617 ~~and 16 of these standards~~ TO INITIATE AND REPLACE.  
618

619 **Section 109. Requirements for approval of an applicant proposing to establish A dedicated**  
620 **pediatric MRI UNIT**  
621

622 Sec. ~~109. (1)~~ An applicant proposing to establish dedicated pediatric MRI shall demonstrate all of the  
623 following:

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

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

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

- 631 (i) pediatric radiology (at least two)
- 632 (ii) pediatric anesthesiology
- 633 (iii) pediatric cardiology
- 634 (iv) pediatric critical care
- 635 (v) pediatric gastroenterology
- 636 (vi) pediatric hematology/oncology
- 637 (vii) pediatric neurology
- 638 (viii) pediatric neurosurgery

- 639 (ix) pediatric orthopedic surgery  
640 (x) pediatric pathology  
641 (xi) pediatric pulmonology  
642 (xii) pediatric surgery  
643 (xiii) neonatology  
644 (d) The applicant shall have in operation the following pediatric specialty programs ~~at the time the~~  
645 ~~application is submitted to the Department:~~  
646 (i) pediatric bone marrow transplant program  
647 (ii) established pediatric sedation program  
648 (iii) pediatric open heart program  
649

650 (2) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the  
651 requirements of Section 4, of these standards.  
652

653 **Section 4410. Pilot program requirements for approval – applicants proposing to initiate, replace,**  
654 **or acquire a hospital based IMRI**  
655

656 Sec. 4410. As a pilot program, an applicant proposing to initiate, replace, or acquire a hospital based  
657 IMRI service shall demonstrate that it meets all of the following:  
658

- 659 (1) The proposed site is a licensed hospital under Part 215 of the Code.  
660  
661 (2) The proposed site has an existing fixed MRI service that has been operational for the previous  
662 36 consecutive months and is meeting its minimum volume requirements.  
663  
664 (3) The proposed site has an existing and operational surgical service and is meeting its minimum  
665 volume requirements pursuant to the CON Review Standards for Surgical Services.  
666  
667 (4) The applicant shall have experienced one of the following:  
668 (a) at least 1,500 oncology discharges in the most recent year of operation; or  
669 (b) at least 1,000 neurological surgeries in the most recent year of operation; or  
670 (c) at least 7,000 pediatric (<18 years old) discharges (excluding normal newborns) and at least  
671 5,000 pediatric (<18 years old) surgeries in the most recent year of operation.  
672  
673 (5) The proposed IMRI unit must be located in an operating room or a room adjoining an operating  
674 room allowing for transfer of the patient between the operating room and this adjoining room.  
675  
676 (6) Non-surgical diagnostic studies shall not be performed on an IMRI unit approved under this  
677 section unless the patient meets one of the following criteria:  
678 (a) the patient has been admitted to an inpatient unit; or  
679 (b) the patient is having the study performed on an outpatient basis, but is in need of general  
680 anesthesia or deep sedation as defined by the American Society of Anesthesiologists.  
681  
682 (7) The approved IMRI unit will not be subject to MRI volume requirements.  
683  
684 (8) The applicant shall not utilize the procedures performed on the IMRI unit to demonstrate need  
685 or to satisfy MRI CON review standards requirements.  
686

687 ~~(9) The applicant agrees to operate the IMRI unit in accordance with all applicable project delivery~~  
688 ~~requirements set forth in Section 13 of these standards.~~  
689

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

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**Section 4211. Requirements for approval—all applicants**

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

**Section 4312. Project delivery requirements – terms of approval**

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

- (a) Compliance with these standards.
- (b) Compliance with applicable safety and operating standards ~~for the specific MRI unit approved.~~
- (c) Compliance with the following quality assurance standards:
  - ~~(i) An applicant shall develop and maintain policies and procedures that establish protocols for the following system performance measures. The protocols shall establish the required benchmarks; identify the testing interval, which shall be at least quarterly; and identify the MRI staff person responsible for testing the system performance measures.~~
    - ~~(A) Signal-to-noise ratio.~~
    - ~~(B) Spatial resolution.~~
    - ~~(C) Slice thickness, location, and separation.~~
    - ~~(D) Spatial linearity.~~
    - ~~(E) Field homogeneity and drift.~~
    - ~~(F) System calibration and stability.~~
    - ~~(G) Cryogen level and boiloff rate.~~
    - ~~(H) Radio frequency power monitor.~~
    - ~~(I) Hard copy image quality.~~
  - ~~In addition to the designated staff person, the system performance measures in subdivisions (A) through (F) and (H) also shall be evaluated by an appropriately trained MRI physicist or engineer. The physicist/engineer shall conduct tests of these system performance measures when the MRI unit begins to operate, and annually thereafter. The purpose of the physicist/engineer test shall be to certify to the Department that the MRI unit meets or exceeds all of the system performance specifications of the manufacturer of the MRI unit in effect for that MRI unit at the time of installation or most recent upgrade. The physicist/engineer shall make available for review the periodic system performance measures test data established in this subsection.~~
  - ~~(ii) An applicant shall develop and maintain policies, procedures, and protocols for assuring the functionality of each of the following MRI accessories. The protocols shall establish the required benchmarks, identify the testing interval for each accessory, and identify the staff person responsible for testing the system performance measures.~~
    - ~~(A) All surface coils.~~
    - ~~(B) Positioning devices.~~
    - ~~(C) Physiologic triggering/monitoring equipment.~~
    - ~~(D) Patient communication devices.~~
    - ~~(E) Scan table position indicator and drives.~~
    - ~~(F) Data network including storage and retrieval.~~
    - ~~(G) Emergency rundown/shutdown units.~~
    - ~~(H) Hard copy devices.~~
  - ~~(iii) An applicant shall develop and maintain policies and procedures that establish protocols for assuring the effectiveness of operation and the safety of the general public, patients, and staff in the MRI service. Each of the following must be included and the staff person responsible for development and enforcement of these policies shall be indicated.~~
    - ~~(A) Access to the MRI service.~~
    - ~~(B) Access to the MRI scan room.~~

- 747 ~~— (C) Patient safety clearance before imaging and safety during imaging.~~
- 748 ~~— (D) Adverse bioeffects, including~~
- 749 ~~— (1) acoustic hazard.~~
- 750 ~~— (2) radio frequency burn hazard.~~
- 751 ~~— (3) specific absorption rates.~~
- 752 ~~— (4) peripheral nerve stimulation.~~
- 753 ~~— (5) pregnancy.~~
- 754 ~~— (6) magnet quench hazard.~~
- 755 ~~— (E) Sedation.~~
- 756 ~~— (F) Contrast administration.~~
- 757 ~~— (G) Treatment of adverse reactions to contrast.~~
- 758 ~~— (H) Patient monitoring for sedation, anesthesia, and unstable patients.~~
- 759 ~~— (I) Patient resuscitation, management of emergencies, maintenance of cardiopulmonary~~
- 760 ~~resuscitation equipment, and certification requirements for personnel for either basic or advanced~~
- 761 ~~cardiopulmonary resuscitation.~~
- 762 ~~— (J) Screening for metallic implants, pacemakers, and metallic foreign bodies, as well as a list of~~
- 763 ~~contraindications.~~
- 764 ~~— (K) Mechanism for consultation regarding difficult cases.~~
- 765 ~~— (L) Pulse sequence protocols for specific indications.~~
- 766 ~~— (M) Institutional review board IRB policies relating to non-FDA approved pulse sequences or~~
- 767 ~~investigational procedures.~~
- 768 ~~— (N) Staff inservice regarding subdivisions (A) through (M).~~
- 769 ~~(ivII) An applicant shall establish a schedule for preventive maintenance for the MRI unit.~~
- 770 ~~— (v) An applicant shall maintain records of the results of the periodic test data required by~~
- 771 ~~subdivisions (i) and (ii), including the results of the tests performed by the MRI physicist/engineer required~~
- 772 ~~in subdivision (i). An applicant, upon request, shall submit annually to the Department a report of the test~~
- 773 ~~data results and evidence of compliance with the applicable project delivery requirements.~~
- 774 ~~(vIII) An applicant shall provide documentation identifying the specific individuals that form the MRI~~
- 775 ~~team. At a minimum, the MRI team shall consist of the following professionals:~~
- 776 ~~— (A) An MRI team leader who shall be responsible for~~
- 777 ~~— (1) developing criteria for procedure performance.~~
- 778 ~~— (2) developing protocols for procedure performance.~~
- 779 ~~— (3) developing a clinical data base for utilization review and quality assurance purposes.~~
- 780 ~~— (4) transmitting requested data to the Department.~~
- 781 ~~— (5) screening of patients to assure appropriate utilization of the MRI service.~~
- 782 ~~— (6) taking and interpretation of scans.~~
- 783 ~~— (7) coordinating MRI activity at MRI host sites for a mobile MRI unit.~~
- 784 ~~— (8) identifying and correcting MRI image quality deficiencies.~~
- 785 ~~(BA) Physicians who shall be responsible for screening of patients to assure appropriate utilization~~
- 786 ~~of the MRI service and taking and interpretation of scans. At least one of these physicians shall be a~~
- 787 ~~board-certified radiologist.~~
- 788 ~~(CB) An appropriately trained MRI technician who shall be responsible for taking an MRI scan.~~
- 789 ~~(DC) An MRI physicist/engineer available as a team member on a full-time, part-time, or contractual~~
- 790 ~~basis. An MRI physicist/engineer shall be responsible for at least the following:~~
- 791 ~~— (1) providing technical specifications for new equipment and assistance in equipment procurement.~~
- 792 ~~— (2) performing or validating technical performance for system acceptance.~~
- 793 ~~— (3) establishing preventive maintenance schedules and quality assurance test procedures and~~
- 794 ~~recording and reviewing preventive maintenance and quality assurance data.~~
- 795 ~~— (4) facilitating the repair of acute system malfunctions.~~
- 796 ~~— (5) training personnel in the MRI service with respect to the technical aspects of MRI scanning and~~
- 797 ~~patient and staff safety.~~
- 798 ~~— (6) assisting in designing and optimizing clinical imaging procedures.~~

799 | ~~— (E) System maintenance personnel who shall be responsible for calibrating the MRI system and~~  
800 | ~~preventive maintenance at regularly scheduled intervals and who shall compile and submit quality control~~  
801 | ~~data to the MRI team leader.~~

802 | (viiV) An applicant shall document that the MRI team members have the following qualifications:

803 | ~~— (A) The MRI team leader is a board-certified or board-eligible radiologist, or other physician trained~~  
804 | ~~in MRI, who spends greater than 75 percent of his or her professional time in multiple anatomic site~~  
805 | ~~medical imaging. The MRI team leader also shall demonstrate that he or she meets the requirements set~~  
806 | ~~forth in subsection (B) for a physician who interprets MRI images.~~

807 | (BA) Each physician credentialed to interpret MRI scans meets the requirements of each of the  
808 | following:

809 | (1) The physician is licensed to practice medicine in the State of Michigan.

810 | (2) The physician has had at least 60 hours of training in MRI physics, MRI safety, and MRI  
811 | instrumentation in a program that is part of an imaging program accredited by the Accreditation Council  
812 | for Graduate Medical Education or the American Osteopathic Association, and the physician meets the  
813 | requirements of subdivision (i), (ii), or (iii):

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

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

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

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

827 | (4) The physician interprets, as the primary interpreting physician, at least 250 unadjusted MRI  
828 | scans annually.

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

835 | (DC) An applicant shall document that an MRI physicist/engineer is appropriately qualified. For  
836 | purposes of evaluating this subdivision, the Department shall consider it *prima facie* evidence as to the  
837 | qualifications of the physicist/engineer if the physicist/engineer is certified as a medical physicist by the  
838 | American Board of Radiology, the American Board of Medical Physics, or the American Board of Science  
839 | in Nuclear Medicine. However, the applicant may submit and the Department may accept other evidence  
840 | that an MRI physicist/engineer is qualified appropriately.

841 | ~~— (E) An applicant shall document that system maintenance personnel are qualified on the basis of~~  
842 | ~~training and experience to perform the calibration, preventive maintenance, and quality control functions~~  
843 | ~~on the specific MRI unit approved.~~

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

848 | ~~— (ix) In addition to all other applicable terms of approval, each mobile MRI unit shall have an~~  
849 | ~~operations committee with members representing each host site, the central service coordinator, and the~~  
850 | ~~medical director. This committee shall oversee the effective and efficient use of the MRI unit, establish~~  
851 | ~~the normal route schedule, identify the process by which changes shall be made to the schedule, develop~~



852 | ~~procedures for handling emergency situations, and review the ongoing operations of the mobile MRI unit~~  
853 | ~~on at least a quarterly basis.~~

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

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

857 | (i) MRI units shall be operating at a minimum average annual level of utilization during the second  
858 | 12 months of operation, and annually thereafter, of 6,000 actual MRI adjusted procedures per unit for  
859 | fixed MRI services, 5,500 actual MRI adjusted procedures per unit for mobile MRI services, and a total of  
860 | 3,500 MRI adjusted procedures per unit for dedicated pediatric MRI. Each mobile host site in a rural or  
861 | micropolitan statistical area county shall have provided at least a total of 400 adjusted procedures during  
862 | its second 12 months of operation, and annually thereafter, from all mobile units providing services to the  
863 | site. Each mobile host site not in a rural or micropolitan statistical area county shall have provided at  
864 | least a total of 600 adjusted procedures during its second 12 months of operation and annually thereafter,  
865 | from all mobile units providing services to the site. In meeting these requirements, an applicant shall not  
866 | include any MRI adjusted procedures performed on an MRI unit used exclusively for research and  
867 | approved pursuant to Section 9(1) or for an IMRI unit approved pursuant to Section 11.

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

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

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

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

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

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

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

890 | (iv) The operation of and referral of patients to the MRI unit shall be in conformance with 1978 PA  
891 | 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

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

895 | ~~(#E)~~ An applicant who is a central service coordinator shall notify the Department of any additions,  
896 | deletions, or changes in the host sites of each approved mobile MRI unit within 10 days after the  
897 | change(s) in host sites is made.

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

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

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

908 |  
909 | (3) The agreements and assurances required by this section shall be in the form of a certification  
910 | agreed to by the applicant or its authorized agent.

911 |  
912 | ~~— (4) An applicant approved to initiate a fixed MRI service pursuant to Section 3(4) of these~~  
913 | ~~standards shall cease operation as a host site and not become a host site for at least 12 months from the~~  
914 | ~~date the fixed service and its unit becomes operational.~~

915 |  
916 | **Section 1413. MRI procedure adjustments**

917 |  
918 | Sec. 1413. (1) The Department shall apply the following formula, as applicable, to determine the  
919 | number of MRI adjusted procedures that are performed by an existing MRI service or unit:

- 920 | (a) The base value for each MRI procedure is 1.0.  
921 | (b) For each MRI visit involving a pediatric patient, 0.25 shall be added to the base value.  
922 | (c) For each MRI visit involving an inpatient, 0.50 shall be added to the base value.  
923 | (d) For each MRI procedure performed on a sedated patient, 0.75 shall be added to the base  
924 | value.  
925 | (e) For each MRI procedure performed on a re-sedated patient, 0.25 shall be added to the base  
926 | value.  
927 | (f) For each MRI procedure performed on a special needs patient, 0.25 shall be added to the base  
928 | value.  
929 | (g) For each MRI visit that involves both a clinical and research scan on a single patient in a single  
930 | visit, 0.25 shall be added to the base value.  
931 | (h) For each contrast MRI procedure performed after use of a contrast agent, and not involving a  
932 | procedure before use of a contrast agent, 0.35 shall be added to the base value.  
933 | (i) For each contrast MRI procedure involving a procedure before and after use of a contrast  
934 | agent, 1.0 shall be added to the base value.  
935 | (j) For each MRI procedure performed at a teaching facility, 0.15 shall be added to the base value.  
936 | (k) The results of subsections (a) through (j) shall be summed, and that sum shall represent an  
937 | MRI adjusted procedure.

938 |  
939 | (2) The Department shall apply not more than one of the adjustment factors set forth in this  
940 | subsection, as applicable, to the number of MRI procedures adjusted in accordance with the applicable  
941 | provisions of subsection (1) that are performed by an existing MRI service or unit.

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

944 | (b) For a mobile MRI unit that serves hospitals and other host sites located in rural, micropolitan  
945 | statistical area, and metropolitan statistical area counties, the number of MRI adjusted procedures for a  
946 | site located in a rural or micropolitan statistical area county, shall be multiplied by a factor of 1.4 and for a  
947 | site located in a metropolitan statistical area county, the number of MRI adjusted procedures shall be  
948 | multiplied by a factor of 1.0.

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

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

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

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

959 | **Section 4514. Documentation of actual utilization**

960  
961 | Sec. 4514. Documentation of the number of MRI procedures performed by an MRI unit shall be  
962 | substantiated by the Department utilizing data submitted by the applicant in a format and media specified  
963 | by the Department and as verified for the 12-month period reported on the most recently published  
964 | "~~Available MRI Adjusted Procedures~~ MRI SERVICE UTILIZATION List" as of the date an application is  
965 | deemed complete by the Department. The number of MRI procedures actually performed shall be  
966 | documented by procedure records and not by application of the methodology required in Section 4615.  
967 | The Department may elect to verify the data through on-site review of appropriate records.  
968

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

970  
971 | Sec. 4615. (1) The number of available MRI adjusted procedures required pursuant to Section 3-~~or~~  
972 | ~~4(2) of these standards~~ shall be computed in accordance with the methodology set forth in this section.  
973 | In applying the methodology, the following steps shall be taken in sequence, and data for the 12-month  
974 | period reported on the most recently published "Available MRI Adjusted Procedures List," as of the date  
975 | an application is deemed complete by the Department, shall be used:

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

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

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

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

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

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

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

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

999 | (A) For each doctor, subtract any available adjusted procedures previously committed. The total  
1000 | for each doctor cannot be less than zero.

1001 | (B) The total number of available adjusted procedures for that service shall be the sum of the  
1002 | results of (A) above.

1003 | (iii) For each MRI service, the available MRI adjusted procedures resulting from the calculation in  
1004 | (ii) above shall be sorted in descending order by the available MRI adjusted procedures for each doctor.  
1005 | Then any duplicate values shall be sorted in descending order by the doctors' license numbers (last 6  
1006 | digits only).

1007 | (iv) Using the data produced in iii above, sum the number of available adjusted procedures in  
1008 | descending order until the summation equals at least 75 percent of the total available adjusted  
1009 | procedures. This summation shall include the minimum number of doctors necessary to reach the 75  
1010 | percent level.

1011 (v) For the doctors representing 75 percent of the total available adjusted procedures in (iv) above,  
1012 sum the available adjusted procedures.

1013 (vi) For the doctors used in subsection (v) above, divide the total number of available adjusted  
1014 procedures identified in (B) above by the sum of those available adjusted procedures produced in (v)  
1015 above.

1016 (vii) For only those doctors identified in (v) above, multiply the result of (vi) above by the available  
1017 adjusted procedures calculated in (c)(ii)(A) above.

1018 (viii) The result shall be the "Available MRI Adjusted Procedures List."  
1019

1020 (2) After publication of the "Available MRI Adjusted Procedures List" resulting from (1) above, the  
1021 data shall be updated to account for a) doctor commitments of available MRI adjusted procedures in  
1022 subsequent MRI CON applications and b) MRI adjusted procedures used in subsequent MRI CON  
1023 applications received in which applicants apply for fixed MRI services pursuant to Section 3(42).  
1024

1025 **Section 4716. Procedures and requirements for commitments of available MRI adjusted**  
1026 **procedures**  
1027

1028 Sec. 4716. (1) If one or more host sites on a mobile MRI service are located within the planning area  
1029 of the proposed site, the applicant may access available MRI adjusted procedures from the entire mobile  
1030 MRI service.

1031 (2)(a) At the time the application is submitted to the Department, the applicant shall submit a signed  
1032 data commitment, on a form provided by the Department in response to the applicant's letter of intent ~~or~~  
1033 ~~at the applicant's discretion, on a more current form subsequently provided by the Department,~~ for each  
1034 doctor committing available MRI adjusted procedures to that application for a new ~~or additional~~ MRI unit  
1035 THAT REQUIRES DOCTOR COMMITMENTS pursuant to Section 3 or Section 4(2), respectively.

1036 (b) An applicant also shall submit, at the time the application is filed with the Department, a  
1037 computer file that lists, for each MRI service from which data are being committed to the same  
1038 application, the name and license number of each doctor for whom a signed and dated data commitment  
1039 form is submitted.

1040 (i) The computer file shall be provided to the Department on mutually agreed upon media and in a  
1041 format prescribed by the Department.

1042 (ii) If the doctor commitments submitted on the Departmental forms do not agree with the data on  
1043 the computer file, the applicant shall be allowed to correct only the computer file data which includes  
1044 adding physician commitments that were submitted at the time of application.

1045 (c) If the required documentation for the doctor commitments submitted under this subsection is  
1046 not submitted with the application on the designated application date, the application will be deemed filed  
1047 on the first applicable designated application date after all required documentation is received by the  
1048 Department.  
1049

1050 (3) The Department shall consider a SIGNED AND DATED data commitment, on a form provided  
1051 by the Department in response to the applicant's letter of intent ~~or at the applicant's discretion, on a more~~  
1052 ~~current form subsequently provided by the Department, submitted by the applicant in support of its~~  
1053 ~~application,~~ that meets the requirements of each of the following, as applicable:

1054 (a) A committing doctor certifies that 100% of his or her available MRI adjusted procedures for  
1055 each specified MRI service, calculated pursuant to Section ~~4615~~, is being committed and specifies the  
1056 CON application number, for the ~~new fixed or mobile~~ MRI unit ~~or for the additional mobile MRI unit~~  
1057 ~~proposed to be located within the planning area,~~ to which the data commitment is made. A doctor shall  
1058 not be required to commit available MRI adjusted procedures from all MRI services to which his or her  
1059 patients are referred for MRI services but only from those MRI services specified by the doctor in the data  
1060 commitment form provided by the Department and submitted by the applicant in support of its application.

1061 (b) A committing doctor certifies ~~that he or she does not have an~~ ownership interest, either direct  
1062 or indirect, in the applicant entity, INDIRECT OWNERSHIP INCLUDES OWNERSHIP IN AN ENTITY  
1063 THAT HAS OWNERSHIP INTEREST IN THE APPLICANT ENTITY. ~~except that this~~ THIS requirement

1064 | shall not apply if the applicant entity is a group practice of which the committing doctor is a member.  
1065 | GROUP PRACTICE MEANS A GROUP PRACTICE AS DEFINED PURSUANT TO THE PROVISIONS  
1066 | OF 42 U.S.C. 1395NN (H)(4), COMMONLY KNOWN AS STARK II, AND THE CODE OF FEDERAL  
1067 | REGULATIONS, 42 CFR, PART 411, PUBLISHED IN THE FEDERAL REGISTER ON AUGUST 14,  
1068 | 1995, OR IT'S REPLACEMENT.

1069 | (c) A committing doctor certifies that he or she has not been provided, or received a promise of  
1070 | being provided, a financial incentive to commit any of his or her available MRI adjusted procedures to the  
1071 | application.

1072 | (4)(a) The Department shall not consider a data commitment from a doctor for available MRI adjusted  
1073 | procedures from a specific MRI service if the available MRI adjusted procedures from that specific MRI  
1074 | service were used to support approval of an application for a new or additional MRI unit, pursuant to  
1075 | Section 3 ~~or 4(2), respectively~~, for which a final decision to approve has been issued by the Director of  
1076 | the Department until either of the following occurs:

1077 | (i) The approved CON is withdrawn or expires.

1078 | (ii) The MRI service or unit to which the data were committed has been in operation for at least 36  
1079 | continuous months.

1080 | (b) The Department shall not consider a data commitment from a doctor for available MRI adjusted  
1081 | procedures from a specific MRI service if the available MRI adjusted procedures from that specific MRI  
1082 | service were used to support an application for a new fixed or mobile MRI unit or additional mobile MRI  
1083 | unit pursuant to Section 3 ~~or 4(2), respectively~~, for which a final decision to disapprove was issued by the  
1084 | Director of the Department until either of the following occurs:

1085 | (i) A final decision to disapprove an application is issued by the Director and the applicant does  
1086 | not appeal that disapproval or

1087 | (ii) If an appeal was made, either that appeal is withdrawn by the applicant or the committing  
1088 | doctor withdraws his or her data commitment pursuant to the requirements of subsection (8).  
1089 |

1090 | (5) The Department shall not consider a data commitment from a committing doctor for available  
1091 | MRI adjusted procedures from the same MRI service if that doctor has submitted a signed data  
1092 | commitment, on a form provided by Department, for more than one (1) application for which a final  
1093 | decision has not been issued by the Department. If the Department determines that a doctor has  
1094 | submitted a signed data commitment for the same available MRI adjusted procedures from the same MRI  
1095 | service to more than one CON application pending a final decision for a new fixed or mobile MRI unit or  
1096 | additional mobile MRI unit pursuant to Section 3 ~~or 4(2), respectively~~, the Department shall,

1097 | (a) if the applications were filed on the same designated application date, notify all applicants,  
1098 | simultaneously and in writing, that one or more doctors have submitted data commitments for available  
1099 | MRI adjusted procedures from the same MRI service and that the doctors' data from the same MRI  
1100 | service shall not be considered in the review of any of the pending applications filed on the same  
1101 | designated application date until the doctor notifies the Department, in writing, of the one (1) application  
1102 | for which the data commitment shall be considered.

1103 | (b) if the applications were filed on different designated application dates, consider the data  
1104 | commitment submitted in the application filed on the earliest designated application date and shall notify,  
1105 | simultaneously in writing, all applicants of applications filed on designated application dates subsequent  
1106 | to the earliest date that one or more committing doctors have submitted data commitments for available  
1107 | MRI adjusted procedures from the same MRI service and that the doctors' data shall not be considered in  
1108 | the review of the application(s) filed on the subsequent designated application date(s).  
1109 |

1110 | (6) The Department shall not consider any data commitment submitted by an applicant after the  
1111 | date an application is deemed complete unless an applicant is notified by the Department, pursuant to  
1112 | subsection (5), that one or more committing doctors submitted data commitments for available MRI  
1113 | adjusted procedures from the same MRI service. If an applicant is notified that one or more doctors' data  
1114 | commitments will not be considered by the Department, the Department shall consider data commitments  
1115 | submitted after the date an application is deemed complete only to the extent necessary to replace the  
1116 | data commitments not being considered pursuant to subsection (5).

1117 | (A) THE APPLICANT WILL HAVE 30 DAYS TO SUBMIT REPLACEMENT OF DOCTOR  
1118 | COMMITMENTS AS IDENTIFIED BY THE DEPARTMENT IN THIS SECTION.

1119 |  
1120 | (7) In accordance with either of the following, the Department shall not consider a withdrawal of a  
1121 | signed data commitment

1122 | (a) during the 120-day period following the date on which the Department's review of an  
1123 | application commences.

1124 | (b) after a proposed decision to approve an application has been issued by the Department.  
1125 |

1126 | (8) The Department shall consider a withdrawal of a signed data commitment if a committing  
1127 | doctor submits a written notice to the Department, that specifies the CON application number and the  
1128 | specific MRI services for which a data commitment is being withdrawn, and if an applicant demonstrates  
1129 | that the requirements of subsection (7) also have been met.  
1130 |

1131 | **Section 4817. Lists of MRI adjusted procedures published by the Department**  
1132 |

1133 | Sec. 4817. (1) ~~At a minimum, on~~ON or before May 1 and November 1 of each year, the Department  
1134 | shall publish the following lists:

1135 | (a) A list, known as the "MRI Service Utilization List," of all MRI services in Michigan that includes  
1136 | at least the following for each MRI service:

1137 | (i) The number of actual MRI adjusted procedures;

1138 | (ii) The number of available MRI adjusted procedures, if any; and

1139 | (iii) The number of MRI units, including whether each unit is a clinical, ~~unit or an MRI unit used~~  
1140 | ~~exclusively for research~~ RESEARCH, OR DEDICATED PEDIATRIC.

1141 | (b) A list, known as the "Available MRI Adjusted Procedures List," that identifies each MRI service  
1142 | that has available MRI adjusted procedures and includes at least the following:

1143 | (i) The number of available MRI adjusted procedures;

1144 | (ii) The name, address, and license number of each referring doctor, identified in Section  
1145 | ~~4615~~(1)(c)(v), whose patients received MRI services at that MRI service; and

1146 | (iii) The number of available MRI adjusted procedures performed on patients referred by each  
1147 | referring doctor, identified in Section ~~4615~~(1)(c)(v), and if any are committed to an MRI service. This  
1148 | number shall be calculated in accordance with the requirements of Section ~~4615~~(1). A referring doctor  
1149 | may have fractional portions of available MRI adjusted procedures.

1150 | (c) For the lists published pursuant to subsections (a) or (b), the May 1 list will report 12 months of  
1151 | data from the previous January 1 through December 31 reporting period, and the November 1 list will  
1152 | report 12 months of data from the previous July 1 through June 30 reporting period. Copies of both lists  
1153 | shall be available upon request.

1154 | (d) The Department shall not be required to publish a list that sorts MRI database information by  
1155 | referring doctor, only by MRI service.  
1156 |

1157 | (2) When an MRI service begins to operate at a site at which MRI services previously were not  
1158 | provided, the Department shall include in the MRI database, data beginning with the second full quarter  
1159 | of operation of the new MRI service. Data from the start-up date to the start of the first full quarter will not  
1160 | be collected to allow a new MRI service sufficient time to develop its data reporting capability. Data from  
1161 | the first full quarter of operation will be submitted as test data but will not be reported in the lists published  
1162 | pursuant to this section.  
1163 |

1164 | (3) In publishing the lists pursuant to subsections (a) and (b), if an MRI service has not reported  
1165 | data in compliance with the requirements of Section ~~43(1)(d)(iii)~~12, the Department shall indicate on both  
1166 | lists that the MRI service is in violation of the requirements set forth in Section ~~43(1)(d)(iii)~~12, and no data  
1167 | will be shown for that service on either list.  
1168 |

1169 | ~~— (4) In the case of an MRI service at which MRI services previously were not provided, the~~  
1170 | ~~Department may use annualized data from at least a consecutive six-month period in publishing the lists~~  
1171 | ~~pursuant to subsections (a) and (b).~~

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1173 | **Section ~~4918~~. Effect on prior CON Review Standards; Comparative reviews**

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1175 | Sec. ~~4918~~. (1) These CON review standards supersede and replace the CON Review Standards for  
1176 | Magnetic Resonance Imaging Services approved by the CON Commission on ~~September 18, 2007~~  
1177 | ~~SEPTEMBER 16, 2008~~ and effective ~~November 13, 2007~~ **NOVEMBER 13, 2008**.

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1179 | (2) Projects reviewed under these standards shall not be subject to comparative review.

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1181 **Section 20. Health Service Areas**

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1183 Sec. 20. Counties assigned to each of the health service areas are as follows:

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1185 **HSA** **COUNTIES**

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1188 1 Livingston Monroe St. Clair  
 1189 Macomb Oakland Washtenaw  
 1190 Wayne

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1192 2 Clinton Hillsdale Jackson  
 1193 Eaton Ingham Lenawee

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1195 3 Barry Calhoun St. Joseph  
 1196 Berrien Cass Van Buren  
 1197 Branch Kalamazoo

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1199 4 Allegan Mason Newaygo  
 1200 Ionia Mecosta Oceana  
 1201 Kent Montcalm Osceola  
 1202 Lake Muskegon Ottawa

1203

1204 5 Genesee Lapeer Shiawassee

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1206 6 Arenac Huron Roscommon  
 1207 Bay Iosco Saginaw  
 1208 Clare Isabella Sanilac  
 1209 Gladwin Midland Tuscola  
 1210 Gratiot Ogemaw

1211

1212 7 Alcona Crawford Missaukee  
 1213 Alpena Emmet Montmorency  
 1214 Antrim Gd Traverse Oscoda  
 1215 Benzie Kalkaska Otsego  
 1216 Charlevoix Leelanau Presque Isle  
 1217 Cheboygan Manistee Wexford

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1219 8 Alger Gogebic Mackinac  
 1220 Baraga Houghton Marquette  
 1221 Chippewa Iron Menominee  
 1222 Delta Keweenaw Ontonagon  
 1223 Dickinson Luce Schoolcraft



CON REVIEW STANDARDS  
FOR MRI SERVICES

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Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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