

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

2
3 **CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR**
4 **MEGAVOLTAGE RADIATION THERAPY (MRT) SERVICES/UNITS**
5

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

10 **Section 1. Applicability**

11
12 Sec. 1. These standards are requirements for approval to initiate, replace, expand, or acquire an
13 MRT service under Part 222 of the Code. MRT services and units are a covered clinical service pursuant
14 to Part 222 of the Code. The Department shall use these in applying Section 22225(1) of the Code, being
15 Section 333.22225(1) of the Michigan Compiled Laws and Section 22225(2)(c) of the Code, being
16 Section 333.22225(2)(c) of the Michigan Compiled Laws.
17

18 **Section 2. Definitions**

19
20 Sec. 2. (1) For purposes of these standards:

21 (a) "Commission" means the Commission created pursuant to Section 22211 of the Code, being
22 Section 333.22211 of the Michigan Compiled Laws.

23 (b) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et
24 seq. of the Michigan compiled Laws.

25 (c) "Dedicated stereotactic radiosurgery/**STEROTACTIC BODY RADIATION THERAPY (SRS/SBRT)**
26 unit" means an MRT unit for which more than 90 percent of cases will be treated with radiosurgery
27 **AND/OR SBRT.**

28 (d) "Department" means the Michigan Department of **Community Health AND HUMAN SERVICES**
29 **(MDCHHS).**

30 (e) "Equivalent treatment visit" or "ETV" means a unit of measure, based on the type of treatment
31 visit that reflects the relative average length of time one patient spends in one treatment visit in an MRT
32 unit.

33 (f) "Excess ETVs" means the number of ETVs performed by an existing MRT service in excess of
34 10,000 per MRT unit. The number of MRT units used to compute excess ETVs shall include both existing
35 and approved but not yet operational MRT units. In the case of an MRT service that operates or has a
36 valid CON to operate that has more than one MRT unit at the same site; the term means number of ETVs
37 in excess of 10,000 multiplied by the number of MRT units at the same site. For example, if an MRT
38 service operates, or has a valid CON to operate, two MRT units at the same site, the excess ETVs is the
39 number that is in excess of 20,000 (10,000 x 2) ETVs.

40 (g) "Existing MRT service" means a CON approved and operational facility and equipment used to
41 provide MRT services including but not limited to the simulator(s), block fabrication materials, and all
42 existing MRT units at a geographic location(s).

43 (h) "Existing MRT unit" means a CON approved and operational equipment used to provide MRT
44 services.

45 (i) "Heavy particle accelerator" means a machine such as a cyclotron which produces beams of high
46 energy particles such as protons, neutrons, pions, carbon ions, or other heavy ions with masses greater
47 than that of an electron.

48 (j) "High MRT unit" or "HMRT unit" means a heavy particle accelerator or any other MRT unit
49 operating at an energy level equal to or greater than 30.0 million electron volts (megavolts or MEV).

50 (k) "Intensity modulated radiation therapy" or "IMRT" means a visit utilizing only the computer
51 controlled multi-leaf collimator part of the CMS definition for IMRT.

52 (l) "Intraoperative MRT unit" or "IORT unit" means an MRT unit that is designed to emit only
53 electrons, located in an operating room in the surgical department of a licensed hospital and available for
54 the treatment of a patient undergoing a surgical procedure with megavoltage radiation.

55 (m) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6
56 and 1396r-8 to 1396v.

57 (n) "Megavoltage radiation therapy" or "MRT" means a clinical modality in which patients with cancer,
58 other neoplasms, cerebrovascular system abnormalities, or certain benign conditions are treated with
59 radiation which is delivered by a MRT unit.

60 (o) "MRT service" means the CON approved MRT utilization of a MRT unit(s) at one geographic
61 location.

62 (p) "MRT unit" or "unit" means a CON approved linear accelerator; cobalt unit; or other piece of
63 medical equipment operating at an energy level equal to or greater than 1.0 million electron volts
64 (megavolts or MEV) for the purpose of delivering doses of radiation to patients with cancer, other
65 neoplasms, or cerebrovascular system abnormalities.

66 (q) "Michigan Cancer Surveillance Program" means the program for the collection and analysis of
67 information on cancer in Michigan operated by the Department mandated by Act 82 of 1984, being
68 Section 333.2619 of the Michigan Compiled Laws.

69 (r) "Non-special MRT unit" or "non-special unit" means an MRT unit other than an MRT unit meeting
70 the definition of a special purpose MRT unit or an HMRT unit.

71 (s) "Simulation" means the precise mock-up of a patient treatment with an apparatus that uses a
72 diagnostic x-ray tube, magnetic resonance imaging device, or computed tomography scanner, which is
73 used in reproducing the two-dimensional or three-dimensional internal or external geometry of the patient,
74 for use in treatment planning and delivery.

75 (t) "Special purpose MRT unit" or "special purpose unit" or "special unit" means any of the following
76 types of MRT units: (i) dedicated stereotactic radiosurgery SRS/SBRT unit, (ii) dedicated total body
77 irradiator (TBI), or (iii) an OR-based IORT unit.

78 (u) "Total body irradiator" or "TBI" means a specially modified dedicated cobalt unit certified as a total
79 body irradiator by the Nuclear Regulatory Commission (NRC) or a permanently modified dedicated linear
80 accelerator that uses a very wide beam of gamma rays or x-rays to irradiate the entire body
81 simultaneously.

82 (v) "Treatment site" means the anatomical location of the MRT treatment.

83 (w) "Treatment visit" means one patient encounter during which MRT is administered and billed. One
84 treatment visit may involve one or more treatment ports or fields. Each separate encounter by the same
85 patient at different times of the same day shall be counted as a separate treatment visit.

86
87 (2) The definitions in Part 222 shall apply to these standards.
88

89 Section 3. Requirements to initiate an MRT service

90
91 Sec. 3. Initiate means the establishment of an MRT service where an MRT service is not currently
92 provided. The term does not include replacement of an existing MRT service. An applicant proposing to
93 initiate an MRT service shall demonstrate the following, as applicable to the proposed project.
94

95 (1) An applicant proposing to initiate an MRT service shall demonstrate the following:

- 96 (a) The applicant projects 8,000 equivalent treatment visits for each proposed unit.
97 (b) The proposed MRT unit is not a special purpose MRT unit.
98

99 (2) An applicant that demonstrates all of the following shall not be required to be in compliance with
100 the requirement in subsection (1):

- 101 (a) The site of the proposed MRT service is located in a rural or micropolitan statistical area county.
102 (b) The site of the proposed MRT service is 60 driving miles or more, verifiable by the Department,
103 from the nearest MRT service.
104 (c) The applicant projects 5,500 equivalent treatment visits for each proposed unit.
105 (d) The proposed MRT unit is not a special purpose MRT unit.
106

107 (3) An applicant that demonstrates all of the following shall not be required to be in compliance with
108 the requirement in subsection (1):

- 109 (a) The applicant is a hospital licensed under part 215 of the Code.

110 (b) The site of the proposed MRT service is a hospital licensed under part 215 of the Code and
111 located in planning area 8.

112 (c) The site of the proposed MRT service is 90 driving miles or more, verifiable by the department,
113 from the nearest MRT service.

114 (d) The applicant provides comprehensive imaging services including at least the following:
115 (i) Fixed magnetic resonance imaging (MRI) services,
116 (ii) Fixed computed tomography (CT) services, and
117 (iii) Mobile positron emission tomography (PET) services.
118 (e) The proposed MRT unit is not a special purpose MRT unit.
119

120 (4) An applicant proposing to initiate an MRT service with an HMRT unit shall demonstrate the
121 following:

122 (a) The applicant is a single legal entity authorized to do business in the State of Michigan.
123 (b) The applicant is a collaborative that consists of at least 40% of all Michigan-based hospital MRT
124 services with more than 30,000 equivalent treatment visits based on the most current data available to
125 the Department. Hospital MRT service means an MRT service owned by a hospital or owned by a
126 corporation that is itself wholly owned by hospital(s).

127 (c) The applicant shall include hospital MRT services from more than one planning area from one or
128 both of the following:
129 (i) Hospital MRT services qualified under subsection (b).
130 (ii) Hospital MRT services with the highest number of equivalent treatment visits in a planning area.
131 (d) Equivalent treatment visits for this subsection shall be those from the most recent CON Annual
132 Survey.
133 (e) An application shall not be approved if it includes an MRT service described in subsection (i) or
134 (ii) except as provided in subsections (iii) or (iv).
135 (i) An MRT service that was part of another application under this subsection.
136 (ii) An MRT service owned by, under common control of, or has a common parent, as an MRT
137 service under subsection (i).
138 (iii) The prior application, or the approved CON, were subsequently disapproved or withdrawn.
139 (iv) The application includes a commitment from the MRT service described in subsection (i) to
140 surrender the CON, or application, described in subsection (i) and that commitment is fulfilled at the time
141 the application under this section is approved.

142 (f) An application shall not be approved if it includes any of the following:
143 (i) An MRT service that is approved but not operational, or that has a pending application, for a
144 heavy particle accelerator.
145 (ii) An MRT service that is owned by, under common control of, or has a common parent, as an MRT
146 service described by subsection (i), unless the application under this subsection includes a commitment
147 from the MRT service described in subsection (i) to surrender the CON, or application, described in
148 subsection (i) and that commitment is fulfilled at the time the application under this section is approved.
149 (g) An application shall not be approved if it includes any of the following:
150 (i) An MRT service that is approved for a heavy particle accelerator that is operational.
151 (ii) An MRT service that is owned by, under common control of, or has a common parent, as an MRT
152 service described by subsection (i), unless the application under this section includes a commitment from
153 the MRT service described in subsection (i) to surrender the CON described in subsection (i), and that
154 commitment is fulfilled at the time the HMRT unit is approved and operational under this subsection.
155 (h) The applicant shall provide documentation of its process, policies and procedures, acceptable to
156 the Department that allows any other interested entities to participate in the collaborative utilization of the
157 HMRT unit.
158 (i) The applicant shall provide an implementation plan, acceptable to the Department, for financing
159 and operating the MRT service utilizing an HMRT that includes how physician staff privileges, patient
160 review, patient selection, and patient care management shall be determined.
161 (j) The applicant shall indicate that its proposed HMRT unit will be available to both adult and
162 pediatric patients.
163 (k) The applicant shall demonstrate simulation capabilities available for use in treatment planning.
164

- 165 (5) Applicants under this section shall demonstrate the following staff will be provided:
166 (a) One (1) FTE board-certified or board-qualified physician trained in radiation oncology.
167 (b) One (1) board-certified or board-qualified radiation physicist certified in therapeutic radiologic
168 physics.
169 (c) One (1) dosimetrist, a person who is familiar with the physical and geometric characteristics of
170 the radiation equipment and radioactive sources commonly employed and who has the training and
171 expertise necessary to measure and generate radiation dose distributions and calculations under the
172 direction of a medical physicist and/or a radiation oncologist.
173 (d) Two (2) FTE radiation therapists registered or eligible by the American Registry of Radiological
174 Technologists (ARRT).
175 (e) One (1) program director who is a board-certified physician trained in radiation oncology who may
176 also be the physician required under subsection (5)(a).
177

178 **Section 4. Requirements to replace an existing MRT unit or service**

179
180 Sec. 4. Replacement of an existing MRT unit means an equipment change that results in a new
181 serial number or requiring the issuance of a new radiation safety certificate from the State of Michigan
182 Radiation Safety Section. Replacement also means the relocation of an MRT service or unit to a new
183 site. Replacement does not include an upgrade to an existing MRT unit with the addition or modification
184 of equipment or software; the replacement components; or change for the purpose of maintaining or
185 improving its efficiency, effectiveness, and/or functionality. An applicant requesting to replace an existing
186 MRT unit(s) or MRT service shall demonstrate the following, as applicable to the proposed project.
187

188 (1) An applicant proposing to replace an existing MRT unit(s) shall demonstrate the following:

189 (a) The replacement unit(s) is a non-special unit and is replacing a non-special unit, or is a special
190 purpose unit and is replacing a non-special purpose unit or a special purpose unit.

191 (b) The MRT unit(s) to be replaced is fully depreciated according to generally accepted accounting
192 principles or either of the following:

193 (i) The existing MRT unit(s) poses a threat to the safety of the patients.

194 (ii) The replacement MRT unit(s) offers technological improvements that enhance quality of care,
195 increased efficiency, and a reduction in operating costs and patient charges.

196 (c) The applicant agrees that the unit(s) to be replaced will be removed from service on or before
197 beginning operation of the replacement unit(s).

198 (d) The site at which a special purpose unit is replaced shall continue to operate a non-special
199 purpose unit.
200

201 (2) An applicant proposing to replace an existing MRT service to a new site shall demonstrate the
202 following:

203 (a) The proposed site is within the same planning area as the existing MRT service site.

204 (b) The existing MRT unit(s) shall be operating at the following volumes, as applicable to the
205 proposed project:

206 (i) Non-special MRT unit(s) at 8,000 equivalent treatment visits per unit or 5,500 for a unit approved
207 under Section 3(2) or 3(3).

208 (ii) HMRT unit(s) AT 8,000 equivalent treatment visits per unit.

209 (iii) Special purpose unit(s) at 1,000 equivalent treatment visits per unit.
210

211 (3) An applicant proposing to replace an MRT unit(s) of an existing MRT service to a new site shall
212 demonstrate the following:

213 (a) The applicant is the same legal entity as the existing MRT service.

214 (b) For volume purposes, the new site shall remain associated with the existing MRT service for a
215 minimum of three years.

216 (c) The MRT unit(s) to be relocated is a non-special MRT unit(s).

217 (d) The existing non-special MRT unit(s) of the MRT services from where the unit is being relocated
218 from shall be operating at a minimum average volume of 8,000 equivalent treatment visits per unit.

219 (e) The proposed site meets the requirements of Section 3(5).

- 220 (f) The proposed site is within the same planning area as the existing MRT service site.
221 (g) The existing MRT service has been in operation for at least 36 months as of the date the
222 application was submitted to the Department.

223
224 **Section 5. Requirements to expand an existing MRT service**

225
226 Sec. 5. An applicant proposing to expand an existing MRT service by adding an MRT unit(s) shall
227 demonstrate the following, as applicable to the proposed project.

228
229 (1) An applicant proposing to add a non-special MRT unit(s) shall demonstrate an average of 10,000
230 equivalent treatment visits was performed in the most recent 12-month period on each of the applicant's
231 existing and approved non-special MRT units.

232
233 (2) An applicant proposing to expand an existing MRT service with a special purpose MRT unit shall
234 demonstrate the following, as applicable to the proposed project:

235 (a) An average of 8,000 equivalent treatment visits was performed in the most recent 12-month
236 period on each of the applicant's existing and approved non-special MRT units and an average of 1,000
237 equivalent treatment visits was performed in the most recent 12-month period on each of the applicant's
238 existing and approved special purpose MRT units.

239 (b) An applicant proposing to add a dedicated total body irradiator shall operate a bone marrow
240 transplantation program or have a written agreement to provide total body irradiation services to a
241 hospital that operates a bone marrow transplantation program.

242 (c) An applicant proposing to add an intraoperative MRT unit in an existing or proposed hospital
243 operating room shall demonstrate that the unit is a linear accelerator with only electron beam capabilities.

244
245 **Section 6. Requirements to acquire an existing MRT service**

246
247 Sec. 6. Acquiring an existing MRT service means obtaining possession and control by contract,
248 ownership, lease, or another comparable arrangement and renewal of lease for an existing MRT unit(s).
249 An applicant proposing to acquire an MRT service shall demonstrate the following, as applicable to the
250 proposed project.

251
252 (1) An application for the first acquisition of an existing MRT service, other than the renewal of a
253 lease, on or after November 21, 2011, shall not be required to be in compliance with the applicable
254 volume requirements set forth in Section 11. The MRT service shall be operating at the applicable
255 volumes set forth in the project delivery requirements in the second 12 months of operation of the service
256 by the applicant and annually thereafter.

257
258 (2) For any application proposing to acquire an existing MRT service, except the first application
259 approved pursuant to subsection (1), an applicant shall be required to document that the MRT service to
260 be acquired is operating in compliance with the volume requirements set forth in Section 11 of these
261 standards applicable to an existing MRT service on the date the application is submitted to the
262 Department.

263
264 (3) An applicant proposing to renew a lease for an existing MRT unit shall demonstrate the renewal
265 of the lease is more cost effective than replacing the equipment.

266
267 **Section 7. Requirements for a dedicated research MRT unit(s)**

268
269 Sec. 7. An applicant proposing to add a dedicated research MRT unit shall demonstrate the
270 following:

271
272 (1) The applicant is an existing MRT service.

273

274 (2) The applicant agrees that the dedicated research MRT unit(s) will be used primarily (70% or more
275 of treatments) for research purposes.

276 (3) The dedicated research MRT unit(s) shall operate under a protocol approved by the applicant's
277 Institutional Review Board (IRB), as defined by Public Law 93-348 and regulated by Title 45 CFR 46.
278

279 (4) The applicant operates a therapeutic radiation residency program approved by the American
280 Medical Association, the American Osteopathic Association, or an equivalent organization.
281

282 (5) The proposed site can have no more than two dedicated research MRT units.
283

284 **Section 8. Requirements for Medicaid participation**

285 Sec. 8. An applicant shall provide verification of Medicaid participation. An applicant that is a new
286 provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided
287 to the Department within six (6) months from the offering of services, if a CON is approved.
288

289 **Section 9. Methodology for projecting equivalent treatment visits**

290 Sec. 9. An applicant being reviewed under Section 3 shall apply the methodology set forth in this
291 section in computing the projected number of equivalent treatment visits.
292

293 (1) An applicant shall demonstrate that the projection is based on the commitments of the
294 treatments provided by the treating physician(s) for the most recent 12-month period immediately
295 preceding the date of the application. The commitments of the treating physician(s) will be verified with
296 the data maintained by the Department through its "CON Annual Survey."
297

298 (a) For the purposes of this section, treating physician means the staff physician of the MRT service
299 directing and providing the MRT treatment, not the referring physician.
300

301 (2) An applicant shall demonstrate that the projected number of commitments to be performed at the
302 proposed site under subsection (1) are from an existing MRT service that is in compliance with the
303 volume requirements applicable to that service and will continue to be in compliance with the volume
304 requirements applicable to that service subsequent to the initiation of the proposed MRT service by an
305 applicant. Only excess ETVs equal to or greater than what is being committed pursuant to this
306 subsection may be used to document projections under subsection (1). In demonstrating compliance with
307 this subsection, an applicant shall provide each of the following:
308

309 (a) A written commitment from each treating physician that he or she will treat at least the volume of
310 MRT treatments to be transferred to the proposed MRT service for no less than 3 years subsequent to
311 the initiation of the MRT service proposed by an applicant.
312

313 (b) The number of treatments committed must have resulted in an actual treatment of the patient at
314 the existing MRT service from which the treatment will be transferred. The committing physician must
315 make available HIPAA compliant audit material if needed upon Department request to verify referral
316 sources and outcomes. Commitments must be verified by the most recent data set maintained by the
317 Department through its "CON Annual Survey."
318

319 (c) The projected commitments are from an existing MRT service within the same planning area as
320 the proposed MRT service.
321

322 **Section 10. Equivalent treatment visits**

323 Sec. 10. Equivalent treatment visits shall be calculated as follows:
324

325 (1) For the time period specified in the applicable sections, assign each actual treatment visit
326 provided to one applicable treatment visit category set forth in Table 1.
327

328 (2) The number of treatment visits for each category in the time period specified in the applicable
 329 section(s) of these standards shall be multiplied by the corresponding equivalent treatment visits weight in
 330 Table 1 to determine the number of equivalent treatment visits for that category for that time period.

331
 332 (3) The number of equivalent treatment visits for each category determined pursuant to subsection
 333 (2) shall be summed to determine the total equivalent treatment visits for the time period specified in the
 334 applicable sections of these standards.

335
 336 (4) THE WEIGHTING IN TABLE 1 IS BASED ON TYPICAL TREATMENT TIMES AND ASSUMES
 337 AN ETV EQUALS APPROXIMATELY 15 MINUTES OF TIME ON THE MRT UNIT.
 338

TABLE 1
Equivalent Treatments

Treatment Visit Category	Non-Special Visit Weight	Special Visit Weight
Simple	1.00	
Intermediate	1.40	
Complex	1.25	
IMRT	2.00	
Total Body Irradiation	85.00	85.00
HMRT Therapy		5.00
Stereotactic radio-surgery/radio-therapy*	84.00	84.00
IORT		20.00

All patients under 5 years of age receive a 2.00 additive factor.

Gating receives a 1.00 additive factor. Gating is the capturing and monitoring of the target's or fiducial's motion during radiation treatment and the modulation of the radiation beam in order to more precisely deliver radiation to the target and/or decrease the radiation dose to the surrounding normal tissue.

MR-GUIDED REAL TIME TRACKING RADIATION W/O ADAPTIVE RECEIVES A 2.00 ADDITIVE FACTOR. MR-GUIDED REAL TIME TRACKING RADIATION W/O ADAPTIVE MEANS A VISIT INVOLVING AN INTEGRATED MRI/MRT UNIT PROVIDING MR IMAGES IN THE TREATMENT ROOM BEFORE AND DURING AN MRT TREATMENT OF ANY COMPLEXITY.

MR-GUIDED REAL TIME TRACKING RADIATION WITH ADAPTIVE RECEIVES A 3.00 ADDITIVE FACTOR. MR-GUIDED REAL TIME TRACKING RADIATION WITH ADAPTIVE MEANS A VISIT INVOLVING AN INTEGRATED MRI/MRT UNIT PROVIDING MR IMAGES IN THE TREATMENT ROOM BEFORE AND DURING AN MRT TREATMENT OF ANY COMPLEXITY; ALONG WITH CREATION, EVALUATION AND DELIVERY OF A NEW RADIATION THERAPY PLAN WHILE THE PATIENT REMAINS IN THE TREATMENT ROOM.

PATIENT SPECIFIC QA FOR IMRT RECEIVES A 2.0 ADDITIVE FACTOR, NOT TO EXCEED TWICE PER COURSE OF TREATMENT. PATIENT SPECIFIC QA FOR IMRT MEANS VERIFICATION OF RADIATION DELIVERED DOSE AND/OR FLUENCE THROUGH PHYSICAL MEASUREMENT WITH A DOSIMETRY PHANTOM AND/OR DETECTOR ARRAY IN THE TREATMENT ROOM. PRIOR TO THE START OF TREATMENT AND USING ALL OF THE PARAMETERS OF THE PATIENT'S TREATMENT PLAN, ONE OR MORE POINTS IN THE DELIVERED DISTRIBUTION SHOULD BE COMPARED AGAINST THE PLANNED DISTRIBUTION.

PATIENT SPECIFIC QA FOR SRS/SBRT RECEIVES A 3.0 ADDITIVE FACTOR, NOT TO EXCEED TWICE PER COURSE OF TREATMENT. PATIENT SPECIFIC QA FOR SRS/SBRT MEANS VERIFICATION OF RADIATION DELIVERED DOSE AND/OR FLUENCE THROUGH PHYSICAL MEASUREMENT WITH A DOSIMETRY PHANTOM AND/OR DETECTOR ARRAY IN THE

TREATMENT ROOM. PRIOR TO THE START OF TREATMENT AND USING ALL OF THE PARAMETERS OF THE PATIENT'S TREATMENT PLAN, ONE OR MORE POINTS IN THE DELIVERED DISTRIBUTION SHOULD BE COMPARED AGAINST THE PLANNED DISTRIBUTION.

* After the first isocenter, each additional isocenter receives 6-1.33 equivalent treatment visits. There is a maximum of five visits per course of therapy.

(4) "Simple treatment visit" means a treatment visit involving a single treatment site, single treatment field, or parallel opposed fields with the use of no more than simple blocks.

(5) "Intermediate treatment visit" means a treatment visit involving two separate treatment sites, three or more fields to a single treatment site, or the use of special blocking.

(6) "Complex treatment visit" means a treatment visit involving three or more treatment sites, tangential fields with wedges, rotational or arc techniques or other special arrangements, or custom blocking.

(7) "IMRT treatment visit" means a visit utilizing only the computer controlled multi-leaf collimator part of the CMS definition for IMRT.

(8) "Stereotactic treatment visit" means a visit involving the use of a stereotactic guiding device with radiotherapy for the ablation of a precisely defined intracranial and/or extracranial tumor or lesion.

(9) "Intraoperative treatment visit" means a treatment visit where a dose of megavoltage radiation is delivered to a surgically exposed neoplasm or cancerous organ/site using a dedicated unit.

(10) "Isocenter" means the virtual point in space about which the MRT unit operates and is placed at the center of the tumor for the delivery of the radiation treatment.

(11) "Course of treatment" means the planned series of visits that compose a plan for treatment of one or more cancer sites for a single patient.

Section 11. Project delivery requirements terms of approval for all applicants

Sec. 11. An applicant shall agree that, if approved, the MRT service, including all existing and approved MRT units, shall be delivered in compliance with the following:

(1) Compliance with these standards.

(2) Compliance with the following quality assurance standards:

(a) An applicant shall assure that the MRT service is staffed and operated by physicians and/or radiation therapists qualified by training and experience to operate the unit safely and effectively. The Department shall consider it prima facie evidence if the applicant requires the equipment to be operated by a physician who is board certified or board qualified in either radiation oncology or therapeutic radiology, and/or a radiation therapist certified by the American Registry of Radiological Technologists (ARRT) or the American Registry of Clinical Radiography Technologists (ARCRT). The applicant may also submit, and the Department may accept, other evidence.

(b) An applicant shall have the following staff:

(i) One (1) full-time equivalent (FTE) board-certified or board-qualified physician trained in radiation oncology for each 250 patients treated with MRT annually.

(ii) One (1) FTE board-certified or board-qualified radiation physicist, certified in therapeutic radiologic physics, immediately available during hours of operation.

(iii) One (1) dosimetrist for every 300 patients treated with MRT annually.

(iv) Two (2) radiation therapists registered or eligible by the American Registry of Radiological Technologists (ARRT), for every MRT unit per shift of operation (not including supervisory time).

387 (v) One (1) FTE program director who is a board-certified physician trained in radiation oncology who
388 may also be the physician required under subsection (i). The Department shall consider it prima facie
389 evidence as to the training of the physician(s) if the physician is board certified or board qualified in
390 radiation oncology and/or therapeutic radiology.

391 (c) All MRT treatments shall be performed pursuant to a radiation oncologist and at least one
392 radiation oncologist will be immediately available during the operation of the unit(s).

393 (d) An applicant shall have equipment and supplies to handle clinical emergencies that might occur.
394 Staff will be trained in CPR and other appropriate emergency interventions and shall be on-site in the
395 MRT unit at all times when patients are treated. A physician shall be on-site or immediately available to
396 the MRT unit at all times when patients are treated.

397 (e) An applicant shall operate a cancer treatment program. The Department shall consider it prima
398 facie evidence if the applicant submits evidence of a cancer treatment program approved by the
399 American College of Surgeons Commission on Cancer. A cancer treatment program is a coordinated,
400 multi-disciplinary approach to the treatment of patients with cancer or other neoplasms, which must
401 provide on-site simulation capability, and, either on-site or through written agreements with other
402 providers, all of the following services: access to consultative services from all major disciplines needed
403 to develop a comprehensive treatment plan, a computer-based treatment planning system, medical
404 radiation physicist involvement, MRT capability including electron beam capability, treatment aid
405 fabrication capability, brachytherapy, a multi-disciplinary cancer committee, a tumor registry, patient care
406 evaluation studies, and cancer prevention and education programs. The applicant may also submit, and
407 the Department may accept, other evidence. Patient care evaluation studies means a system of patient
408 care evaluation, conducted at least twice annually, that documents the methods used to identify problems
409 and the opportunities to improve patient care. Tumor registry means a manual or computerized data
410 base containing information about all malignancies and only those that are diagnosed and/or treated at
411 the applicant's facility. The malignancies must be reportable to the Michigan Cancer Surveillance
412 Program as required pursuant to Public Act 82 of 1984, as amended.

413 (i) An applicant shall submit evidence of accreditation by the American College of Surgeons
414 Commission on cancer, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO),
415 or the Healthcare Facilities Accreditation Program (HFAP) within the first three years of operation and
416 continue to participate annually thereafter.

417 (ii) An applicant shall submit evidence of accreditation by the American College of Radiology (ACR),
418 American Society for Radiation Oncology (ASTRO) or the American College of Radiation Oncology
419 (ACRO) within the first three years of operation and continue to participate annually thereafter.

420 (f) The MRT service will have simulation capability at the same location.

421 (g) An applicant shall participate in the Michigan Cancer Surveillance Program.

422 (h) The applicant agrees to operate a special purpose MRT unit(s) only for the specific use for which
423 it was approved.

424 (i) An applicant approved to operate a dedicated total body irradiator that uses cobalt as the source
425 of radiation shall obtain and maintain Nuclear Regulatory Commission certification. An applicant
426 approved to operate a dedicated total body irradiator that is a permanently modified linear accelerator, or
427 an HMRT unit, shall meet any requirements specified by the State of Michigan Radiation Safety Section.

428 (j) All patients treated on an HMRT unit shall be evaluated for potential enrollment in research
429 studies focusing on the applicability and efficacy of utilizing an HMRT unit for treatment of specific cancer
430 conditions. The number of patients treated, number enrolled in research studies, and the types of cancer
431 conditions involved shall be provided to the Department as part of the CON Annual Survey.

432 (k) The operation of and referral of patients to the MRT unit shall be in conformance with 1978 PA
433 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

434 (3) Compliance with the following access to care requirements:

435 (a) The applicant shall accept referrals for MRT services from all appropriately licensed health care
436 practitioners.

437 (b) To assure that the MRT service and its unit(s) will be utilized by all segments of the Michigan
438 population, the applicant shall:

439 (i) not deny MRT services to any individual based on ability to pay or source of payment,
440

441 (ii) provide MRT services to an individual based on the clinical indications of need for the service,
442 and
443 (iii) maintain information by payor and non-paying sources to indicate the volume of care from each
444 source provided annually. Compliance with selective contracting requirements shall not be construed as
445 a violation of this term.
446 (c) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years
447 of operation and continue to participate annually thereafter.

448
449 (4) Compliance with the following monitoring and reporting requirements:

450 (a) Non-special MRT units ~~and HMRT units~~ shall be operating at a minimum average volume of
451 ~~84,000~~ Equivalent Treatment Visits per unit annually by the end of the third full year of operation, and
452 annually thereafter. ~~HMRT UNITS SHALL BE OPERATING AT A MINIMUM AVERAGE VOLUME OF~~
453 ~~8,000 EQUIVALENT TREATMENT VISITS PER UNIT ANNUALLY BY THE END OF THE THIRD FULL~~
454 ~~YEAR OF OPERATION, AND ANNUALLY THEREAFTER.~~ All special purpose MRT units shall be
455 operating at a minimum average volume of 1,000 equivalent treatment visits per special purpose unit by
456 the end of the third full year of operation, and annually thereafter. An applicant shall not include any
457 treatments conducted on a dedicated research MRT unit.

458 (b) ~~Non-special MRT units and~~ HMRT units approved pursuant to Section 3(2) or 3(3) of these
459 standards shall be operating at a minimum average volume of 5,500 equivalent treatment visits per unit
460 by the end of the third full year of operation, and annually thereafter. An applicant shall not include any
461 treatments conducted on a dedicated research MRT unit.

462 (c) An applicant is not required to be in compliance with subsections (4)(a) or (b) if the applicant is
463 replacing an MRT unit under ~~section~~ Section 4(1).

464 (d) An applicant shall participate in a data collection network established and administered by the
465 Department or its designee. The data may include, but is not limited to, annual budget and cost
466 information, operating schedules, through-put schedules, demographic and diagnostic information, and
467 the volume of care provided to patients from all payor sources and other data requested by the
468 Department. Data shall be provided by each type of MRT unit in a format established by the Department
469 and in a mutually agreed upon media. The Department may elect to verify the data through on-site
470 review of appropriate records.

471 (e) Services provided on a dedicated research MRT unit shall be delivered in compliance with the
472 following terms:

473 (i) Capital and operating costs for research treatment visits shall be charged only to a specific
474 research account(s) and not to any patient or third-party payor.

475 (ii) The dedicated research MRT unit shall not be used for any purposes other than as approved by
476 the IRB.

477 (iii) The treatments on a dedicated research MRT unit shall not be used for any volume purposes.

478
479 (5) The applicable agreements and assurances required by this section shall be in the form of a
480 certification agreed to by the applicant or its authorized agent.

481 **Section 12. Effect on prior CON review standards; comparative reviews**

482
483 Sec. 12. Proposed projects reviewed under these standards shall not be subject to comparative
484 review. These standards supersede and replace the CON Review Standards for MRT Services/Units
485 approved by the CON Commission on ~~March 28, 2013~~ JUNE 11, 2015 and effective ~~May 24,~~
486 ~~2013~~ SEPTEMBER 14, 2015.
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APPENDIX A

PLANNING AREAS BY COUNTY

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1	Livingston Macomb Wayne	Monroe Oakland	St. Clair Washtenaw
2	Clinton Eaton	Hillsdale Ingham	Jackson Lenawee
3	Barry Berrien Branch	Calhoun Cass Kalamazoo	St. Joseph Van Buren
4	Allegan Ionia Kent Lake	Mason Mecosta Montcalm Muskegon	Newaygo Oceana Osceola Ottawa
5	Genesee	Lapeer	Shiawassee
6	Arenac Bay Clare Gladwin Gratiot	Huron Iosco Isabella Midland Ogemaw	Roscommon Saginaw Sanilac Tuscola
7	Alcona Alpena Antrim Benzie Charlevoix Cheboygan	Crawford Emmet Gd Traverse Kalkaska Leelanau Manistee	Missaukee Montmorency Oscoda Otsego Presque Isle Wexford
8	Alger Baraga Chippewa Delta Dickinson	Gogebic Houghton Iron Keweenaw Luce	Mackinac Marquette Menominee Ontonagon Schoolcraft

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APPENDIX B

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

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