

**MICHIGAN DEPARTMENT OF COMMUNITY HEALTH (MDCH)
MEGAVOLTAGE RADIATION THERAPY
STANDARD ADVISORY COMMITTEE (MRTSAC) MEETING**

Wednesday, November 19, 2014

Capitol View Building
201 Townsend Street
MDCH Conference Center
Lansing, Michigan 48913

APPROVED MINUTES

I. Call to Order

Chairperson Chuba called the meeting to order at 9:38 a.m.

A. Members Present:

Paul J. Chuba, MD, Chairperson, St. John Providence Health System
Bruce Carl, MD, UAW Retiree Medical Benefits Trust
Praveen Dalmia, McLaren Health Care
Joseph Delikat, Chrysler Group, LLC
James George-Herman, MD, Sparrow Health System
James A. Hayman, MD, University of Michigan Health System (UMHS)
Christine Kupovits, Oakwood Healthcare, Inc. arrived at 9:37 a.m.
Gwendolyn Parker, MD, Blue Cross Blue Shield of MI
M. Salim U. Siddiqui, MD, Henry Ford Health System
Archana Somnay, MS, Huron Valley Sinai Hospital/DMC

B. Members Absent:

Jeffery Forman, MD, 21st Century Oncology
Robert Evans, the International UAW Aerospace and Agriculture
Implement Workers of America
Tewfik Bichay, MD, Mercy Health-St. Mary's via conference call
Michael Mahacek, MD, Spectrum Health via conference call

C. Michigan Department of Community Health Staff present:

Tulika Bhattacharya
Natalie Kellogg
Beth Nagel
Tania Rodriguez

Brenda Rogers
Matt Weaver

II. Declaration of Conflicts of Interests

No conflicts were declared.

III. Review of Minutes October 2, 2014

Motion by Dr. Dalmia and seconded by Dr. Siddiqui to approve the minutes as presented. Motion Carried.

IV. Review of Agenda

Motion by Dr. Herman and seconded by Dr. Parker to accept the agenda as modified. Motion Carried.

V. First Acquisition Draft Language

Dr. Chuba provided an overview of the proposed changes to the acquisition section of the MRT Review Standards (see Attachment A).

No public comment.

Motion by Ms. Kuptovits and seconded by Dr. Siddiqui to approve the clarification to the first and subsequent acquisition language in Section 6(1) and Section 6(2). Motion Carried in a vote of 9-Yes, 0-No, and 0-Abstained.

VI. Weight for Respiratory Gating

Dr. Dalmia presented on the possible weights associated with respiratory gating (see Attachment B).

Motion by Dr. Dalmia and seconded by Dr. Herman to accept the definition of gating as amended. Motion carried in a vote of 9- Yes, 0- No, and 0- Abstained.

No public comment.

Motion by Dr. Dalmia and seconded by Dr. Siddiqui to add on ETV weight of 1.0 for radiation treatment delivered using respiratory gating or motion management. Motion carried in a vote of 9-Yes, 0-No, and 0-Abstained.

VII. Collection of Data for the Future

Dr. Chuba provided an overview of the accreditation and quality criteria that are described in the MRTSAC charge.

Discussion followed.

Public Comment:

Dennis MCCafferty, Economic Alliance of Michigan (EAM)

Motion by Dr. Carl and seconded by Dr. Parker to require on a yearly basis any facility with MRT services be required to submit their American College of Surgeon scores to the Department. Motion failed in a vote of 3-Yes, 5-No and 1-Abstained.

VIII. Review of Draft Language

Ms. Rogers reviewed all proposed changes to draft language from past meetings to present.

The MRTSAC accepted a new definition for simulation.

Ms. Rogers stated that the Department will make the necessary edits to the draft language and will send a finalized draft to the MRTSAC for their review to determine that edits were made correctly.

IX. Public Comment

None.

X. Future Meeting Dates- None

XI. Adjournment

Motion by Dr. Siddiqui and seconded by Dr. Carl to adjourn the meeting at 12:32 p.m. Motion Carried.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR
MEGAVOLTAGE RADIATION THERAPY (MRT) SERVICES/UNITS

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

Section 1. Applicability

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

Section 2. Definitions

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

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

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

~~(c) "Cyber knife" means a treatment device that is a frameless special stereotactic radiosurgery unit that consists of three key components: (i) an advanced, lightweight linear accelerator (linac) (this device is used to produce a high energy megavoltage of radiation), (ii) a robot which can point the linear accelerator from a wide variety of angles, and (iii) several x-ray cameras (imaging devices) that are combined with software to track patient position. The cameras obtain frequent pictures of the patient during treatment and use this information to target the radiation beam emitted by the linear accelerator.~~

~~—(d) "DEDICATED STEREOTACTIC RADIOSURGERY UNIT" MEANS AN MRT UNIT FOR WHICH MORE THAN 90 PERCENT OF CASES WILL BE TREATED WITH RADIOSURGERY.~~

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

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

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

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

~~(gh)~~ "Existing MRT unit" means a CON approved and operational equipment used to provide MRT services.

~~—(h) "Gamma knife" means a special stereotactic radiosurgery unit consisting of multiple cobalt sources all simultaneously focused to irradiate cancer or other neoplasms in the brain or cerebrovascular system abnormalities.~~

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

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

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

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

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

64 (n) "Megavoltage radiation therapy" or "MRT" means a clinical modality in which patients with cancer,
 65 other neoplasms, ~~or~~ cerebrovascular system abnormalities, **OR CERTAIN BENIGN CONDITIONS** are
 66 treated with radiation which is delivered by a MRT unit.

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

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

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

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

78 (s) "Simulation" means the precise mock-up of a patient treatment with an apparatus that uses a
 79 diagnostic x-ray tube, **MAGNETIC RESONANCE IMAGING OR COMPUTED TOMOGRAPHY**
 80 **SCANNERS, WHICH IS USED IN DUPLICATING** ~~and duplicates~~ an MRT unit in terms of its geometrical,
 81 mechanical, and optical properties **IN CLINICAL TREATMENT**.

82 (t) "Special purpose MRT unit" or "special purpose unit" or "special unit" means any of the following
 83 types of MRT units: (i) ~~gamma knife~~, (ii) dedicated stereotactic radiosurgery unit, (iii) dedicated total body
 84 irradiator (TBI), **OR** ~~(iv)~~ an OR-based IORT unit, ~~or (v) cyber knife~~.

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

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

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

93
 94 (2) The definitions in Part 222 shall apply to these standards.

96 Section 3. Requirements to initiate an MRT service

97
 98 Sec. 3. Initiate means the establishment of an MRT service where an MRT service is not currently
 99 provided. The term does not include replacement of an existing MRT service. An applicant proposing to
 100 initiate an MRT service shall demonstrate the following, as applicable to the proposed project.

101
 102 (1) An applicant proposing to initiate an MRT service shall demonstrate the following:

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

105
 106 (2) An applicant that demonstrates all of the following shall not be required to be in compliance with
 107 the requirement in subsection (1):

- 108 (a) The site of the proposed MRT service is located in a rural or micropolitan statistical area county.

- 109 (b) The site of the proposed MRT service is 60 driving miles or more, verifiable by the Department,
 110 from the nearest MRT service.
- 111 (c) The applicant projects 5,500 equivalent treatment visits for each proposed unit.
- 112 (d) The proposed MRT unit is not a special purpose MRT unit.
- 113
- 114 (3) An applicant that demonstrates all of the following shall not be required to be in compliance with
 115 the requirement in subsection (1):
- 116 (a) The applicant is a hospital licensed under part 215 of the Code.
- 117 (b) The site of the proposed MRT service is a hospital licensed under part 215 of the Code and
 118 located in planning area 8.
- 119 (c) The site of the proposed MRT service is 90 driving miles or more, verifiable by the department,
 120 from the nearest MRT service.
- 121 (d) The applicant provides comprehensive imaging services including at least the following:
- 122 (i) Fixed magnetic resonance imaging (MRI) services,
- 123 (ii) Fixed computed tomography (CT) services, and
- 124 (iii) Mobile positron emission tomography (PET) services.
- 125 (e) The proposed MRT unit is not a special purpose MRT unit.
- 126
- 127 (4) An applicant proposing to initiate an MRT service with an HMRT unit shall demonstrate the
 128 following:
- 129 (a) The applicant is a single legal entity authorized to do business in the State of Michigan.
- 130 (b) The applicant is a collaborative that consists of at least 40% of all Michigan-based hospital MRT
 131 services with more than 30,000 equivalent treatment visits based on the most current data available to
 132 the Department. Hospital MRT service means an MRT service owned by a hospital or owned by a
 133 corporation that is itself wholly owned by hospital(s).
- 134 (c) The applicant shall include hospital MRT services from more than one planning area from one or
 135 both of the following:
- 136 (i) Hospital MRT services qualified under subsection (b).
- 137 (ii) Hospital MRT services with the highest number of equivalent treatment visits in a planning area.
- 138 (d) Equivalent treatment visits for this subsection shall be those from the most recent CON Annual
 139 Survey.
- 140 (e) An application shall not be approved if it includes an MRT service described in subsection (i) or
 141 (ii) except as provided in subsections (iii) or (iv).
- 142 (i) An MRT service that was part of another application under this subsection.
- 143 (ii) An MRT service owned by, under common control of, or has a common parent, as an MRT
 144 service under subsection (i).
- 145 (iii) The prior application, or the approved CON, were subsequently disapproved or withdrawn.
- 146 (iv) The application includes a commitment from the MRT service described in subsection (i) to
 147 surrender the CON, or application, described in subsection (i) and that commitment is fulfilled at the time
 148 the application under this section is approved.
- 149 (f) An application shall not be approved if it includes any of the following:
- 150 (i) An MRT service that is approved but not operational, or that has a pending application, for a
 151 heavy particle accelerator.
- 152 (ii) An MRT service that is owned by, under common control of, or has a common parent, as an MRT
 153 service described by subsection (i), unless the application under this subsection includes a commitment
 154 from the MRT service described in subsection (i) to surrender the CON, or application, described in
 155 subsection (i) and that commitment is fulfilled at the time the application under this section is approved.
- 156 (g) An application shall not be approved if it includes any of the following:
- 157 (i) An MRT service that is approved for a heavy particle accelerator that is operational.
- 158 (ii) An MRT service that is owned by, under common control of, or has a common parent, as an MRT
 159 service described by subsection (i), unless the application under this section includes a commitment from
 160 the MRT service described in subsection (i) to surrender the CON described in subsection (i), and that
 161 commitment is fulfilled at the time the HMRT unit is approved and operational under this subsection.

162 (h) The applicant shall provide documentation of its process, policies and procedures, acceptable to
 163 the Department that allows any other interested entities to participate in the collaborative utilization of the
 164 HMRT unit.

165 (i) The applicant shall provide an implementation plan, acceptable to the Department, for financing
 166 and operating the MRT service utilizing an HMRT that includes how physician staff privileges, patient
 167 review, patient selection, and patient care management shall be determined.

168 (j) The applicant shall indicate that its proposed HMRT unit will be available to both adult and
 169 pediatric patients.

170 (k) The applicant shall demonstrate simulation capabilities available for use in treatment planning.

171 (5) Applicants under this section shall demonstrate the following staff will be provided:

172 (a) One (1) FTE board-certified or board-qualified physician trained in radiation oncology.

173 (b) One (1) board-certified or board-qualified radiation physicist certified in therapeutic radiologic
 174 physics.

175 (c) One (1) dosimetrist, a person who is familiar with the physical and geometric characteristics of
 176 the radiation equipment and radioactive sources commonly employed and who has the training and
 177 expertise necessary to measure and generate radiation dose distributions and calculations under the
 178 direction of a medical physicist and/or a radiation oncologist.

179 (d) Two (2) FTE radiation therapists registered or eligible by the American Registry of Radiological
 180 Technologists (ARRT).

181 (e) One (1) program director who is a board-certified physician trained in radiation oncology who may
 182 also be the physician required under subsection (5)(a).

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

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

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

193 (a) The replacement unit(s) is ~~the same type as the MRT unit(s) to be replaced~~ A NON-SPECIAL
 194 UNIT AND IS REPLACING A NON-SPECIAL UNIT, OR IS A SPECIAL PURPOSE UNIT REPLACING A
 195 NON-SPECIAL PURPOSE UNIT OR A SPECIAL PURPOSE UNIT.

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

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

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

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

203 (d) THE SITE AT WHICH A SPECIAL PURPOSE UNIT IS REPLACED SHALL ALSO OPERATE A
 204 NON-SPECIAL PURPOSE UNIT.

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

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

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

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

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

217 (iii) Special purpose unit(s) at 1,000 equivalent treatment visits per unit.
218

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

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

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

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

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

227 (e) The proposed site meets the requirements of Section 3(45).

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

229 (g) The existing MRT service has been in operation for at least 36 months as of the date the
230 application was submitted to the Department.

231 **Section 5. Requirements to expand an existing MRT service**

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

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

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

239 (a) An average of 8,000 equivalent treatment visits was performed in the most recent 12-month
240 period on each of the applicant's existing and approved non-special MRT units **AND AN AVERAGE OF
241 1000 EQUIVALENT TREATMENT VISITS WAS PERFORMED IN THE MOST RECENT 12-MONTH
242 PERIOD ON EACH OF THE APPLICANT'S EXISTING AND APPROVED SPECIAL PURPOSE MRT
243 UNITS.**

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

247 ~~(c) An applicant proposing to add a dedicated stereotactic radiosurgery unit such as a gamma knife
248 or cyber knife, shall demonstrate that the applicant has a contractual relationship with a board-eligible or
249 board-certified neurosurgeon(s) trained in stereotactic radiosurgery and on-site 3-dimensional imaging
250 and 3-dimensional treatment planning capabilities.~~

251 ~~—(d)—~~An applicant proposing to add an intraoperative MRT unit in an existing or proposed hospital
252 operating room shall demonstrate that the unit is a linear accelerator with only electron beam capabilities.
253

254 **Section 6. Requirements to acquire an existing MRT service**

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

259 (1) **For the first AN** application **proposing to FOR THE FIRST acquire acquisition OF** an existing MRT
260 service, other than the renewal of a lease, on or after November 21, 2011, ~~the existing MRT service~~ shall
261 not be required to be in compliance with the applicable volume requirements set forth in ~~this~~
262 **sectionSection 11. THE MRT SERVICE SHALL BE OPERATING AT THE APPLICABLE VOLUMES SET**
263 **FORTH IN THE PROJECT DELIVERY REQUIREMENTS IN THE SECOND 12 MONTHS OF**
264 **OPERATION OF THE SERVICE BY THE APPLICANT AND ANNUALLY THEREAFTER.**
265
266
267
268
269
270
271

272 (2) ~~an applicant proposing to acquire an existing MRT service shall demonstrate the following:~~
 273 ~~—(a) The existing MRT unit(s) shall be operating at the following volumes, as applicable to the~~
 274 ~~proposed project:~~
 275 ~~—(i) Non-special MRT unit(s) at 8,000 equivalent treatment visits per unit or 5,500 for a unit approved~~
 276 ~~under Section 3(2) or 3(3).~~
 277 ~~—(ii) HMRT unit(s) at 8,000 equivalent treatment visits per unit.~~
 278 ~~—(iii) Special purpose unit(s) at 1,000 equivalent treatment visits per unit.~~ **FOR ANY APPLICATION**
 279 **PROPOSING TO ACQUIRE AN EXISTING MRT SERVICE, EXCEPT THE FIRST APPLICATION**
 280 **APPROVED PURSUANT TO SUBSECTION (1), AN APPLICANT SHALL BE REQUIRED TO**
 281 **DOCUMENT THAT THE MRT SERVICE TO BE ACQUIRED IS OPERATING IN COMPLIANCE WITH**
 282 **THE VOLUME REQUIREMENTS SET FORTH IN SECTION 11 OF THESE STANDARDS APPLICABLE**
 283 **TO AN EXISTING MRT SERVICE ON THE DATE THE APPLICATION IS SUBMITTED TO THE**
 284 **DEPARTMENT.**

285
 286 (3) An applicant proposing to renew a lease for an existing MRT unit shall demonstrate the renewal
 287 of the lease is more cost effective than replacing the equipment.

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

290
 291 Sec. 7. An applicant proposing to add a dedicated research MRT unit shall demonstrate the
 292 following:

293
 294 (1) The applicant is an existing MRT service.

295
 296 (2) The applicant agrees that the dedicated research MRT unit(s) will be used primarily (70% or more
 297 of treatments) for research purposes.

298
 299 (3) The dedicated research MRT unit(s) shall operate under a protocol approved by the applicant's
 300 Institutional Review Board (IRB), as defined by Public Law 93-348 and regulated by Title 45 CFR 46.

301
 302 (4) The applicant operates a therapeutic radiation residency program approved by the American
 303 Medical Association, the American Osteopathic Association, or an equivalent organization.

304
 305 (5) The proposed site can have no more than two dedicated research MRT units.

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

308
 309 Sec. 8. An applicant shall provide verification of Medicaid participation. An applicant that is a new
 310 provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided
 311 to the Department within six (6) months from the offering of services, if a CON is approved.

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

314
 315 Sec. 9. An applicant being reviewed under Section 3 shall apply the methodology set forth in this
 316 section in computing the projected number of equivalent treatment visits.

317
 318 (1) An applicant shall demonstrate that the projection is based on the commitments of the
 319 treatments provided by the treating physician(s) for the most recent 12-month period immediately
 320 preceding the date of the application. The commitments of the treating physician(s) will be verified with
 321 the data maintained by the Department through its "CON Annual Survey."

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

324
 325 (2) An applicant shall demonstrate that the projected number of commitments to be performed at the
 326 proposed site under subsection (1) are from an existing MRT service that is in compliance with the

327 volume requirements applicable to that service, and will continue to be in compliance with the volume
 328 requirements applicable to that service subsequent to the initiation of the proposed MRT service by an
 329 applicant. Only excess ETVs equal to or greater than what is being committed pursuant to this
 330 subsection may be used to document projections under subsection (1). In demonstrating compliance with
 331 this subsection, an applicant shall provide each of the following:

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

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

340 (Cc) The projected commitments are from an existing MRT service within the same planning
 341 area as the proposed MRT service.

342

343 Section 10. Equivalent treatment visits

344

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

346

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

349

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

353

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

357

TABLE 1
Equivalent Treatments

Treatment Visit Category	Non-Special Visit Weight	Special Visit Weight
Simple	1.00	
Intermediate	1.10	
Complex	1.25	
IMRT	2.00	
Total Body Irradiation	8.00	8.00
HMRT Therapy		5.00
Stereotactic radio-surgery/radio-therapy**	8.00	8.00
IORT (non-gamma knife and		20.00
cyber knife**)		
Gamma Knife**		8.00
IORT		20.00

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

~~*_After the first visit, each additional visit receives 2.5 additional equivalent treatment visits with a maximum of five visits per course of therapy.~~

~~**~~

~~**After the first isocenter, each additional isocenter receives 4_6 additional equivalent treatment visits.~~

~~THERE IS A MAXIMUM OF FIVE VISITS PER COURSE OF THERAPY.~~

358
359 (4) "Simple treatment visit" means a treatment visit involving a single treatment site, single treatment
360 field, or parallel opposed fields with the use of no more than simple blocks.

361
362 (5) "Intermediate treatment visit" means a treatment visit involving two separate treatment sites,
363 three or more fields to a single treatment site, or the use of special blocking.

364
365 (6) "Complex treatment visit" means a treatment visit involving three or more treatment sites,
366 tangential fields with wedges, rotational or arc techniques or other special arrangements, or custom
367 blocking.

368
369 (7) "IMRT treatment visit" means a visit utilizing only the computer controlled multi-leaf collimator part
370 of the CMS definition for IMRT.

371
372 (8) "Stereotactic treatment visit" means a visit involving the use of a stereotactic guiding device with
373 radiotherapy for the ablation of a precisely defined intracranial and/or extracranial tumor or lesion.

374
375 (9) "Intraoperative treatment visit" means a treatment visit where a dose of megavoltage radiation is
376 delivered to a surgically exposed neoplasm or cancerous organ/site using a dedicated unit.

377
378 (10) "Isocenter" means the virtual point in space about which the MRT unit operates and is placed at
379 the center of the tumor for the delivery of the radiation treatment.

380
381 (11) "Course of treatment" means the planned series of visits that compose a plan for treatment of one
382 or more cancer sites for a single patient.

383 384 **Section 11. Project delivery requirements terms of approval for all applicants**

385
386 Sec. 11. An applicant shall agree that, if approved, the MRT service, including all existing and
387 approved MRT units, shall be delivered in compliance with the following:

- 388
389 (1) Compliance with these standards.
- 390
391 (2) Compliance with the following quality assurance standards:
- 392 (a) An applicant shall assure that the MRT service is staffed and operated by physicians and/or
393 radiation therapists qualified by training and experience to operate the unit safely and effectively. The
394 Department shall consider it prima facie evidence if the applicant requires the equipment to be operated
395 by a physician who is board certified or board qualified in either radiation oncology or therapeutic
396 radiology, and/or a radiation therapist certified by the American Registry of Radiological Technologists
397 (ARRT) or the American Registry of Clinical Radiography Technologists (ARCRT). The applicant may
398 also submit, and the Department may accept, other evidence. An applicant approved to operate a
399 | dedicated stereotactic radiosurgery unit ~~or a gamma knife~~ has on the active medical staff a
400 neurosurgeon(s) trained in the special type of MRT unit being operated.
- 401 (b) An applicant shall have the following staff:
- 402 (i) One (1) full-time equivalent (FTE) board-certified or board-qualified physician trained in radiation
403 oncology for each 250 patients treated with MRT annually.
- 404 (ii) One (1) FTE board-certified or board-qualified radiation physicist, certified in therapeutic
405 radiologic physics, immediately available during hours of operation.
- 406 (iii) One (1) dosimetrist for every 300 patients treated with MRT annually.
- 407 (iv) Two (2) radiation therapists registered or eligible by the American Registry of Radiological
408 Technologists (ARRT), for every MRT unit per shift of operation (not including supervisory time).
- 409 (v) One (1) FTE program director who is a board-certified physician trained in radiation oncology who
410 may also be the physician required under subsection (i). The Department shall consider it prima facie

411 evidence as to the training of the physician(s) if the physician is board certified or board qualified in
 412 radiation oncology and/or therapeutic radiology.

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

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

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

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

439 (ii) An applicant shall submit evidence of accreditation by the American College of Radiology (ACR),
 440 ~~American Society for Radiation Oncology (ASRO)~~ or the American College of Radiation Oncology
 441 (ACRO) within the first three years of operation and continue to participate annually thereafter.

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

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

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

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

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

454 (k) The operation of and referral of patients to the MRT unit shall be in conformance with 1978 PA
 455 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

456

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

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

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

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

463 (ii) provide MRT services to an individual based on the clinical indications of need for the service,

464 and

465 (iii) maintain information by payor and non-paying sources to indicate the volume of care from each
 466 source provided annually. Compliance with selective contracting requirements shall not be construed as
 467 a violation of this term.

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

470
 471 (4) Compliance with the following monitoring and reporting requirements:

472 (a) Non-special MRT units and HMRT units shall be operating at a minimum average volume of
 473 8,000 Equivalent Treatment Visits per unit annually by the end of the third full year of operation, and
 474 annually thereafter. All special purpose MRT units shall be operating at a minimum average volume of
 475 1,000 equivalent treatment visits per special purpose unit by the end of the third full year of operation, and
 476 annually thereafter. An applicant shall not include any treatments conducted on a dedicated research
 477 MRT unit.

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

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

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

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

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

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

497 (iii) The treatments on a dedicated research MRT unit shall not be used for any volume purposes.
 498

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

501
 502 **Section 12. Effect on prior CON review standards; comparative reviews**

503
 504 Sec. 12. proposed projects reviewed under these standards shall not be subject to comparative
 505 review. These standards supersede and replace the CON Review Standards for MRT Services/Units
 506 approved by the CON Commission on ~~September 22, 2014~~ **MARCH 28, 2013** and effective ~~November 21,~~
 507 **2014** **MAY 24, 2013**.

508

APPENDIX A509
510
511
512
513**PLANNING AREAS BY COUNTY**

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

515
516
517
518
519

520
521
522**APPENDIX B**

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

523
524
525
526
527
528
529

Source:

65-75 F.R., p. 82238-37245 (December 27, 2000) (JUNE 28, 2000-2010)

Statistical Policy Office

Office of Information and Regulatory Affairs

United States Office of Management and Budget

Simulation Definition

- *Simulation is defined as the process whereby three-dimensional volumetric information is obtained about the patient's internal organs and external geometry obtained in the clinical treatment position. The collected data is used to recreate a three-dimensional virtual patient for tumor localization and organ segmentation to allow the design and calculation of radiation treatment plan for a target area, while minimizing the radiation delivered to the surrounding normal tissue.*

Respiratory Gating Background

- Some tumors, especially in the lung and abdomen, are not stationary and move with the patient's breathing.
- 4D-Simulation is used to capture this motion, along with the patient's breathing cycle. The breathing cycle and corresponding images are processed and split into 10 phases.
- The motion is studied and, if appropriate, the radiation treatment is planned based on just a few phases of the patient's breathing cycle.
- This spares the surrounding normal, healthy tissue that would have otherwise been in the radiation beam during treatment.

Respiratory Gating Background

- During treatment, the patient is placed in the treatment position, the patient's breathing cycle is captured and monitored during treatment. The radiation beam turns "on" and "off" during treatment as the tumor moves in and out of the beam.
- As a result, the clinician is able to target the moving tumor more precisely target and decrease the radiation dose to the surrounding normal tissue, improving treatment quality and decreasing side affects.
- The downside is that this takes MRT time and decreases the throughput on the unit.

Gating Definition

- Gating is the capturing and monitoring of the target's motion during radiation treatment and the modulation of the radiation beam by turning the radiation beam "on" and "off" or actively moving the radiation beam to track fiducial markers in order to more precisely deliver radiation to the target and/or decrease the radiation dose to the surrounding normal tissue.

Respiratory Gating MRT Time Study

- The time taken in the MRT room from setup to treatment completion was monitored over a 2 month period.
- The average time taken to capture the breathing cycle, image the patient with gated fluoro and/or gated images to correct setup errors, and treat the patients with a gated radiation beam was recorded. This time included setup time which would be the same as for a regular IMRT treatment.
- The average time taken to deliver the gated radiation treatment was 45 minutes (ranged from 40 – 55 minutes).

Respiratory Gating ETV Recommendation

- Since an IMRT treatment takes approximately 20 minutes, a gated radiation treatment takes over 2X as much as an IMRT time, decreasing the machine throughput by over 50%.
- Recommendation: Allow an add-on ETV weight of 2.0 for treatments delivered using Respiratory Gating motion management.