

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

Thursday October 2, 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
E. Michael Beck, Oaklawn Hospital
Tewfik Bichay, MD, Mercy Health-St. Mary's
Bruce Carl, MD, UAW Retiree Medical Benefits Trust
Praveen Dalmia, McLaren Health Care
James A. Hayman, MD, University of Michigan Health System (UMHS)
Christine Kupovits, Oakwood Healthcare, Inc.
Michael Mahacek, MD, Spectrum Health
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:

Joseph Delikat, Chrysler Group, LLC
Jeffery Forman, MD, 21st Century Oncology
Robert Evans, the International UAW Aerospace and Agriculture
Implement Workers of America
James George-Herman, MD, Sparrow Health System

C. Michigan Department of Community Health Staff present:

Scott Blakeney
Natalie Kellogg

Beth Nagel
Tania Rodriguez
Brenda Rogers
Matt Weaver

II. Declaration of Conflicts of Interests

No conflicts were declared.

III. Review of Minutes August 28, 2014

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

IV. Review of Agenda

Motion by Dr. Siddiqui and seconded by Dr. Mahacek to accept the agenda as presented. Motion Carried.

V. Charge 1 - Update and clarify the definition of a “special purpose MRT unit” to reflect new technologies

Dr. Chuba provided an overview of the proposed changes to the MRT Review Standards that address charge number one (see Attachment A). Dr. Dalmia and Dr. Bichay will draft specific language to further refine the definition of “simulation.”

Motion by Dr. Bichay and seconded by Dr. Siddiqui to approve the changes outlined by Dr. Chuba related to charge number one specifically an update to the definition of “Megavoltage radiation therapy” and the insertion of a definition of “Dedicated Stereotactic Radiosurgery.” Motion Carried. Motion by Dr. Dalmia and seconded by Dr. Bichay to approve the language addition within Section (4)(1)(a) modified as follows: Add “replacing a non-special purpose unit or a special purpose unit” at the end of Section 4(1)(a); and move the new language presented under Section 4(2)(b)(iv) to Section 4(1)(d). Motion Carried.

VI. Charge 2 - Review and revise the current definition and use of a “Cyber Knife”

Dr. Chuba provided an overview of the proposed changes to the MRT Review Standards that address charge number two (see Attachment A).

Motion by Ms. Kuptovits and seconded by Dr. Siddiqui to approve the addition of “medically necessary” to the definition of “Equivalent Treatment

Visits” definition and delete the definitions of Cyber knife and Gamma knife.
Motion Carried.

Motion by Dalmia to maintain weight of 8.0 for all stereotactic radio-surgery/radio-therapy with an equal weight of 8.0 for additional, and each additional isocenter receives 4 ETVs. Motion Failed Due to Lack of a Second.

Motion by Dr. Hayman and seconded by Dr. Siddiqui to remove gamma knife and non-gamma knife from Table 1 listed in Section 10, remove the text in the first asterisk under the table, maintain a weight of 8.0 for all stereotactic radio-surgery and change the number of ETVs to 6 for each additional isocenter after the first isocenter with a maximum of 5 visits per course of therapy.
Motion Carried.

Motion by Dr. Siddiqui and seconded by Dr. Bichay to accept and keep all other current weighting in Table 1 in Section 10 the same. Motion Carried.

VII. Charge 3 - Determine and add language that addresses the expansion of more than one special purpose MRT unit

Dr. Chuba provided an overview of the proposed changes to the MRT Review Standards that address charge number three (see Attachment A) specifically addressing the number of ETV’S that need to be performed within the most recent 12-month period on each of the applicant’s existing and approved special purpose MRT units. The MRT SAC concurred.

VIII. Charge 6 - Consider any technical or other changes from the Department e.g., updates or modifications consistent with other CON review standards and the Public Health Code

Motion by Dr. Hayman and seconded by Dr. Siddiqui to accept the technical changes proposed by the Department in regards to the updating of the rural, micropolitan, and metropolitan statistical area counties given to the Department by the state demographer. Motion Carried.

Motion by Dr. Mahacek and seconded by Dr. Siddiqui to remove the language in the standards in Section 5(2)(c). Motion Carried.

IX. Charge 4 - Consider methodologies of need that utilize patient residence data

Mr. Beck stated that no changes are being recommended at this time to the MRT Review Standards that address charge number four regarding methodologies of need that utilize patient residence data.

Ms. Nagel provided an overview of the report received from Michigan State University (MSU) regarding “Mastectomies and MRT Access.”

Discussion followed.

X. Charge 5 - Develop specific measurable quality metrics in the project delivery requirements

Motion by Dr. Hayman and seconded by Dr. Siddiqui to amend the language in Section 11(2)(e)(ii): An applicant shall submit evidence of accreditation by the American College of Radiology (ACR), American Society of Radiation Oncology (ASTRO) or the American College of Radiation Oncology (ACRO). Motion Carried.

XI. Public Comment

Dennis MCCafferty, Economic Alliance of Michigan (EAM)

XII. Future Meeting Dates - November 6, 2014, and December 17, 2014.

Chairperson Chuba stated the following topics for the next meeting on November 6, 2014:

1. First acquisition language
2. Weight for respiratory gating
3. Collection of data for the future

XIII. Adjournment

Motion by Dr. Hayman and seconded by Dr. Dalmia to adjourn the meeting at 12:16 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) "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).

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

~~(i) "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.~~

(j) "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.

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

55 | (~~KJ~~) "Intensity modulated radiation therapy" or "IMRT" means a visit utilizing only the computer
56 | controlled multi-leaf collimator part of the CMS definition for IMRT.

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

60 | (~~ML~~) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6
61 | and 1396r-8 to 1396v.

62 | (~~PM~~) "Megavoltage radiation therapy" or "MRT" means a clinical modality in which patients
63 | with cancer, other neoplasms, ~~or~~ cerebrovascular system abnormalities, AND CERTAIN BENIGN
64 | CONDITIONS, are treated with radiation which is delivered by a MRT unit.

65 | (~~PN~~) "MRT service" means the CON approved MRT utilization of a MRT unit(s) at one
66 | geographic location.

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

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

74 | (~~Q~~) "Non-special MRT unit" or "non-special unit" means an MRT unit other than an MRT unit meeting
75 | the definition of a special purpose MRT unit or an HMRT unit.

76 | (~~SR~~) "Simulation" means the precise mock-up of a patient treatment with an apparatus that
77 | uses a diagnostic x-ray tube, MRI, OR CT, and WHICH IS DEDICATED TO USE IN duplicates
78 | DUPLICATING an MRT unit in terms of its geometrical, AND/OR mechanical, and optical properties.

79 | (~~S~~) "Special purpose MRT unit" or "special purpose unit" or "special unit" means any of the following
80 | types of MRT units: ~~(i) gamma-knife,~~ ~~(iii)~~ dedicated stereotactic radiosurgery unit, ~~(iii)~~ dedicated total
81 | body irradiator (TBI), (iv) OR an OR-based IORT unit, ~~or (v) cyber-knife.~~

82 | (UT) "DEDICATED STEREOTACTIC RADIOSURGERY UNIT MEANS AN MRT UNIT OR A
83 | DEDICATED COBALT UNIT FOR WHICH MORE THAN 90 PERCENT OF CASES WILL BE TREATED
84 | WITH ONE TO FIVE TREATMENTS"

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

89 | (~~WV~~) "Treatment site" means the anatomical location of the MRT treatment.

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

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

96 | Section 3. Requirements to initiate an MRT service

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.

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.

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

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

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

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

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

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

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

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

194
 195 (1) An applicant proposing to replace an existing MRT unit(s) shall demonstrate the following:

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

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

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

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

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

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

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

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

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

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

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

215 ~~(IV) THE SITE TO WHICH A SPECIAL PURPOSE UNIT IS REPLACED MUST ALSO OPERATE A~~
 216 ~~NON-SPECIAL PURPOSE UNIT. _____~~

- 217
- 218 (3) An applicant proposing to replace an MRT unit(s) of an existing MRT service to a new site shall
- 219 demonstrate the following:
- 220 (a) The applicant is the same legal entity as the existing MRT service.
- 221 (b) For volume purposes, the new site shall remain associated with the existing MRT service for a
- 222 minimum of three years.
- 223 (c) The MRT unit(s) to be relocated is a non-special MRT unit(s).
- 224 (d) The existing non-special MRT unit(s) of the MRT services from where the unit is being relocated
- 225 from shall be operating at a minimum average volume of 8,000 equivalent treatment visits per unit-
- 226 (e) The proposed site meets the requirements of Section 3(45).
- 227 (f) The proposed site is within the same planning area as the existing MRT service site.
- 228 (g) The existing MRT service has been in operation for at least 36 months as of the date the
- 229 application was submitted to the Department.

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

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

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

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

242 (a) An average of 8,000 equivalent treatment visits was performed in the most recent 12-month
243 period on each of the applicant's existing and approved non-special MRT units **AND AN AVERAGE OF**
244 **1000 EQUIVALENT TREATMENT VISITS WAS PERFORMED IN THE MOST RECENT 12-MONTH**
245 **PERIOD ON EACH OF THE APPLICANT'S EXISTING AND APPROVED SPECIAL PURPOSE MRT**
246 **UNITS.**

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

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

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

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

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

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

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270 (2) **an applicant proposing to acquire an existing MRT service shall demonstrate the following:**

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272 (a) The existing MRT unit(s) shall be operating at the following volumes, as applicable to the
 273 proposed project:
 274 (i) Non-special MRT unit(s) at 8,000 equivalent treatment visits per unit or 5,500 for a unit approved
 275 under Section 3(2) or 3(3).
 276 (ii) HMRT unit(s) at 8,000 equivalent treatment visits per unit.
 277 (iii) Special purpose unit(s) at 1,000 equivalent treatment visits per unit. FOR ANY APPLICATION
 278 PROPOSING TO ACQUIRE AN EXISTING MRT SERVICE, EXCEPT THE FIRST APPLICATION
 279 APPROVED PURSUANT TO SUBSECTION (1), AN APPLICANT SHALL BE REQUIRED TO
 280 DOCUMENT THAT THE MRT SERVICE TO BE ACQUIRED IS OPERATING IN COMPLIANCE WITH
 281 THE VOLUME REQUIREMENTS SET FORTH IN SECTION 9 OF THESE STANDARDS APPLICABLE
 282 TO AN EXISTING MRT SERVICE ON THE DATE THE APPLICATION IS SUBMITTED TO THE
 283 DEPARTMENT.

284
 285 (3) An applicant proposing to renew a lease for an existing MRT unit shall demonstrate the renewal
 286 of the lease is more cost effective than replacing the equipment.

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

288
 289 Sec. 7. An applicant proposing to add a dedicated research MRT unit shall demonstrate the
 290 following:

- 291
 292 (1) The applicant is an existing MRT service.
 293
 294 (2) The applicant agrees that the dedicated research MRT unit(s) will be used primarily (70% or more
 295 of treatments) for research purposes.
 296
 297 (3) The dedicated research MRT unit(s) shall operate under a protocol approved by the applicant's
 298 Institutional Review Board (IRB), as defined by Public Law 93-348 and regulated by Title 45 CFR 46.
 299
 300 (4) The applicant operates a therapeutic radiation residency program approved by the American
 301 Medical Association, the American Osteopathic Association, or an equivalent organization.
 302
 303 (5) The proposed site can have no more than two dedicated research MRT units.
 304
 305

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

307
 308 Sec. 8. An applicant shall provide verification of Medicaid participation. An applicant that is a new
 309 provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided
 310 to the Department within six (6) months from the offering of services, if a CON is approved.
 311

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

313
 314 Sec. 9. An applicant being reviewed under Section 3 shall apply the methodology set forth in this
 315 section in computing the projected number of equivalent treatment visits.

- 316
 317 (1) An applicant shall demonstrate that the projection is based on the commitments of the
 318 treatments provided by the treating physician(s) for the most recent 12-month period immediately
 319 preceding the date of the application. The commitments of the treating physician(s) will be verified with
 320 the data maintained by the Department through its "CON Annual Survey."
 321 (a) For the purposes of this section, treating physician means the staff physician of the MRT service
 322 directing and providing the MRT treatment, not the referring physician.
 323
 324 (2) An applicant shall demonstrate that the projected number of commitments to be performed at the
 325 proposed site under subsection (1) are from an existing MRT service that is in compliance with the
 326 volume requirements applicable to that service, and will continue to be in compliance with the volume

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

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

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

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

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342 Section 10. Equivalent treatment visits

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

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

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

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

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 356

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* (non-gamma knife and cyber knife**)	8.00	8.00
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 additional equivalent treatment visits.

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

- 360
361 (5) "Intermediate treatment visit" means a treatment visit involving two separate treatment sites,
362 three or more fields to a single treatment site, or the use of special blocking.
363
364 (6) "Complex treatment visit" means a treatment visit involving three or more treatment sites,
365 tangential fields with wedges, rotational or arc techniques or other special arrangements, or custom
366 blocking.
367
368 (7) "IMRT treatment visit" means a visit utilizing only the computer controlled multi-leaf collimator part
369 of the CMS definition for IMRT.
370
371 (8) "Stereotactic treatment visit" means a visit involving the use of a stereotactic guiding device with
372 radiotherapy for the ablation of a precisely defined intracranial and/or extracranial tumor or lesion.
373
374 (9) "Intraoperative treatment visit" means a treatment visit where a dose of megavoltage radiation is
375 delivered to a surgically exposed neoplasm or cancerous organ/site using a dedicated unit.
376
377 (10) "Isocenter" means the virtual point in space about which the MRT unit operates and is placed at
378 the center of the tumor for the delivery of the radiation treatment.
379
380 (11) "Course of treatment" means the planned series of visits that compose a plan for treatment of one
381 or more cancer sites for a single patient.

382
383 **Section 11. Project delivery requirements terms of approval for all applicants**

384
385 Sec. 11. An applicant shall agree that, if approved, the MRT service, including all existing and
386 approved MRT units, shall be delivered in compliance with the following:

- 387 (1) Compliance with these standards.
388
389 (2) Compliance with the following quality assurance standards:
390 (a) An applicant shall assure that the MRT service is staffed and operated by physicians and/or
391 radiation therapists qualified by training and experience to operate the unit safely and effectively. The
392 Department shall consider it prima facie evidence if the applicant requires the equipment to be operated
393 by a physician who is board certified or board qualified in either radiation oncology or therapeutic
394 radiology, and/or a radiation therapist certified by the American Registry of Radiological Technologists
395 (ARRT) or the American Registry of Clinical Radiography Technologists (ARCRT). The applicant may
396 also submit, and the Department may accept, other evidence. An applicant approved to operate a
397 dedicated stereotactic radiosurgery unit or a gamma knife has on the active medical staff a
398 neurosurgeon(s) trained in the special type of MRT unit being operated.
399 (b) An applicant shall have the following staff:
400 (i) One (1) full-time equivalent (FTE) board-certified or board-qualified physician trained in radiation
401 oncology for each 250 patients treated with MRT annually.
402 (ii) One (1) FTE board-certified or board-qualified radiation physicist, certified in therapeutic
403 radiologic physics, immediately available during hours of operation.
404 (iii) One (1) dosimetrist for every 300 patients treated with MRT annually.
405 (iv) Two (2) radiation therapists registered or eligible by the American Registry of Radiological
406 Technologists (ARRT), for every MRT unit per shift of operation (not including supervisory time).
407 (v) One (1) FTE program director who is a board-certified physician trained in radiation oncology who
408 may also be the physician required under subsection (i). The Department shall consider it prima facie
409 evidence as to the training of the physician(s) if the physician is board certified or board qualified in
410 radiation oncology and/or therapeutic radiology.
411 (c) All MRT treatments shall be performed pursuant to a radiation oncologist and at least one
412 radiation oncologist will be immediately available during the operation of the unit(s).
413

- 414 (d) An applicant shall have equipment and supplies to handle clinical emergencies that might occur.
 415 Staff will be trained in CPR and other appropriate emergency interventions and shall be on-site in the
 416 MRT unit at all times when patients are treated. A physician shall be on-site or immediately available to
 417 the MRT unit at all times when patients are treated.
- 418 (e) An applicant shall operate a cancer treatment program. The Department shall consider it prima
 419 facie evidence if the applicant submits evidence of a cancer treatment program approved by the
 420 American College of Surgeons Commission on Cancer. A cancer treatment program is a coordinated,
 421 multi-disciplinary approach to the treatment of patients with cancer or other neoplasms, which must
 422 provide on-site simulation capability, and, either on-site or through written agreements with other
 423 providers, all of the following services: access to consultative services from all major disciplines needed
 424 to develop a comprehensive treatment plan, a computer-based treatment planning system, medical
 425 radiation physicist involvement, MRT capability including electron beam capability, treatment aid
 426 fabrication capability, brachytherapy, a multi-disciplinary cancer committee, a tumor registry, patient care
 427 evaluation studies, and cancer prevention and education programs. The applicant may also submit, and
 428 the Department may accept, other evidence. Patient care evaluation studies means a system of patient
 429 care evaluation, conducted at least twice annually, that documents the methods used to identify problems
 430 and the opportunities to improve patient care. Tumor registry means a manual or computerized data
 431 base containing information about all malignancies and only those that are diagnosed and/or treated at
 432 the applicant's facility. The malignancies must be reportable to the Michigan Cancer Surveillance
 433 Program as required pursuant to Public Act 82 of 1984, as amended.
- 434 (i) An applicant shall submit evidence of accreditation by the American College of Surgeons
 435 Commission on cancer, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO),
 436 or the Healthcare Facilities Accreditation Program (HFAP) within the first three years of operation and
 437 continue to participate annually thereafter.
- 438 (ii) An applicant shall submit evidence of accreditation by the American College of
 439 Radiology/American Society for Radiation Oncology (ACR/ASTRO) or the American College of Radiation
 440 Oncology (ACRO) within the first three years of operation and continue to participate annually thereafter.
- 441 (f) The MRT service will have simulation capability at the same location.
- 442 (g) An applicant shall participate in the Michigan Cancer Surveillance Program.
- 443 (h) The applicant agrees to operate a special purpose MRT unit(s) only for the specific use for which
 444 it was approved.
- 445 (i) An applicant approved to operate a dedicated total body irradiator that uses cobalt as the source
 446 of radiation shall obtain and maintain Nuclear Regulatory Commission certification. An applicant
 447 approved to operate a dedicated total body irradiator that is a permanently modified linear accelerator, or
 448 an HMRT unit, shall meet any requirements specified by the State of Michigan Radiation Safety Section.
- 449 (j) All patients treated on an HMRT unit shall be evaluated for potential enrollment in research
 450 studies focusing on the applicability and efficacy of utilizing an HMRT unit for treatment of specific cancer
 451 conditions. The number of patients treated, number enrolled in research studies, and the types of cancer
 452 conditions involved shall be provided to the Department as part of the CON Annual Survey.
- 453 (k) The operation of and referral of patients to the MRT unit shall be in conformance with 1978 PA
 454 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).
- 455
- 456 (3) Compliance with the following access to care requirements:
- 457 (a) The applicant shall accept referrals for MRT services from all appropriately licensed health care
 458 practitioners.
- 459 (b) To assure that the MRT service and its unit(s) will be utilized by all segments of the Michigan
 460 population, the applicant shall:
- 461 (i) not deny MRT services to any individual based on ability to pay or source of payment,
 462 (ii) provide MRT services to an individual based on the clinical indications of need for the service,
 463 and
- 464 (iii) maintain information by payor and non-paying sources to indicate the volume of care from each
 465 source provided annually. Compliance with selective contracting requirements shall not be construed as
 466 a violation of this term.
- 467 (c) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years
 468 of operation and continue to participate annually thereafter.

- 469
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 (5) The applicable agreements and assurances required by this section shall be in the form of a
499 certification agreed to by the applicant or its authorized agent.

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

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

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512**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 Griiot	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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521**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	

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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
Gratiot	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

Source:

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

Statistical Policy Office

Office of Information and Regulatory Affairs

United States Office of Management and Budget

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