

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

Wednesday July 30, 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 9:33 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
Robert Evans, the International UAW Aerospace and Agriculture
Implement Workers of America
Jeffery Forman, MD, 21st Century Oncology
James A. Hayman, MD, University of Michigan Health System (UMHS)
James George-Herman, MD, Sparrow Health System
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

C. Michigan Department of Community Health Staff present:

Tulika Bhattacharya
Natalie Kellogg
Beth Nagel

Tania Rodriguez
Brenda Rogers
Matt Weaver

II. Introduction of Members & Staff

Introductions were made.

III. Declaration of Conflicts of Interests

Chairperson Chuba gave a brief summary of the declaration of conflicts of interests (see Attachment A).

No conflicts were declared.

IV. Review of Agenda

Motion by Dr. Foreman and seconded by Dr. Herman to approve the agenda as presented. Motion Carried.

V. Basic CON Review

Ms. Rogers gave a brief review of the CON Process (see Attachment B).

VI. Overview of Current MRT Programs in Michigan

Mr. Weaver and Ms. Moore gave a brief overview of the current MRT programs and data from the CON Annual Survey (see Attachment C).

VII. Review and Discussion of Charge

Chairperson Chuba gave a review of the charge (see Attachment D).

Sub-Committees:

Charges 1-3: Ms. Somnay, Dr. Hayman, Dr. Bichay, Ms. Kupovits, Ms. Dalmia, and Dr. Parker.

Charge 4- Mr. Beck, Dr. Bichay, Dr. Herman, and Dr. Mahacek.

VIII. Background Material

Chairperson Chuba explained that the items within the electronic binder were for the SAC members to review on their own time and was not pertinent to the discussion at the moment.

IX. Public Comment

Dennis McCafferty, Economic Alliance for Michigan (EAM)

X. Next Steps and Future Agenda Items

Chairperson Chuba reviewed items for the next meeting as follows:

A. Data presentations

1. Breakout of MRT equivalents data
2. Number of patients treated per unit
3. Results from the 2013 CON Annual Survey for questions 39 and 40 regarding accreditation

B. Comparison of how service areas are defined in other CON review standards

C. Subcommittee 1 (Charge #4) update

D. Subcommittee 2 (Charges #1 – 3) update

XI. Future Meeting Dates - August 28, 2014, October 2, 2014, October 30, 2014, November 6, 2014, and December 17, 2014.

XII. Adjournment

Motion by Dr. Herman and seconded by Dr. Siddiqui to adjourn the meeting at 11:57 a.m. Motion Carried.

EXCERPT FROM CON COMMISSION BYLAWS
ARTICLE IX – CONFLICT OF INTEREST PROVISIONS

B. Definition - Conflict of Interest

1. Under the State Ethics Act, 1973 PA 196, MCL 15.341, et seq, and in accordance with the Advisory Opinion of the State Board of Ethics of November 5, 2004, a conflict of interest for Commission members exists when the individual member has a financial or personal interest in a matter under consideration by the Commission. The personal interest of a Commission member includes the interest of the member's employer, even though the member may not receive monetary or pecuniary remuneration as a result of an adopted CON review standard.
2. A Commission member does not violate the State Ethics Act if the member abstains from deliberating and voting upon the matter in which the member's personal interest is involved.
3. A Commission member may deliberate and vote on matters of general applicability that do not exclusively benefit certain health care facilities or providers who employ the Commission member, even if the matter involves the member's employer or those for whom the member's employer does work.
4. Deliberating includes all discussions of the pertinent subject matter, even before a motion being made.

C. Procedures - Conflict of Interest

1. A Commission member must disclose any potential conflict of interest after the start of a meeting, when the Commission begins to consider a substantive matter, or, where consideration has already commenced, when a conflict or potential conflict of interest becomes apparent to the member.
2. After a meeting is called to order and the agenda reviewed, the chairperson must inquire whether any Commission member has a conflict or potential conflict of interest with regard to any matters on the agenda.
3. A Commission member who is disqualified from deliberating and voting on a matter under consideration due to a conflict of interest may not be counted to establish a quorum regarding that particular matter.
4. Where a Commission member has not discerned any conflict of interest, any other Commission member may raise a concern whether another member has a conflict of interest on a matter. If a second member joins in the concern, the Commission must discuss and vote on whether the member has a conflict of interest before continuing discussion or taking any action on the matter under consideration. The question of conflict of interest is settled by an affirmative vote of a majority of those Commission members appointed and serving, excluding the member or members in question.
5. The minutes of the meeting must reflect when a conflict of interest had been determined and that an abstention from deliberation and voting had occurred.

**Basics of Certificate of Need
(CON)
MRT SAC
July 30, 2014**



Certificate of Need Federal Background

Attachment B

- The District of Columbia and New York developed CON programs in 1964 in an effort to contain rising health care costs.
- Federally mandated CON programs were established in 1974 as a national health care cost containment strategy.



Certificate of Need Federal Background

Attachment B

- The federal mandate for CON was not renewed by the U.S. Congress in 1986.
- CON regulations are structured, in principle, to improve access to quality health care services while containing costs. Health care organizations are required to demonstrate need before investing in a regulated facility, service or equipment.

Michigan CON Background Attachment B

- Public Act 368 of 1978 mandated the Michigan Certificate of Need (CON) Program.
- The CON Reform Act of 1988 was passed to develop a clear, systematic standards development system and reduce the number of services requiring a CON.

CON Commission

- Members appointed by Governor
 - Three year terms
 - No more than six from either political party
 - Responsible for developing and approving CON review standards w/legislative oversight
- Public Act 619 of 2002 made several modifications.
 - Expanded the Commission from 5 to 11
 - Key stakeholders are now represented on the Commission (e.g., physicians)

What is Covered by the CON Program?

Attachment B

The following projects must obtain a CON:

- Increase in the number or relocation of licensed beds
- Acquisition of an existing health facility
- Operation of a new health facility
- Initiation, replacement, or expansion of covered clinical services



Capital expenditure projects (i.e., construction, renovation) must obtain a CON if the projects meet the following threshold:

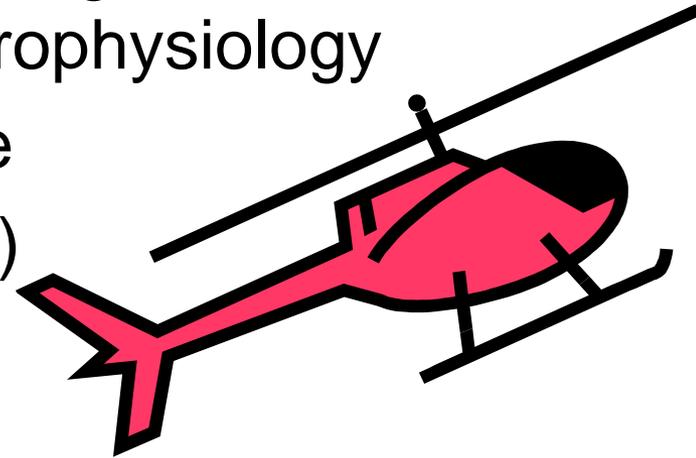
- \$3,160,000 for clinical service areas (January 2014)

Note: Threshold is indexed annually by the Department based on the Consumer Price Index.

Categories That Require CON Approval

Attachment B

- Air ambulances (helicopters)
- Cardiac catheterization, including diagnostic, therapeutic, angioplasty, and electrophysiology
- Hospital beds – general acute care
- Magnetic resonance imaging (MRI)
- Megavoltage radiation therapy
- Neonatal intensive care units
- Nursing home/hospital long-term care beds
- Urinary lithotripters



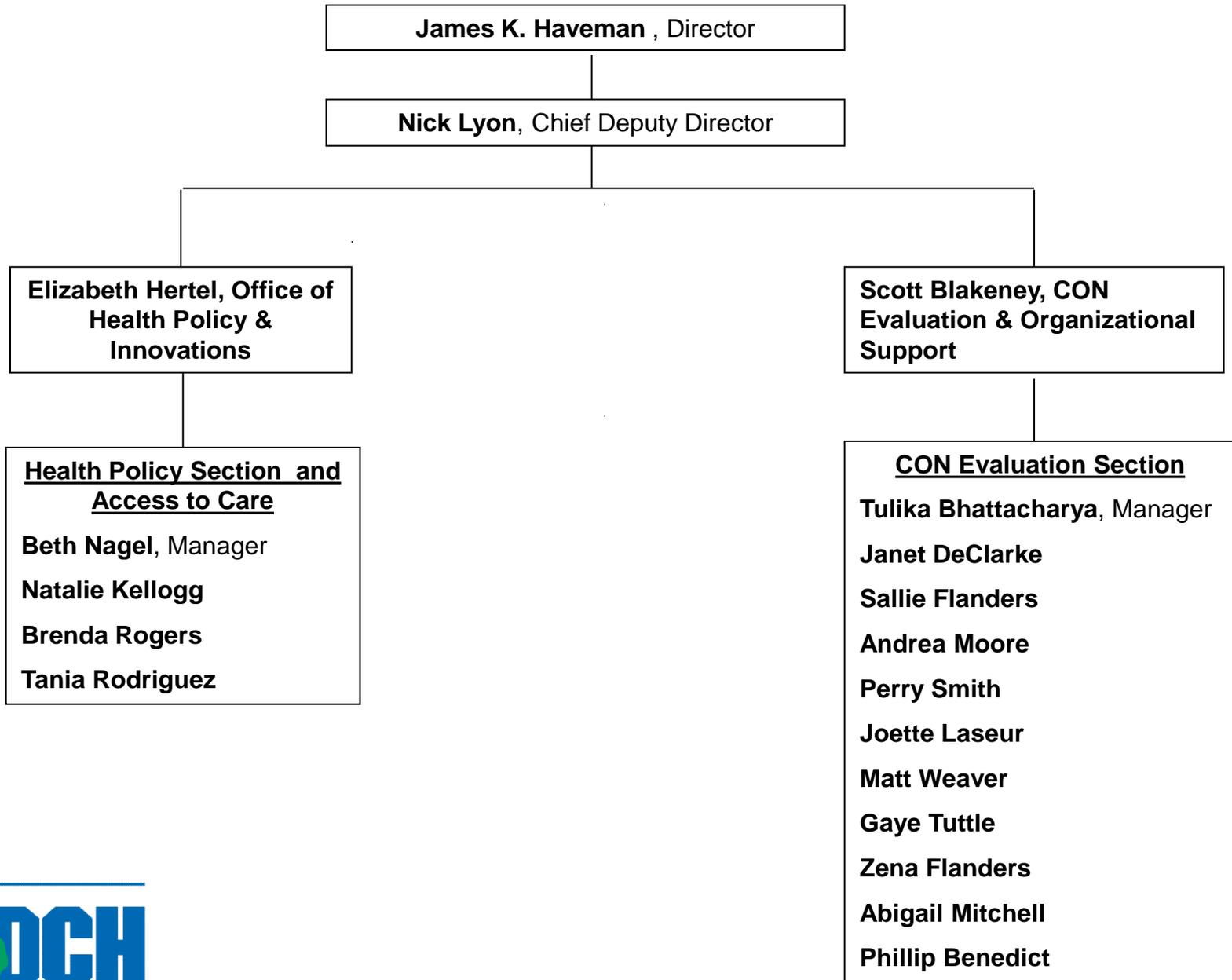
Categories That Require CON Approval

Attachment B

- Open heart surgery
- Positron Emission Tomography (PET)
- Psychiatric beds – acute inpatient
- Surgical services – hospital and free-standing
- Transplantation services – bone marrow, including peripheral stem cell, heart-lung, liver, and pancreas
- Computed tomography (CT) scanners

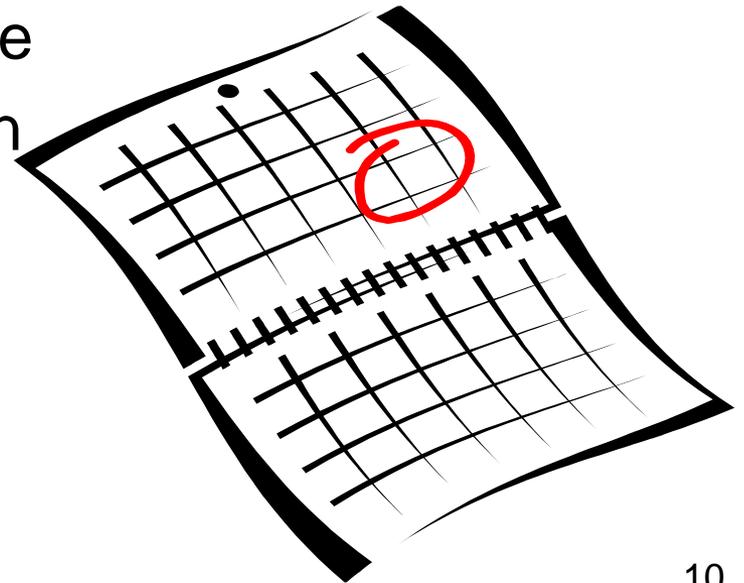


MDCH CON Org Chart



The CON Process

1. Applicant files letter of intent
2. Applicant files completed application
3. Department reviews application
4. Applicant has 15 days to submit information to DCH
5. DCH determines the review type
6. Proposed decision issued within deadlines for each review type
 - Nonsubstantive – 45 days
 - Substantive – 120 days
 - Comparative – 150 days



CON Process Continued...

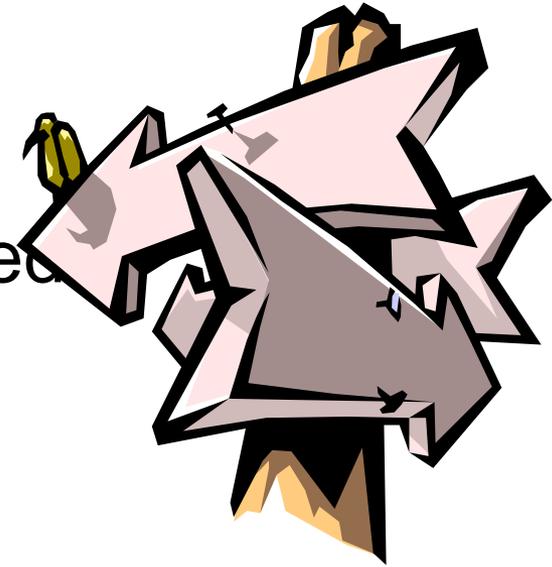
7. Proposed decision approved

8. Proposed decision not approved

9. Hearing is not requested

10. Hearing is requested

11. DCH Director makes final decision



Statutory Authority for Review of Standards

Attachment B

- MCL 22215(1)(m) requires that standards be reviewed, and revised if necessary, every 3 years. Statute also requires that the Commission “If determined necessary by the Commission, revise, add to, or delete 1 or more of the covered clinical services listed in section 22203....” [MCL 22215(1)(a)]



Statutory Authority for Review of Standards Continued

Attachment B

- MCL 22215(1)(n) states “If a standard advisory committee is not appointed by the commission and the commission determines it necessary, submit a request to the department to engage the services of private consultants or request the department to contract with any private organization for professional and technical assistance and advice or other services to assist the commission in carrying out its duties and functions under this part.”

Standard Advisory Committee (SAC) Responsibility

Attachment B

- Public Health Code, Act 368 of 1978
 - MCL 333.22215 “...(1)(I) If the Commission determines it necessary, appoint standard advisory committees to assist in the development of proposed certificate of need review standards. A standard advisory committee shall complete its duties under this subdivision and submit its recommendations to the Commission within 6 months unless a shorter period of time is specified by the Commission when the standard advisory committee is appointed....”

Development of the Charge

- Public Comment Period in October
- Acceptance of written comments/testimony by MDCH on behalf of the Commission
- Commission members and MDCH staff review all of the comments/testimony received
- Recommendations offered to the Commission by the MDCH
- CON Commission develops and approves the final charge to the SAC

**MRT STANDARDS SERVICES/UNITS
STANDARD ADVISORY COMMITTEE (SAC) DRAFT CHARGE**

**Approved by the CON Commission Chairperson as Delegated by the CON Commission on
January 28, 2014**

At a minimum, the Megavoltage Radiation Therapy Services/Units SAC should consider reviewing and recommending any necessary changes to the Cardiac Catheterization Services Standards regarding the following:

1. Update and clarify the definition of a “special purpose MRT unit” to reflect new technologies.
2. Review and revise the current definition and use of a “Cyber Knife.”
3. Determine and add language that addresses the expansion of more than one special purpose MRT unit.
4. Consider methodologies of need that utilize patient residence data.
5. Develop specific measurable quality metrics in the project delivery requirements.
4. 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.

SAC Operations

- Operates using modified Roberts' Rules
- Subject to Open Meeting Act; including public comment period which is placed on the agenda
- The Chair or a designee (SAC member) appointed by the Chair can run the meeting
- A physical quorum is necessary to conduct business
- Although SAC members may participate by phone; phone participation is not included in the quorum count or a vote
- A quorum is defined as a majority of the members appointed and serving
- If a quorum of the SAC members is present at any gathering, this becomes a public meeting
- Final recommendations are made by the SAC to the CON Commission. The SAC presents a written report and/or final draft language.

CON Commission Action

- Commission receives final report of the SAC
- Determines what proposed action will be taken based upon SAC recommendations



Legislative Oversight of Proposed Changes to CON Standards

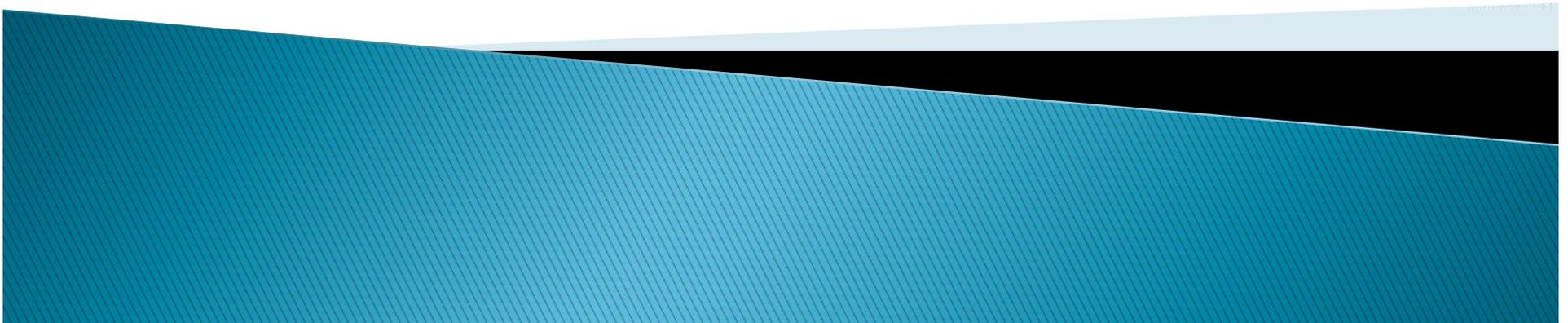
- Any potential changes to existing standards are required to be reviewed by the Joint Legislative Committee (JLC)
- The JLC includes the chairs of the health policy committees from both the Senate and the House of Representatives
- After the CON Commission has take proposed action and no less than 30 days prior to the Commission taking final action, a Public Hearing is conducted by the Commission
- Notice of the proposed action, along with a brief summary of the impact of any changes, is provided and sent to the JLC for its review

.....Legislative Oversight Continued

- Upon the Commission taking final action, the JLC and the Governor are provided notice of the proposed final action as well as a brief summary of the impact of any changes that have been proposed by the CON Commission
- The JLC and Governor have a 45-day review period to disapprove the proposed final action. Such 45-day review period shall commence on a legislative session day and must include 9 legislative session days
- If the proposed final action is not disapproved, then it becomes effective upon the expiration of the 45-day review period or on a later date specified in the proposed final action

Megavoltage Radiation Therapy (MRT) Standard Advisory Committee

Overview of CON Review Standards & Survey Data
Matt Weaver & Andrea Moore
CON Evaluation Section



MRT Services / Units

- ▶ "Megavoltage radiation therapy" or "MRT" means a clinical modality in which patients with cancer, other neoplasms, or cerebrovascular system abnormalities are treated with radiation which is delivered by a MRT unit.
 - ▶ "MRT unit" or "unit" means a CON approved linear accelerator; cobalt unit; or other piece of medical equipment operating at an energy level equal to or greater than 1.0 million electron volts (megavolts or MEV) for the purpose of delivering doses of radiation to patients with cancer, other neoplasms, or cerebrovascular system abnormalities.
 - ▶ "Non-special MRT unit" or "non-special unit" means an MRT unit other than an MRT unit meeting the definition of a special purpose MRT unit or an HMRT unit.
 - ▶ "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).
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MRT Services / Units

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

** An applicant proposing to initiate a special purpose unit must currently operate a non-special MRT unit(s).



Types of MRT Visits

Visit Category	Non-Special Visit Wt.	Special Visit Wt.
Simple	1.00	–
Intermediate	1.10	–
Complex	1.25	–
IMRT	2.00	–
Total Body Irradiation	8.00	8.00
HMRT Therapy	–	5.00
Stereotactic Radiourgery/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.

Types of MRT Visits

- ▶ “Simple treatment visit” means a treatment visit involving a single treatment site, single treatment field, or parallel opposed fields with the use of no more than simple blocks.
 - ▶ “Intermediate treatment visit” means a treatment visit involving two separate treatment sites, three or more fields to a single treatment site, or the use of special blocking.
 - ▶ “Complex treatment visit” means a treatment visit involving three or more treatment sites, tangential fields with wedges, rotational or arc techniques or other special arrangements, or custom blocking.
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Types of MRT Visits

- ▶ "IMRT treatment visit" means a visit utilizing only the computer controlled multi-leaf collimator part of the CMS definition for IMRT.
- ▶ "Stereotactic treatment visit" means a visit involving the use of a stereotactic guiding device with radiotherapy for the ablation of a precisely defined intracranial and/or extracranial tumor or lesion.
- ▶ "Intraoperative treatment visit" (IORT) means a treatment visit where a dose of megavoltage radiation is delivered to a surgically exposed neoplasm or cancerous organ/site using a dedicated unit.



MRT Survey Data (CY2013)

- ▶ 69 facilities provide MRT services
 - 30 MRT services are hospital based
 - 39 MRT services are freestanding

 - ▶ 124 MRT units in Michigan
 - 117 Linear Accelerators
 - 3 Gamma Knives
 - 3 Cyber Knives
 - 1 High MRT

 - ▶ 940,930 MRT equivalents were completed on the 124 MRT units
 - 913,316 non-special MRT visits
 - 27,614 special MRT visits
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Questions

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MEGAVOLTAGE RADIATION THERAPY (MRT) SERVICES/UNITS STANDARDS

STANDARD ADVISORY COMMITTEE (SAC) DRAFT CHARGE

Approved by the CON Commission Chairperson as Delegated by the CON Commission on January 28, 2014

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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.