

Notice of Public Hearing

Pursuant to Section 22215 of Public Act 368 of 1978, as amended, the Michigan Department of Health and Human Services (MDHHS) will hold a hearing on Certificate of Need (CON) Review Standards.

Date: Thursday, April 25, 2019
Time: 9:30 a.m.
Location: South Grand Building
 333 S. Grand Avenue, 1st floor
 Conference Rooms K & L
 Lansing, MI 48933



CON Review Standards for Megavoltage Radiation Therapy (MRT) Services/Units

The proposed language changes include the following:

1. Department name updated throughout.
2. Section 2 (c) and (t) definition of Dedicated stereotactic radiosurgery updated to include Stereotactic Body Radiation Therapy as follows:
 - (c) "Dedicated stereotactic radiosurgery/**STEROTACTIC BODY RADIATION THERAPY (SRS/SBRT)** unit" means an MRT unit for which more than 90 percent of cases will be treated with radiosurgery **AND/OR SBRT**.
 - (t) "Special purpose MRT unit" or "special purpose unit" or "special unit" means any of the following types of MRT units: (i) dedicated ~~stereotactic radiosurgery~~**SRS/SBRT** unit, (ii) dedicated total body irradiator (TBI), or (iii) an OR-based IORT unit.
3. Section 10 (4) was added and Table 1 was updated to align the equivalent treatment visits with typical treatment times as follows:

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

TABLE 1
Equivalent Treatments

Treatment Visit Category	Non-Special Visit Weight	Special Visit Weight
Simple	1.00 <u>1.66</u>	
Intermediate	1.40 <u>1.00</u>	
Complex	1.25 <u>2.00</u>	
IMRT	2.00 <u>1.66</u>	
Total Body Irradiation	85 .00	85 .00
HMRT Therapy		5.00 <u>3.33</u>
Stereotactic radio- surgery/radio-therapy*	84 .00	84 .00
IORT		20.00

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

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

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

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

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

PATIENT SPECIFIC QA FOR SRS/SBRT RECEIVES A 3.0 ADDITIVE FACTOR, NOT TO EXCEED TWICE PER COURSE OF TREATMENT. PATIENT SPECIFIC QA FOR SRS/SBRT MEANS VERIFICATION OF RADIATION DELIVERED DOSE AND/OR FLUENCE THROUGH PHYSICAL MEASUREMENT WITH A DOSIMETRY PHANTOM AND/OR DETECTOR ARRAY IN THE TREATMENT ROOM. PRIOR TO THE START OF TREATMENT AND USING ALL OF THE PARAMETERS OF THE PATIENT'S TREATMENT PLAN, ONE OR MORE POINTS IN THE DELIVERED DISTRIBUTION SHOULD BE COMPARED AGAINST THE PLANNED DISTRIBUTION.

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

4. Section 11(4) (a) and (b) were revised to update the minimum average volume for non-special MRT units. Note that the language that follows does not change the minimum average volume for High MRT (HMRT) units.
 - (a) Non-special MRT units ~~and HMRT units~~ shall be operating at a minimum average volume of 84,000 Equivalent Treatment Visits per unit annually by the end of the third full year of operation, and annually thereafter. HMRT UNITS SHALL BE OPERATING AT A MINIMUM AVERAGE VOLUME OF 8,000 EQUIVALENT TREATMENT VISITS PER UNIT ANNUALLY BY THE END OF THE THIRD FULL YEAR OF OPERATION, AND ANNUALLY THEREAFTER. All special purpose MRT units shall be operating at a minimum average volume of 1,000 equivalent treatment visits per special purpose unit by the end of the third full year of operation, and annually thereafter. An applicant shall not include any treatments conducted on a dedicated research MRT unit.
 - (b) ~~Non-special MRT units and~~ HMRT units approved pursuant to Section 3(2) or 3(3) of these standards shall be operating at a minimum average volume of 5,500 equivalent treatment visits per unit by the end of the third full year of operation, and annually thereafter. An applicant shall not include any treatments conducted on a dedicated research MRT unit.



Oral or written comments may be presented in person at the hearing on Thursday, April 25, 2019, or submitted in writing by sending an email to the following email address:

MDHHS-ConWebTeam@michigan.gov

Please submit written comments no later than 5:00 p.m., Thursday, May 2, 2019.

If your comment is in written form at the hearing, please provide a copy of your testimony.

If you have any questions or concerns, please contact Tania Rodriguez at 517-335-6708.

Be sure all phones and devices are turned off or set to vibrate during the hearing.

The hearing location is accessible for persons with physical disability. Interpreters will be available for the hearing impaired, if requested, seven days in advance.

4/2/19