

MDCH Recommendations for CON Standards Scheduled for 2011 Review

Megavoltage Radiation Therapy (MRT) (Please refer to the attached MDCH staff analysis for additional details.)		
Should the covered service continue to be regulated?	Yes	MRT services still require large initial capital investment as well as long term operating expenditures. Further, recent concerns have been raised concerning patient large-dose radiation exposure from MRT services.
Identified Issues	Recommended Review	Comments
Consider refinement to current utilization methodology for replacement and expansion of existing MRT units and services, respectively.	Yes	Current methodology is labor intensive for existing providers to accurately collect and report to the Department.
Consider modifications to Project Delivery Requirements.	Yes	Reduce number of project delivery requirements for approved services that are enforceable, objectively measurable, and achieve major objectives of assuring affordable, quality MRT services without overwhelming providers.
Consider modification to replace/upgrade definition and section.	Yes	Create distinction between replacing and upgrading an MRT unit. Simplify requirements to replace existing and outdated MRT units, while allowing upgrades without CON review/approval.

MDCH Staff Analysis of the Megavoltage Radiation Therapy (MRT) Standards

Statutory Assignment

Pursuant to MCL 333.22215 (1)(m), the Certificate of Need (CON) Commission is to "...review, and if necessary, revise each set of CON standards at least every 3 years." In accordance with the established review schedule on the Commission Work Plan, the MRT Standards are scheduled for review in calendar year 2011.

Public Hearing Testimony

The Department held a Public Hearing to receive testimony regarding the Standards on October 13, 2010, with written testimony being received for an additional seven (7) days after the hearing. Testimony was received from five (5) organizations and is summarized as follows:

1. *Walter M. Sahjidak, MD, Michigan Society of Therapeutic Radiologists & Oncologists*
 - Supports continued CON regulation.
 - Supports the formation of a Standard Advisory Committee (SAC) Workgroup.
 - Supports an update of the current review standards including the equivalent treatment visit (ETV) factoring.
 - Recommends utilizing the changes in Michigan's decreasing demographics and populations levels along with national changes in the standard of care for cancer patients as a factor in determining MRT usage in Michigan to prevent over utilization.
2. *Dennis McCafferty, Economic Alliance for Michigan, (EAM)*
 - Supports continued CON regulation.
 - Supports the formation of a SAC Workgroup to address strengthening the patient safety requirements related to MRT services.
 - Suggests the SAC consider strengthening the standards for additional MRT units to achieve greater proficiency, cost-effectiveness, and appropriate access.
3. *Tina Weatherwax Grant, Trinity Health*
 - Supports continued CON regulation.
 - Supports the formation of a SAC Workgroup to analyze and update the weights assigned to the MRT Standards.
 - Advises that the current weights used to calculate equivalent treatment visits were established nearly 5 years ago, and do not consider recent technology, techniques, and application changes to radiation therapy.
4. *Sean Gehle, The Michigan Health Ministries of Ascension Health*
 - Supports continued CON regulation.
 - Supports the formation of a SAC Workgroup to review the requirements for initiating a new MRT service.
 - Recommends that the language in the standards be modified to distinguish between replacement and upgrade.
5. *Amr Aref, MD, Radiation Oncology Specialists, PC*
 - Supports continued CON regulation.
 - Supports the formation of a SAC Workgroup to review MRT unit standards to prevent over and under utilization.
 - Supports an update of the current review standards including the equivalent treatment visit (ETV) factoring.
6. *Jim Gilson, Beaumont Hospitals*
 - Supports continued CON regulation.
 - Recommends the review of Section 4 and Section 12 relating to the initiation of MRT Services; specifically "relating to initiation of MRT Services: under the current standards, there is the potential for double counting of new cancer cases, which could result in overcapacity of MRT services."

Summary of Covered Service

The Department did not receive any testimony against de-regulation of MRT Services Standards. Michigan is one of 25 states which regulate MRT services within CON. Per the 2009 CON Annual Survey 579,241 patients received radiation treatment in some capacity from one of 117 approved units within the 65 facilities located in the state.

MDCH Staff Recommendations

- **Conduct departmental review of standards with an emphasis to assure uniformity among the various standards, where applicable, and create a user-friendly format.**
- **Conduct departmental review of project delivery requirements. Project delivery requirements are those requirements that a recipient of an approved CON must comply with throughout the life of the services, or unless modified by a subsequent CON approval. Review is to assure that each requirement is measurable, comports with today's standard of care, does not duplicate other regulatory requirements already established, and have cost-effective value in achieving the goals and objectives of the program to assure affordable, quality health care services for both the consumer and provider.**
- **Conduct departmental review to simplify projection and utilization methodologies, where possible, in a manner that is comparable to existing thresholds but reduces the labor-intensive collection process for the provider and potential applicants using readily available data.**
- **Conduct departmental review to simplify replacement requirements for existing providers to replace covered equipment in a more streamlined process that assures consumer access to advance technology and treatment services.**
- **Present proposed draft standards to Commission at the June 9, 2011 meeting.**