

**MEGAVOLTAGE RADIATION
THERAPY**

STATE HEALTH PLAN
CERTIFICATE OF NEED STANDARDS AND CRITERIA
FOR
MEGAVOLTAGE RADIATION THERAPY SERVICES

The Health Services and Development Agency (HSDA) may consider the following standards and criteria for applications seeking to provide Megavoltage Radiation Therapy (MRT) Services. Existing providers of MRT services are not affected by these standards and criteria unless they take an action that requires a new certificate of need (CON) for MRT services.

These standards and criteria are effective immediately as of December 21, 2011, the date of approval and adoption by the Governor of the State Health Plan changes for 2011. Applications to provide MRT services that were deemed complete by HSDA prior to this date shall be considered under the Guidelines for Growth, 2000 Edition.

Definitions

External Beam Radiation Therapy (EBRT). Radiation therapy delivered by an MRT Unit from outside the body.

Linear Accelerator. A type of EMRT Unit that delivers a beam of high energy x-rays (photon or electron particles) from an external source to the location of the patient's tumor and/or other tissue being irradiated. Linear accelerators may deliver conventional EBRT, intensity modulated radiation therapy, image-guided radiation therapy, and SRT services. Linear accelerators are the only MRT Unit type specifically listed in Tennessee Code Annotated Section 68-11-1607 (a)(4) as requiring a CON in order for services to be initiated.

Linear Accelerator Service Area Capacity: The estimate of the number of Linear Accelerator MRT units needed in a given service area, based upon an Optimal Capacity of 7,688 procedures per year.

MRT Procedure: Each discrete MRT treatment related to services performed on a single patient during a single visit, designated by CPT code. The Health Services and Development Agency (HSDA) shall be responsible for setting reporting requirements consistent with this definition, including the development of a selected set of CPT codes.

MRT Unit: Medical equipment that performs radiation therapy.

Proton Beam Therapy Unit. A type of EBRT MRT Unit that uses proton beams rather than photon beams. Although not specifically listed as requiring a CON, the cost of initiating proton

beam therapy services likely falls above the capital expenditure threshold set forth in TCA Section 68-11-1607 (2).

Radiation Therapy. A medical procedure that allows non-invasive treatment of tumors and cancer cells using X-rays, gamma rays, and charged particles. The radiation may be delivered by a machine outside the body (external-beam radiation therapy), or it may come from radioactive material placed in the body near cancer cells (internal radiation therapy, also called brachytherapy).

Radiation Therapy is also known as **Stereotactic Radiotherapy (SRT)** when used to target lesions in the brain and as **Stereotactic Body Radiotherapy (SBRT)** when used to target lesions in the body.

Service Area: For linear accelerators that do not perform SRT or SBRT procedures, the contiguous counties representing a reasonable area in which an applicant intends to provide MRT services and in which at least 120,000 people reside and where the applicant is able to reach the optimal capacity set forth below. Otherwise, a Service Area shall be the contiguous counties representing a reasonable area in which an applicant intends to provide MRT services.

Standards and Criteria

1. Utilization Standards for MRT Units.

- a. Linear Accelerators not dedicated to performing SRT and/or SBRT procedures:
 - i. **Full capacity of a Linear Accelerator MRT Unit** is 8,736 procedures, developed from the following formula: 3.5 treatments per hour, times 48 hours (6 days of operation, 8 hours per day, or 5 days of operation, 9.6 hours per day), times 52 weeks.
 - ii. **Linear Accelerator Minimum Capacity:** 6,000 procedures per Linear Accelerator MRT Unit annually, except as otherwise noted herein.
 - iii. **Linear Accelerator Optimal Capacity:** 7,688 procedures per Linear Accelerator MRT Unit annually, based on a 12% average downtime per MRT unit during normal business hours annually.
 - iv. An applicant proposing a new Linear Accelerator should project a minimum of at least 6000 MRT procedures in the first year of service in its Service Area, building to a minimum of 7,688 procedures per year by the third year of service and for every year thereafter.
- b. For Linear Accelerators dedicated to performing only SRT procedures, full capacity is 500 annual procedures.
- c. For Linear Accelerators dedicated to performing only SRT/SBRT procedures, full capacity is 850 annual procedures.
- d. An exception to the standard number of procedures may occur as new or improved technology and equipment or new diagnostic applications for Linear Accelerators develop. An applicant must demonstrate that the proposed Linear

Accelerator offers a unique and necessary technology for the provision of health care services in the proposed Service Area.

- e. Proton Beam MRT Units. As of the date of the approval and adoption of these Standards and Criteria, insufficient data are available to enable detailed utilization standards to be developed for Proton Beam MRT Units.

2. Need Standards for MRT Units.

- a. For Linear Accelerators not dedicated solely to performing SRT and/or SBRT procedures, need for a new Linear Accelerator in a proposed Service Area shall be demonstrated if the average annual number of Linear Accelerator procedures performed by existing Linear Accelerators in the proposed Service Area exceeds 6,000.
- b. For Linear Accelerators dedicated to performing only SRT procedures, need in a proposed Service Area shall be demonstrated if the average annual number of MRT procedures performed by existing Linear Accelerators dedicated to performing only SRT procedures in a proposed Service Area exceeds 300, based on a full capacity of 500 annual procedures.
- c. For Linear Accelerators dedicated to performing only SRT/SBRT procedures, need in a proposed Service Area shall be demonstrated if the average annual number of MRT procedures performed by existing Linear Accelerators dedicated to performing only SRT/SBRT procedures in a proposed Service Area exceeds 510, based on a full capacity of 850 annual procedures.
- d. Need for a new Proton Beam MRT Unit: Due to the high cost and extensive service areas that are anticipated to be required for these MRT Units, an applicant proposing a new Proton Beam MRT Unit shall provide information regarding the utilization and service areas of existing or planned Proton Beam MRT Units' utilization and service areas (including those that have received a CON), if they provide MRT services in the proposed Service Area and if that data are available, and the impact its application, if granted, would have on those other Proton Beam MRT Units.
- e. An exception to the need standards may occur as new or improved technology and equipment or new diagnostic applications for MRT Units develop. An applicant must demonstrate that the proposed MRT Unit offers a unique and necessary technology for the provision of health care services in the proposed Service Area.

3. Access to MRT Units.

- a. An MRT unit should be located at a site that allows reasonable access for residents of the proposed Service Area.

- b. An applicant for any proposed new Linear Accelerator should document that the proposed location of the Linear Accelerator is within a 45 minute drive time of the majority of the proposed Service Area's population.
 - c. Applications that include non-Tennessee counties in their proposed Service Areas should provide evidence of the number of existing MRT units that service the non-Tennessee counties and the impact on MRT unit utilization in the non-Tennessee counties, including the specific location of those units located in the non-Tennessee counties, their utilization rates, and their capacity (if that data are available).
4. Economic Efficiencies. All applicants for any proposed new MRT Unit should document that lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.
5. Separate Inventories for Linear Accelerators and for other MRT Units. A separate inventory shall be maintained by the HSDA for Linear Accelerators, for Proton Beam Therapy MRT Units, and, if data are available, for Linear Accelerators dedicated to SRT and/or SBRT procedures and other types of MRT Units.
6. Patient Safety and Quality of Care. The applicant shall provide evidence that any proposed MRT Unit is safe and effective for its proposed use.
- a. The United States Food and Drug Administration (FDA) must certify the proposed MRT Unit for clinical use.
 - b. The applicant should demonstrate that the proposed MRT Units shall be housed in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.
 - c. The applicant should demonstrate how emergencies within the MRT Unit facility will be managed in conformity with accepted medical practice. Tennessee Open Meetings Act and/or Tennessee Open Records Act.
 - d. The applicant should establish protocols that assure that all MRT Procedures performed are medically necessary and will not unnecessarily duplicate other services.
 - e. An applicant proposing to acquire any MRT Unit shall demonstrate that it meets the staffing and quality assurance requirements of the American Society of Therapeutic Radiation and Oncology (ASTRO), the American College of Radiology (ACR), the American College of Radiation Oncology (ACRO) or a similar accrediting authority such as the National Cancer Institute (CNI). Additionally, all applicants shall commit to obtain accreditation from ASTRO, ACR or a comparable accreditation authority for MRT Services within two years following initiation of the operation of the proposed MRT Unit.

- f. All applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. An applicant's arrangements with its physician medical director must specify that said physician be an active member of the subject transfer agreement hospital medical staff.
 - g. All applicants should provide evidence of any onsite simulation and treatment planning services to support the volumes they project and any impact such services may have on volumes and treatment times.
7. The applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.
8. In light of Rule 0720-11.01, which lists the factors concerning need on which an application may be evaluated, and Principle No. 2 in the State Health Plan, "Every citizen should have reasonable access to health care," the HSDA may decide to give special consideration to an applicant:
- a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;
 - b. Who is a "safety net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program; or
 - c. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program.

Comments:

1. The Office of Health Planning recognizes the need to review MRT Services standards and criteria on a frequent basis due to the evolving nature of the technology involved.
2. It is anticipated that the Tennessee Cancer Registry data, maintained by the Department of Health, will in the future become available for use by applicants to support the need for new MRT Units.

Rationale for Revised and Updated Standards and Criteria for Megavoltage Radiation Therapy Services

Definitions

Linear Accelerator Units. The Office of Health Planning recognizes that Linear Accelerators performing SRT and/or SBRT procedures do not reach the level of utilization of Linear Accelerators that do not perform these procedures. Consequently, standards have been developed that endeavor to recognize these significant differences in utilization.

Proton Beam Therapy Units. Given the increasing interest in proton beam therapy units, surprisingly little data exist on optimal capacity and geographic service areas. However, the Office thought it important to include a specific category for proton beam therapy units to help inform the application and decision-making process.

MRT Procedure. To provide for uniform procedure reporting, the Health Services and Development Agency is responsible for setting CPT code reporting requirements.

Capacity. The Health Services and Development Agency staff solicited operating schedule information from owners/operators of MRT Units and the number of procedures performed annually. The capacity numbers were developed from this information.

Standards and Criteria Regarding Certificate of Need Applications for Magnetic Resonance Imaging Services

1. **Exceptions to Utilization Standards:** Exceptions to the standard number of procedures have been added for new or improved technology and treatment applications. The Office recognizes the rapidly advancing technological changes in this area and the need for flexibility on the part of the HSDA in making its decisions.
2. **Other Access Issues:** The provision of health care doesn't recognize state boundaries. Accordingly, applicants may include non-Tennessee counties in proposed Service Areas if that data are available. Proton Beam Therapy Units are anticipated to require extremely large Service Areas that may include other states' counties.
3. **Economic Efficiencies:** To support the goal of reducing health care costs, applicants should document that other options have been investigated and found less advantageous.
4. **Inventories:** If data are available, separate inventories should be maintained for Linear Accelerators based on procedures performed as well as for other types of MRT Units.

5. **Quality of Care:** Reference to specific recognized authorities' recommendations on staffing, training, and education standards are included to help ensure patient safety and quality of care are provided.