STATE OF TENNESSEE

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 __________________, 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 EBRT MRT 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.

Proton Beam Therapy Unit. A type of EBRT MRT Unit that uses proton beams rather than photon beams. Photons deposit energy in small packets all along their path through tissue, while protons deposit much of their energy at the end of their path (called the Bragg peak) and deposit less energy along the way. In theory, use of protons should reduce the exposure of normal tissue to radiation, possibly allowing the delivery of higher doses of radiation to a tumor.
**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 (a well-known type of SRT equipment is the “Gamma Knife”), and **Stereotactic Body Radiotherapy (SBRT)** when used to target lesions in the body (a well-known type of SBRT equipment is the “Cyber Knife”).

**MRT Procedure:** A single, discrete MRT procedure performed on a single patient during a single visit. 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.

**Linear Accelerator Full Capacity:** 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.

**Linear Accelerator Minimum Capacity:** 6,000 procedures per Linear Accelerator MRT Unit annually, except as otherwise noted herein.

**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.

**Stereotactic Radiotherapy (SRT) Unit Full Capacity:** For a designated SRT Unit, 800 procedures annually (slightly lower than manufacturers’ stated capacity).

**Stereotactic Radiotherapy (SRT) Unit Minimum Capacity:** 60% times 800 procedures annually, or 480 procedures annually.

**Stereotactic Radiotherapy (SRT) Unit Optimal Capacity:** 80% times 800 procedures annually, or 640 procedures annually.

**Stereotactic Body Radiotherapy (SBRT) Unit Full Capacity:** Full capacity of an SBRT Unit is 1,300 procedures annually, developed from the following formula: 5 procedures per 8 hour day, times 5 days of operation per week, times 52 weeks.

**Stereotactic Body Radiotherapy (SBRT) Unit Minimum Capacity:** 60% times 1,300 procedures annually, or 780 procedures annually.
**Stereotactic Body Radiotherapy (SBRT) Unit Optimal Capacity:** 80% times 1,300 procedures annually, or 1,040 procedures annually.

**Service Area:** For non-Proton Beam MRT Units, a Service Area is the counties, or portions thereof, that represent a contiguous area in which an applicant intends to provide MRT services and in which at least 120,000 people reside. Until more is known about population requirements for Proton Beam MRT Units, there is no Service Area minimum population requirement for a Proton Beam MRT Unit; Service Areas for these MRT Units are anticipated to extend into states adjoining Tennessee in order to obtain sufficient number of patients to support operating and capital costs.

**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.

**Stereotactic Radiotherapy (SRT) Unit Service Area Capacity:** The estimate of the number of SRT units needed in a given service area, based upon an Optimal Capacity of 640 procedures per year.

**Stereotactic Body Radiotherapy (SBRT) Unit 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 1,040 procedures per year.

**Standards and Criteria**

1. **Utilization Standards for MRT Units.**
   a. Linear Accelerators. An applicant proposing a new Linear Accelerator should project a minimum of at least 6000 MRT procedures in the first year of service, building to a minimum of 7,688 procedures per year by the third year of service and for every year thereafter.
   b. SRT Units. An applicant proposing a new SRT Unit should project a minimum of at least 480 MRT procedures in the first year of service, building to a minimum of 800 procedures per year by the third year of service and for every year thereafter.
   c. SBRT Units. An applicant proposing a new SBRT Unit should project a minimum of at least 780 MRT procedures in the first year of service, building to a minimum of 1,040 procedures per year by the third year of service and for every year thereafter.
   d. An exception to the standard number of procedures may occur as new or improved technology and equipment or new diagnostic applications for MRT Units are developed. 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.

e. Proton Beam MRT Units. An applicant proposing a new Proton Beam MRT Unit shall provide evidence that it will perform the minimum number of procedures over the first three years of operation that enables it to cover its capital and operating costs. Additionally, such an applicant shall also agree to the inclusion on the face of its Certificate of Need that its proposed Proton Beam MRT Unit shall not be used to treat types of cancer that would ordinarily be treated with traditional forms of radiotherapy, or, in the alternative, that its use of its proposed Proton Beam MRT Unit for such purpose shall not cause any current MRT Unit in the proposed Service Area to drop below its minimum number of MRT procedures a year.

A need likely exists for one additional non-Specialty MRI unit in a Service Area when the combined average utilization of existing MRI service providers is at or above 80% of the total capacity of 3600 procedures, or 2880 procedures, during the most recent twelve-month period reflected in the provider medical equipment report maintained by the HSDA.

2. **Need Standards for MRT Units.**

   a. 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 7,688.

   b. Need for a new SRT Unit in a proposed Service Area shall be demonstrated if the average annual number of MRT Procedures performed by existing SRT Units in a proposed Service Area exceeds 640.

   c. Need for a new SBRT Unit in a proposed Service Area shall be demonstrated if the average annual number of MRT Procedures performed by existing SBRT Units in a proposed Service Area exceeds 1,040.

   d. Need for a new Proton Beam MRT Unit shall be demonstrated: (i) if there are no other Proton Beam MRT Units that have received CONs to provide MRT procedures to the general population in the state; (ii) that there are no Proton Beam MRT Units in adjacent states that are existing or that have received permission for construction; and (iii) if it provides evidence that it will perform the minimum number of procedures over the first three years of operation that enables it to cover its capital and operating costs.

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 100% 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 alternate shared services and 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, for SBRT Units, and for SRT 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) and the American College of Radiology (ACR). Additionally, all applicants shall commit to obtain
accreditation from ASTRO, ACR or a comparable accreditation authority for MRT Services within two years following instigation 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.