

DRAFT

Approved by Governor
Date: XXXXXX

MEGAVOLTAGE RADIATION THERAPY SERVICES/UNITS

Exemption from Certificate of Need (CON) which requires submission of information to the Health Care Authority (Authority).

Those providing Megavoltage Radiation Therapy (MRT) Services/Units, which meet the following criteria, will not be required to address the standards.

West Virginia Code § 16-2D-11(b)(9) states:

The replacement of major medical equipment with like equipment, only if the replacement major medical equipment cost is more than the expenditure minimum.

The expenditure minimum is updated annually by the Authority and can be found on the Authority's website at www.hca.wv.gov.

Like Equipment means medical equipment in which functional and technological capabilities are similar to the equipment being replaced; and the replacement equipment is to be used for the same or similar diagnostic, therapeutic, or treatment purposes as currently in use; and it does not constitute a substantial change in health services or a proposed health service.

Major Medical Equipment means a single unit of medical equipment or a single system of components with related functions which is used for the provision of medical and other health services and costs in excess of the expenditure minimum. This term does not include medical equipment acquired by or on behalf of a clinical laboratory to provide clinical laboratory services if the clinical laboratory is independent of a physician's office and a hospital and it has been determined under the Title XVIII of the Social Security Act to meet the requirements of paragraphs ten and eleven, Section 1861(s) of such act, Title 42 U.S.C. §1395x. In determining whether medical equipment is major medical equipment, the cost of studies, surveys, designs, plans, working drawings, specifications and other activities essential to the acquisition of such equipment shall be included. If the equipment is acquired for less than fair market value, the term "cost" includes the fair market value.

The exemption application is available on the Authority's website at: <https://hca.wv.gov/certificateofneed/Pages/Exemptions.aspx>.

The provision of MRT Services/Units that does not qualify for the above exemption must submit an expedited application that addresses the standards below.

I. INTRODUCTION

Radiation therapy (also called radiotherapy or x-ray therapy) is the use of a certain type of radiation (called ionizing radiation) to treat cancer as well as a limited number of noncancerous conditions (e.g. arteriovenous malformations). Radiation therapy damages or destroys cells in the area being treated primarily by damaging their genetic material, making it impossible for those cells to continue to grow and divide. Although radiation damages both cancer cells and normal cells, most normal cells can recover from the effects of radiation and function properly. The goal of radiation therapy is to damage as many cancer cells as possible, while limiting harm to nearby healthy tissue.

Radiation may come from a unit (external radiation, teletherapy, beam radiation), may be placed inside or next to the tumor site (internal radiation, brachytherapy), or may use unsealed radioactive materials that go throughout the body (systemic radiation therapy).

II. DEFINITIONS

A. Acquisition of an existing MRT service or existing MRT unit(s) – The acquisition (including purchase, lease, donation, or other comparable arrangement) of an existing MRT service or MRT unit(s).

B. Brachytherapy/Internal radiation therapy – Use of a radioactive material that is placed very close to or inside the tumor. The radiation source is usually placed in a small holder called an implant (thin wires, catheters, ribbons, capsules, or seeds). Internal radiation therapy is of two types, Interstitial or Intracavitary implants or as surface applications.

C. Calibration Equipment – Is used to determine the accuracy of treatment equipment by measuring its variation from a standard to ascertain necessary correction factors.

D. Cancer – A malignant tumor or neoplasm, varying from highly curable local skin, oral and cervix cancers to rapidly fatal advanced cancers.

E. Cancer Incidence – The number of patients newly diagnosed with cancer in a specific calendar year within a defined population. This is often expressed as the ratio of new cases per unit of population per year.

F. Cancer Prevalence – Means the total number of patients (old or new) with cancer present during a specified time period within a defined population. This number excludes non-melanoma skin cancers.

G. Complete Comprehensive Cancer Center – A coordinated, multidisciplinary approach to the treatment of patients with cancer or other neoplasms which must provide on-site simulation capability, and, either on-site or through written agreements with other providers as further defined in Subsection IV.D.

H. Computerized Treatment Planning – The use of a computer and dedicated software that are capable of calculating and displaying radiation dose distributions within a patient using clinical data from that patient and dosimetric data from the MRT unit to treat the patient.

I. Collimator – A mechanical element of a MRT unit, which defines the dimension, direction, or focus of the radiation beam by means of metal multileaf, or diaphragms interposed in the path of the beam.

J. Dosimetrist – A person who is familiar with the physical and geometric characteristics of the radiation equipment and radioactive sources commonly employed and who has the training and expertise necessary to compute and generate radiation dose distributions and calculations under the direction of a medical physicist and/or a radiation oncologist.

K. Dosimetry Equipment – Equipment used to determine the amount, rate and distribution of ionizing radiation, including for example phantoms, film, ionization chambers and solid state dosimeters. Such equipment permits accurate measurement of the dose of radiation to be delivered.

L. Driving miles – The number of miles from the address of the proposed MRT services to the address of the closest existing MRT unit.

M. External Beam Radiation Therapy (EBRT) –the energy (source of radiation) used in external radiation therapy may come from the following:

1. X-rays -- Are created by units called linear accelerators. Depending on the amount of energy the x-rays have, they can be used to treat cancers more superficially or deep into tissues and organs.
2. Gamma rays -- Are produced when isotopes of certain elements (such as iridium and Cobalt 60) release energy as they break down. Each element breaks down at a specific rate and emits radiation with specific energies, which affects how deeply the element can penetrate into the body.
3. Electrons -- Are produced by linear accelerators, without the x-ray target in place. Electron beams are commonly used to treat superficial tumors and special skin cancers.

4. Proton beam therapy -- A type of particle beam radiation therapy. Protons are generated by a heavy particle accelerator and deposit most of their energy over a very small distance, which is called the Bragg peak. The Bragg peak can be exploited to deliver radiation to a deep-seated tumor while depositing less radiation damage to surrounding normal tissues.
 5. Intensity Modulated Radiation Therapy (IMRT) -- Is a treatment delivery utilizing a radiation therapy plan optimized using an inverse or forward planning technique to modulate the particle or energy fluency to create a highly conformal dose distribution. This beam modulated treatment delivery can be accomplished either by the use of the computer controlled multileaf collimator or high resolution milled or casted compensators.
- N. Heavy particle accelerator – A unit such as a cyclotron which produces beams of high energy particles such as protons, neutrons, pions, or heavy ions with masses greater than that of an electron.
- O. Megavoltage Radiation Therapy (MRT) – A clinical modality in which patients with cancer, other neoplasm, or cerebrovascular system abnormalities are treated with radiation which is delivered by a MRT unit.
- P. Megavoltage Radiation Therapy (MRT) Unit – A linear accelerator, cobalt unit, particle accelerator 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.
- Q. Multi-Purpose (MRT) Unit – A Non-Special Purpose MRT Unit that is capable of providing both regular linear accelerator MRT services and SRS/SRT services.
- R. Non-Special Purpose (MRT) Unit – A MRT unit that does not meet the definition of a special purpose MRT unit or a multi-purpose MRT unit.
- S. Operating room based intraoperative (MRT) unit (OR-based IORT unit) – A MRT unit that is located in an operating room in the surgical department of a licensed hospital, and is available for the treatment of a patient undergoing a surgical procedure with megavoltage radiation.
- T. Special Purpose (MRT) Unit – Any of the following types of megavoltage radiation therapy units: (1) heavy particle accelerator; (2) stereotactic radiosurgery services consisting of multiple cobalt sources; (3) dedicated linear accelerator stereotactic radiosurgery unit (SRS LINAC); and, (4) OR based intraoperative radiation therapy (IORT) unit.

U. Stereotactic Radiation Therapy (SRT) – A procedure(s) performed in one (1) to five (5) treatment visits, using a stereotactic MRT unit to treat lesions in the brain (intracranial) or elsewhere in the body (extracranial).

V. Stereotactic Radiosurgery (SRS) – A form of radiation therapy for treating abnormalities, functional disorders, and tumors of the brain, neck, spine, lung, pancreas, prostate, bone, and liver. There are two basic methods in which SRS can be delivered to patients: (1) linear accelerator-based treatment; and, (2) multi-source photon-based treatment (often referred to as Cobalt 60). Advances in technology have distinguished linear accelerator-based SRS therapy into two types: (1) image-guided robotic SRS systems and, (2) gantry-based systems. These two types of linear accelerator based SRS therapies may be delivered in a complete session or in a fractionated course of therapy up to a maximum of five sessions.

W. SRS LINAC – A dedicated linear accelerator stereotactic radio therapy unit that consists of three key components: (1) a linear accelerator used to produce a high energy megavoltage of radiation-rays; (2) a device which can point the beam from a wide variety of angles; and, (3) an image-guidance patient positioning system using x-rays before or during treatment which uses this information to target the radiation beam emitted by the linear accelerator. The devices obtain pictures of the patient (planar x-ray or computed tomography) before or during treatment and use this information to target the radiation beam emitted by the linear accelerator.

X. Treatment Simulation – The process during which the patient is optimally positioned for treatment and all necessary data are collected to develop the radiation treatment plan. It can also permit a simulation or test of the chosen treatment parameters prior to actual treatment. Treatment simulation uses various imaging modalities including, but not limited to, diagnostic x-ray and fluoroscopic units, CT, and MRI.

Y. Treatment Visit – One patient encounter during which MRT is administered. One visit may involve one or more treatment ports or fields. Each separate encounter by the same patient at different times during the same day shall be counted as a separate treatment visit.

III. CURRENT INVENTORY

A current inventory of approved MRT service providers in the state may be obtained from the Authority.

IV. NON-SPECIAL PURPOSE MRT UNITS or MULTI-PURPOSE MRT UNITS

A. Need Methodology

Applicants proposing new MRT services that do not meet the definition of a “special purpose MRT unit” shall demonstrate that a proposed new radiation therapy unit will serve a population of 350 patients using the following methodology:

1. Study Area/Service Area

The study area/service area for MRT services consists of the county of proposal and any contiguous county significantly impacted.¹ A significantly impacted county is a county:

- a. Wherein at least 25% of the residents rely on acute care services in the county of proposal; or,
- b. Which generates at least 10% of the patient load of the applicant.

2. Applicants shall use the projected population for the proposed study area/service area for the third year of the project.

3. Using the average of the number of new cancer cases for the last five (5) years, as compiled by the West Virginia Cancer Registry, the applicant shall calculate a crude rate for the incidence of cancer on a statewide basis or for the delineated study area/service area.

4. The applicant shall apply this crude rate to the study area/service area population to arrive at an estimated number of cancer patients within the study area/service area.

5. The applicant shall then calculate 60% (the number of cancer patients who may be expected to utilize radiation therapy) of the estimated number of cancer patients within the study area/service area.

6. An applicant must conduct a written survey of all existing Non-Special Purpose MRT or Multi-Purpose MRT providers in the applicant’s proposed study area/service area to determine the number of machines in the study area/service area.

7. Each operational Non-Special Purpose MRT Unit or Multi-Purpose MRT Unit within the study area/service area is equivalent to 350 patients. The applicant shall deduct 350 patients per operational Non-Special Purpose MRT or Multi-Purpose MRT within the study area/service area from the

¹ NOTE: The definition of a significantly impacted county may include contiguous counties outside West Virginia. Applicants shall document the location and description of all other MRT units in the proposed study area/service area.

estimated number of cancer patients within the study area/service area and for each unit approved but not operational.

8. If the resulting number is 350 or greater the applicant has demonstrated a need for the new unit.

The Authority may consider an application for a new radiation therapy unit if the applicant can demonstrate, using the above methodology, the unit would treat a population of 200 patients not within 60 minutes normal driving time of an existing radiation therapy provider.

B. Applicants meeting the criteria contained in this section for a complete comprehensive cancer center may provide an alternative need methodology at the sole discretion of the Authority. The applicant shall demonstrate, with specificity, that there is an unmet need for the proposed MRT services within the proposed service area, that the proposed services will not have a negative impact on the community by significantly limiting the availability and viability of other services or providers, and that the proposed services are the most cost effective alternative. In developing the service area and need methodology, the applicant may submit testimony or documentation based upon national data or statistics or upon projections generally relied upon by professionals engaged in health planning for the development of health services.

The proposal for the comprehensive cancer center must include, at a minimum, the following services:

1. Inpatient and outpatient radiation oncology;
2. Inpatient and outpatient medical oncology services and chemotherapy suites;
3. Surgical oncology;
4. High quality diagnostic and therapeutic equipment including, MRT, CT and PET or PET/CT;
5. Hematology/oncology laboratory;
6. Patient resource services and center;
7. Advanced level experimental therapy programs and clinical trials with strict protocols;
8. Intensive cancer research capabilities;

9. Advanced treatment capabilities;
10. Ongoing participation in more than one recognized National Cancer Institute sponsored cooperative clinical trial group; and,
11. Recruitment of highly skilled physicians with advanced medical experience.

V. SPECIAL PURPOSE MRT UNITS

A. Need Methodology

Applicants proposing to acquire a Special Purpose MRT Unit must be an existing provider of MRT services. The need for the addition of a Special Purpose MRT Unit shall be determined as follows:

1. Study Area/Service Area

The applicant shall delineate the study area/service area by documenting the expected areas from which the center can reasonably expect to draw patients. The applicant may submit testimony or documentation on the expected study area/service area, based upon national data or statistics, or upon projections generally relied upon by professionals engaged in health planning or the development of health services.

2. Need Methodology

The need may be demonstrated by using cancer prevalence and cancer incidence rates to show the number of persons within the study area/service area that can be appropriately treated using the Special Purpose MRT Unit by documenting the number of patients within the study area/service area transferred out of the study area/service area for Special Purpose Radiation Therapy services.

- a. Applicants shall use the projected population for the proposed study area/service area for the third year of the project.
- b. Using the average number of new cancer cases for the last five (5) years, as compiled by the West Virginia Cancer Registry, the applicant shall calculate a crude rate for the incidence of cancer on a statewide basis or for the delineated study area/service area.

- c. The applicant shall apply this crude rate to the study area/service area population to arrive at an estimated number of cancer patients within the study area/service area.
- d. The applicant shall then calculate 60% (the number of cancer patients who may be expected to utilize radiation therapy) of the estimated number of cancer patients within the study area/service area.
- e. An applicant must conduct a written survey of all existing Special Purpose MRT providers in the applicant's proposed study area/service area to determine the number of machines in the study area/service area.
- f. Each operational Special Purpose MRT Unit within the study area/service area is equivalent to 350 patients. The applicant shall deduct 350 patients per operational Special Purpose Unit within the study area/service area from the estimated number of cancer patients within the study area/service area and for each unit approved but not operational.
- g. If the resulting number is 350 or greater the applicant has demonstrated a need for the new unit.

B. An applicant may request that an existing Special Purpose MRT unit be declared obsolete, although retained and used as back-up for a replacement unit. An existing unit will only be determined to be a back-up unit and thus not counted as an existing unit as long as documentation is supplied to the effect that the back-up unit is subject to substantial down time, and the unit will only be used when the primary unit is not in operation. Further, it must be documented that a back-up unit will not substantially increase capital or operating costs.

C. Applicants meeting the definition of a complete comprehensive cancer center may provide an alternative need methodology at the sole discretion of the Authority for new and emerging Special-Purpose MRT Units.

VI. QUALITY

A. Applicants seeking to provide new Non-Special Purpose MRT services shall demonstrate compliance with the following criteria:

- 1. One (1) board-certified or board-eligible physician trained in radiation oncology by the American Board of Radiology in Radiation Oncology must

be available consistent with the current CMS Guidelines, when services are being provided.

2. A medical dosimetrist or medical physicist with dosimetry training and experience must be available to create treatment plans for MRT equipment. A medical dosimetrist or medical physicist with dosimetry training shall be a member of the radiation oncology team, who has knowledge of the overall characteristics and clinical relevance of radiation oncology treatment units and equipment, who is cognizant of procedures commonly used in brachytherapy, who has the education and expertise necessary to generate radiation dose distributions and dose calculations in collaboration with the medical physicist and radiation oncologists.
3. Radiation therapy technologists, who shall be registered or eligible by the American Registry of Radiological Technologists (ARRT) or the American Registry of Clinical Radiography Technologists (ARCRT); and who shall be on-site when services are being provided.
4. One (1) program director who shall be a board-certified or board-eligible physician trained in radiation oncology, who shall be available by means of direct communication in person or by radio, telephone, or telecommunication.
5. There shall be a quality assurance program to monitor the quality and appropriateness of MRT services provided. In addition to the clinical quality assurance program, the applicant will document the following:
 - a. Applicants providing or seeking to provide MRT services shall demonstrate that the facility in which the services are to be provided meets or will meet the equipment manufacturer's safety and operating standards as well as applicable state and federal standards.
 - b. Applicants providing or seeking to provide MRT services shall document the development of policies and procedures for responding to equipment malfunction or operator error which minimize risk to the patient.
 - c. Applicants providing or seeking to provide MRT services shall document that their policies and procedures are or will be responsive to patient requests for information and concerns regarding treatment.

B. In addition to the above mentioned criteria, an applicant for Special Purpose MRT or Multi-Purpose MRT services shall provide evidence of a cancer treatment program, which shall include the provision of the following, either on-site or through written agreements with other providers:

1. Access to simulation capabilities, which may include a dedicated simulator, a radiation therapy treatment unit, a virtual-reality based three-dimensional simulation system, or diagnostic X-ray, MRI, ultrasound, or nuclear medicine equipment that has been modified to localize volumes to define the area requiring treatment; and which must be at the defined location of the unit.
2. Access to a computer-based treatment planning system, which shall be a computer system capable of interfacing with diagnostic patient data acquisition systems such as CT, MRI, and PET or PET/CT to obtain the patient specific anatomical data. The planning system must be able to display radiation doses and 3-D dose distributions within a patient anatomical contour and utilize measured or modeled radiation output data from the specific unit used to treat the patient.
3. The capability to fabricate treatment aids as applicable.
4. Existence of a multi-disciplinary cancer committee, which shall be a standing committee that:
 - a. Includes representatives from the medical specialties or subspecialties which refer patients to the MRT service; representatives from the specialties of diagnostic radiology, radiation oncology, and pathology; representatives from those who oversee the tumor registry; and representatives from administration, nursing social services, pharmacy and rehabilitation:
 - b. Meets at least on a quarterly basis; and,
 - c. Is responsible for the following:
 - i. Establishing educational and problem oriented multi-disciplinary, facility wide cancer conferences that include the major anatomic locations of cancer seen at the facility;
 - ii. Monitoring, evaluating, and reporting to the medical staff and governing body on the quality of care provided to patients with cancer; and,

- iii. Oversight of the applicant's tumor registry for quality control, staging and abstracting.
- 5. Participation in patient care evaluation studies, which shall include a system of patient care evaluation, conducted annually, that documents the methods used to identify problems and the opportunities to improve patient care. Examples of patient care evaluation studies include nationwide patient care evaluation studies, facility quality assurance activities, and ongoing monitoring, evaluating, and action planning.
- 6. Cancer prevention and education programs.
- 7. Consultation - The applicant must affirm that it has access to consultative services from all major disciplines needed to develop a comprehensive treatment plan.
- 8. An applicant shall demonstrate that the following staff, at a minimum, will be identified and available:
 - a. For applicants seeking the addition of stereotactic radiosurgery services consisting of multiple cobalt sources:
 - i. One (1) board-certified physician trained in radiation oncology, who shall have received special training in performing stereotactic radiosurgery procedures with the multiple cobalt sources unit, and who shall be available on-site when services are being provided; and,
 - ii. One (1) board- certified medical radiation physicist who has received special training with the multiple cobalt sources unit, who shall be on-site when services are being provided; and,
 - iii. One (1) board-certified Neurosurgeon.
 - b. For applicants seeking the addition of Heavy Particle Accelerator services:
 - i. Two (2) radiation therapy technologists, who shall be registered or eligible by the ARRT or the ARCRT who shall have received special training in operating a Heavy Particle Accelerator and who shall be on-site at all times during the operation of the facility.

- c. For applicants seeking the addition of a dedicated SRS LINAC:
 - i. One (1) board-certified physician trained in radiation oncology, who shall have received special training in operating an SRS LINAC and who shall be on-site when services are provided; and,
 - ii. One (1) medical radiation physicist who shall be available on-site when services are provided; and,
 - iii. One (1) radiation therapy technologist, who shall be registered or eligible by the ARRT or ARCRT, who shall have received special training in operating a SRS LINAC; and who shall be on-site when services are being provided.

- d. For applicants seeking the addition of an OR-Based IORT unit:
 - i. One (1) board-certified physician trained in radiation oncology, who shall have received special training in operating an OR-Based IORT unit and who shall be available on-site when services are being rendered; and,
 - ii. One (1) medical radiation physicist who shall be available onsite when services are being provided.

VII. CONTINUUM OF CARE

Organizations proposing MRT services shall document the development of procedures to ensure that the referring physician or the patient's primary care physician is apprised of treatment results in a timely fashion.

VIII. COST

Applicants shall demonstrate the financial feasibility of a proposed MRT service by presenting projections which will show that revenues will equal expenses by the end of the third year of operation, or identify other sources of revenue or income which will subsidize the deficit.

IX. ACCESSIBILITY

Applicants seeking to provide new MRT services shall demonstrate compliance with the following criteria:

- A. Written clinical criteria clearly specifying who is eligible for the service;
- B. Patient selection policies which provide that no person shall be denied appropriate services on account of age, sex, race, color, creed, national origin, physical or behavioral disability, type of payor, or ability to pay;
- C. A scheduling priority system based on patient need;
- D. Accessibility to the disabled in accordance with all applicable state and federal laws.

X. REPORTING

An applicant for new MRT services, special purpose MRT services or multi-purpose MRT services shall agree to provide the Authority with all requested information and statistical data related to the operation and provision of services and to report that data to the Authority in the time frame and format requested.