

SYNOPSIS

Rule 111-2-2-.42

Specific Review Considerations for MegaVoltage Radiation Therapy Services/Units

STATEMENT OF PURPOSE AND MAIN FEATURES OF PROPOSED RULE

The purpose of this proposed amendment is to amend an existing regulation relating to standards for the review of certificate of need applications associated with radiation therapy services in light of changes in the nature and delivery of radiation therapy and stereotactic radiosurgery services since the last time the rules for such services have been modified.

An amended rule is being proposed to address these service changes. While the current rule addresses standards for conventional radiation therapy only, the new rule addresses both conventional radiation therapy and stereotactic radiosurgery and shall be known as the MegaVoltage Radiation Therapy (MRT) rule.

The proposed amendment has the following features:

1. defines the applicability of the rule and creates two main categories of MRT: special purpose and non-special;
2. delineates applicable definitions;
3. develops need standards specific to non-special MRT and special purpose MRT;
4. defines certain exceptions applicable to non-special MRT and special purpose MRT;
5. develops adverse impact standards applicable to special and non-special MRT;
6. provides for standards relating to financial accessibility of the services;
7. provides for quality of care through requirements relating to cancer treatment programs;
8. requires access to consultative services, requires reporting to the Georgia Comprehensive Cancer Registry;

9. provides staffing standards for special purpose and non-special MRT;
and
10. mandates the provision of data to the Department.

DIFFERENCES BETWEEN EXISTING RULE AND PROPOSED RULE

For the most part, the entire rule and all of its standards have been revised with most existing standards deleted and new standards created. New standards are proposed as follows:

APPLICABILITY

The proposed rule adds standards to the applicability section of the existing rules at 111-2-2-.42(1) to clarify that:

- The MRT rules and standards shall include Stereotactic Radiosurgery (SRS), Stereotactic Body Radiation Therapy (SBRT), and conventional radiation therapy where previously there were two separate rules;
- There shall be two distinct and separate categories of MRT: non-special units and special purpose units; and
- An operator of a non-special unit shall not be authorized to operate a special purpose unit without obtaining a separate CON to do so, and vice versa.

The applicability section at 111-2-2-.42(1) also indicates which sections of the rules and standards apply to non-special and which apply to special purpose MRT.

DEFINITIONS

The proposed rule adds standards to the definition section of the existing rules at 111-2-2-.41(2) to define the main terms used throughout the rule.

The following new definitions have been added:

- Brachytherapy;
- Complex treatment visit;

- Course of treatment;
- Gamma knife;
- Heavy particle accelerator;
- Intensity modulated radiation therapy or IMRT;
- Intermediate treatment visit;
- Megavoltage radiation therapy or MRT;
- MRT service;
- MRT unit;
- Non-special MRT unit or non-special unit;
- Operating room based intraoperative MRT unit;
- Simple treatment visit;
- Simulation;
- Special purpose MRT unit or special purpose unit;
- Stereotactic body radiation therapy;
- Stereotactic treatment visit or SRS treatment visit;
- Stereotactic Radiosurgery;
- SRS LINAC;
- Treatment site; and
- Treatment visit

The proposed rule deletes the existing rule's definition of "most recent two years" as that term's definition is now used in place of the term in the standards contained in 111-2-2-.42(3).

The proposed rule deletes the existing rule's definition of "radiation therapy" as that term is more accurately defined as MRT in the proposed rule.

The proposed rule deletes the existing rule's definition of "optimal utilization" as the term no longer needs a definition; rather, the actual optimal utilization number (9000 equivalent treatment visits) is utilized throughout the standards.

The proposed rule modifies the definition of "health planning area" to delineate two separate planning areas maps: the state service delivery regions for non-special MRT and 5 special purpose delivery regions.

The proposed rule modifies the definitions of "horizon year" and "unit" to reflect the change from "radiation therapy" to MRT.

NEED STANDARDS

The proposed rule modifies the need methodology contained in 111-2-2.42(3)(a)(1), which is currently used for conventional radiation therapy to be applicable to non-special MRT units once the proposed rule is adopted. These modifications are as follows:

- References to radiation therapy are changed to non-special MRT;
- References to the incidence of cancer have been altered to exclude basal, epithelial, papillary, and squamous cell carcinomas in certain situations where MRT would not be an acceptable treatment option;
- Instead of projecting need based on the number of cases, the rule projects the number of visits needed in the future based on a two year running average specific to each planning region;
- Future projected equivalent visits are calculated based on weighted equivalents of a simple, intermediate, complex, IMRT, or SRS treatment visit and the actual past two years average experience of treatment visits in the planning area attributable to those classification of treatment visits; and
- The capacity of a non-special unit has been changed to 9000 weighted equivalent visits as opposed to the current capacity of 250 patients or 6000 un-weighted treatment visits.

The aggregate utilization standard of 111-2-2.42(3)(a)(2) has been amended to clarify that if a provider does not exist in the planning area at the time of the need projection, the provider will not be calculated in the aggregate utilization; furthermore, any provider that exists but who does not report data to

the Department shall be included at the statewide average utilization rate for the most recent survey year when calculating the aggregate utilization.

The rule proposes a new need standard for special purpose MRT units that varies based on the type of unit. These standards are located at 111-2-2-.42(4)(a)

EXCEPTIONS TO NEED

The proposed rule modifies the exceptions to the need methodology contained in 111-2-2.42(3)(b) as follows:

- References to radiation therapy have been changed to MRT;
- The rural exception has been modified to require applicants seeking the exception to demonstrate that they will serve 150 patients in lieu of the current requirement that they serve 200 patients;
- The existing utilization exception, whereby a provider who exceeds 90% utilization over the most recent two years is excepted from the need projection, has been maintained; however, a provision has been added that provides any non-special unit added pursuant to this exception is not counted in the calculation for the need and aggregate utilization for new units in the applicable state service delivery region; and
- The existing exception for significant out of state utilization has been amended to apply to the addition of a non-special unit at the same defined location and to actually provide for the number of weighted visits that must be achieved from out of state residents before the exception conditions would apply.

The proposed rule adds an exception based on cost, quality, financial access, and geographic accessibility for special purpose MRT units at 111-2-2-.42(4)(b).

ADVERSE IMPACT

The proposed rule modifies the adverse impact standards that are applicable to non-special MRT and which are contained in 111-2-2-.42(3)(c) as follows:

- Added specifications of how an applicant for a new/expanded non-special MRT unit will not adversely impact existing and

approved facilities or programs; a decreased annual utilization of an existing and approved facility that was at or above 80% to less than 70%, and a decreased annual utilization by 10% to existing facilities/programs whose current utilization is below 80%, is considered an adverse impact. The current standard has similar provisions but they have been slightly modified;

- Addition requirements have been added to maintain that adverse impact shall be calculated based on future population growth and market share; and
- A time frame of 24 months has been added to the adverse impact standard.

The proposed rule adds an adverse impact standard for special purpose MRT at 111-2-2-.42(4)(c).

FINANCIAL ACCESSIBILITY

The proposed rule modifies the standards relating to financial accessibility contained in 111-2-2-.42(3)(d) as follows:

- Removes references to radiation therapy and replaces those terms with MRT; and
- Deletes the provision that would allow a health care facility to make a facility wide commitment in lieu of a service specific commitment.

At 111-2-2-.42(4)(d), the proposed rule adds a financial accessibility standard for special purpose MRT that is in all ways similar to the non-special MRT standards.

CANCER TREATMENT PROGRAM

At 111-2-2-.42(3)(e), the proposed rule deletes the requirement that an applicant demonstrate that they meet certain continuity of care standards and expands this requirement by requiring the applicant document a cancer treatment program that meets certain minimum specifications. A similar requirement is added for special purpose units, and other necessary medical equipment, at 111-2-2-.42(4)(e) with slight modification to remove reference to those facets of a cancer treatment program that would not be applicable to special purpose MRT providers.

CONSULTATIVE SERVICES

The proposed rule adds standards to require an applicant for both special purpose and non-special MRT to have access to consultative services from major disciplines, a multi-disciplinary cancer committee, patient evaluation studies, and educational programs. The non-special MRT standard is located at 111-2-2-.42(3)(f), and the special purpose standard is located at 111-2-2-.42(4)(f).

CANCER REGISTRY

The proposed rule has moved the standard relating to participation in the State Cancer Registry. This is a requirement of the current rule, but would be located at 111-2-2-.42(3)(g) for non-special MRT and at 111-2-2-.42(4)(g) for special purpose MRT.

STAFFING

The proposed rule adds minimum staffing standards for non-special MRT at 111-2-2-.42(3)(h) and for special purpose MRT at 111-2-2-.42(4)(h).

PROVISION OF DATA

Provisions relating to the provision of data to the Department have been relocated to 111-2-2-.42(3)(i) for non-special MRT and to 111-2-2-.42(4)(i) for special purpose MRT.

111-2-2-.42 Specific Review Considerations for MegaVoltage Radiation Therapy Services/Units.

(1) **Applicability.**

(a) A certificate of need will be required for the establishment of any new or expanded MegaVoltage Radiation Therapy Service.

(b) MegaVoltage Radiation Therapy, including Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) may be conducted on non-special units or on special purpose units.

(c) A certificate of need will be required for the addition of a non-special MRT unit. An application for the addition of a non-special MRT unit shall address the standards contained in 111-2-2-.42(3) in addition to the general review considerations of 111-2-2-.09(1). A certificate holder who has been authorized to provide MRT service solely on a non-special unit may not provide service on a special purpose unit without obtaining a special purpose MRT certificate of need.

(d) A certificate of need will be required for the addition of a special purpose MRT unit. An application for the addition of a special purpose MRT unit shall address the standards contained in 111-2-2-.42(4) in addition to the general review considerations of 111-2-2-.09(1). A certificate holder who has been authorized to provide MRT service solely on a special purpose unit may not provide service on a non-special unit without obtaining a non-special MRT certificate of need.

(e) An application for the establishment of a new or expanded MegaVoltage Radiation Therapy Service with the addition of both non-special and special purpose MRT units shall address the standards of 111-2-2-.42(3), 111-2-2-.42(4) and the general review considerations of 111-2-2-.09(1).

(2) **Definitions.**

(a) “Brachytherapy” means the administration of radiation therapy by applying a radioactive material inside or in close proximity to the patient. The material may be contained in various types of apparatus; may be on the surface of plaques; or may be enclosed in tubes, needles, wire, seeds, or other small containers. Common materials that are or have been used for the administration of brachytherapy include but are not limited to radium, Cobalt-60, Cesium-137, Iodine-125, Palladium-103 and Iridium-192.

(b) “Complex treatment visit” means a treatment visit involving three or more treatment sites, tangential fields with wedges, rotational or arc techniques or other special arrangements, or custom blocking.

(c) “Course of treatment” means the planned series of visits that compose a plan for treatment of one or more cancer sites for a single patient.

(d) "Gamma knife" means a special stereotactic radiosurgery unit consisting of multiple cobalt sources all simultaneously focused to irradiate cancer or other neoplasms in the brain or cerebrovascular system abnormalities.

(a)(e) "Health Planning Area" or "Planning Area" means the geographic regions in Georgia as defined in the official State Health Plan for use in planning for radiation therapy MRT services.

1. The Health Planning Areas or Planning Areas for non-special MRT services are the twelve state service delivery regions established by O.C.G.A. § 50-4-7.

2. The Health Planning Areas or Planning Areas for special purpose MRT services are five sub-state regions comprised as follows:

(i) Special Purpose MRT Region 1, including the following counties:

Dade, Walker, Catoosa, Whitfield, Murray, Gilmer, Fannin, Union, Towns, Rabun, Stephens, Habersham, White, Lumpkin, Dawson, Pickens, Gordon, Chattooga, Floyd, Bartow, Cherokee, Forsyth, Hall, Banks, Franklin, Hart, Gwinnett, Fulton, Cobb, Paulding, Polk, Haralson, Douglas, DeKalb, Rockdale, Newton, Henry, Clayton, and Fayette;

(ii) Special Purpose MRT Region 2, including the following counties:

Elbert, Madison, Jackson, Barrow, Oconee, Clarke, Oglethorpe, Greene, Morgan, Walton, Wilkes, Lincoln, Columbia, McDuffie, Warren, Taliaferro, Glascock, Jefferson, Richmond, Burke, Screven, Jenkins, and Emmanuel;

(iii) Special Purpose MRT Region 3, including the following counties:

Carroll, Coweta, Heard, Troup, Meriwether, Pike, Spalding, Lamar, Upson, Harris, Talbot, Taylor, Muscogee, Chattahoochee, Marion, Schley, Macon, Sumter, Webster, Stewart, Quitman, Randolph, Terrell, Lee, Worth, Dougherty, Calhoun, Clay, Early, Baker, Mitchell, Colquitt, Miller, Brooks, Thomas, Grady, Decatur, and Seminole;

(iv) Special Purpose MRT Region 4, including the following counties:

Hancock, Putnam, Jasper, Butts, Monroe, Jones, Baldwin, Washington, Johnson, Treutlen, Montgomery, Wheeler, Telfair, Wilcox, Dodge, Laurens, Pulaski, Bleckley, Houston, Peach, Twiggs, Wilkinson, Bibb, Crawford, Dooly, Crisp, Ben Hill, Irwin, Turner, Cook, Tift, Berrien, Lanier, Echols, and Lowndes; and

(v) Special Purpose MRT Region 5, including the following counties:

Effingham, Bulloch, Candler, Toombs, Tattnall, Evans, Bryan, Chatham, Liberty, Long, McIntosh, Wayne, Appling, Jeff Davis, Coffee, Bacon, Pierce, Brantley, Glynn, Camden, Charlton, Ware, Atkinson, and Clinch.

(f) “Heavy particle Accelerator” means a machine such as a cyclotron, which produces beams of high-energy particles such as protons, neutrons, pions, or heavy ions with rest masses greater than that of an electron ($m_0c^2 = 0.511$ MeV).

~~(b)~~(g) “Horizon Year” means the last year of a five-year projection period for need determinations for radiation therapy MRT services.

(h) “Intensity modulated radiation therapy” or “IMRT” means a treatment delivery utilizing a radiotherapy treatment plan optimized using an inverse or forward planning technique to modulate the particle or energy fluence to create a highly conformal dose distribution. This beam modulated treatment delivery can be accomplished either by the use of the computer controlled multi-leaf collimator or high resolution milled or cast compensators.

(i) “Intermediate treatment visit” means a treatment visit involving two separate treatment sites, three or more fields to a single treatment site, or the use of special blocking.

(j) “Megavoltage radiation therapy” or “MRT” means a clinical modality in which patients with cancer, other neoplasms, or cerebrovascular system abnormalities are treated with radiation which is delivered by an MRT unit.

~~(c) “Most recent two years” means the twenty-four month period immediately prior to the month of application, in the case of data submitted by the applicant, or the twenty-four month period documented in the agency annual or ad-hoc survey process provided that the most recent such survey covers a period of time ending not more than six (6) months prior to the month of application.~~

(k) “MRT service” means the CON approved MRT utilization of a MRT unit(s) at one geographic location.

(l) “MRT unit” or “unit” means a CON approved linear accelerator; cobalt unit; 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.

(m) “Non-special MRT unit” or “non-special unit” means an MRT unit other than an MRT unit meeting the definition of a special purpose MRT unit.

(n) “Operating room based intraoperative MRT unit” or “OR-based IORT unit” means an MRT unit that is designed to emit only electrons, 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.

~~(d) “Optimal Utilization” refers to patient treatment visits and shall be defined as 6,000 treatment visits per year per radiation therapy unit.~~

~~(e) "Radiation Therapy" means the use of penetrating rays, including to linear accelerators, x-rays and other sources of radiation, or subatomic particles to destroy cancer cells or treat medical conditions.~~

~~(o) "Simple treatment visit" means a treatment visit involving a single treatment site, single treatment field, or parallel opposed fields with the use of no more than simple blocks.~~

~~(p) "Simulation" is the process of defining relevant normal and abnormal anatomy, acquiring the images and data necessary to develop the patient's approved radiation treatment plan. Simulation always occurs prior to treatment and may be repeated multiple times during the course of treatment depending on the type of cancer, the radiation therapy technique utilized and the patient's clinical response to treatment. Simulation is used to direct the treatment beams to the specific volume.~~

~~(q) "Special purpose MRT unit" or "special purpose unit" or "special unit" means any of the following types of MRT units: (i) heavy particle accelerator, (ii) gamma knife, (iii) dedicated linear accelerator stereotactic radiosurgery unit (SRS LINAC), including CyberKnife, or (iv) an OR-based IORT unit.~~

~~(r) "Stereotactic body radiation therapy (SBRT)" is a term used to describe extracranial stereotactic radiosurgery (SRS) or radiotherapy (SRT). SBRT is a radiotherapy treatment method to deliver a high dose of radiation to the target, utilizing either a single dose or a small number of fractions with a high degree of precision within the body.~~

~~(s) "Stereotactic treatment visit" or "SRS treatment visit" means a visit involving SRS or SBRT treatment techniques.~~

~~(t) "Stereotactic Radiosurgery (SRS)" is performed in a limited number of treatment visits (up to a maximum of five), using a rigidly attached stereotactic guiding device, other immobilization technology and/or a stereotactic image-guidance system to treat lesions in the body (extracranial) or brain (intracranial). Technologies that are used to perform SRS include linear accelerators, particle beam accelerators and multi source Cobalt-60 units.~~

~~(u) "SRS LINAC" is a dedicated linear accelerator stereotactic radiosurgery unit that consists of three key components: (i) an advanced linear accelerator (linac) (this device is used to produce a high energy megavoltage of radiation), (ii) a device which can point the linear accelerator from a wide variety of angles, and (iii) image-guidance patient positioning system using kilovoltage x-rays for either in-room diagnostic x-rays or tomographic images. 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, SRS LINAC includes units such as CyberKnives.~~

~~(v) "Treatment site" means the anatomical location of the MRT treatment.~~

(w) "Treatment visit" means one patient encounter during which MRT is administered. One treatment visit may involve one or more treatment ports or fields. Each separate encounter by the same patient at different times of the same day shall be counted as a separate treatment visit.

(f)(x) "Unit" means a single machine used for radiation therapy, generally a linear accelerator MRT services.

(g)(y) "Urban County" means a county with a projected population for the horizon year of 100,000 or more and a population density for that year of 200 or more people per square mile. All other counties are "rural."

(3) Standards for Non-Special MRT.

(a) The need for a new or expanded radiation therapy service the addition of a non-special MRT unit shall be determined through the application of a Numerical Need method and an assessment of the aggregate utilization rate of existing services not including units added through the exception in section (3)(b)(2) of this rule.

1. The numerical need for a new or expanded radiation therapy service the addition of a non-special MRT unit in a planning area shall be determined through the application of a demand-based forecasting model. The model is outlined in the steps listed below, and all data elements relate to each planning area:

(i) Calculate the projected incidence of cancer excluding basal, epithelial, papillary, and squamous cell carcinomas of the skin from other than a genital area for each county by multiplying the most recent Cancer Incidence Rate, as published by the State Cancer Registry, for each county by the horizon year population for the county;

(ii) Multiply the projected incidence of cancer by 50% to determine the number of projected cancer cases in each county that could be treated with radiation therapy a non-special MRT unit;

(iii) Add the number of treatable cases for each county within a Health Planning Area to determine the projected number of patients needing treatment with a non-special MRT unit need for radiation therapy services within the Health Planning Area for in the horizon year;

(iv) Multiply the number obtained in step (iii) above by the most recent two year average of treatment visits per patient for the respective planning area of each county to project the number of projected patient visits in the horizon year;

(v) Determine the percentage of total visits in each planning area attributable to (1) Simple treatment visits, (2) Intermediate treatment visits, (3) Complex treatment visits, (4) IMRT, and (5) SRS treatment visits performed on non-special equipment as based on a running average of the most recent two annual surveys for facilities located in each respective planning area. Prior to the 2008 survey

year, the percentage of total visits in each planning area shall be based on the most recent annual survey for facilities located in each respective planning area;

(vi) Determine the number of projected equivalent visits in the horizon year for each planning area as follows:

A. Project the number of equivalent simple visits by multiplying the percentage obtained in step (v) for simple visits by the projected patient visits in the horizon year obtained in step (iv);

B. Project the number of equivalent intermediate visits by multiplying the percentage obtained in step (v) for intermediate visits by the projected patient visits in the horizon year obtained in step (iv) and multiply the product by the weighted equivalent for intermediate visits, 1.1;

C. Project the number of equivalent complex visits by multiplying the percentage obtained in step (v) for complex visits by the projected patient visits in the horizon year obtained in step (iv) and multiply the product by the weighted equivalent for complex visits, 1.3;

D. Project the number of equivalent IMRT visits by multiplying the percentage obtained in step (v) for IMRT visits by the projected patient visits in the horizon year obtained in step (iv) and multiply the product by the weighted equivalent for IMRT visits, 1.8;

E. Project the number of equivalent SRS visits by multiplying the percentage obtained in step (v) for SRS visits by the projected patient visits in the horizon year obtained in step (iv) and multiply the product by the weighted equivalent for SRS visits, 7.0; and

F. Sum the products obtained in step (vi) A. through step (vi) E.;

(iv)(vii) Calculate the number of needed ~~radiation therapy service~~ non-special MRT units by dividing the number of ~~treatable cases by 250~~ projected equivalent visits obtained in step (iv) F. by 9,000, which represents the ~~Soptimal number of unduplicated patients to be served by a radiation therapy~~ weighted equivalent capacity of a non-special MRT unit within a given year.; and

(v)(viii) Determine the net numerical unmet need for ~~radiation therapy services~~ non-special MRT units by subtracting the total number of ~~radiation therapy~~ non-special MRT units currently existing or approved for use, not including units approved pursuant to the exception in section (3)(b)(2) of this rule, from the number of needed ~~radiation therapy~~ non-special MRT units obtained in step (vii).

2. Prior to approval of an additional non-special MRT unit ~~new or expanded radiation therapy service~~ in a planning area, the aggregate utilization rate for all ~~radiation therapy services~~ existing non-special MRT units, not including units approved pursuant to the exception in section (3)(b)(2) of this rule, in that planning area shall equal or exceed 80% of ~~optimal utilization for the most recent survey year.~~ capacity based on 9,000 weighted equivalent visits. For those

existing non-special MRT units that have not reported data in the most recent survey year, the Department shall include the non-reporting unit at the statewide average utilization rate.

(b) Exceptions to the need standard referenced in (3)(a) may be granted for applicants proposing any of the following:

1. To assure geographic access to ~~a new radiation therapy~~ non-special MRT services in rural areas when the proposed service is:

(i) to be located in a rural county;

(ii) to be located a minimum of 45 miles away from any existing ~~radiation therapy or approved non-special MRT~~ service; and

(iii) projected to serve a minimum of ~~200~~ 150 patients per year. For purposes of this requirement, service projections must be submitted by the applicant using, at a minimum, state cancer registry data and documented cancer treatments within the service area.

~~2. To allow expansion of an existing service, if the actual utilization of each radiation therapy unit within that service has exceeded 90 % of optimal utilization over the most recent two years.~~

2. To allow expansion of an existing service, if the actual utilization of each radiation therapy unit within that service has exceeded 90% of optimal utilization over the most recent two years. Any such units approved pursuant to this exception shall not be included in the calculation of need and aggregate utilization for the applicable service delivery region but will be included in the Department non-special MRT unit inventory.

3. To allow ~~expansion of an existing service,~~ the addition of a non-special MRT unit at the same defined location if the applicant has a substantial out-of-state patient base. 'Substantial out of state patient base' shall be defined as using at least 33% of ~~optimal utilization capacity or 2,970 weighted equivalent visits at the applicant's own percentage of treatment visits weighted by treatment type using the statewide weighted equivalent factor~~ for each ~~radiation therapy non-special MRT~~ unit over the most recent two years to treat patients who reside outside of the State of Georgia.

4. To remedy an atypical barrier to ~~radiation therapy non-special MRT~~ services based on cost, quality, financial access and geographic accessibility.

(c) An applicant for a new or expanded ~~radiation therapy non-special MRT~~ service shall document the impact on existing and approved services which already provide ~~radiation therapy non-special MRT~~ to the residents of the planning area with the goal of minimizing adverse impact on ~~the delivery system and shall document that the new or expanded service would not result in an existing service falling below 80% of optimal utilization.~~ For those existing and approved services which already provide services to the residents of the planning

~~area and who are already performing below 80% of optimal utilization, the application shall document that it will not cause such existing service to fall more than 10% below its current utilization. existing and approved services of the same type in its planning area. An applicant for a new or expanded non-special MRT service shall have an adverse impact on existing and approved programs if it will:~~

~~1. decrease annual utilization of an existing service, whose current utilization is at or above 80%, to a projected utilization of less than 70% within the first twenty-four months of the initial operation of the service or additional non-special MRT unit; or~~

~~2. decrease annual utilization of an existing service, whose current utilization is below 80%, by 10% or more within the first twenty-four months of the initial operation of the service or additional non-special MRT unit.~~

~~An applicant shall provide evidence of projected impact by taking into account existing planning area market share of existing non-special MRT services and future population growth or by providing sufficient evidence that the current population is underserved by the existing non-special MRT services, if any, within the planning area. An applicant proposing an additional non-special MRT unit service pursuant to the exceptions to need standards referenced in (3)(ab)(42). and (3)(a)2. shall not be required to document impact on existing and approved services as required by this paragraph.~~

(d) An applicant for a new or expanded ~~radiation therapy~~ non-special MRT service shall foster an environment that assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:

1. providing evidence of written administrative policies that prohibit the exclusion of services to any patient on the basis of age, race, or ability to pay;

2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds three percent of annual, adjusted gross revenues for the ~~radiation therapy~~ non-special MRT service; ~~or, in the case of an applicant providing other health services, the applicant may request that the Division allow the commitment for services to indigent and charity patients to be applied to the entire facility;~~

3. providing a written commitment to participate in the Medicaid and Peach Care programs;

4. providing a written commitment to participate in any other state health benefits insurance programs for which the radiation therapy service is eligible; and

5. providing documentation of the past record of performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid, and indigent and charity patients.

(e) An applicant for a new or expanded ~~radiation therapy~~ non-special MRT service shall provide evidence of ability to meet the following continuity of care standards: a cancer treatment program, which shall include the provision of the following, either on-site or through written agreements with other providers:

~~1. Document a plan whereby the facility and its medical staff agree to provide or, in the case of a free-standing facility, agree to participate in a full array of cancer services to the community, including, but not limited to, community education and outreach, prevention, screening, diagnosis, and treatment.~~

~~2. Document current and ongoing participation in the State Cancer Registry Program; and~~

~~1. Access to stimulation capabilities, which may include a dedicated simulator, a radiation therapy treatment unit, a virtual-reality based three-dimensional simulation system, or other diagnostic X-ray, magnetic resonance, 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 non-special MRT service;~~

~~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, 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's anatomical contour and utilize measured or modeled radiation output data from the specific unit used to treat the patient. The minimum software requirements for the treatment planning system are an external beam program, an irregular field routine, and a Brachytherapy package;~~

~~3. Non-Special MRT capability including electron beam capability;~~

~~4. Capability to fabricate treatment aids;~~

~~5. Access to brachytherapy;~~

~~(f) The applicant must provide a written commitment that physicians providing professional radiation oncology services at the MRT facility shall at all times have privileges or be eligible for and have an active pending application for privileges and be members in good standing of the medical staff, or are eligible for and have an active pending application for privileges, of a hospital with a comprehensive cancer treatment program located within the applicant's service area which will provide those physicians with access to participate in all of the following:~~

~~1. Consultative services from all major disciplines needed to develop a comprehensive treatment plan.~~

~~2. A multi-disciplinary cancer committee, which shall be a standing committee that:~~

(i) includes representatives from the medical specialties or sub-specialties 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;

(ii) meets at least on a quarterly basis; and

(iii) is responsible for the following:

A. establishing educational and problem oriented multi-disciplinary, facility-wide cancer conferences that include the major anatomic locations of cancer seen at the facility;

B. monitoring, evaluating, and reporting to the medical staff and governing body on the quality of care provided to patients with cancer; and

C. oversight of the applicant's tumor registry for quality control, staging, and abstracting;

3. Patient care evaluation studies, which shall be 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 evaluation studies; facility quality assurance activities; and ongoing monitoring, evaluating, and action planning; and

4. Cancer prevention and education programs.

(g) The applicant must participate and report to the Georgia Comprehensive Cancer Registry of the Georgia Department of Human Resources, Division of Public Health.

(h) An applicant shall demonstrate that the following staff, at a minimum, will be identified and available:

1. One (1) FTE board-certified or board-qualified physician trained in radiation oncology, which shall be available by continuous means of direct communication with the non-special MRT unit in person or by radio, telephone, or telecommunication;

2. One (1) medical radiation physicist, who shall be an individual who is board-certified or board-qualified by the American Board of Radiology in therapeutic radiological physics; or board-certified by the American Board of Medical Physics in medical physics with a special competence in radiation oncology physics; and who shall be available by means of direct communication with the non-special MRT unit in person or by radio, telephone, or telecommunication;

3. One (1) medical dosimetrist, who shall be a member of the radiation oncology team who has the knowledge of the overall characteristics and clinical

relevance of radiation oncology treatment machines and equipment, is cognizant of procedures commonly used in brachytherapy and has the education and expertise necessary to generate radiation dose distributions and dose calculations in collaboration with the medical physicist and radiation oncologists; and who shall be available by means of direct communication with the non-special MRT unit in person or by radio, telephone, or telecommunication;

4. Two (2) 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 at all times of operation of the facility; and

5. One (1) program director, who shall be a board-certified physician trained in radiation oncology who may also be the physician required under (h)(1); and who shall be available by means of direct communication with the non-special MRT unit in person or by radio, telephone, or telecommunication;

(f)(i) An applicant for a new or expanded radiation therapy non-special MRT service shall agree to provide the department with all requested information and statistical data related to the operation and provision of services and to report that data to the department in the time frame and format requested by the Division.

(4) Standards for Special Purpose MRT.

(a) The need for the addition of a special purpose MRT unit shall be determined through analysis of the capacity and utilization of the existing units of the same type in the planning area and an applicant's reasonable and documented projection of a minimum volume as follows:

| <u>Special MRT Equipment</u> | <u>Capacity</u> | <u>Minimum Aggregate Utilization</u> | <u>Minimum Projected Volume</u> |
|---|-------------------------|---|---|
| <u>Gamma Knife</u> | <u>500</u> | <u>80%</u> | <u>300 by 3rd Year of Operation</u> |
| <u>Heavy Particle Accelerator</u> | <u>4,000 per Gantry</u> | <u>80%</u> | <u>2,400 per Gantry by 3rd Year of Operation</u> |
| <u>Dedicated SRS LINAC (including CyberKnife)</u> | <u>850</u> | <u>80%</u> | <u>510 by 3rd Year of Operation</u> |
| <u>OR-based IORT</u> | <u>250</u> | <u>80%</u> | <u>150 by 3rd Year of Operation</u> |

Where capacity is measured in annual procedures; where minimum aggregate utilization is the aggregate utilization rate for all existing special purpose MRT units of the same type (Gamma Knife utilization for Gamma Knife, etc.) in the planning area, except that for those existing special purpose MRT units that have not reported data in the most recent survey year, the Department shall include the non-reporting unit at the statewide average utilization rate for special purpose equipment of the same type; and where the minimum projected volume is measured in procedures per year.

(b) Exceptions to the need standards referenced in (3)(a) may be granted for applicants proposing to remedy an atypical barrier to special purpose MRT services based on cost, quality, financial access and geographic accessibility.

(c) An applicant for a new or expanded special purpose MRT service shall document the impact on existing and approved services of the same type (Gamma Knife for Gamma Knife application, etc) which already provide special purpose MRT to the residents of the planning area with the goal of minimizing adverse impact on existing and approved services of the same type in its planning area. An applicant for a new or expanded special purpose MRT service shall have an adverse impact on existing and approved programs if it will:

1. decrease annual utilization of an existing service of the same type, whose current utilization is at or above 70%, to a projected utilization of less than 60% within the first twenty-four months of the initial operation of the service or additional special purpose MRT unit; or

2. decrease annual utilization of an existing service of the same type, whose current utilization is below 70%, by 10% or more within the first twenty-four months of the initial operation of the service or additional special purpose MRT unit.

An applicant shall provide evidence of projected impact by taking into account existing planning area market share of existing special purpose MRT services and future population growth or by providing sufficient evidence that the current population is underserved by the existing special purpose MRT services, if any, within the planning area.

(d) An applicant for a new or expanded special purpose MRT service shall foster an environment that assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:

1. providing evidence of written administrative policies that prohibit the exclusion of services to any patient on the basis of age, race, or ability to pay;

2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds three percent of annual, adjusted gross revenues for the special purpose MRT service;

3. providing a written commitment to participate in the Medicaid and PeachCare for Kids™ programs;

4. providing a written commitment to participate in any other state health benefits insurance programs for which the radiation therapy service is eligible; and

5. providing documentation of the past record of performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid, and indigent and charity patients.

(e) An applicant for a new or expanded special purpose MRT service 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 other diagnostic X-ray, magnetic resonance, 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 special purpose MRT service;

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, 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's anatomical contour and utilize measured or modeled radiation output data from the specific unit used to treat the patient;

3. Capability to fabricate treatment aids as applicable;

(f) The applicant must provide written commitment that physicians providing professional radiation oncology services at the special purpose MRT facility shall at all times have privileges or be eligible for and have an active pending application for privileges and be members in good standing of the medical staff of a hospital with a comprehensive cancer treatment program located within the applicant's service area which will provide those physicians with access to participate in all of the following:

1. Consultative services from all major disciplines needed to develop a comprehensive treatment plan.

2. A multi-disciplinary cancer committee, which shall be a standing committee that:

(i) includes representatives from the medical specialties or sub-specialties 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;

(ii) meets at least on a quarterly basis; and

(iii) is responsible for the following:

A. establishing educational and problem oriented multi-disciplinary, facility-wide cancer conferences that include the major anatomic locations of cancer seen at the facility;

B. monitoring, evaluating, and reporting to the medical staff and governing body on the quality of care provided to patients with cancer; and

C. oversight of the applicant's tumor registry for quality control, staging, and abstracting;

3. Patient care evaluation studies, which shall be 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; and

4. Cancer prevention and education programs.

(g) The applicant must participate and report to the Georgia Comprehensive Cancer Registry of the Georgia Department of Human Resources, Division of Public Health.

(h) An applicant shall demonstrate that the following staff, at a minimum, will be identified and available:

1. For applicants seeking the addition of a Gamma Knife:

(i) One (1) FTE board-certified or board-qualified physician trained in radiation oncology, who shall have received special training in operating a Gamma Knife and who shall be available on-site; and

(ii) One (1) medical radiation physicist, who shall be an individual who is board-certified or board-qualified by the American Board of Radiology in therapeutic radiological physics; or board-certified by the American Board of Medical Physics in medical physics with special competence in radiation oncology physics; who shall have received special training in operating a Gamma Knife; and who shall be available on-site;

2. For applicants seeking the addition of a Heavy Particle Accelerator, Two (2) 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); who shall have received special training in operating a Heavy Particle Accelerator and who shall be on-site at all times of operation of the facility;

3. For applicants seeking the addition of a dedicated SRS LINAC:

(i) One (1) FTE board-certified or board-qualified physician trained in radiation oncology, who shall have received special training in operating an SRS LINAC and who shall be available on-site; and

(ii) One (1) medical radiation physicist, who shall be an individual who is board-certified or board-qualified by the American Board of Radiology in therapeutic radiological physics; or board-certified by the American Board of Medical Physics in medical physics with special competence in radiation oncology physics; who shall have received special training in operating an SRS LINAC; and who shall be available on-site;

(iii) One (1) radiation therapy technologist, who shall be registered or eligible by the American Registry of Radiological Technologists (ARRT) or the American Registry of Clinical Radiography Technologists (ARCRT); who shall have received special training in operating an SRS LINAC; and who shall be on-site at all times of operation of the facility; and

4. For applicants seeking the addition of an OR-Based IORT unit:

(i) One (1) FTE board-certified or board-qualified 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; and

(ii) One (1) medical radiation physicist, who shall be an individual who is board-certified or board-qualified by the American Board of Radiology in therapeutic radiological physics; or board-certified by the American Board of Medical Physics in medical physics with special competence in radiation oncology physics; who shall have received special training in operating an OR-Based IORT unit; and who shall be available on-site.

(i) An applicant for a new or expanded special purpose MRT service shall agree to provide the department with all requested information and statistical data related to the operation and provision of services and to report that data to the department in the time frame and format requested by the Division.

Authority O.C.G.A. §§ 31-5A et seq., 31-6 et seq. **History.** Original Rule entitled “Specific Review Considerations for Radiation Therapy Services” adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.