MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
CERTIFICATE OF NEED (CON) SPECIAL COMMISION MEETING

Wednesday, July 23, 2008

Capitol View Building
201 Townsend Street
MDCH Conference Center
Lansing, Michigan 48913

APPROVED-MINUTES

I. Call To Order

Chairperson Goldman called the meeting to order at 1:15 p.m.

A. Members Present:

Edward B. Goldman, Chairperson
Norma Hagenow, Vice-Chairperson
Peter Ajluni, DO
Bradley N. Cory
Dorothy E. Deremo
Marc Keshishian, MD
Adam Miller
Michael A. Sandler, MD
Thomas M. Smith
Michael W. Young, DO (Arrived @ 1:17p.m.)

B. Members Absent:

Vicky L. Schroeder

C. Department of Attorney General Staff:

Ronald J. Styka

D. Michigan Department of Community Health Staff Present:

William Hart
John Hubinger
Joette Laseur
Irma Lopez
Nick Lyon
James McCurtis
Andrea Moore
Taleitha Pytlowanyj
Brenda Rogers

II. Review of Agenda

Motion by Commissioner Ajluni, seconded by Commissioner Smith, to accept the agenda as presented. Motion Carried.

III. Declaration of Conflicts of Interest

Commissioner Sandler stated that he has a conflict of interest because Henry Ford Health Systems has submitted an application for Proton Beam Therapy (PBT).

Chairperson Goldman stated he too has conflict of interest because the University of Michigan has submitted a Letter of Intent (LOI) for PBT.

IV. Review of Minutes – June 11, 2008

Motion by Commissioner Deremo, seconded by Commissioner Ajluni, to approve the minutes as presented. Motion Carried.

V. Megavoltage Radiation Therapy (MRT) Services/Units

A. Concerns

1. Department of Justice

Mr. Styka stated he felt the MRT Services/Units standards abide by the anti-trust laws. He also gave a brief overview of his memo to the Department and Commissioners (Attachment A).

Chairperson Goldman and Vice-Chairperson Hagenow stated they felt the Commissioners should write a formal letter to the Governor in response to her letter.

2. Carbon Ion and Similar Technologies

The Commissioners requested more background information regarding Carbon Ion and similar technologies at the September 16 Commission meeting.

B. On-site Oncologist and Other Technical Changes

Mr. Lyon provided a brief summary of the recommended technical changes to the proposed standards regarding on-site oncologists (Attachment B). Ms. Rogers reviewed the remaining technical changes made to the proposed standards (Attachment B).

C. Public Comment

Liz Palazzolo, Henry Ford (Attachment C)
Doug Rich, St. John Health/Ascension Michigan (Attachment D)
Steve Szelag, University of Michigan (Attachment E)
Carol Christner, Karmanos Cancer Institute
Barb Jackson, Blue Cross Blue Shield of Michigan (Attachment F)
Bob Meeker, Spectrum Health
Larry Horwitz, Economic Alliance for Michigan
James Falahee, Bronson

D. Commission Proposed Action

Motion by Commissioner Keshishian, seconded by Commissioner Deremo, to accept the language proposed by the Department and move it forward for a public hearing, along with the language submitted by Henry Ford regarding Alternative Methodology. Motion Carried, 8-0, Chairperson Goldman and Commissioner Sandler abstained.

VI. Future Meeting Dates

September 16, 2008
December 9, 2008

VII. Public Comment

None.

VIII. Review of Commission Work Plan

A. Commission Discussion

Ms. Rogers provided a brief overview of the Work Plan (Attachment G). Commissioner Sandler asked if language regarding CT would be at the September 16 Commission meeting. Mr. Lyon stated that, at a minimum, there will be a summary of the meetings regarding CT at the September meeting.

B. Commission Action

Motion by Commissioner Ajluni, seconded by Commissioner Miller, to accept the Work Plan. Motion Carried.

IX. Adjournment

Motion by Commissioner Sandler, seconded by Deremo, to adjourn the meeting at 2:40 p.m. Motion Carried.

DEPARTMENT OF

ATTORNEY GENERAL

M E M O R A N D U M

July 22, 2008

TO: Nick Lyon, Deputy Director, Department of Community Health
Ed Goldman, Chairman, Certificate of Need Commission

FROM: Ron Styka, Division Chief, Community Health Division, Department of Attorney General

RE: Proposed Review Standards Governing PBT Services and Federal Antitrust Laws

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It has been suggested that the review standards proposed for final adoption by the Certificate of Need Commission (CON Comm), which would apply to proton beam therapy units and services (PBT), and that were vetoed by the Governor on June 19, 2008, would have violated federal anti-trust laws. Specifically, a concern has been expressed that the requirement in the proposed standard that PBT be made available to the citizens of Michigan through a collaborative of hospitals constitutes a restraint of trade or is anti-competitive in violation of federal law.

Section 1 of the Sherman Act makes illegal any contract, combination or conspiracy in restraint of trade. 15 U.S.C. § 1. However, it is well-established that the Sherman Act does not apply to state actions. *See Parker v. Brown*, 317, U.S. 341 (1943).

The Supreme Court has established a two part test for determining whether a challenged action is exempt under *Parker*: (1) whether there is a clearly articulated and affirmatively expressed state policy; and (2) whether the policy is actively supervised by the state. *California Retail Liquor Dealers Assn v. Midcal Aluminum, Inc.*, 445 U.S. 97, 105 (1980). In *Midcal*, the Court found that the exception to the Sherman Act did not apply to a state liquor pricing scheme, because it was not adequately supervised by the state. In its analysis, the Court emphasized that the state "neither establishe[d] prices nor review[ed] the reasonableness of the price schedules" and that the state did not "monitor market conditions or engage in any 'pointed reexamination' of the program." *Id.*

The Court further emphasized the rigidness of the "active supervision" component in *Patrick v. Burget*, 486 U.S. 92, 101 (1988), stating that this prong "requires that state officials have and exercise power to review particular anticompetitive acts of private parties and disapprove those that fail to accord with state policy." The mere presence of some state involvement or monitoring does not suffice. *See 324 Liquor Corp. v. Duffy*, 479 U.S. 335, 345 n. 7 (1987). Further, it is the conduct that violates the antitrust laws that states must "actively supervise" in order for *Parker* immunity to attach. *A.D. Bedell Wholesale Co., Inc. v. Philip Morris Inc.* 263 F.3d 239, 262 (3d Cir. 2001).

In the situation before us, a threshold question is whether a collaborative among hospitals to build and share a PBT unit is anticompetitive. In my opinion, it is not. While the collaborative technically fits the definition of a "contract, combination or conspiracy," it is not

clear that the collaborative required in the PBT review standard language will restrain trade. Under the proposed PBT standards, the collaborative must provide documentation of its process, policy, and procedure for allowing any other interested entities to participate in the collaborative and the PBT services it offers.[1] Since there is no barrier for competitors to enter the collaborative, there is arguably no restraint of trade.[2]

If there is no restraint of trade, the collaborative requirement of the proposed PBT standards cannot violate federal antitrust laws. However, even if the collaborative did have an anticompetitive effect, it would still be exempt under *Parker*. Specifically, the legality of the collaborative depends on the degree of state involvement and supervision. The standards appear to set out significant state involvement and supervision in the initial application process, [3] and additional involvement and supervision on an annual basis.[4] As such, they do not violate the federal anti-trust laws.

I understand that the CON Commission is going to reexamine its proposed PBT review standard language at a special meeting. In doing so, if it is going to continue to require a collaborative as part of the review standards, the Commission must pay careful attention to the requirement of state involvement and supervision.

The level of supervision by the State must be carefully designed to satisfy the state involvement and supervision requirement as it was elucidated in the decision in *Patrick v. Burget*, 486 U.S. 92, 102 (1988). In that case the State of Oregon had the following supervisory involvement over a challenged peer-review statutory requirement:

> Hospitals in Oregon are under statutory obligation to establish peer-review procedures and to review those procedures on a regular basis. The State Health Division, exercising its enforcement powers, may initiate judicial proceedings against any hospital violating this law. In addition, the Health Division may deny, suspend or revoke a hospital's license for failure to comply with the statutory requirement.

Yet, the Supreme Court concluded this was not active supervision, because "the Health Division's statutory authority over peer review relate[d] only to a hospital's procedures; that authority [did] not encompass the actual decisions made by hospital peer-review committees." *Id.*

Whatever review standards that the CON Commission proposes that include the requirement of a single collaboration of hospitals, the State's involvement must include review of

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[1] Sect 10(E)

[2] It can be argued that the "real" restraint of trade is that the standards only provide for one collaborative in the state. However, this is a part of the state's comprehensive certificate of need program, which is exempt from federal antitrust laws under *Parker*.

[3] Sect. 10(F) provides that "an applicant shall provide an implementation plan for financing and operating the proposed PBT service, including, but not limited to, how physician staff privileges, patient review, patient selection, and patient care management shall be determined.

[4] Sect 16(3) (B) provides that "the PBT service shall provide the CON Commission, on an annual basis, with the reports designed to assess the affordability, quality. and accessibility of PBT services in Michigan.

the delivery of the PBT service, not just the collaborative's application procedures. In order to satisfy *Midcal*, the state has to take an active approach, seeking to insure that cost, access, and quality are being properly managed by the collaborative. This can be provided for through required conditions for approval, coupled with mandatory reporting requirements that are subject to State verification.

It has also been brought to my attention that new language for a review standard governing PBT services has been proposed for consideration by the CON Commission at its special meeting scheduled for July 23, 2008. As I understand it, the proposed language makes significant changes from the PBT review standard that was not approved by the governor. These changes appear to be consistent with the legal analysis in this memorandum of advice. In particular, I note that it would be possible for there to be more than one collaborative of hospitals providing this service under the revised language. However, I urge the Commission to carefully review Section 16 of the proposed standards, to be certain that the State will take an active approach to insuring that cost, access, and quality are being properly managed by any collaborative approved under the PBT standard.

Thank you for your inquiry. This is division level advice and not an opinion of the Attorney General.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR MEGAVOLTAGE RADIATION THERAPY (MRT) SERVICES/UNITS

(By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207, and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. (1) These standards are requirements for approval and delivery of services for all projects approved and certificates of need issued under Part 222 of the Code that involve MRT services/units.

(2) An MRT service/unit is a covered clinical service for purposes of Part 222 of the Code. An MRT service/unit previously approved pursuant to Section 7 of these standards now seeking approval to operate pursuant to sections 4, 5, 6, 8, OR 9~~, or 10~~ shall be considered as a person requesting CON approval to begin or expand, as applicable, operation of an MRT service/unit. An MRT unit approved to operate as a special purpose MRT unit seeking approval to operate as a non-special MRT unit shall be considered as a person requesting CON approval to begin or expand, as applicable, operation of a non-special MRT service/unit.

(3) The Department shall use sections 4, 5, 6, 8, 9, and 10, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

(4) The Department shall use Section ~~15~~16, as applicable, in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

Section 2. Definitions

Sec. 2. (1) ~~As used in~~FOR PURPOSES OF these standards:

(a) "Acquisition of an existing MRT service or existing MRT unit(s)" means the acquisition (including purchase, lease, donation, or other comparable arrangement) of an existing MRT service or existing MRT unit(s).

(b) "Begin operation of an MRT service" means the establishment of a non-special MRT unit at a geographic location where an MRT service is not currently provided. The term does not include the acquisition or relocation of an existing MRT service and/or unit(s) or the renewal of a lease.

(c) "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, and Iridium-192.

(d) "Cancer treatment program" means a coordinated, multi-disciplinary 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, all of the following services: (i) access to consultative services from all major disciplines needed to develop a comprehensive treatment plan, (ii) a computer-based treatment planning system, (iii) medical radiation physicist involvement, (iv) MRT capability including electron beam capability, (v) treatment aid fabrication capability, (vi) brachytherapy, (vii) a multi-disciplinary cancer committee, (viii) a tumor registry, (ix) patient care evaluation studies, and (x) cancer prevention and education programs.

(e) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

(f) “Code” means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan compiled Laws.

(g) "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.

(h) "Computer based treatment planning system" means a computer system capable of displaying radiation doses and dose distributions within a patient using anatomical data from that patient and using measured 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.

(i) "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.

(j) "Cyber knife" means~~, for purposes of these standards,~~ a treatment device that is a frameless special stereotactic radiosurgery unit that consists of three key components: (i) an advanced, lightweight linear accelerator (linac) (this device is used to produce a high energy megavoltage of radiation), (ii) a robot which can point the linear accelerator from a wide variety of angles, and (iii) several x-ray cameras (imaging devices) that are combined with software to track patient position. The cameras obtain frequent pictures of the patient during treatment and use this information to target the radiation beam emitted by the linear accelerator.

(k) "Department" means the Michigan Department of Community Health (MDCH).

(l) "Dosimetrist" means 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 measure and generate radiation dose distributions and calculations under the direction of a medical physicist and/or a radiation oncologist.

(m) “Driving miles” means the number of miles from the address of the proposed MRT service to the address of the closest existing MRT unit. Driving miles is the number of miles from address to address as identified by use of mapping software that is verifiable by the Department.

(n) "Duplication factor" means the number derived by subtracting the duplication rate from 1.

(o) "Duplication rate" means the percent of new cancer cases in each planning area determined by the Department, Vital Records and Health Data Development Section, that have been reported more than one time to the Michigan Cancer Surveillance Program.

(p) "Equivalent treatment visit" or "ETV" means a unit of measure, based on the type of treatment visit, that reflects the relative average length of time one patient spends in one treatment visit in an MRT unit. Section 12 sets forth how ETVs shall be calculated.

(q) "Existing MRT service" means a CON approved and operational facility and equipment used to provide MRT services including but not limited to the simulator(s), block fabrication materials, and all existing MRT units at a geographic location(s).

(r) “Existing MRT unit” means a CON approved and operational equipment used to provide MRT services.

(s) "Expand an existing MRT service" means adding one additional MRT unit to the number of existing MRT units.

(t) "Full time equivalent" or "FTE" means an individual(s) with normally scheduled working hours of 40 hours per week.

(u) "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.

(v) "Geographic location" means either (i) the geographic location of a licensed health facility as defined in the CON Review Standards applicable to the type of health facility or (ii) if the location is not a health facility as defined in Part 222 of the Code, a distinct geographic location separate from another location.

(w) "Heavy particle accelerator" means a machine such as a cyclotron which produces beams of high energy particles such as protons, neutrons, pions, CARBON IONS, or OTHER heavy ions with masses greater than that of an electron.

(X) “HIGH MRT UNIT” OR “HMRT UNIT” MEANS A HEAVY PARTICLE ACCELERATOR OR ANY OTHER MRT UNIT OPERATING AT AN ENERGY LEVEL EQUAL TO OR GREATER THAN 30.0 MILLION ELECTRON VOLTS (MEGAVOLTS OR MEV).

(Y) "HOSPITAL MRT SERVICE" MEANS AN MRT SERVICE OWNED BY A HOSPITAL OR OWNED BY A CORPORATION THAT IS ITSELF WHOLLY OWNED BY HOSPITAL(S).

(~~x~~Z) "Image guided radiation therapy" or "IGRT" means the use of in-room imaging to allow precise target localization using ultrasound, implanted fiducial markers or image reconstruction using kV or megavoltage beams. Two-dimensional port films using patient anatomy for localization do not constitute IGRT.

(~~y~~AA) "Immediately available" means continuous availability of direct communication with the MRT unit in person or by radio, telephone, or telecommunication.

(~~z~~BB) "Intensity modulated radiation therapy" or "IMRT" means a visit utilizing only the computer controlled multi-leaf collimator part of the CMS definition for IMRT.

(~~aa~~CC) "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.

(~~bb~~DD) "Intraoperative treatment visit" means a treatment visit where a dose of megavoltage radiation is delivered to a surgically exposed neoplasm or cancerous organ/site using a dedicated unit.

(~~cc~~EE) "Institutional review board" or "IRB" means an institutional review board, as defined by Public Law 93-348, that is regulated by Title 45 CFR 46.

(~~dd~~FF) "Isocenter" means the virtual point in space about which the MRT unit operates and is placed at the center of the tumor for the delivery of the radiation treatment.

(~~ee~~GG) "Licensed hospital site" means either: (i) in the case of a single site hospital, the location of the hospital authorized by license and listed on that licensee's certificate of licensure or (ii) in the case of a hospital with multiple sites, the location of each separate and distinct inpatient site as authorized by licensure.

(~~ff~~HH) "Licensed MRT unit" means an MRT unit that is licensed by the Nuclear Regulatory Commission (NRC) or registered by the Michigan Department of Community Health, Division of Health Facilities and Services, Radiation Safety Section.

(~~gg~~II) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6 and1396r-8 to 1396v.

(~~hh~~JJ) "Medical radiation physicist" means an individual who is (i) board certified or board qualified by the American Board of Radiology in radiological physics or therapeutic radiological physics or (ii) board certified or board qualified by the American Board of Medical Physics in medical physics with special competence in radiation oncology physics.

(~~ii~~KK) "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 a MRT unit.

(~~jj~~LL) "MRT program" means one or more MRT services operated at one or more geographic locations under the same administrative unit.

(~~kk~~MM) "MRT service" means the CON approved MRT utilization of a MRT unit(s) at one geographic location.

(~~ll~~NN) "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.

(~~mm~~OO) "Metropolitan statistical area county" means a county located in a metropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix C.

(~~nn~~PP) "Michigan Cancer Surveillance Program" means the program for the collection and analysis of information on cancer in Michigan operated by the Department, Vital Records and Health Data Development Section, mandated by Act 82 of 1984, being Section 333.2619 of the Michigan Compiled Laws.

(~~oo~~QQ) "Micropolitan statistical area county" means a county located in a micropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix C.

(~~pp~~RR) "Multi-disciplinary cancer committee" means 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 (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.

(~~qq~~SS) "New cancer case," ~~for purposes of these standards,~~ means a person with any newly diagnosed cancer excluding basal, epithelial, papillary, and squamous cell carcinomas of the skin from other than a genital area.

(~~rr~~TT) "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 OR AN HMRT UNIT.

(~~ss~~UU) "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.

(~~tt~~VV) "Patient care evaluation studies" means a system of patient care evaluation, conducted at least twice 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; hospital wide quality assurance activities; and ongoing monitoring, evaluating, and action planning.

(~~uu~~WW) "Planning area" means the groups of counties shown in Section 16.

(~~vv~~XX) "Relocation of an existing MRT service and/or MRT unit(s)" means a change in the geographic location within the same planning area.

(~~ww~~YY) "Replace/upgrade an existing MRT unit" means an equipment change that results in an applicant operating the same number of non-special and the same number and type of special purpose MRT units before and after the equipment change.

(~~xx~~ZZ) "Rural county" means a county not located in a metropolitan statistical area or micropolitan statistical areas as those terms are defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R., p. 82238 (December 27, 2000) and as shown in Appendix C.

(~~yy~~AAA) "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.

(~~zz~~BBB) "Simulation" means the precise mock-up of a patient treatment with an apparatus that uses a diagnostic x-ray tube and duplicates an MRT unit in terms of its geometrical, mechanical, and optical properties.

(~~aaa~~CCC) "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, (~~i~~ii) dedicated stereotactic radiosurgery unit, (~~iv~~III) dedicated total body irradiator (TBI), (Iv) an OR-based IORT unit, or (v~~i~~) cyber knife.

(~~bbb~~DDD) "Stereotactic treatment visit" means a visit involving the use of a stereotactic guiding device with radiotherapy for the destruction of a precisely defined intracranial and/or extracranial tumor or lesion.

(~~ccc~~EEE) "Total body irradiator" or "TBI" means a specially modified dedicated cobalt unit certified as a total body irradiator by the Nuclear Regulatory Commission (NRC) or a permanently modified dedicated linear accelerator that uses a very wide beam of gamma rays or x-rays to irradiate the entire body simultaneously.

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

(~~eee~~GGG) "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.

(~~fff~~HHH) "Tumor registry," ~~for the purposes of these standards,~~ means a manual or computerized data base containing information about all malignancies and only those that are diagnosed and/or treated at the applicant's facility. The malignancies must be reportable to the Michigan Cancer Surveillance Program as required pursuant to Public Act 82 of 1984, as amended.

(~~ggg~~III) "Very complex treatment visit" means those visits listed in Section 12 that involve special techniques in the performance of the MRT.

(2) The definitions in Part 222 shall apply to these standards.

Section 3. Modification of the Appendices

Sec. 3. (1) The Commission may modify the Duplication Rates and the Duplication Factors set forth in Appendix A based on data obtained from the Michigan Cancer Surveillance Program presented to the Commission by the Department.

(2) The Commission may periodically modify the Distribution of MRT Courses by Treatment Visit Category set forth in Appendix B based on data provided by MRT providers as part of a Department survey presented to the Commission by the Department.

(3) The Commission shall establish the effective date of the modifications made pursuant to subsections (1) or (2).

(4) Modifications made by the Commission pursuant to subsections (1) or (2) shall not require standard advisory committee action, a public hearing, or submittal of the standard to the Legislature and the Governor in order to become effective.

Section 4. Requirements for approval - applicants proposing to begin operation of a MRT service OTHER THAN AN MRT SERVICE UTILIZING AN HMRT UNIT

Sec. 4. (1) An applicant proposing to begin operation of a MRT service, OTHER THAN AN MRT SERVICE UTILIZING AN HMRT UNIT, shall demonstrate that:

(a) a minimum of 8,000 equivalent treatment visits (ETVs) for each proposed unit results from application of the methodology described in Section 11, and

(b) the proposed MRT unit is not a special purpose MRT unit.

(2) An applicant that demonstrates all of the following shall not be required to be in compliance with the requirement in subsection (1):

(a) The site of the proposed MRT service is located in a rural or micropolitan statistical area county.

(b) The site of the proposed MRT service is 60 driving miles or more from the nearest MRT service.

(c) The proposed MRT service projects a minimum of 5,500 equivalent treatment visits (ETVs) for each proposed unit based on the application of the methodology described in Section 11.

(d) The proposed MRT unit is not a special purpose MRT unit.

(3) All applicants under this section shall demonstrate, at the time the application is submitted to the Department, that the following staff, at a minimum, will be provided:

(a) 1 FTE board-certified or board-qualified physician trained in radiation oncology,

(b) 1 board-certified or board-qualified radiation physicist certified in therapeutic radiologic physics,

(c) 1 dosimetrist or physics assistant,

(d) 2 radiation therapy technologists [registered or eligible by the American Registry of Radiological Technologists (ARRT)], and

(e) 1 program director who is a board-certified physician trained in radiation oncology who may also be the physician required under subsection (3)(a).

Section 5. Requirements for approval - applicants proposing to expand an existing MRT service OTHER THAN AN MRT SERVICE UTILIZING AN HMRT UNIT

Sec. 5. (1) An applicant proposing to expand an existing MRT service, OTHER THAN AN MRT SERVICE UTILIZING AN HMRT UNIT, with an additional non-special MRT unit shall demonstrate:

(a) an average of 10,000 ETVs was performed in the most recent 12-month period on each of the applicant's non-special MRT units, and

(b) the additional unit shall be located at the same site, unless the requirements of section 9(2) also have been met.

(2) An applicant proposing to expand an existing MRT service, OTHER THAN AN MRT SERVICE UTILIZING AN HMRT UNIT, with a special purpose MRT unit shall demonstrate each of the following, as applicable:

(a) An average of 8,000 ETVs was performed in the most recent 12-month period on each of the applicant's non-special MRT units at the location where the special purpose unit is to be located.

(b) An applicant proposing to expand by adding a dedicated total body irradiator shall have either (i) a valid CON to operate a bone marrow transplantation program or (ii) a written agreement to provide total body irradiation services to a hospital that has a valid CON to operate a bone marrow transplantation program. Documentation of the written agreement shall be included in the application at the time it is submitted to the Department.

~~(c) An applicant proposing to expand by adding a heavy particle accelerator shall have available, either on-site or through written agreement(s), 3-dimensional imaging and 3-dimensional treatment planning capabilities. Documentation of the written agreement shall be included in the application at the time it is submitted to the Department.~~

(~~d~~C) An applicant proposing to expand by adding and operating a dedicated stereotactic radiosurgery unit (including a gamma knife and cyber knife) shall demonstrate that (i) the applicant has, at the time the application is filed, a contractual relationship with a board-eligible or board-certified neurosurgeon(s) trained in stereotactic radiosurgery and (ii) on-site 3-dimensional imaging and 3-dimensional treatment planning capabilities.

(~~e~~D) An applicant proposing to expand by adding an operating room based intraoperative MRT unit shall demonstrate that (i) the hospital at which the OR-based IORT unit will be located meets the CON review standards for surgical facilities if the application involves the replacement of or an increase in the number of operating rooms and (ii) the OR-based IORT unit to be installed is a linear accelerator with only electron beam capabilities.

Section 6. Requirements for approval - applicants proposing to replace/upgrade an existing MRT unit(s) OTHER THAN AN MRT SERVICE UTILIZING AN HMRT UNIT

Sec. 6. An applicant requesting to replace/upgrade an existing MRT unit(s), OTHER THAN AN HMRT UNIT, shall demonstrate each of the following, as applicable.

(1) An applicant requesting to replace/upgrade an existing non-special MRT unit which is the only unit at that geographic location, shall demonstrate each of the following:

(a) The unit performed at least 5,500 ETVs in the most recent 12-month period.

(b) The replacement unit will be located at the same geographic location as the unit to be replaced, unless the applicant demonstrates that the requirements of Section 9 have been met.

(2) An applicant requesting to replace/upgrade an existing non-special MRT unit at a MRT service which is the only MRT service in the planning area shall demonstrate each of the following:

(a) Each unit at the geographic location of the unit to be replaced operated at an average of at least 5,500 ETVs in the most recent 12-month period.

(b) The replacement unit will be located at the same geographic location as the unit to be replaced, unless the applicant demonstrates that the requirements of Section 9 have been met.

(3) An applicant, other than an applicant meeting all of the applicable requirements of subsection (1) or (2), requesting to replace/upgrade a non-special MRT unit shall demonstrate each of the following:

(a) Each non-special unit at the geographic location of the unit to be replaced operated at a total of at least 13,000 ETVs for two units and an additional 5,500 ETVs for each additional unit (i.e., 13,000 ETVs + 5,500 ETVs = 18,500 ETVs for three units, 13,000 ETVs + 5,500 etvs + 5,500 ETVs = 24,000 ETVs for four units, etc.) in the most recent 12-month period.

(b) The replacement unit will be located at the same geographic location as the unit to be replaced, unless the applicant demonstrates that the requirements of Section 9 have been met.

(4) An applicant requesting to replace/upgrade an existing special purpose unit shall demonstrate each of the following, as applicable:

(a) The special purpose unit to be replaced operated at ~~the following level of utilization during the most recent 12-month period, as applicable:~~

~~(i) an average of 7,000 ETVs for each heavy particle accelerator;~~

~~(ii)~~ an average of 1,000 ETVs for each OR-based IORT unit, gamma knife, cyber knife, dedicated stereotactic radiosurgery unit, or dedicated total body irradiator DURING THE MOST RECENT 12-MONTH PERIOD.

(b) The replacement special purpose unit will be located at the same geographic location as the special purpose unit to be replaced, unless the applicant demonstrates that the applicable requirements of sections 5 and 9 have been met.

(c) An applicant proposing to replace a dedicated total body irradiator shall have either (i) a valid CON to operate a bone marrow transplantation program or (ii) a written agreement to provide total body irradiation services to a hospital that has a valid CON to operate a bone marrow transplantation program.

(5) An applicant under this section shall demonstrate that the MRT unit proposed to be replaced/upgraded is fully depreciated according to generally accepted accounting principles; that the existing unit clearly poses a threat to the safety of the public; or that the proposed replacement unit offers technological improvements which enhance quality of care, increase efficiency, and/or reduce operating costs and patient charges.

(6) Equipment that is replaced shall be removed from service and disposed of or rendered considerably inoperable within 30 days of the replacement equipment becoming operational.

Section 7. Requirements for approval - applicants proposing to use MRT units exclusively for research

Sec. 7. (1) An applicant proposing a MRT unit to be used exclusively for research shall demonstrate each of the following:

(a) The applicant operates a therapeutic radiation residency program approved by the American Medical Association, the American Osteopathic Association, or an equivalent organization.

(b) The MRT unit shall operate under a protocol approved by the applicant's IRB.

(c) The applicant agrees to operate the unit in accordance with the terms of approval in Section ~~15~~16(1)(c)(v), (viii), (xiii); ~~15~~16(2); ~~15~~16(~~3~~4); and ~~15~~16(45).

(2) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the requirements and terms of sections 4, 5; 6; and ~~15~~16(1)(c)(i), (ii), (iii), (iv), (vi), (vii), (ix), (x), (xi), and (xii) of these standards.

(3) Equipment that is replaced shall be removed from service and disposed of or rendered considerably inoperable within 30 days of the replacement equipment becoming operational.

Section 8. Requirements for approval - applicants proposing to acquire an existing MRT service or an existing MRT unit(s) OTHER THAN AN MRT SERVICE UTILIZING AN HMRT UNIT

Sec. 8. (1) An applicant proposing to acquire an existing MRT service and its MRT unit(s), OTHER THAN AN MRT SERVICE UTILIZING AN HMRT UNIT, shall demonstrate that it meets all of the following:

(a) The project is limited solely to the acquisition of an existing MRT service and its MRT unit(s).

(b) The project will not change the number or type (special, non-special) of MRT units at the geographic location of the MRT service being acquired unless the applicant demonstrates that the project is in compliance with the requirements of Section 4 or 5, as applicable.

(c) The project will not result in the replacement/upgrade of the MRT unit(s) to be acquired unless the applicant demonstrates that the requirements of Section 6, as applicable, have been met.

(2) An applicant proposing to acquire an existing MRT unit(s) of an existing MRT service, OTHER THAN AN MRT SERVICE UTILIZING AN HMRT UNIT, shall demonstrate that it meets all of the following:

(a) The project is limited solely to the acquisition of an existing MRT unit(s) of an existing MRT service.

(b) The project will not change the number or type (special, non-special) of MRT units at the geographic location of the MRT service being acquired unless the applicant demonstrates that the project is in compliance with the requirements of Section 4 or 5, as applicable.

(c) The project will not result in the replacement/upgrade of an existing MRT unit(s) to be acquired unless the applicant demonstrates that the requirements of Section 6, as applicable, also have been met.

(d) The requirements of Section 4(3) have been met.

Section 9. Requirements for approval - applicants proposing to relocate an existing MRT service and/or MRT unit(s) OTHER THAN AN MRT SERVICE UTILIZING AN HMRT UNIT

Sec. 9. (1) An applicant proposing to relocate an existing MRT service and its MRT unit(s), OTHER THAN AN MRT SERVICE UTILIZING AN HMRT UNIT, shall demonstrate that it meets all of the following:

(a) The relocation of the existing MRT service and its MRT unit(s) will not change the number or type (special, non-special) of MRT units in the planning area, unless subsections (c) and/or (d), as applicable, have been met.

(b) The new geographic location will be in the same planning area as the existing geographic location.

(c) The project will not result in the replacement/upgrade of the existing MRT unit(s) to be relocated unless the applicant demonstrates that the requirements of Section 6, as applicable, have been met.

(d) The project will not result in the expansion of an existing MRT service unless the applicant demonstrates that the requirements of Section 5, as applicable, have been met.

(2) An applicant proposing to relocate an MRT unit(s) of an existing MRT service, OTHER THAN AN MRT SERVICE UTILIZING AN HMRT UNIT, shall demonstrate that it meets all of the following:

(a) The relocation of the MRT unit(s) will not change the number or type (special, non-special) of MRT units in the planning area, unless subsections (c) and/or (d), as applicable, have been met.

(b) The new geographic location will be in the same planning area as the existing geographic location.

(c) The project will not result in the replacement/upgrade of the existing MRT (unit)s to be relocated unless the applicant demonstrates that the requirements of Section 6, as applicable, have been met.

(d) The project will not result in the expansion of an existing MRT service unless the applicant demonstrates that the requirements of Section 5, as applicable, have been met.

(e) For volume purposes, the new site shall remain associated to the original site for a minimum of three years.

(f) For a micropolitan statistical area or rural county, each existing MRT unit at the geographic location of the MRT unit to be relocated operated at an average of at least 5,500 ETVs in the most recent 12-month period. For a metropolitan statistical area county, each existing MRT unit at the geographic location of the MRT unit to be relocated operated at an average of at least 8,000 ETVs in the most recent 12-month period.

(g) The requirements of Section 4(3) have been met.

(h) A special purpose unit cannot be relocated to a site that does not have an existing non-special purpose unit.

SECTION 10. REQUIREMENTS FOR APPROVAL – APPLICANTS PROPOSING TO INITIATE AN MRT SERVICE UTILIZING AN HMRT UNIT

SEC. 10. THE USE OF AN HMRT UNIT REPRESENTS EMERGING CANCER TREATMENT TECHNOLOGY AND CONSEQUENTLY PROVIDES A MIXTURE OF BOTH TREATMENT AND RESEARCH USES. THIS SECTION OF THE CON REVIEW STANDARDS FOR MRT SERVICES/UNITS RECOGNIZES THE UNIQUE NATURE OF THIS TECHNOLOGY.

(1) AN APPLICANT PROPOSING TO INITIATE AN MRT SERVICE UTILIZING AN HMRT UNIT SHALL DEMONSTRATE EACH OF THE FOLLOWING:

(A) AN APPLICANT IS A SINGLE LEGAL ENTITY AUTHORIZED TO DO BUSINESS IN THE STATE OF MICHIGAN.

(B) AN APPLICANT IS A COLLABORATIVE THAT CONSISTS OF AT LEAST 40% OF ALL MICHIGAN HOSPITAL MRT SERVICES WITH MORE THAN 30,000 ETVS PERFORMED IN THE MOST RECENT 12-MONTH PERIOD OF DATA AVAILABLE TO THE DEPARTMENT***.***

(C) THE COLLABORATIVE SHALL INCLUDE HOSPITAL MRT SERVICES FROM MORE THAN ONE PLANNING AREA FROM EITHER OR BOTH OF THE FOLLOWING:

(I) THE PARTICIPATING SERVICES UNDER SUBSECTION (B).

(II) HOSPITAL MRT SERVICES WITH THE HIGHEST NUMBER ETVS IN A PLANNING AREA BASED ON THE MOST RECENT 12-MONTH PERIOD OF DATA AVAILABLE TO THE DEPARTMENT.

(D) MRT SERVICES THAT ARE ALREADY PART OF A COLLABORATIVE APPLICATION UNDER THIS SECTION FOR AN MRT SERVICE UTILIZING AN HMRT UNIT OR PART OF AN EXISTING COLLABORATIVE UTILIZING AN HMRT UNIT APPROVED UNDER THIS SECTION SHALL NOT BE INCLUDED IN THE APPLICATION.

(E) AN APPLICANT SHALL PROVIDE DOCUMENTATION OF ITS PROCESS, POLICY AND PROCEDURES***, ACCEPTABLE TO THE DEPARTMENT,*** THAT WILL ALLOW ANY OTHER INTERESTED ENTITIES TO PARTICIPATE IN THE COLLABORATIVE UTILIZING AN HMRT UNIT.

(F) AN APPLICANT SHALL PROVIDE AN IMPLEMENTATION PLAN***, ACCEPTABLE TO THE DEPARTMENT,*** FOR FINANCING AND OPERATING THE PROPOSED MRT SERVICE UTILIZING AN HMRT UNIT INCLUDING, BUT NOT LIMITED TO, HOW PHYSICIAN STAFF PRIVILEGES, PATIENT REVIEW, PATIENT SELECTION, AND PATIENT CARE MANAGEMENT SHALL BE DETERMINED.

(G) AN APPLICANT SHALL INDICATE THAT ITS PROPOSED HMRT UNIT WILL BE AVAILABLE TO BOTH ADULT AND PEDIATRIC PATIENTS.

(H) AN APPLICANT SHALL DEMONSTRATE THAT THE MRT SERVICE UTILIZING AN HMRT UNIT WILL HAVE SIMULATION CAPABILITIES AVAILABLE FOR USE IN TREATMENT PLANNING.

(2) AN APPLICANT PROPOSING TO INITIATE AN MRT SERVICE UTILIZING AN HMRT UNIT SHALL ALSO DEMONSTRATE COMPLIANCE WITH THE REQUIREMENTS OF SECTION 4(3).

Section 11~~10~~. Requirements for approval -- all applicants

Sec. 11~~0~~. ~~An applicant shall provide verification of Medicaid participation at the time the application is submitted to the Department. An applicant that is initiating a new service or is a new provider not currently enrolled in Medicaid shall provide a signed affidavit stating that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services if a CON is approved. If the required documentation is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.~~AN APPLICANT SHALL PROVIDE VERIFICATION OF MEDICAID PARTICIPATION. AN APPLICANT THAT IS A NEW PROVIDER NOT CURRENTLY ENROLLED IN MEDICAID SHALL CERTIFY THAT PROOF OF MEDICAID PARTICIPATION WILL BE PROVIDED TO THE DEPARTMENT WITHIN SIX (6) MONTHS FROM THE OFFERING OF SERVICES, IF A CON IS APPROVED.

Section 12~~1~~. Methodology for computing the projected number of equivalent treatment visits

Sec. 12~~1~~. The applicant being reviewed under Section 4 shall apply the methodology set forth in this section in computing the projected number of equivalent treatment visits (ETVs).

(1) Identify the number of new cancer cases documented in accord with the requirements of Section 14.

(2) Multiply the number of new cancer cases identified in subsection (1) by the duplication factor identified in Appendix A, for the planning area in which the proposed unit will be located.

(3) Multiply the number of new cancer cases produced in subsection (2) by 0.55 to determine the estimated number of courses of MRT.

(4) Multiply the estimated number of courses of MRT by 20 to determine the total estimated number of treatment visits.

(5) Determine the number of estimated simple, intermediate, complex, and IMRT treatment visits by multiplying the total estimated number of treatment visits produced in subsection (4) by the percent allocations for each category as set forth in Appendix B.

(6) Multiply the estimated number of treatment visits in the simple category produced in subsection (5) by 1.0.

(7) Multiply the estimated number of treatment visits in the intermediate category produced in subsection (5) by 1.1.

(8) Multiply the estimated number of treatment visits in the complex category produced in subsection (5) by 1.25.

(9) Multiply the estimated number of treatment visits in the IMRT category produced in subsection (5) by 2.5.

(10) Sum the numbers produced in subsections (6) through (9) to determine the total number of estimated ETVs.

Section 13~~2~~. Equivalent treatment visits

Sec. 13~~2~~. For purposes of these standards, equivalent treatment visits shall be calculated as follows:

(1) For the time period specified in the applicable section(s) of these standards, assign each actual treatment visit provided to one applicable treatment visit category set forth in Table 1.

(2) The number of treatment visits for each category in the time period specified in the applicable section(s) of these standards shall be multiplied by the corresponding ETV weight in Table 1 to determine the number of equivalent treatment visits for that category for that time period.

(3) The number of ETVs for each category determined pursuant to subsection (2) shall be summed to determine the total ETVs for the time period specified in the applicable section(s) of these standards.

TABLE 1 Equivalent Treatments		
Treatment Visit Category	Non-Special Visit Weight	Special Visit Weight
Simple	1.00	
Intermediate	1.10	
Complex	1.25	
IMRT	2.50	
Very Complex:		
Total Body Irradiation		5.00
Hemi Body Irradiation		4.00
~~Heavy Particle Accelerator~~HMRT UNIT		5.00
Stereotactic radio-surgery/radio-therapy*		8.00
(non-gamma knife and cyber knife**)		
Gamma Knife**		8.00
Dedicated OR-Based IORT		20.00

All patients under 5 years of age receive a 2.00 additive factor.

*After the first visit, each additional visit receives 2.5 additional ETVs with a maximum of five visits per course of therapy.

**After the first isocenter, each additional isocenter receives 4 additional ETVs.

Section 14~~3~~. Commitment of new cancer cases

Sec. 14~~3~~. (1) An applicant proposing to use new cancer cases shall demonstrate all of the following:

(a) Each entity contributing new cancer case data provides, as part of the application at the time it is submitted to the Department, a signed governing body resolution that states that the number of new cancer cases committed to the application shall not be used in support of any other application for an MRT unit(s) for the duration of the MRT service for which the data are being committed.

(b) The geographic locations of all entities contributing new cancer case data are in the same planning area as the proposed MRT service.

(2) An entity currently operating or approved to operate a MRT service shall not contribute new cancer cases to initiate any MRT service.

Section 15~~4~~. Documentation of new cancer case data

Sec. 15~~4~~. (1) An applicant required to document volumes of new cancer cases shall submit, as part of its application, documentation from the Department, Vital Records and Health Data Development Section, verifying the number of new cancer cases provided in support of the application for the most recent calendar year for which verifiable data is available from the State Registrar.

(2) New cancer case data supporting an application under these standards shall be submitted to the Michigan Cancer Surveillance Program using a format and media specified in instructions from the State Registrar.

Section 16~~5~~. Project delivery requirements terms of approval for all applicants

Sec. 16~~5~~. (1) An applicant shall agree that, if approved, MRT services shall be delivered in compliance with the following applicable terms of CON approval for each geographical location where the applicant operates an MRT unit:

(a) Compliance with these standards.
(b) Compliance with applicable safety and operating standards.
(c) Compliance with the following quality assurance standards:

(i)(A) The non-special MRT units and ~~heavy particle accelerator~~HMRT UNITs approved pursuant to these standards shall be operating at a minimum average volume of 8,000 ETVs per unit annually by the end of the third full year of operation, and annually thereafter. The following types of special purpose MRT units: OR-based IORT unit, gamma knife, dedicated stereotactic radiosurgery unit and dedicated total body irradiator approved pursuant to these standards shall be operating at a minimum average volume of 1,000 ETVs per special purpose unit annually by the end of the third full year of operation, and annually thereafter. In meeting this requirement the applicant shall not include any treatment visits conducted by MRT units approved exclusively for research pursuant to Section 7.

(B) The non-special MRT units and ~~heavy particle accelerator~~HMRT UNITs approved pursuant to Section 4(2) of these standards shall be operating at a minimum average volume of 5,500 ETVs per unit annually by the end of the third full year of operation, and annually thereafter. In meeting this requirement, the applicant shall not include any treatment visits conducted by MRT units approved exclusively for research pursuant to Section 7.

(ii) An applicant shall establish a mechanism to assure that (a) the MRT service is staffed so that the MRT unit is operated by physicians and/or radiation therapy technologists qualified by training and experience to operate the unit safely and effectively. For purposes of evaluating this subsection, the Department shall consider it prima facie evidence of a satisfactory quality assurance mechanism as to the operation of the unit if the applicant requires the equipment to be operated by a physician who is board certified or board qualified in either radiation oncology or therapeutic radiology, and/or a radiation therapy technologist certified by the American Registry of Radiological Technologists (ARRT) or the American Registry of Clinical Radiography Technologists (ARCRT). However, the applicant may submit and the department may accept other evidence that the applicant has established and operates a satisfactory quality assurance mechanism to assure that the MRT unit is appropriately staffed, and (b) for the MRT service/program operating a dedicated stereotactic radiosurgery unit or a gamma knife, a neurosurgeon(s) trained in each type of special MRT unit being operated is on the active medical staff of the applicant organization.

(iii) At a minimum, the following staff shall be provided: (a) 1 FTE board-certified or board- qualified physician trained in radiation oncology for each 250 patients treated with MRT annually, (b) 1 board-certified or board-qualified radiation physicist, certified in therapeutic radiologic physics, immediately available during hours of operation, (c) 1 dosimetrist or physics assistant for every 300 patients treated with MRT annually, (d) 2 FTE radiation therapy technologists [registered or eligible by the American Registry of Radiological Technologists (ARRT)] for every MRT unit per shift of operation (not including supervisory time), and (e) 1 FTE program director who is a board-certified physician trained in radiation oncology who may also be the physician required under subsection (iii)(a). For purposes of evaluating this subsection, the department shall consider it prima facie evidence as to the training of the physician(s) if the physician is board certified or board qualified in radiation oncology and/or therapeutic radiology.

(iv) All MRT treatments shall be performed PURSUANT~~under the supervision of a~~ TO A radiation oncologist and at least one radiation oncologist will be IMMEDIATELY AVAILABLE ~~on site at the geographic location of the unit~~ during the operation of the unit(s).

(v) The applicant shall have equipment and supplies within the megavoltage therapy unit/facility to handle clinical emergencies that might occur in the unit. MRT facility staff will be trained in CPR and other appropriate emergency interventions and shall be on-site in the MRT unit at all times when patients are treated. A physician shall be on-site in or immediately available to the MRT unit at all times when patients are treated.

(vi) An applicant shall operate a cancer treatment program. For purposes of evaluating this subsection, the department shall consider it prima facie evidence of meeting this requirement if the applicant submits evidence of a cancer treatment program approved by the American College of Surgeons Commission on Cancer. However, the applicant may submit and the Department may accept other evidence that the applicant operates a cancer treatment program as defined in these standards.

(vii) A MRT service will have simulation capability at the same geographic location of the MRT service/unit.

(viii) An applicant shall participate in the Michigan Cancer Surveillance Program.

(ix) An applicant required to document new cancer cases shall agree to pay the State Registrar's costs for verification of the new cancer case data.

(x) The applicant shall accept referrals for MRT services from all appropriately licensed health care practitioners.

(xi) The applicant, to assure that the MRT unit will be utilized by all segments of the Michigan population, shall: (a) not deny MRT services to any individual based on ability to pay or source of payment, (b) provide MRT services to an individual based on the clinical indications of need for the service, and (c) maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually. Compliance with selective contracting requirements shall not be construed as a violation of this term.

(xii)(A) The applicant shall participate in a data collection network established and administered by the department or its designee. The data may include but is not limited to annual budget and cost information, operating schedules, through-put schedules, demographic and diagnostic information, and the volume of care provided to patients from all payor sources and other data requested by the Department or its designee, and approved by the CON Commission. The applicant shall provide the required data on a separate basis for each separate and distinct geographic location or unit, and separately for non-special MRT units and each type of special purpose MRT unit, as required by the Department; in a format established by the Department; and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(B) If the applicant intends to include research treatment visits conducted by a MRT unit other than an MRT unit approved exclusively for research pursuant to Section 7 in its utilization statistics, the applicant shall submit to the department a copy of the research protocol with evidence of approval by the IRB. The applicant shall submit this at the time the applicant intends to include research procedures in its utilization statistics. The applicant shall not report to the Department any treatment visits conducted by an MRT unit approved pursuant to Section 7.

(xiii) The applicant shall provide the Department with a notice stating the first date on which the MRT service and its unit(s) became operational, and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules.

(xiv) The applicant agrees to operate a special purpose MRT unit(s) only for the specific use for which it was approved and to seek approval under a separate CON application to operate the unit as a non-special MRT unit.

(xv) An applicant approved to operate a dedicated total body irradiator that uses cobalt as the source of radiation shall obtain and maintain Nuclear Regulatory Commission certification as a total body irradiator. An applicant approved to operate a dedicated total body irradiator that is a permanently modified linear accelerator, OR AN HMRT UNIT, shall meet any requirements specified by the Department, Division of Health Facilities and Services, Radiation Safety Section.

(xvi) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter.

(2) An applicant for an MRT unit under Section 7 shall agree that the services provided by the MRT unit approved pursuant to Section 7 shall be delivered in compliance with the following terms of CON approval:

(a) The capital and operating costs relating to the research use of the MRT unit approved pursuant to Section 7 shall be charged only to a specific research account(s) and not to any patient or third-party payor.

(b) The MRT unit approved pursuant to Section 7 shall not be used for any purposes other than as approved by the IRB unless the applicant has obtained CON approval for the MRT unit pursuant to Part 222 and these standards, other than Section 7.

(3) AN APPLICANT FOR AN MRT SERVICE UTILIZING AN HMRT UNIT APPROVED UNDER SECTION 10 SHALL AGREE TO DELIVER THE SERVICE IN COMPLIANCE WITH THE FOLLOWING ADDITIONAL TERMS:

(A) ALL PATIENTS TREATED SHALL BE EVALUATED FOR POTENTIAL ENROLLMENT IN RESEARCH STUDIES FOCUSING ON THE APPLICABILITY AND EFFICACY OF UTILIZING AN HMRT UNIT TO TREAT SITE SPECIFIC CANCER TUMORS. A SUMMARY OF THE INFORMATION

REQUIRED BY THIS SUBSECTION SHALL BE PROVIDED BY THE MRT SERVICE UTILIZING AN HMRT UNIT TO THE DEPARTMENT ON AN ANNUAL BASIS.

(B) THE MRT SERVICE UTILIZING AN HMRT UNIT SHALL PROVIDE THE DEPARTMENT, ON AN ANNUAL BASIS, WITH A REPORT DESIGNED TO ASSESS THE AFFORDABLITY, QUALITY, AND ACCESSIBILITY OF THE MRT SERVICE UTILIZING AN HMRT UNIT. ***IN ADDITION THE REPORT SHALL INCLUDE ANNUAL UPDATES TO THE INFORMATION PROVIDED IN SUBSECTIONS 10(E), (F), AND (G).***

(C) AS A CONDITION OF APPROVAL OF AN MRT SERVICE UTILIZING AN HMRT UNIT SHALL AGREE THAT UPON REVIEW OF THE REPORT SUBMITTED UNDER SUBSECTION (B) ABOVE, THE DEPARTMENT MAY ORDER CHANGES WITH REGARD TO THE PROVISION OF THE SERVICE.

(~~4~~3) The operation of and referral of patients to the MRT unit shall be in conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

(~~5~~4) The applicable agreements and assurances required by this section shall be in the form of a certification ~~authorized by the owner or governing body of~~AGREED TO BY the applicant or its authorized agent.

Section 17~~6~~. Planning areas

Sec. 17~~6~~. Counties assigned to each planning area are as follows:

PLANNING AREA	COUNTIES		
1	Livingston	Monroe	St. Clair
	Macomb	Oakland	Washtenaw
	Wayne		
2	Clinton	Hillsdale	Jackson
	Eaton	Ingham	Lenawee
3	Barry	Calhoun	St. Joseph
	Berrien	Cass	Van Buren
	Branch	Kalamazoo	
4	Allegan	Mason	Newaygo
	Ionia	Mecosta	Oceana
	Kent	Montcalm	Osceola
	Lake	Muskegon	Ottawa
5	Genesee	Lapeer	Shiawassee
6	Arenac	Huron	Roscommon
	Bay	Iosco	Saginaw
	Clare	Isabella	Sanilac
	Gladwin	Midland	Tuscola
	Gratiot	Ogemaw	
7	Alcona	Crawford	Missaukee
	Alpena	Emmet	Montmorency
	Antrim	Gd Traverse	Oscoda
	Benzie	Kalkaska	Otsego
	Charlevoix	Leelanau	Presque Isle
	Cheboygan	Manistee	Wexford

8	Alger	Gogebic	Mackinac
	Baraga	Houghton	Marquette
	Chippewa	Iron	Menominee
	Delta	Keweenaw	Ontonagon
	Dickinson	Luce	Schoolcraft

Section 18~~7~~. Effect on prior CON review standards; comparative reviews

Sec. 18~~7~~. (1) These CON review standards supersede and replace the CON Review Standards for Megavoltage Radiation Therapy (MRT) Services/Units approved by the CON Commission on ~~March 14, 2000~~DECEMBER 13, 2005 and effective ~~April 28, 2000~~JANUARY 20, 2006.

(2) Projects reviewed under these standards shall not be subject to comparative review.

APPENDIX A

DUPLICATION RATES AND FACTORS

The following Duplication Rates and Factors are effective December 11, 2007 and remain in effect until otherwise changed by the Commission.

PLANNING AREA	DUPLICATION RATE	DUPLICATION FACTOR
1	0.21085	0.78915
2	0.23517	0.76483
3	0.11219	0.88781
4	0.25664	0.74336
5	0.21849	0.78151
6	0.34615	0.65385
7	0.21865	0.78135
8	0.12314	0.87686

APPENDIX B

DISTRIBUTION OF MRT COURSES BY TREATMENT VISIT CATEGORY

The following Distribution of MRT Courses by Treatment Visit Category is effective December 11, 2007 and remains in effect until otherwise changed by the Commission.

Treatment Visit Category	Statewide Percent
Simple	1.6%
Intermediate	.8%
Complex	73.4%
IMRT	24.2%

Source: 2006 Annual Hospital Statistical Survey

APPENDIX C

CON REVIEW STANDARDS FOR MRT SERVICES

Rural Michigan counties are as follows:

Alcona	Hillsdale	Ogemaw
Alger	Huron	Ontonagon
Antrim	Iosco	Osceola
Arenac	Iron	Oscoda
Baraga	Lake	Otsego
Charlevoix	Luce	Presque Isle
Cheboygan	Mackinac	Roscommon
Clare	Manistee	Sanilac
Crawford	Mason	Schoolcraft
Emmet	Montcalm	Tuscola
Gladwin	Montmorency	
Gogebic	Oceana	

Micropolitan statistical area Michigan counties are as follows:

Allegan	Gratiot	Mecosta
Alpena	Houghton	Menominee
Benzie	Isabella	Midland
Branch	Kalkaska	Missaukee
Chippewa	Keweenaw	St. Joseph
Delta	Leelanau	Shiawassee
Dickinson	Lenawee	Wexford
Grand Traverse	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry	Ionia	Newaygo
Bay	Jackson	Oakland
Berrien	Kalamazoo	Ottawa
Calhoun	Kent	Saginaw
Cass	Lapeer	St. Clair
Clinton	Livingston	Van Buren
Eaton	Macomb	Washtenaw
Genesee	Monroe	Wayne
Ingham	Muskegon	

Source:

65 F.R., p. 82238 (December 27, 2000)
Statistical Policy Office
Office of Information And Regulatory Affairs
United States Office of Management And Budget

Alternative Methodology noted in Red below.

SECTION 10. REQUIREMENTS FOR APPROVAL – APPLICANTS PROPOSING TO INITIATE AN MRT SERVICE UTILIZING AN HMRT UNIT

SEC. 10. THE USE OF AN HMRT UNIT REPRESENTS EMERGING CANCER TREATMENT TECHNOLOGY AND CONSEQUENTLY PROVIDES A MIXTURE OF BOTH TREATMENT AND RESEARCH USES. THIS SECTION OF THE CON REVIEW STANDARDS FOR MRT SERVICES/UNITS RECOGNIZES THE UNIQUE NATURE OF THIS TECHNOLOGY.

(1) AN APPLICANT PROPOSING TO INITIATE AN MRT SERVICE UTILIZING AN HMRT UNIT SHALL DEMONSTRATE EACH OF THE FOLLOWING:

(A) AN APPLICANT IS A SINGLE LEGAL ENTITY AUTHORIZED TO DO BUSINESS IN THE STATE OF MICHIGAN THAT CONSISTS OF THE FOLLOWING:

(I) ALL ENTITIES WITH OWNERSHIP INTEREST IN THE APPLICANT ENTITY OWN AT LEAST ONE HOSPITAL LICENSED IN THE STATE OF MICHIGAN UNDER PART 215 OF THE CODE.

(II) NO OWNERSHIP ENTITIES CURRENTLY OPERATE AN HMRT UNIT , OR HAVE A VALID CON ISSUED UNDER PART 222 TO OPERATE A HMRT UNIT, UNLESS THE OWNERSHIP ENTITY TREATED PATIENTS WITH THE HMRT UNIT PRIOR TO THE EFFECTIVE DATE OF THESE STANDARDS.

(B) THE APPLICANT SHALL HAVE COLLECTIVELY PERFORMED AT LEAST 200,000 ETVS IN THE MOST RECENT 12-MONTHS FOR WHICH VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT AND CALCULATED AS FOLLOWS:

(I) THE SUM OF ALL ETVS PERFORMED AT MRT FACILITIES WHOLLY OWNED BY OWNERSHIP ENTITIES; PLUS

(II) THE PERCENTAGE OF ETVS PERFORMED AT MRT FACILITIES PARTIALLY OWNED BY OWNERSHIP ENTITIES, EQUAL TO THE PERCENTAGE OF OWNERSHIP OF THE FACILITY HELD BY THE OWNERSHIP ENTITIES.

~~AN APPLICANT IS A COLLABORATIVE THAT CONSISTS OF AT LEAST 40% OF ALL MICHIGAN HOSPITAL MRT SERVICES WITH MORE THAN 30,000 ETVS PERFORMED IN THE MOST RECENT 12-MONTH PERIOD OF DATA AVAILABLE TO THE DEPARTMENT.~~

~~(C) THE COLLABORATIVE SHALL INCLUDE HOSPITAL MRT SERVICES FROM MORE THAN ONE PLANNING AREA FROM EITHER OR BOTH OF THE FOLLOWING:~~

~~(I) THE PARTICIPATING SERVICES UNDER SUBSECTION (B).~~

~~(II) HOSPITAL MRT SERVICES WITH THE HIGHEST NUMBER ETVS IN A PL, BASED ON THE DEPARTMENT.~~

~~(D) MRT SERVICES THAT ARE ALREADY PART OF A COLLABORATIVE APPLICATION UNDER THIS SECTION FOR AN MRT SERVICE UTILIZING AN HMRT UNIT OR PART OF AN EXISTING COLLABORATIVE UTILIZING AN HMRT UNIT APPROVED UNDER THIS SECTION SHALL NOT BE INCLUDED IN THE~~

(E) AN APPLICANT SHALL PROVIDE DOCUMENTATION OF ITS PROCESS, POLICY AND PROCEDURES THAT WILL ALLOW ANY OTHER INTERESTED ENTITIES TO PARTICIPATE IN THE COLLABORATIVE UTILIZING AN HMRT UNIT.

(F) AN APPLICANT SHALL PROVIDE AN IMPLEMENTATION PLAN FOR FINANCING AND OPERATING THE PROPOSED MRT SERVICE UTILIZING AN HMRT UNIT INCLUDING, BUT NOT LIMITED TO, HOW PHYSICIAN STAFF PRIVILEGES, PATIENT REVIEW, PATIENT SELECTION, AND PATIENT CARE MANAGEMENT SHALL BE DETERMINED.

(G) AN APPLICANT SHALL INDICATE THAT ITS PROPOSED HMRT UNIT WILL BE AVAILABLE TO BOTH ADULT AND PEDIATRIC PATIENTS.

(H) AN APPLICANT SHALL DEMONSTRATE THAT THE MRT SERVICE UTILIZING AN HMRT UNIT WILL HAVE SIMULATION CAPABILITIES AVAILABLE FOR USE IN TREATMENT PLANNING.

(2) AN APPLICANT PROPOSING TO INITIATE AN MRT SERVICE UTILIZING AN HMRT UNIT SHALL ALSO DEMONSTRATE COMPLIANCE WITH THE REQUIREMENTS OF SECTION 4(3).

[NOTE: Other methodologies accomplishing similar outcomes could also be considered.]

HMRT Testimony for CON Commission
7/23/08

Good afternoon. My name is Doug Rich, Vice President Strategic Planning and Business Development for St John Health and the Michigan Health Ministries of Ascension Health. I also represent the Genesys/Hurley Cancer Institute regarding high megavoltage radiation therapy.

I have worked on behalf of these organizations along with the other organizations Liz Palazzolo mentioned (Henry Ford, Karmanos, and the University of Michigan) to review the proposed MDCH language, and the development of our proposed alternative language regarding the definition of an entity that can apply for initiation of a High Megavoltage Radiation Therapy service. My organizations fully concur with Liz's testimony.

My organizations support the Commission's adoption of language today regarding a collaborative or joint venture approach for this technology. We also ask that the Commission submit for public comment the alternate language we have crafted regarding the definition of an entity that represents hospital owned or partially owned programs with a collective minimum threshold of 200,000 Equivalent Treatment Visits (ETV's). In this way, the Commission is soliciting public comment on the Department's proposed language, and our alternative thereby maximizing the Commission's options when a final decision is made in September.

I appreciate the opportunity to provide this testimony to the Commission, and am happy to respond to any questions you may have.

University of Michigan
Health System

University of Michigan Health System
1500 East Medical Center Drive
Ann Arbor, MI 48109

Public Testimony
Certificate of Need (CON) Review Standards for MRT Services
July 23, 2008

My name is Steven Szelag and I am a Senior Health System Planner at the University of Michigan Health System (UMHS). UMHS wishes to take this opportunity today to offer support for the CON language that requires health systems to work together as a collaborative to bring online high cost technologies such as the Heavy Particle Accelerator being discussed today.

We believe that a collaborative of providers working together on these types of projects is the best public policy and in the best interest of the citizens of the State of Michigan. For the specific CON language being discussed today, UMHS believes that the alternative language offered today provides a better framework of ensuring the highest level of success of creating an environment for the future of having health systems work together on these costly sets of services. The ETV methodology is consistent with other CON language that require volumes as being the primary driver for approval, and it addresses objections raised about the previous proton therapy language.

We ask that the Commission to keep both options viable for further development thru public comment. This will allow discussion and comment on the alternative proposal as well as the MDCH proposed language before final action on these standards, and allow the Commission to adopt the alternative language if it sees fit in September without it being viewed as a substantive change. Thank you for according us this opportunity to make this statement. We stand ready to work with you and with the Department on this issue.

Jackson

ATTACHMENT F

Blue Cross
Blue Shield
Of Michigan

600 E. Lafayette Blvd.
Detroit, Michigan 48226-2998

Testimony
Blue Cross Blue Shield of Michigan/Blue Care Network
CON Commission Meeting
July 23, 2008

On behalf of Blue Cross Blue Shield of Michigan and Blue Care Network, I would like to thank the Commission for this opportunity to testify regarding the Megavoltage Radiation Therapy standards that address Proton Beam Therapy. BCBSM and BCN strongly support the newly revised language and urge the Commission to move this forward today as a proposed action. We remain committed to providing access to cost-effective, high quality health care and continue to support Certificate of Need to ensure the effective expenditure of health care dollars in Michigan.

To reiterate and underscore prior communications, the Blues continue to support a collaborative approach, based on the following key points:

- Proton beam therapy has a limited established application for treatment of a small number of cancers. At BCBSM and BCN, based on medical necessity and evidence-based, peer-reviewed medical literature, PBT is considered a useful therapeutic option when indicated for patients who meet specific criteria.
- There is <u>not</u> enough demand or number of cancer cases that fit its exclusionary criteria to justify the need to invest in multiple facilities throughout the State of Michigan. Thus there appears to be no evidence of access constraints.
- Proton beam therapy has been in existence for decades but is only now being utilized in non-academic clinical settings. Currently there is a dearth of data that supports its impact on clinical outcomes, quality of care, as well as cost-effectiveness.
- In fact, following the exclusion of a small specific set of malignancies; there is a continuing lack of consensus within the medical community, including radiation oncologists, regarding its efficacy in treating a wide range of cancer types.

Blue Cross
Blue Shield
Of Michigan

600 E. Lafayette Blvd.
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Again, we support the proposed language and urge the Commissioners to approve it at today's meeting. As stated in numerous prior communications to Commissioners and the Governor, the Blues endorse the collaborative approach approved by the Commission at its June 11th meeting. However, we recognize the concerns raised by Governor Granholm and others and believe that this language addresses those concerns as follows:

- Based on the fact that collaborative participation by high volume MRT hospitals may be diminished, the required participation of the majority of high volume MRT hospitals would be reduced to at least 40% for the entire state.
- In order to be open to future treatment innovations, these standards would apply to the application of any type of high megavoltage radiation (including carbon ion therapy).

In summary, BCBSM and BCN continue to have concerns that the proliferation of proton beam accelerators would encourage hospitals to place pressure on physicians to direct patients toward proton therapy, when in fact less costly alternatives utilizing photon therapy are just as effective. We feel that this proposed language addresses these issues as well as those raised by the Governor and others, providing an equitable approach to assure high quality, appropriate use and valid research as well as preventing unnecessary costs for ALL of our stakeholders.

We are very appreciative of all those who shared their expertise and insight regarding this issue. We'd like to thank the Commission for their actions (past and future) regarding this issue.

Note: New or revised standards may include the provision that make the standard applicable, as of its effective date, to all CON applications for which a final decision has not been issued.

DRAFT CERTIFICATE OF NEED (CON) COMMISSION WORK PLAN

	2007												2008											
	J	F	M*	A	M	J*	J	A	S*	O	N	D*	J*	F	M*	A*	M	J*	J*	A	S*	O	N	D*
Air Ambulance Services	PH		D R	•	•	• —	P		▲												F			
Bone Marrow Transplantation (BMT) Services																		• —	• P	•	• ▲ F	PH		
Computed Tomography (CT) Scanner Services	PH		D R	S ▮	▮	▮	▮	▮	▮	▮	▮	▮ —		P	▲ F P	• ▲ F	•	•	•	•	•			
Heart/Lung and Liver Transplantation Services																						PH		
Hospital Beds	•	•	•	•	•	• R				PH			D R	•	•	•	•	•	•	•	• —	• P	•	• ▲ F
Magnetic Resonance Imaging (MRI) Services	P	•	▲F—		P				▲F				•	•	• R	•	•	• —	• P	•	• ▲ F	PH		
Megavoltage Radiation Therapy (MRT) Services/Units										PH		R	D R	•	• — P	• ▲ F	• R	•	• — P	•	• ▲ F			
Pancreas Transplantation Services																						PH		
Psychiatric Beds and Services																						PH		
New Medical Technology Standing Committee	• M	• M	• M R	• M	• M	• M R	• M	• M	• M R	• M	• M	• M R A	• M	• M	• M R	• M	• M	• M R	• M	• M	• M R	• M	• M	• M R
Commission & Department Responsibilities			M			M			M			M			M			M			M			M R

KEY

— - Receipt of proposed standards/documents, proposed Commission action
* - Commission meeting
▮ - Staff work/Standard advisory committee meetings
▲ - Consider Public/Legislative comment
** - Current in-process standard advisory committee or Informal Workgroup
• Staff work/Informal Workgroup/Commission Liaison Work/Standing Committee Work

A - Commission Action
C - Consider proposed action to delete service from list of covered clinical services requiring CON approval
D - Discussion
F - Final Commission action, Transmittal to Governor/Legislature for 45-day review period
M - Monitor service or new technology for changes
P - Commission public hearing/Legislative comment period
PH - Public Hearing for initial comments on review standards
R - Receipt of report
S - Solicit nominations for standard advisory committee or standing committee membership

For Approva; Juuly 23, 2008

Updated July 18, 2008

The CON Commission may revise this work plan at each meeting. For information about the CON Commission work plan or how to be notified of CON Commission meetings, contact the Michigan Department of Community Health, Health Policy, Regulation & Professions Administration, CON Policy Section, 7th Floor Capitol View Bldg., 201 Townsend St., Lansing, MI 48913, 517-335-6708, www.michigan.gov/con.

SCHEDULE FOR UPDATING CERTIFICATE OF NEED (CON) STANDARDS EVERY THREE YEARS*

Standards	Effective Date	Next Scheduled Update**
Air Ambulance Services	June 4, 2004	2010
Bone Marrow Transplantation Services	March 8, 2007	2009
Cardiac Catheterization Services	February 25, 2008	2011
Computed Tomography (CT) Scanner Services	June 20, 2008	2010
Heart/Lung and Liver Transplantation Services	June 4, 2004	2009
Hospital Beds and Addendum for HIV Infected Individuals	March 8, 2007	2011
Magnetic Resonance Imaging (MRI) Services	November 13, 2007	2009
Megavoltage Radiation Therapy (MRT) Services/Units	January 30, 2006	2011
Neonatal Intensive Care Services/Beds (NICU)	November 13, 2007	2010
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups	June 20, 2008	2010
Open Heart Surgery Services	February 25, 2008	2011
Pancreas Transplantation Services	June 4, 2004	2009
Positron Emission Tomography (PET) Scanner Services	March 8, 2007	2011
Psychiatric Beds and Services	February 25, 2008	2009
Surgical Services	June 20, 2008	2011
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	February 25, 2008	2010

*Pursuant to MCL 333.22215 (1)(m): "In addition to subdivision (b), review and, if necessary, revise each set of certificate of need review standards at least every 3 years."

**A Public Hearing will be held in October prior to the review year to determine what, if any, changes need to be made for each standard scheduled for review. If it is determined that changes are necessary, then the standards can be deferred to a standard advisory committee (SAC), workgroup, or the Department for further review and recommendation to the CON Commission. If no changes are determined, then the standards are scheduled for review in another three years.