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

Tuesday, September 16, 2008

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

APPROVED MINUTES

I. Call To Order

Vice-Chairperson Hagenow called the meeting to order at 9:23 a.m.

A. Members Present:

Edward B. Goldman, Chairperson (arrived at 9:26 a.m.)
Norma Hagenow, Vice-Chairperson
Peter Ajluni, DO
Dorothy E. Deremo
Marc Keshishian, MD
Adam Miller
Michael A. Sandler, MD
Vicky L. Schroeder
Thomas M. Smith
Michael W. Young, DO

B. Members Absent:

Bradley N. Cory

C. Department of Attorney General Staff:

Ronald J. Styka

D. Michigan Department of Community Health Staff Present:

Carrie Barr
William Hart
Kasi Kelley
Irma Lopez
Nick Lyon
Andrea Moore
Brenda Rogers
Perry Smith

II. Review of Agenda

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

Ms. Rogers noted that all Commissioner travel vouchers need to be returned to the Department by Tuesday, September 23, 2008.

III. Declaration of Conflicts of Interest

Commissioner Sandler noted that Henry Ford Health Systems has submitted an application for Proton Beam Therapy (PBT) and will abstain from both the discussion and voting on this matter.

Chairperson Goldman noted the University of Michigan is part of a proposed PBT collaborative (Letter of Intent has been submitted) and will abstain from both the discussion and voting on this matter.

Chairperson Goldman assumed operation of the meeting.

IV. Review of Minutes – June 11, 2008

Motion by Commissioner Deremo, seconded by Vice-Chairperson Hagenow, to approve the minutes as presented. Motion Carried.

V. Public Comments for Action Items

Thomas Ruane, MD, Blue Cross Blue Shield (Attachment A)
Patrick O'Donovan, William Beaumont Hospitals
Liz Palazzolo, Henry Ford Health System
Carol Christner, Karmanos Cancer Institute
Robert Meeker, Spectrum Health
Marsha Manning, General Motors (Attachment B)
Dennis McCafferty, Economic Alliance of Michigan
Sean Gehle, Ascension Health Michigan (Attachment C)

VI. Megavoltage Radiation Therapy (MRT) Services/Units

Vice-Chairperson Hagenow assumed operation of the meeting.

Ms. Rogers provided an overview of the public hearing comments (Attachment D) and the proposed standards with amendments (Attachment E). Discussion followed.

Motion by Commissioner Miller, seconded by Commissioner Smith, to approve the Standards with amendments and move forward to the Joint Legislative Committee (JLC) and the Governor for the 45-day review period. Motion Carried 8 – 0, Chairperson Goldman and Commissioner Sandler abstained.

VII. Magnetic Resonance Imaging (MRI) Services

Chairperson Goldman assumed operation of the meeting.

Ms. Rogers provided an overview of the public hearing comments (Attachment F) and the proposed standards (Attachment G). Discussion followed. An amendment was made to Section 11(5) to read as follows:

"The proposed IMRI unit must be located in an Operating Room or a room adjoining an operating room allowing for transfer of the patient between the operating room and this adjoining room."

Motion by Commissioner Deremo, seconded by Commissioner Ajluni, to approve the Standards with the amendment to Section 11(5) and move forward to the JLC and the Governor for the 45-day review period. Motion Carried.

VIII. Bone Marrow Transplantation (BMT) Services

Ms. Rogers provided an overview of the public hearing comments (Attachment H) and the proposed standards (Attachment I).

Motion by Vice-Chairperson Hagenow, seconded by Commissioner Smith to approve the Standards and move forward to the JLC and the Governor for the 45-day review period. Motion Carried 8 – 0, as Commissioner Deremo and Commissioner Sandler were absent from the room at the time of the vote.

IX. Hospital Beds

Ms. Rogers provided an overview of the technical changes to the Standards and the new bed need numbers (Attachment J). She noted that the Commission needs to set an effective date for the new bed need numbers. Discussion followed.

Motion by Commissioner Smith, seconded by Vice-Chairperson Hagenow, to approve the Standards using the effective date of the Standards for the date of the new bed need numbers. The Standards will be moved forward to the JLC and scheduled for public hearing. Motion Carried.

Break from 10:31 a.m. until 10:49 a.m.

X. Computed Tomography (CT) Scanner Services – Mini CT Scanners

Mr. Lyon noted that a written report (Attachment K) of the actions taken was provided in the binder and that an additional meeting was currently being scheduled. Discussion followed.

XI. Hospital Beds (continued)

Chairperson Goldman noted that during the break the Department located two dates on Appendix E of the Standards that would require a technical correction. The correct dates will be on the Standards for the public hearing.

XII. New Medical Technology Advisory Committee (NEWTAC)

Commissioner Keshishian provided that there was nothing to report at this time.

XIII. Legislative Report

Mr. Lyon reported that there was no CON legislation to report at this time.

Public Comment: Larry Hortwitz, Economic Alliance of Michigan

XIV. Compliance Report

Mr. Lyon gave an overview of the compliance report (Attachment L) provided. Discussion followed.

XV. Administrative Report

Mr. Hart reported the following staff modifications:

A. Taleitha Pytlowanyj has accepted a position with DLEG and that Carrie Barr will be helping in the interim.
B. Kasi Kelley is the new analyst for the section.

He also noted that a comprehensive evaluation of the data requirements and systems is being completed by MPHI. The hospital bed need methodology calculation was completed by MSU Geography Department. A copy of their report will be forwarded to the Commissioners for their records.

XVI. CON Program Update

Chairperson Goldman accepted the written report (Attachment M).

XVII. Legal Activity

Mr. Styka provided an overview of the report (Attachment N). Discussion followed.

XVIII. Future Meeting Dates

December 9, 2008
January 13, 2009
March 26, 2009
June 9, 2009
September 10, 2009
December 9, 2009

XIX. Public Comment

Dennis McCafferty, Economic Alliance of Michigan
Barbara Jackson, Blue Cross Blue Shield of Michigan

XX. Review of Commission Work Plan

Ms. Rogers gave an overview of the Work Plan (Attachment O). Discussion followed.

Motion by Vice-Chairperson Hagenow, seconded by Commissioner Keshishian, to approve the Work Plan as presented. Motion Carried.

XXI. Adjournment

Motion by Commissioner Deremo, seconded by Commissioner Smith, to adjourn the meeting at 11:30 a.m. Motion Carried.

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Testimony
Blue Cross Blue Shield of Michigan/Blue Care Network

CON Commission Meeting
September 16, 2008

Presented by

Thomas Ruane, MD,

Medical Director of PPO and Care Management Programs

On behalf of Blue Cross Blue Shield of Michigan (BCBSM) and Blue Care Network (BCN), I would like to thank the Commission for this opportunity to testify. BCBSM and BCN continue to support the Certificate of Need (CON) process, which is designed to ensure the delivery of cost-effective, high quality health care in the state.

HMRT (defined as any high megavoltage radiation including proton beam therapy and carbon ion therapy)

BCBSM and BCN strongly support the proposed language and urge the Commission to move this forward today as a final action. This action fits with BCBSM's support of Certificate of Need as a means to ensure the effective use of health care dollars in the state.

As indicated in prior testimony, BCBSM and BCN support a restrained introduction of new clinical applications and technology to help ensure that Michigan citizens receive access to effective and safe care, as demonstrated through clinical outcomes and research trials, while minimizing cost to the health care system.

- Proton beam therapy (PBT) has a limited established application; evidence indicates that it benefits only a limited number and types of cancer cases. At this time, appropriate use of carbon ion therapy is even less well-defined by the medical community.
- There is an insufficient volume of cancer cases in Michigan that meet the PBT criteria to justify an investment in multiple facilities throughout the state.
- There is a scarcity of data and lack of consensus on the impact of PBT and other HMRT on clinical outcomes and the quality and cost-effectiveness of care.
- There is little evidence of utilization controls, which may lead to the increased use of the more expensive HMRT services instead of existing radiation therapy simply because the new technology is available, rather than because of evidence-based need.

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Based on these concerns, BCBSM and BCN continue to believe that Michigan needs only one PBT unit, which is why we continue to support the collaborative approach endorsed and approved by the Commission previously.

Given the concerns raised by the Governor and others, BCBSN and BCN will support the alternative language proposed by the Michigan Department of Community Health (MDCH). BCBSM and BCN commend MDCH on its response and believe that its proposal reflects a reasonable compromise. BCBSM and BCN believe that the MCH proposal goes a long way toward addressing many of the concerns outlined above regarding the proliferation of HMRT units. BCBSN and BCN, thus, urge the Commissioners to take final action on this issue at today's meeting.

MRI Services

BCSM and BCN strongly support this proposed language, particularly the provision that allows for the use of intra-operative MRI units (IMRI) in the acute care setting. We believe that this new application of MRI technology improves patient safety and quality of health care and is the right thing to do for the well being of patients needing this treatment. We urge the Commission to take final action on these standards today.

Bone Marrow Therapy Services

BCBSM and BCN support this proposed standard language. It is our understanding that this language allows the Karmanos Cancer Institute to retain its federal designation, and thus, its CON. We believe that this modification of the BMT standards represents a technical solution to support the retention of a highly regarded BMT program already in operation with a long history of service to residents throughout the State of Michigan. We ask the Commission to take final action today.

Hospital Beds

BCBSM and BCN support the proposed language which appears to be an update of definition and the hospital bed inventory. It is important to keep the standards as current as possible. These updates allow that to happen.

Mini CT Units

BCBSM and BCN understand that a status report will be shared today with final recommendations presented at the December Commission meeting; however, we want to share our current position on this issue. Please note that BCBSM and BCN representatives have been involved in the ongoing discussion of mini-CT units, actively

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participating on the current Work Group and serving on the most recent CT Standard Advisory Committee (SAC).

Based on information received at these meetings and internal discussions, BCBSM and BCN continue to endorse the position put forth by the SAC requiring that all specialists, including ENTs and dentists, follow current CON CT standards with no additional exemptions, for the following reasons:

- **No access problems**: A state wide survey of 30 Michigan hospitals performed by BCN staff over the past two years indicated no access problems with CT scans readily available within three days or less.
- **No cost savings:** No cost savings are generated as there is no difference in billing for these imaging studies despite the location or type of unit.
- **Potential over-utilization:** A June 2008 GAO study, *Medicare Part B Imaging Services: Rapid Spending Growth and Shift to Physician Offices Indicate Need for CMS to Consider Additional Management Practices* strongly suggests that the potential for self-referral generates potential over-utilization, increasing the cost of health care:
  - "From 2000-2006, Medicare spending for imaging services paid to doctors more than doubled to $14 billion, much faster than the increase for hospital-based imaging."
  - "Spending on advanced imaging such as CT scans, MRI and nuclear medicine rose substantially faster than other imaging services…. "
  - "GAO's analysis of this 6-year period showed certain trends linking spending growth to the provision of imaging services in phsycian offices."

  Also, BCBSM's Radiology Management Program partners at American Imaging Management agree that the same dynamics exist in the commercial insurance environment.

With reference to dental CT units, BCBSM and BCN continue to support our prior position regarding excluding orthodontics. There continues to be no new compelling evidence that supports changing the recommendations of the SAC, supported and moved forward by the Commission.

BCBSM and BCN are appreciative of all the individuals who shared their expertise and insight regarding these issues. Specifically, BCBSM and BCN commends the CON Commissioners and MDCH staff for their work in maintaining CON as a strong, vibrant program that continues to help ensure the delivery of high quality, safe and effective care to patients across the state. We thank the Commission for their action on these issues and for the opportunity to share our viewpoint.

CON Commission Public Comments– September 16, 2008

Testimony presented on behalf of The Economic Alliance for Michigan
By Marsha Manning, Manager, Southeast Michigan Health Care Initiatives
General Motors Corp.

I preface my EAM remarks by reporting that General Motors and our colleagues at Chrysler and Ford have found that strong and well developed CON programs have been effective in controlling costs and improving the quality of healthcare services for our employees and retirees. We have found that a strong CON program, such as that found here in Michigan, is effective in accomplishing this objective, as evidenced by the data we have analyzed in ten states where our companies collectively have a significant population of employees, dependents and retirees.

My comments today will address two of the issues before the commission; HMRT, and office-based CT.

HMRT

- We supported the collaborative approach for only ONE of these very high-cost, yet unproven cancer treatment programs in Michigan. Given the Governor's veto in June of the prior proposed standards, we now support the revised standards as a means of limiting the number of these programs in Michigan to no more than TWO.
- The proposed standard calls for a collaborative made up of at least 4 of the 9 highest volume hospital cancer programs in Michigan. We feel this approach has the strongest guarantee that only one additional HMRT program will be built in Michigan. Any standard requiring less than 4 of the highest volume hospital cancer programs has the potential for allowing two HMRT collaborative programs to be built. Given the very limited projected need and the extremely high cost of these HMRT programs, more than one collaborative HMRT programs will only add hundreds of millions of dollars to the cost of healthcare in Michigan at a time when our economy can least afford it, without significant added benefit to patients.
- The revisions to the proposed HMRT standards being considered today address the issues raised by the Governor in her veto letter. Expanding the scope to include all heavy particle accelerators (Proton and Carbon Ion), reducing the number required for a collaborative (from a majority to 40%) and the inclusion of specific supervisory oversight by MDCH (in response to the anti-trust concerns), we believe, responds to all of her concerns.

Specialty CT

- We are concerned that the diffusion of imaging equipment to practitioners' offices will result in dramatic increases in both utilization and costs.
- Recent reports from both Congressional Budget Office (CBO) and the US Government Accountability Office (GAO) state that the largest contributor to the rising costs of healthcare is new technology and within new technology the most rapid increase is in imaging costs.
- The three domestic autos reviewed our own experience across the 10 states in which we collectively have significant populations. We found that the cost of CT services was 60% higher is the states without CON compared to Michigan.
- Regarding dental CT, we oppose expanding the use to include orthodontics until such time as evidence has been provided that this provides greater value to patients. A prior key concern of the MDA regarding these standards was the administrative burden associated with filing for a CON. During the last few months the MDCH has streamlined this process by implementing a new, on-line CON application process. The Commission needs to reaffirm that this administrative change has addressed the issue raised by MDA and that Dental CT will next be addressed at the 2010 review of the CT standards.
- Regarding the ENT CT issue, we support the Commission's long-standing position that all CT scanners are covered under the CON standards. We also support the Commission's position that the standards for each specialty CT (ENT and whatever else comes along) specify appropriate minimum volume and uses for the office based CT. We also support that any provider applying for a CON for an office-based CT can demonstrate need by providing historical evidence that their practice will be performing a minimum number of scans per year. And, that this minimum number of scans per year should be high enough to ensure proficiency and quality.

Thank you for your attention to these matters.

THE MICHIGAN
HEALTH MINISTRIES OF
ASCENSION
HEALTH

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Good morning, my name is Sean Gehle and I am here today on behalf of the Michigan Health Ministries of Ascension Health. The Michigan Health Ministries of Ascension Health continues to be supportive of language that would be incorporated into the current CON MRI standards to provide for a pilot program that would allow applicants to acquire a hospital based Intra-operative MRI unit.

IMRI offers the ability of surgeons to obtain a more accurate MRI scan during surgical and interventional procedures that can offer substantial benefit for the patient as it significantly reduces the additional risks associated with a second anesthetic and/or increased infection from re-operating through a fresh surgical site. We believe that this technology should be available to the residents of Michigan.

I testified on behalf of the Ascension Health Ministries of Ascension Health at the July 30 public hearing that we were concerned about a requirement in the standards that would require that the proposed IMRI unit be located in an operating room. Other notable medical facilities around the country have successfully utilized an alternative configuration which utilizes a fixed IMRI unit in a room adjacent to the Operating Room. We believe one benefit of this configuration is in not bringing a very powerful magnet into the OR environment. We contend that this alternative configuration has not been shown to result in any significant additional risk to the patient and should be allowed for in this language.

After working with the Department and other interested parties we would suggest that the current language appearing in Section 11, Subsection 5, line 561 in the CON Review Standards for MRI Services which reads "The Proposed IMRI unit must be located in an Operating Room" be replaced with "The proposed Intra operative MRI unit must be located in an approved Operating Room or a room adjoining to an approved operating room with the capability of transferring the patient between the operating room and the room adjoining."

Thank you for the opportunity to provide comment today.

9/16/08

Michigan Department of Community Health
MEMORANDUM
Lansing, MI

DATE: August 14, 2008

TO: Irma Lopez

FROM: Andrea Moore

RE: Review of Public Hearing Testimony on the Proposed Megavoltage Radiation Therapy (MRT) Services/Units Standards

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Pursuant to MCL 333.22215 (3), the Certificate of Need (CON) Commission "...shall conduct a public hearing on its proposed action." The Commission took proposed action on the MRT Standards at its July 23, 2008 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed MRT Standards on August 5, 2008. Written testimony was accepted for an additional 7 days after the hearing via an electronic link on the Commission's website. Testimony was received from nine organizations and is summarized as follows:

1. Blue Cross Blue Shield and Blue Care Network
   - Supports the proposed Standards.
   - Opposes the alternative methodology.
   - Supports any additional measures to prevent the initiation of multiple HMRT programs.
   - Recommends clarification of the Department supervisory/oversight language related to the operation of the programs.

2. Economic Alliance of Michigan
   - Supports the proposed Standards.
   - Opposes the alternative methodology.
   - Recommends clarification of the supervisory language.

3. Henry Ford Health System
   - Supports the changes to the Standards that require HMRT services to be provided by a group of hospital-based services.
   - Supports the alternative methodology.

4. Karmanos Cancer Institute
   - Supports the alternative methodology. Will continue to work with the Department and Commission to address any issues with this methodology.

- Recommends modification of Section 16 (3)(c) to ensure that the language is not burdensome to the Department or the providers.

5. Michigan Health Ministries of Ascension Health
   - Supports a collaborative approach to HMRT services.
   - Supports the alternative methodology.

6. Oakwood Healthcare, Inc.
   - Supports a methodology that facilitates a successful collaborative while maintaining access to the service among all interested parties.

7. Spectrum Health
   - Supports the proposed Standards.
   - Opposes the alternative methodology.

8. William Beaumont Hospital
   - Opposes proposed Standards.
   - Recommends establishing a Standard Advisory Committee to evaluate cost, quality and access of need issues related to HMRT.
   - Contends that law does not allow Standards to dictate how providers, and which providers, must organize to qualify for a Certificate of Need.
   - Recommends that the Standards be reviewed by the Department of Justice to ensure the legality of the Standards.
   - Opposes the alternative methodology.

9. University of Michigan Health System
   - Supports the alternative methodology.

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 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 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) 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 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 13 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).

(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.

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

(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.

(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.

(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.

(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.

(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.

(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.

(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.

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

(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.

(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.

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

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

(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.

(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.

(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.

(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.

(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.

(SS) "New cancer case," 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.

(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.

(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.

(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.

(WW) "Planning area" means the groups of counties shown in Section 17.

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

(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.

(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.

(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.

(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.

(CCC) "Special purpose MRT unit" or "special purpose unit" or "special unit" means any of the following types of MRT units: (i) gamma knife, (ii) dedicated stereotactic radiosurgery unit, (III) dedicated total body irradiator (TBI), (Iv) an OR-based IORT unit, or (v) cyber knife.

(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.

(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.

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

(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.

(HHH) "Tumor registry," 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.

(III) "Very complex treatment visit" means those visits listed in Section 13 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 12, 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 12.
(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 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.
(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 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 16(1)(c)(v), (viii), (xiii); 16(2); 16(4); and 16(5).

(2) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the requirements and terms of sections 4, 5; 6; and 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.

(C) *AN APPLICANT* 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 *OF* ETVS IN A PLANNING AREA.

(D) FOR THE PURPOSES OF THIS SECTION, ETVS SHALL BE THOSE FROM THE APRIL 30, 2008 LIST (REVISED) PUBLISHED BY THE DEPARTMENT. THE DEPARTMENT SHALL UPDATE THE LIST EVERY THREE YEARS THEREAFTER.

(*E*) *AN* APPLICATION UNDER THIS SECTIONSHALL NOT BE *APPROVED* *IF IT INCLUDES AN MRT SERVICE DESCRIBED IN SUBSECTION (I) OR (II) EXCEPT AS PROVIDED IN SUBSECTIONS (III) OR (IV).*

(I) AN MRT SERVICE THAT WAS PART OF ANOTHER APPLICATION UNDER THIS SECTION.

(II) AN MRT SERVICE OWNED BY, UNDER COMMON CONTROL OF, OR HAS A COMMON PARENT, AS AN MRT SERVICE UNDER SUBSECTION (I).

(III) THE PRIOR APPLICATION, OR THE APPROVED CON, UNDER THIS SECTION WERE SUBSEQUENTLY DISAPPROVED, WITHDRAWN.

(IV) THE APPLICATION UNDER THIS SECTION INCLUDES A COMMITMENT FROM THE MRT SERVICE DESCRIBED IN SUBSECTION (I) TO SURRENDER THE CON, OR APPLICATION, DESCRIBED IN SUBSECTION (I) AND THAT COMMITMENT IS FULFILLED AT THE TIME THE APPLICATION UNDER THIS SECTION IS APPROVED. (F) AN APPLICATION UNDER THIS SECTION SHALL NOT BE APPROVED IF IT INCLUDES ANY OF THE FOLLOWING:

(I) AN MRT SERVICE THAT IS APPROVED BUT NOT OPERATIONAL, OR THAT HAS A PENDING APPLICATION, FOR A HEAVY PARTICLE ACCELERATOR.

(II) AN MRT SERVICE THAT IS OWNED BY, UNDER COMMON CONTROL OF, OR HAS A COMMON PARENT, AS AN MRT SERVICE DESCRIBED BY SUBSECTION (I), UNLESS THE APPLICATION UNDER THIS SECTION INCLUDES A COMMITMENT FROM THE MRT SERVICE DESCRIBED IN SUBSECTION (I) TO SURRENDER THE CON, OR APPLICATION, DESCRIBED IN SUBSECTION (I) AND THAT COMMITMENT IS FULFILLED AT THE TIME THE APPLICATION UNDER THIS SECTION IS APPROVED.

(G) AN APPLICATION UNDER THIS SECTION SHALL NOT BE APPROVED IF IT INCLUDES ANY OF THE FOLLOWING:

(I) AN MRT SERVICE THAT IS APPROVED FOR A HEAVY PARTICLE ACCELERATOR THAT IS OPERATIONAL.

(II) AN MRT SERVICE THAT IS OWNED BY, UNDER COMMON CONTROL OF, OR HAS A COMMON PARENT, AS AN MRT SERVICE DESCRIBED BY SUBSECTION (I), UNLESS THE APPLICATION UNDER THIS SECTION INCLUDES A COMMITMENT FROM THE MRT SERVICE DESCRIBED IN SUBSECTION (I) TO SURRENDER THE CON DESCRIBED IN SUBSECTION (I), AND THAT COMMITMENT IS FULFILLED AT THE TIME THE HMRT UNIT APPROVED UNDER THIS SECTION IS OPERATIONAL.

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

(*I*) 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.**

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

(*K*) 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. Requirements for approval -- all applicants

Sec. 11. 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. Methodology for computing the projected number of equivalent treatment visits

Sec. 12. 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 15.

(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. Equivalent treatment visits

Sec. 13. 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**
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. Commitment of new cancer cases

Sec. 14. (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. Documentation of new cancer case data

Sec. 15. (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. Project delivery requirements terms of approval for all applicants

Sec. 16. (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 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 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 TO A radiation oncologist and at least one radiation oncologist will be IMMEDIATELY AVAILABLE 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 *FOR* **TREAT***MENT OF* **SPECIFIC CANCER** *CONDITIONS***.** ***THE NUMBER OF PATIENTS TREATED, NUMBER ENROLLED IN RESEARCH STUDIES, AND THE TYPES OF CANCER CONDITIONS INVOLVED, SHALL BE PROVIDED TO THE DEPARTMENT AS PART OF THE CON ANNUAL SURVEY.***

(B) UPON COMPLETION OF ANY STUDY, AND AUTHORIZATION BY STUDY SPONSOR, THE FINDINGS AND SUMMARY OF ANY RESEARCH STUDIES, CONSISTENT WITH PATIENT CONFIDENTIALITY, SHALL BE PROVIDED TO THE DEPARTMENT BY THE APPLICANT.

(C) THE MRT SERVICE UTILIZING AN HMRT UNIT SHALL PROVIDE THE DEPARTMENT, ON AN ANNUAL BASIS, *FOLLOWING THE INITIATION OF THE SERVICE,* **WITH** UPDATES TO THE INFORMATION PROVIDED *AND APPROVED BY THE DEPARTMENT PURSUANT TO* SUBSECTIONS 10*(1)*(*H*), (*I*), *(J), (K),* AND ***10***(*2*).

(D) ON AN ANNUAL BASIS, FOLLOWING THE INITIATION OF THE SERVICE, *THE DEPARTMENT WILL ASSESS THE AFFORDABILITY OF THE PROJECT BY EVALUATING THE "HOSPITAL* ***COST*** *REPORT" AND ANY OTHER APPLICABLE* ***INFORMATION SUPPLIED TO THE CENTERS OF MEDICARE AND MEDICAID*** *SERVICES (CMS) AND THE MICHIGAN MEDICAL SERVICES ADMINISTRATION (MSA).*

(*E*) UPON REVIEW**,** ***BY THE DEPARTMENT,*** OF THE ***INFORMATION*** SUBMITTED UNDER SUBSECTION***S*** (***C***) ***AND (D)*** ABOVE, ***AND THE DEPARTMENT'S FINDING THAT THE SERVICE HAS NOT FULFILLED PROJECT DELIVERY REQUIREMENTS,*** THE DEPARTMENT MAY ORDER CHANGES WITH REGARD TO THE PROVISION OF THE *HMRT* SERVICE *TO ASSURE FULFILLMENT OF PROJECT DELIVERY REQUIREMENTS. THE DEPARTMENT MAY ELECT TO VERIFY THE INFORMATION AND DATA THROUGH ON-SITE REVIEW OF APPROPRIATE RECORDS*.

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

Section 17. Planning areas

Sec. 17. 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. Effect on prior CON review standards; comparative reviews

Sec. 18. (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 DECEMBER 13, 2005 and effective 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

Michigan Department of Community Health

MEMORANDUM

Lansing, MI

DATE: August 13, 2008

TO: Irma Lopez

FROM: Andrea Moore

RE: Summary of Public Hearing Testimony on the Proposed Magnetic Resonance Imaging (MRI) Services Standards

---

Pursuant to MCL 333.22215 (3), the Certificate of Need (CON) Commission "...shall conduct a public hearing on its proposed action." The Commission took proposed action on the MRI Standards at its June 11, 2008 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed MRI Standards on July 30, 2008. Written testimony was accepted for an additional 7 days after the hearing via an electronic link on the Commission's website. Testimony was received from four organizations and is summarized as follows:

10. Blue Cross Blue Shield of Michigan
    - Supports the recommended modifications.

11. Bronson Healthcare Group
    - Supports the expansion of the Standards to include Intra-Operative MRI, but opposes the draft language.
    - Recommends modification to Section 3 to enable more patients to benefit from this technology.
    - Recommends the required number of neurological surgeries be reduced to 700.
    - Recommends the required number of pediatric discharges be reduced.
    - Recommends defining the term neurological surgeries.
    - Recommends separate criteria for Level I Trauma Centers.
    - Recommends that the length of the pilot program be shortened by at least one year.

12. Michigan Health Ministries of Ascension Health
    - Support the recommended modifications.
    - Recommends that Section 11 (5) be modified to read "The proposed IMRI unit must be located in an approved Operating Room or a diagnostic suite directly adjacent to an approved operating room with the capability of transferring the patient between the Operating Room and the diagnostic suite."

13. Spectrum Health
    - Supports the recommended modifications.

Michigan Department of Community Health
MEMORANDUM
Lansing, MI

DATE: August 13, 2008

TO: Irma Lopez

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RE: Summary of Public Hearing Testimony on the Proposed Magnetic Resonance Imaging (MRI) Services Standards

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14. Blue Cross Blue Shield of Michigan
    - Supports the recommended modifications.

15. Bronson Healthcare Group
    - Supports the expansion of the Standards to include Intra-Operative MRI, but opposes the draft language.
    - Recommends modification to Section 3 to enable more patients to benefit from this technology.
    - Recommends the required number of neurological surgeries be reduced to 700.
    - Recommends the required number of pediatric discharges be reduced.
    - Recommends defining the term neurological surgeries.
    - Recommends separate criteria for Level I Trauma Centers.
    - Recommends that the length of the pilot program be shortened by at least one year.

16. Michigan Health Ministries of Ascension Health
    - Support the recommended modifications.
    - Recommends that Section 11 (5) be modified to read "The proposed IMRI unit must be located in an approved Operating Room or a diagnostic suite directly adjacent to an approved operating room with the capability of transferring the patient between the Operating Room and the diagnostic suite."

17. Spectrum Health
    - Supports the recommended modifications.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS
FOR MAGNETIC RESONANCE IMAGING (MRI) SERVICES

(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 the approval of the initiation, expansion, replacement, relocation, or acquisition of MRI services and the delivery of services for all projects approved and Certificates of Need issued under Part 222 of the Code that involve magnetic resonance imaging services.

(2) Magnetic resonance imaging is a covered clinical service for purposes of Part 222 of the Code. An MRI unit approved pursuant to Section 9(1) seeking approval to operate pursuant to sections 3, 4, 5, 6, 7, or 8 shall be considered as a person requesting CON approval to initiate, expand, replace, relocate, or acquire a covered clinical service, as applicable.

(3) The Department shall use sections 3, 4, 5, 6, 7, 8, 9, 10, 13, 14, 15, 16, 17, AND 18 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 13, 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) For purposes of these standards:

(a) "Acquisition of an existing MRI service or existing MRI unit(s)" means obtaining control or possession of an existing fixed or mobile MRI service or existing MRI unit(s) by contract, ownership, lease, or other comparable arrangement.

(b) "Actual MRI adjusted procedures," for purposes of sections 16 and 17, means the number of MRI procedures, adjusted in accordance with the applicable provisions of Section 14, performed on an existing MRI unit, or if an MRI service has two or more MRI units at the same site, the average number of MRI adjusted procedures performed on each unit, for the 12-month period reported on the most recently published "Available MRI Adjusted Procedures List," as of the date an application is deemed complete by the Department.

(c) "Available MRI adjusted procedures," for purposes of Section 16, means the number of MRI adjusted procedures performed by an existing MRI service in excess of 8,000 per fixed MRI unit and 7,000 per mobile MRI unit. For either a fixed or mobile MRI service, the number of MRI units used to compute available MRI adjusted procedures shall include both

existing and approved but not yet operational MRI units. In determining the number of available MRI adjusted procedures, the Department shall use data for the 12-month period reported on the most recently published list of available MRI adjusted procedures as of the date an application is deemed complete by the Department.

In the case of an MRI service that operates, or has a valid CON to operate, more than one fixed MRI unit at the same site, the term means the number of MRI adjusted procedures in excess of 8,000 multiplied by the number of fixed MRI units at the same site. For example, if an MRI service operates, or has a valid CON to operate, two fixed MRI units at the same site, the available number of MRI adjusted procedures is the number that is in excess of 16,000 (8,000 x 2) MRI adjusted procedures.

In the case of a mobile MRI unit, the term means the sum of all MRI adjusted procedures performed by the same mobile MRI unit at all of the host sites combined that is in excess of 7,000. For example, if a
mobile MRI unit serves five host sites, the term means the sum of MRI adjusted procedures for all five host sites combined that is in excess of 7,000 MRI adjusted procedures.

(d) "Central service coordinator" means the organizational unit that has operational responsibility for a mobile MRI unit(s). It shall be a legal entity authorized to do business in the State of Michigan.

(e) "Certificate of Need Commission" or “CON 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) "Contrast MRI procedure" means an MRI procedure involving either of the following: (i) a procedure following use of a contrast agent or (ii) procedures performed both before and after the use of a contrast agent.

(h) "Dedicated pediatric MRI" means an MRI unit on which at least 80% of the MRI procedures are performed on patients under 18 years of age

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

(j) "Doctor" means an individual licensed under Article 15 of the Code to engage in the practice of medicine, osteopathic medicine and surgery, chiropractic, dentistry, or podiatry.

(k) "Existing magnetic resonance imaging service" or "existing MRI service" means either the utilization of a CON-approved and operational MRI unit(s) at one site in the case of a fixed MRI service, and in the case of a mobile MRI service, the utilization of a CON-approved and operational mobile MRI unit(s) at each host site, on the date an application is submitted to the Department.

(l) "Existing magnetic resonance imaging unit" or "existing MRI unit" means a CON-approved and operational MRI unit used to provide MRI services.

(m) "Expand an existing fixed MRI service" means an increase in the number of fixed MRI units to be operated by the applicant.

(n) "Expand an existing mobile MRI service" means the addition of a mobile MRI unit that will be operated by a central service coordinator that is approved to operate one or more mobile MRI units as of the date an application is submitted to the Department.

(o) "Group practice," for purposes of Section 17(3)(b), means a group practice as defined pursuant to the provisions of 42 U.S.C. 1395nn (h)(4), commonly known as Stark II,

and the Code of Federal Regulations, 42 CFR, Part 411, published in the Federal Register on August 14, 1995, or its replacement.

(p) “Health service area” or “HSA” means the geographic areas set forth in Section 19.

(q) "Host site" means the site at which a mobile MRI unit is authorized by CON to provide MRI services.

(r) "Initiate a fixed MRI service" means begin operation of a fixed MRI service at a site that does not provide or is not CON approved to provide fixed MRI services as of the date an application is submitted to the Department. The term does not include the acquisition or relocation of an existing fixed MRI service or the renewal of a lease.

(s) “Initiate a mobile MRI host site” means the provision of MRI services at a host site that has not received any MRI services within 12 months from the date an application is submitted to the Department.

The term does not include the renewal of a lease.

(t) "Initiate a mobile MRI service" means begin operation of a mobile MRI unit that serves two or more host sites.

The term does not include the acquisition of an existing mobile MRI service or the renewal of a lease.

(u) "Inpatient," for purposes of Section 14 of these standards, means an MRI visit involving an individual who has been admitted to the licensed hospital at the site of the MRI service/unit or in the case of an MRI unit that is not located at that licensed hospital site, an admitted patient transported from a licensed hospital site by ambulance to the MRI service.

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

(w) “INTRA-OPERATIVE MAGNETIC RESONANCE IMAGING” OR “IMRI” MEANS THE INTEGRATED USE OF MRI TECHNOLOGY DURING SURGICAL AND INTERVENTIONAL PROCEDURES WITHIN A LICENSED OPERATIVE ENVIRONMENT.

(X) "Licensed hospital site" means a health facility licensed under Part 215 of the Code. In the case of a single site hospital, it is the location of the facility authorized by license and listed on that licensee's certificate of licensure or in the case of a hospital with multiple sites, the location of each separate and distinct inpatient unit of the health facility as authorized by the licensee’s certificate of licensure.

(Y) "Magnetic resonance" or "MR" means the analysis of the interaction that occurs between radio frequency energy, atomic nuclei, and strong magnetic fields to produce cross sectional images similar to those displayed by computed tomography (CT) but without the use of ionizing radiation.

(Z) "Magnetic resonance imaging adjusted procedure" or "MRI adjusted procedure" means an MRI visit, at an existing MRI service, that has been adjusted in accordance with the applicable provisions of Section 14.

(AA) "Magnetic resonance imaging database" or "MRI database" means the database, maintained by the Department pursuant to Section 13 of these standards, that collects information about each MRI visit at MRI services located in Michigan.

(BB) "Magnetic resonance imaging procedure" or "MRI procedure" means a procedure conducted by an MRI unit approved pursuant to sections 3, 4, 5, 6, 7, 8 or 10 of these standards which is either a single, billable diagnostic magnetic resonance procedure or a procedure conducted by an MRI unit at a site participating with an approved diagnostic radiology residency program, under a research protocol approved by an institutional review

board. The capital and operating costs related to the research use are charged to a specific research account and not charged to or collected from third-party payors or patients. The term does not include a procedure conducted by an MRI unit approved pursuant to Section 9(1).

(CC) "Magnetic resonance imaging services" or "MRI services" means either the utilization of an authorized MRI unit(s) at one site in the case of a fixed MRI service or in the case of a mobile MRI service, the utilization of an authorized mobile MRI unit at each host site.

(DD) "Magnetic resonance imaging unit" or "MRI unit" means the magnetic resonance system consisting of an integrated set of machines and related equipment necessary to produce the images and/or spectroscopic quantitative data from scans.

(EE) "Magnetic resonance imaging visit" or "MRI visit" means a single patient visit to an MRI service/unit that may involve one or more MRI procedures.

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

(GG) "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 A.

(HH) "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 A.

(II) "Mobile MRI unit" means an MRI unit operating at two or more host sites and that has a central service coordinator. The mobile MRI unit shall operate under a contractual agreement for the provision of MRI services at each host site on a regularly scheduled basis.

(JJ) "Ownership interest, direct or indirect," for purposes of these standards, means a direct ownership relationship between a doctor and an applicant entity or an ownership relationship between a doctor and an entity that has an ownership relationship with an applicant entity.

(KK) "Pediatric patient," for purposes of these standards, except for Section 10, means a patient who is 12 years of age or less.

(LL) "Planning area," for purposes of these standards, means

(i) in the case of a proposed fixed MRI service or unit, the geographic area within a 20-mile radius from the proposed site if the proposed site is not in a rural or micropolitan statistical area county and a 75-mile radius from the proposed site if the proposed site is in a rural or micropolitan statistical area county. For purposes of Section 7(3) of these standards, the planning area shall be measured from the original site at which the MRI service was first initiated.

(ii) in the case of a proposed mobile MRI service or unit, except as provided in subsection (iii), the geographic area within a 20-mile radius from each proposed host site if the proposed site is not in a rural or micropolitan statistical area county and within a 75-mile radius from each proposed host site if the proposed site is in a rural or micropolitan statistical area county.

(iii) in the case of a proposed mobile MRI service or unit meeting the requirement of Section 14(2)(d), the health service area in which all the proposed mobile host sites will be located.

(MM) "Referring doctor," for purposes of these standards, means the doctor of record who ordered the MRI procedure(s) and either to whom the primary report of the results of an MRI procedure(s) is sent or in the case of a teaching facility, the attending doctor who is responsible for the house officer or resident that requested the MRI procedure.

(NN) "Relocate an existing MRI service and/or MRI unit(s)" means a change in the location of an existing MRI service and/or MRI unit(s) from the existing site to a different site within the relocation zone.

(OO) "Relocation zone," for purposes of these standards, means the geographic area that is within a 10-mile radius of the existing site of the MRI service or unit to be relocated.

(PP) "Renewal of a lease" means extending the effective period of a lease for an existing MRI unit that does not involve either replacement of the MRI unit, as defined in Section 2(1)(pp)(i), or (ii) a change in the parties to the lease.

(QQ) "Replace an existing MRI unit" means (i) any equipment change involving a change in, or replacement of, the magnet resulting in an applicant operating the same number and type (fixed or mobile) of MRI units before and after project completion or (ii) an equipment change other than a change in the magnet that involves a capital expenditure of $750,000 or more in any consecutive 24-month period or (iii) the renewal of a lease. The term does not include an upgrade of an existing MRI service or unit, and it does not include a host site that proposes to receive mobile MRI services from a different central service coordinator if the requirements of Section 3(5)(a)-(e), as applicable, have been met.

(RR) “Research scan” means an MRI scan administered under a research protocol approved by the applicant’s institutional review board.

(SS) “Re-sedated patient” means a patient, either pediatric or adult, who fails the initial sedation during the scan time and must be extracted from the unit to rescue the patient with additional sedation.

(TT) "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 regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.

(UU) "Sedated patient" means a patient that meets all of the following:

(i) whose level of consciousness is either conscious-sedation or a higher level of sedation, as defined by the American Association of Anesthesiologists, the American Academy of Pediatrics, the Joint Commission on the Accreditation of Health Care Organizations, or an equivalent definition.

(ii) who is monitored by mechanical devices while in the magnet.

(iii) who requires observation while in the magnet by personnel, other than employees routinely assigned to the MRI unit, who are trained in cardiopulmonary resuscitation (CPR).

(VV) "Site," for purposes of these standards, means

(i) in the case of a licensed hospital site, a location that is part of the licensed hospital site or a location that is contiguous to the licensed hospital site or

(ii) in the case of a location that is not a licensed hospital site, a location at the same address or a location that is contiguous to that address.

(WW) “Special needs patient” means a non-sedated patient, either pediatric or adult, with any of the following conditions: down syndrome, autism, attention deficit hyperactivity disorder (ADHD), developmental delay, malformation syndromes, hunter’s syndrome, multi-system disorders, psychiatric disorders, and other conditions that make the patient unable to comply with the positional requirements of the exam.

(XX) “Teaching facility," for purposes of these standards, means a licensed hospital site, or other location, that provides either fixed or mobile MRI services and at which residents or fellows of a training program in diagnostic radiology, that is approved by the Accreditation Council on Graduate Medical Education or American Osteopathic Association, are assigned.

(YY) "Unadjusted MRI scan" means an MRI procedure performed on a single anatomical site as defined by the MRI database and that is not adjusted pursuant to the applicable provisions of Section 14.

(ZZ) "Upgrade an existing MRI unit" means any equipment change that

(i) does not involve a change in, or replacement of, the magnet; does not result in an increase in the number of MRI units; or does not result in a change in the type of MRI unit (e.g., changing a mobile MRI unit to a fixed MRI unit); and

(ii) involves a capital expenditure of less than $750,000 in any consecutive 24-month period.

(2) Terms defined in the Code have the same meanings when used in these standards.

Section 3. Requirements for approval of applicants proposing to initiate an MRI service or mobile MRI host site

Sec. 3. (1) An applicant proposing to initiate a fixed MRI service shall demonstrate that 6,000 available MRI adjusted procedures, from within the same planning area as the proposed service/unit, per proposed unit result from application of the methodology in Section 16 of these standards.

(2)(a) An applicant proposing to initiate a mobile MRI service that involves beginning operation of a mobile MRI unit shall demonstrate that a minimum of 5,500 available MRI adjusted procedures, from within the same planning area as the proposed service/unit, per proposed unit result from application of the methodology in Section 16 of these standards.

(b) The applicant, whether the central service coordinator or the host site, must demonstrate that a minimum of 600 available MRI adjusted procedures, from within the same planning area as the proposed service/unit, result from the application of the methodology in Section 16 of these standards, for each proposed host site that

(i) is not located in a rural or micropolitan statistical area county and

(ii) has not received any mobile MRI service within the most recent 12-month period as of the date an application is submitted to the Department.

(c) The applicant, whether the central service coordinator or the host site, must demonstrate that a minimum of 400 available MRI adjusted procedures, from within the same planning area as the proposed service/unit, result from the application of the methodology in Section 16 of these standards for each proposed host site that

(i) is located in a rural or micropolitan statistical area county and

(ii) has not received any mobile MRI service within the most recent 12-month period as of the date an application is submitted to the Department.

(3)(a) An applicant, whether the central service coordinator or a proposed host site, proposing to initiate a mobile MRI host site not in a rural or micropolitan statistical area county, that is to be part of an existing mobile MRI service, must demonstrate that at least 600 available MRI adjusted procedures, from within the same planning area as the proposed service/unit, result from the application of the methodology in Section 16 of these standards for that host site.

(b) An applicant, whether the central service coordinator or a proposed host site, proposing to initiate a mobile MRI host site in a rural or micropolitan statistical area county, that is to be part of an existing mobile MRI service, must demonstrate that at least 400 available MRI adjusted procedures, from within the same planning area as the proposed service/unit, result from the application of the methodology in Section 16 of these standards for that host site.

(4) An applicant that meets all of the following requirements shall not be required to be in compliance with subsection (1):

(a) The applicant is proposing to initiate a fixed MRI service.

(b) The applicant is currently a host site being served by one or more mobile MRI units.

(c) The applicant has received, in aggregate, the following:

(i) at least 6,000 MRI adjusted procedures within the most recent 12-month period for which data, verifiable by the Department, are available or

(ii) at least 4,000 MRI adjusted procedures within the most recent 12-month period for which data, verifiable by the Department, are available, and the applicant meets all of the following:

(A) is located in a county that has no fixed MRI machines that are pending, approved by the Department, or operational at the time the application is deemed submitted;

(B) the nearest fixed MRI machine is located more than 15 radius miles from the application site;

(C) the applicant is a nonprofit licensed hospital site;

(D) the applicant certifies in its CON application, by providing a governing body resolution, that the board of trustees of the facility has performed a due diligence investigation and has determined that the fixed MRI service will be economically viable to ensure provision of safe and appropriate patient access within the community hospital setting.

(d) All of the MRI adjusted procedures provided at the applicant's approved site in the most recent 12-month period, referenced in (c) above, by each mobile MRI service/units from which any of the MRI adjusted procedures are being utilized to meet the minimum 6,000 or 4,000 MRI adjusted procedures shall be utilized to meet the requirements of (c). [For example: If mobile network 19 provided 4,000 adjusted procedures, network 21 provided 2,100, and network 18 provided 1,000, all of the adjusted procedures from network 19 and 21 must be used (i.e., 6,100) but the 1,000 adjusted procedures from network 18 do not need to be used to meet the 6,000 minimum.]

(e) The applicant shall install the fixed MRI unit at the same site as the existing approved host site or at the applicant’s licensed hospital site as defined in these standards.

(5) Initiation of a mobile MRI host site does not include the provision of mobile MRI services at a host site if the applicant, whether the host site or the central service coordinator, demonstrates or provides each of the following, as applicable:

(a) The host site has received mobile MRI services from an existing mobile MRI unit within the most recent 12-month period as of the date an application is submitted to the Department.

(b) The addition of a host site to a mobile MRI unit will not increase the number of MRI units operated by the central service coordinator or by any other person.

(c) Notification to the Department of the addition of a host site prior to the provision of MRI services by that mobile MRI unit in accordance with (d).

(d) A signed certification, on a form provided by the Department, whereby each host site for each mobile MRI unit has agreed and assured that it will provide MRI services in accordance with the terms for approval set forth in Section 13 of these standards, as applicable. The central service coordinator also shall identify all current host sites, on this form, that are served by the mobile route as of the date of the signed certification or are committed in writing to be served by the mobile route.

(e) The central service coordinator requires, as a condition of any contract with a host site, compliance with the requirements of these standards by that host site, and the central service coordinator assures compliance, by that host site, as a condition of the CON issued to the central service coordinator.

Section 4. Requirements for approval of an application proposing to expand an existing MRI service

Sec. 4. (1) An applicant proposing to expand an existing fixed MRI service shall demonstrate that its existing fixed MRI units (excluding MRI units approved pursuant to Section 10) have performed at least an average of 11,000 adjusted procedures for each fixed unit based on the application of the methodology in Section 14 and as documented in accordance with Section 15 of these standards.

(a) The additional unit shall be located at the same site unless the requirements of Section 7(2) have been met.

(2) An applicant proposing to expand an existing fixed MRI service approved pursuant to Section 10 shall demonstrate that its existing fixed MRI units have performed at least an average of 3,500 adjusted procedures for each fixed unit, based on the application of the methodology in Section 14 and as documented in accordance with Section 15 of these standards.

(a) The additional unit shall be located at the same site unless the requirements of Section 7(2) have been met.

(3) An applicant proposing to expand an existing mobile MRI service shall demonstrate that 4,000 available MRI adjusted procedures, from within the same planning area as the proposed unit, per proposed additional unit result from application of the methodology in Section 16 of these standards.

(4) An applicant proposing to expand an existing mobile MRI service must provide a copy of the existing or revised contracts between the central service coordinator and each host site(s) that includes the same stipulations as specified in Section 6(2).

Section 5. Requirements for approval of an applicant proposing to replace an existing MRI unit

Sec. 5. An applicant proposing to replace an existing MRI unit shall demonstrate that the proposed project meets each of the following requirements:

(1) Within the most recent 12-month period for which data, verifiable by the Department, are available, at least the applicable minimum number of MRI adjusted procedures set forth in subdivision (a), (b), or (c) has been performed. In meeting this requirement, an applicant shall not include any procedures conducted by an MRI unit approved pursuant to Section 9(1).

(a) Each existing mobile MRI unit on the network has performed in excess of an average of 5,500 MRI adjusted procedures per MRI unit.

(b) Each existing fixed MRI unit at the current site has performed in excess of an average of 6,000 MRI adjusted procedures per MRI unit.

(c) Each existing dedicated pediatric MRI unit at the current site has performed in excess of 3,500 MRI adjusted procedures per MRI unit.

(2) An applicant proposing to replace an existing MRI unit that does not involve a renewal of a lease shall demonstrate that the MRI unit to be replaced is fully depreciated according to generally accepted accounting principles; the existing equipment clearly poses a threat to the safety of the public; or the proposed replacement equipment offers a significant technological improvement which enhances quality of care, increases efficiency, and reduces operating costs.

(3) Equipment that is replaced shall be removed from service and disposed of or rendered considerably inoperable on or before the date that the replacement equipment becomes operational.

(4) An applicant proposing to replace an existing mobile MRI unit must provide a copy of the existing or revised contracts between the central service coordinator and each host site(s) that includes the same stipulations as specified in Section 6(2).

(5) The replacement unit shall be located at the same site unless the requirements of Section 7(2) have been met.

Section 6. Additional requirements for approval of an applicant proposing to initiate a mobile MRI service

Sec. 6. (1) An applicant proposing to initiate a mobile MRI service that involves beginning operation of a mobile MRI unit shall identify the proposed regular route schedule and the procedures for handling emergency situations.

(2) An applicant proposing a mobile MRI service shall submit copies of all proposed contracts related to the mobile MRI service in the CON application submitted by the central service coordinator. The contract shall include at least the following:

(a) A signed certification, on a form provided by the Department, whereby each host site has agreed and assured that it will provide MRI services for each mobile MRI unit in accordance with the terms of approval set forth in Section 13 of these standards, as applicable. The central service coordinator also shall identify all current host sites, on this form, as of the date of the signed certification.

(b) A statement that requires compliance with the requirements of these standards by that host site and assures compliance, by that host site, as a condition of the CON issued to the central service coordinator.

(c) A signed agreement between the central service coordinator and the host site(s) that states that for any host site applying, at any time in the future, for a fixed MRI unit under Section 3(4), that the mobile services at the host site will not cease until the fixed unit is in operation or upon the request of the host site. Further, the applicant applying for the fixed MRI unit must stipulate in the application at the time it is submitted to the Department that it has notified all affected host sites as well as the central service coordinator at least six months prior to beginning operation of the fixed MRI unit.

Section 7. Requirements for approval of an applicant proposing to relocate an existing MRI service and/or MRI unit(s)

Sec 7. (1) An applicant proposing to relocate an existing fixed MRI service and its unit(s) shall demonstrate that the proposed project meets all of the following:

(a) The existing MRI service and its unit(s) to be relocated has been in operation for at least 36 months as of the date an application is submitted to the Department.

(b) The proposed new site of the existing MRI service and its unit(s) to be relocated is in the relocation zone.

(c) The proposed project will not result in the replacement of the existing MRI unit(s) to be relocated unless the applicant demonstrates that the requirements of Section 5, as applicable, have been met.

(d) The proposed project will not result in an increase of the number of MRI units operated by the existing MRI service at the proposed site unless the applicant demonstrates that the requirements of Section 4, as applicable, have been met.

(e) Each existing MRI unit to be relocated performed at least the applicable minimum number of MRI adjusted procedures set forth in Section 13(1)(d)(i) of these standards based on the most recent 12-month period for which the Department has verifiable data.

(f) The applicant agrees to operate the MRI service and its unit(s) in accordance with all applicable project delivery requirements set forth in Section 13 of these standards.

(2) An applicant proposing to relocate a fixed MRI unit of an existing MRI service shall demonstrate that the proposed project meets all of the following:

(a) The existing MRI service from which the MRI unit(s) to be relocated has been in operation for at least 36 months as of the date an application is submitted to the Department.

(b) The proposed new site for the MRI unit(s) to be relocated is in the relocation zone.

(c) The proposed project will not result in the replacement of the MRI unit(s) to be relocated unless the applicant demonstrates that the requirements of Section 5, as applicable, have been met.

(d) The proposed project will not result in an increase of the number of MRI units operated by an existing MRI service at the proposed site unless the applicant demonstrates that the requirements of Section 4, as applicable, have been met.

(e) Each existing MRI unit at the service from which a unit is to be relocated performed at least the applicable minimum number of MRI adjusted procedures set forth in Section 13(1)(d)(i) of these standards based on the most recent 12-month period for which the Department has verifiable data.

(f) The applicant agrees to operate the MRI unit(s) at the proposed site in accordance with all applicable project delivery requirements set forth in Section 13 of these standards.

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

(3) An applicant that meets all of the following requirements shall be exempt from relocating within the relocation zone:

(a) The licensed hospital site to which the MRI service is to be relocated and the MRI service at the site from which the MRI service is to be relocated are owned by the same person as defined in Section 1106 of this public act or the same governmental entity.

(b) The licensed hospital site to which the MRI service is to be relocated is located within the planning area.

(c) As evidenced in the governing body resolution required in (e), the MRI service to be relocated shall cease at its current location within 24 months after the date the application receives a final decision of approval from the Department or upon the date the service becomes operational at the relocation site, whichever occurs first.

(d) The MRI service shall be relocated and shall be operational within 24 months after the date the application receives a final decision of approval from the Department or the CON to relocate the MRI service shall expire.

(e) The CON application includes a resolution of the applicant's governing body that commits to the provisions of (c) and (d).

(f) The relocation of the MRI service shall not result in the licensed hospital site having more than one fixed MRI unit.

Section 8. Requirements for approval of an applicant proposing to acquire an existing MRI service or an existing MRI unit(s)

(1) An applicant proposing to acquire an existing fixed or mobile MRI service and its unit(s) shall demonstrate that the proposed project meets all of the following:

(a) The project will not change the number of MRI units at the site of the MRI service being acquired unless the applicant demonstrates that the project is in compliance with the requirements of Section 3 or 4, as applicable.

(b) The project will not result in the replacement of an MRI unit at the MRI service to be acquired unless the applicant demonstrates that the requirements of Section 5 have been met.

(c) The applicant agrees to operate the MRI service and its unit(s) in accordance with all applicable project delivery requirements set forth in Section 13 of these standards.

(d) For the first application proposing to acquire an existing fixed or mobile MRI service on or after July 1, 1997, the existing MRI service and its unit(s) to be acquired shall not be required to be in compliance with the volume requirements applicable to a seller/lessor on the date the acquisition occurs. The MRI service shall be operating at the applicable volume requirements set forth in Section 13(1)(d)(i) of these standards in the second 12 months after the effective date of the acquisition, and annually thereafter.

(e) For any application proposing to acquire an existing fixed or mobile MRI service and its unit(s), except the first application approved pursuant to subsection (d), an applicant shall be required to document that the MRI service and its unit(s) to be acquired is operating in compliance with the volume requirements set forth in Section 13(1)(d)(i) of these standards applicable to an existing MRI service on the date the application is submitted to the Department.

(2) An applicant proposing to acquire an existing fixed or mobile MRI unit of an existing MRI service shall demonstrate that the proposed project meets all of the following:

(a) The project will not change the number of MRI units at the site of the MRI service being acquired, subject to the applicable requirements under Section 7(2), unless the applicant demonstrate**s** that the project is in compliance with the requirements of Section 3 or 4, as applicable.

(b) The project will not result in the replacement of an MRI unit at the MRI service to be acquired unless the applicant demonstrates that the requirements of Section 5 have been met.

(c) The applicant agrees to operate the MRI unit(s) in accordance with all applicable project delivery requirements set forth in Section 13 of these standards.

Section 9. Requirements for approval of an applicant proposing an MRI unit to be used exclusively for research

Sec. 9. (1) An applicant proposing an MRI unit to be used exclusively for research shall demonstrate each of the following:

(a) The applicant operates a diagnostic radiology residency program approved by the Accreditation Council for Graduate Medical Education, the American Osteopathic Association, or an equivalent organization.

(b) The MRI unit shall operate under a protocol approved by the applicant's institutional review board.

(c) The applicant agrees to operate the unit in accordance with the terms of approval in Section 13(2).

(2) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the requirements and terms of sections 3, 4, 5, 6, 7, 8, 13 [with the exception of 13(1)(d)(iii)], 15, and 16 of these standards.

Section 10. Requirements for approval of an applicant proposing to establish dedicated pediatric MRI

Sec. 10. (1) An applicant proposing to establish dedicated pediatric MRI shall demonstrate all of the following:

(A) THE APPLICANT SHALL HAVE EXPERIENCED AT LEAST 7,000 PEDIATRIC (< 18 YEARS OLD) DISCHARGES (EXCLUDING NORMAL NEWBORNS) IN THE MOST RECENT YEAR OF OPERATION.

(B) THE APPLICANT SHALL HAVE PERFORMED AT LEAST 5,000 PEDIATRIC (< 18 YEARS OLD) SURGERIES IN THE MOST RECENT YEAR OF OPERATION.

(c) The applicant shall have an active medical staff, at the time the application is submitted to the Department, that includes, but is not limited to, physicians who are fellowship-trained in the following pediatric specialties:

(i) pediatric radiology (at least two)
(ii) pediatric anesthesiology
(iii) pediatric cardiology
(iv) pediatric critical care
(v) pediatric gastroenterology
(vi) pediatric hematology/oncology
(vii) pediatric neurology
(viii) pediatric neurosurgery
(ix) pediatric orthopedic surgery
(x) pediatric pathology
(xi) pediatric pulmonology
(xii) pediatric surgery
(xiii) neonatology

(d) The applicant shall have in operation the following pediatric specialty programs at the time the application is submitted to the Department:

(i) pediatric bone marrow transplant program
(ii) established pediatric sedation program
(iii) pediatric open heart program

(2) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the requirements of Section 4, of these standards.

SECTION 11. PILOT PROGRAM REQUIREMENTS FOR APPROVAL – APPLICANTS PROPOSING TO INITIATE, REPLACE, OR ACQUIRE A HOSPITAL BASED IMRI

SEC. 11. AS A PILOT PROGRAM, AN APPLICANT PROPOSING TO INITIATE, REPLACE, OR ACQUIRE A HOSPITAL BASED IMRI SERVICE SHALL DEMONSTRATE THAT IT MEETS ALL OF THE FOLLOWING:

(1) THE PROPOSED SITE IS A LICENSED HOSPITAL UNDER PART 215 OF THE CODE.

(2) THE PROPOSED SITE HAS AN EXISTING FIXED MRI SERVICE THAT HAS BEEN OPERATIONAL FOR THE PREVIOUS 36 CONSECUTIVE MONTHS AND IS MEETING ITS MINIMUM VOLUME REQUIREMENTS.

(3) THE PROPOSED SITE HAS AN EXISTING AND OPERATIONAL SURGICAL SERVICE AND IS MEETING ITS MINIMUM VOLUME REQUIREMENTS PURSUANT TO THE CON REVIEW STANDARDS FOR SURGICAL SERVICES.

(4) THE APPLICANT SHALL HAVE EXPERIENCED ONE OF THE FOLLOWING:
(A) AT LEAST 1,500 ONCOLOGY DISCHARGES IN THE MOST RECENT YEAR OF OPERATION; OR
(B) AT LEAST 1,000 NEUROLOGICAL SURGERIES IN THE MOST RECENT YEAR OF OPERATION; OR
(C) AT LEAST 7,000 PEDIATRIC (<18 YEARS OLD) DISCHARGES (EXCLUDING NORMAL NEWBORNS) AND AT LEAST 5,000 PEDIATRIC (<18 YEARS OLD) SURGERIES IN THE MOST RECENT YEAR OF OPERATION.

(5) THE PROPOSED IMRI UNIT MUST BE LOCATED IN AN OPERATING ROOM.

(6) NON-SURGICAL DIAGNOSTIC STUDIES SHALL NOT BE PERFORMED ON AN IMRI UNIT APPROVED UNDER THIS SECTION UNLESS THE PATIENT MEETS ONE OF THE FOLLOWING CRITERIA:
(A) THE PATIENT HAS BEEN ADMITTED TO AN INPATIENT UNIT; OR
(B) THE PATIENT IS HAVING THE STUDY PERFORMED ON AN OUTPATIENT BASIS, BUT IS IN NEED OF GENERAL ANESTHESIA OR DEEP SEDATION AS DEFINED BY THE AMERICAN SOCIETY OF ANESTHESIOLOGISTS.

(7) THE APPROVED IMRI UNIT WILL NOT BE SUBJECT TO MRI VOLUME REQUIREMENTS.

(8) THE APPLICANT SHALL NOT UTILIZE THE PROCEDURES PERFORMED ON THE IMRI UNIT TO DEMONSTRATE NEED OR TO SATISFY MRI CON REVIEW STANDARDS REQUIREMENTS.

(9) THE APPLICANT AGREES TO OPERATE THE IMRI UNIT IN ACCORDANCE WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS SET FORTH IN SECTION 13 OF THESE STANDARDS.

(10) THE PROVISIONS OF SECTION 11 ARE PART OF A PILOT PROGRAM APPROVED BY THE CON COMMISSION AND SHALL EXPIRE AND BE OF NO FURTHER FORCE AND EFFECT, AND SHALL NOT BE APPLICABLE TO ANY APPLICATION WHICH HAS NOT BEEN SUBMITTED BY DECEMBER 31, 2010.

Section 12. Requirements for approval – all applicants

Sec. 12. 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 13. Project delivery requirements – terms of approval

Sec. 13. (1) An applicant shall agree that, if approved, MRI services, whether fixed or mobile, shall be delivered and maintained in compliance with the following terms of CON approval for each geographical location where the applicant operates an MRI unit:

(a) Compliance with these standards.

(b) Compliance with applicable safety and operating standards for the specific MRI unit approved.

(c) Compliance with the following quality assurance standards:

(i) An applicant shall develop and maintain policies and procedures that establish protocols for the following system performance measures. The protocols shall establish the required benchmarks; identify the testing interval, which shall be at least quarterly; and identify the MRI staff person responsible for testing the system performance measures.

(A) Signal-to-noise ratio.

(B) Spatial resolution.

(C) Slice thickness, location, and separation.

(D) Spatial linearity.

(E) Field homogeneity and drift.

(F) System calibration and stability.

(G) Cryogen level and boiloff rate.

(H) Radio frequency power monitor.

(I) Hard copy image quality.

In addition to the designated staff person, the system performance measures in subdivisions (A) through (F) and (H) also shall be evaluated by an appropriately trained MRI physicist or engineer. The physicist/engineer shall conduct tests of these system performance measures when the MRI unit begins to operate, and annually thereafter. The purpose of the physicist/engineer test shall be to certify to the Department that the MRI unit meets or exceeds all of the system performance specifications of the manufacturer of the MRI unit in effect for that MRI unit at the time of installation or most recent upgrade. The physicist/engineer shall make available for review the periodic system performance measures test data established in this subsection.

(ii) An applicant shall develop and maintain policies, procedures, and protocols for assuring the functionality of each of the following MRI accessories. The protocols shall establish the required benchmarks, identify the testing interval for each accessory, and identify the staff person responsible for testing the system performance measures.

(A) All surface coils.

(B) Positioning devices.

(C) Physiologic triggering/monitoring equipment.

(D) Patient communication devices.

(E) Scan table position indicator and drives.

(F) Data network including storage and retrieval.

(G) Emergency rundown/shutdown units.

(H) Hard copy devices.

(iii) An applicant shall develop and maintain policies and procedures that establish protocols for assuring the effectiveness of operation and the safety of the general public,

patients, and staff in the MRI service. Each of the following must be included and the staff person responsible for development and enforcement of these policies shall be indicated.

(A) Access to the MRI service.

(B) Access to the MRI scan room.

(C) Patient safety clearance before imaging and safety during imaging.

(D) Adverse bioeffects, including

(1) acoustic hazard.

(2) radio frequency burn hazard.

(3) specific absorption rates.

(4) peripheral nerve stimulation.

(5) pregnancy.

(6) magnet quench hazard.

(E) Sedation.

(F) Contrast administration.

(G) Treatment of adverse reactions to contrast.

(H) Patient monitoring for sedation, anesthesia, and unstable patients.

(I) Patient resuscitation, management of emergencies, maintenance of cardiopulmonary resuscitation equipment, and certification requirements for personnel for either basic or advanced cardiopulmonary resuscitation.

(J) Screening for metallic implants, pacemakers, and metallic foreign bodies, as well as a list of contraindications.

(K) Mechanism for consultation regarding difficult cases.

(L) Pulse sequence protocols for specific indications.

(M) Institutional review board policies relating to non-FDA approved pulse sequences or investigational procedures.

(N) Staff inservice regarding subdivisions (A) through (M).

(iv) An applicant shall establish a schedule for preventive maintenance for the MRI unit.

(v) An applicant shall maintain records of the results of the periodic test data required by subdivisions (i) and (ii), including the results of the tests performed by the MRI physicist/engineer required in subdivision (i). An applicant, upon request, shall submit annually to the Department a report of the test data results and evidence of compliance with the applicable project delivery requirements.

(vi) An applicant shall provide documentation identifying the specific individuals that form the MRI team. At a minimum, the MRI team shall consist of the following professionals:

(A) An MRI team leader who shall be responsible for

(1) developing criteria for procedure performance.

(2) developing protocols for procedure performance.

(3) developing a clinical data base for utilization review and quality assurance purposes.

(4) transmitting requested data to the Department.

(5) screening of patients to assure appropriate utilization of the MRI service.

(6) taking and interpretation of scans.

(7) coordinating MRI activity at MRI host sites for a mobile MRI unit.

(8) identifying and correcting MRI image quality deficiencies.

(B) Physicians who shall be responsible for screening of patients to assure appropriate utilization of the MRI service and taking and interpretation of scans. At least one of these physicians shall be a board-certified radiologist.

(C) An appropriately trained MRI technician who shall be responsible for taking an MRI scan.

(D) An MRI physicist/engineer available as a team member on a full-time, part-time, or contractual basis. An MRI physicist/engineer shall be responsible for at least the following:

(1) providing technical specifications for new equipment and assistance in equipment procurement.

(2) performing or validating technical performance for system acceptance.

(3) establishing preventive maintenance schedules and quality assurance test procedures and recording and reviewing preventive maintenance and quality assurance data.

(4) facilitating the repair of acute system malfunctions.

(5) training personnel in the MRI service with respect to the technical aspects of MRI scanning and patient and staff safety.

(6) assisting in designing and optimizing clinical imaging procedures.

(E) System maintenance personnel who shall be responsible for calibrating the MRI system and preventive maintenance at regularly scheduled intervals and who shall compile and submit quality control data to the MRI team leader.

(vii) An applicant shall document that the MRI team members have the following qualifications:

(A) The MRI team leader is a board-certified or board-eligible radiologist, or other physician trained in MRI, who spends greater than 75 percent of his or her professional time in multiple anatomic site medical imaging. The MRI team leader also shall demonstrate that he or she meets the requirements set forth in subsection (B) for a physician who interprets MRI images.

(B) Each physician credentialed to interpret MRI scans meets the requirements of each of the following:

(1) The physician is licensed to practice medicine in the State of Michigan.

(2) The physician has had at least 60 hours of training in MRI physics, MRI safety, and MRI instrumentation in a program that is part of an imaging program accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association, and the physician meets the requirements of subdivision (i), (ii), or (iii):

(i) Board certification by the American Board of Radiology, the American Osteopathic Board of Radiology, or the Royal College of Physicians and Surgeons of Canada. If the diagnostic radiology program completed by a physician in order to become board certified did not include at least two months of MRI training, that physician shall document that he or she has had the equivalent of two months of postgraduate training in clinical MRI imaging at an institution which has a radiology program accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association.

(ii) Formal training by an imaging program(s), accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association, that included two years of training in cross-sectional imaging and six months training in organ-specific imaging areas.

(iii) A practice in which at least one-third of total professional time, based on a full-time clinical practice during the most recent 5-year period, has been the primary interpretation of MR imaging.

(3) The physician has completed and will complete a minimum of 40 hours every two years of Category in Continuing Medical Education credits in topics directly involving MR imaging.

(4) The physician interprets, as the primary interpreting physician, at least 250 unadjusted MRI scans annually.

(C) An MRI technologist who is registered by the American Registry of Radiologic Technicians or by the American Registry of Magnetic Resonance Imaging Technologists (ARMRIT) and has, or will have within 36 months of the effective date of these standards or the date a technologist is employed by an MRI service, whichever is later, special certification in MRI. If a technologist does not have special certification in MRI within either of the 3-year periods of time, all continuing education requirements shall be in the area of MRI services.

(D) An applicant shall document that an MRI physicist/engineer is appropriately qualified. For purposes of evaluating this subdivision, the Department shall consider it prima facie evidence as to the qualifications of the physicist/engineer if the physicist/engineer is certified as a medical physicist by the American Board of Radiology, the American Board of Medical Physics, or the American Board of Science in Nuclear Medicine. However, the applicant may submit and the Department may accept other evidence that an MRI physicist/engineer is qualified appropriately.

(E) An applicant shall document that system maintenance personnel are qualified on the basis of training and experience to perform the calibration, preventive maintenance, and quality control functions on the specific MRI unit approved.

(viii) The applicant shall have, within the MRI unit/service, equipment and supplies to handle clinical emergencies that might occur in the unit. MRI service staff will be trained in CPR and other appropriate emergency interventions. A physician shall be on-site, in, or immediately available to the MRI unit at all times when patients are undergoing scans.

(ix) In addition to all other applicable terms of approval, each mobile MRI unit shall have an operations committee with members representing each host site, the central service coordinator, and the medical director. This committee shall oversee the effective and efficient use of the MRI unit, establish the normal route schedule, identify the process by which changes shall be made to the schedule, develop procedures for handling emergency situations, and review the ongoing operations of the mobile MRI unit on at least a quarterly basis.

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

(d) Compliance with the following terms of approval, as applicable:

(i) MRI units shall be operating at a minimum average annual level of utilization during the second 12 months of operation, and annually thereafter, of 6,000 actual MRI adjusted procedures per unit for fixed MRI services, 5,500 actual MRI adjusted procedures per unit for mobile MRI services, and a total of 3,500 MRI adjusted procedures per unit for dedicated pediatric MRI. Each mobile host site in a rural or micropolitan statistical area county shall have provided at least a total of 400 adjusted procedures during its second 12 months of operation, and annually thereafter, from all mobile units providing services to the site. Each mobile host site not in a rural or micropolitan statistical area county shall have provided at least a total of 600 adjusted procedures during its second 12 months of operation and annually thereafter, from all mobile units providing services to the site. In meeting these requirements, an applicant shall not include any MRI adjusted procedures performed on an

MRI unit used exclusively for research and approved pursuant to Section 9(1) OR FOR AN IMRI UNIT APPROVED PURSUANT TO SECTION 11.

(ii) The applicant, to assure that the MRI unit will be utilized by all segments of the Michigan population, shall

(A) provide magnetic resonance services to all individuals based on the clinical indications of need for the service and not on ability to pay or source of payment.

(B) maintain information by source of payment 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.

(iii) 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, throughout schedules, demographic and diagnostic information, and the volume of care provided to patients from all payor sources, as well as other data requested by the Department or its designee and approved by the Commission. The applicant shall provide the required data in a format established by the Department and in a mutually agreed upon media no later than 30 days following the last day of the quarter for which data are being reported to the Department. An applicant shall be considered in violation of this term of approval if the required data are not submitted to the Department within 30 days following the last day of the quarter for which data are being reported. However, the Department shall allow an applicant up to an additional 60 days to submit the required data if reasonable efforts are made by an applicant to provide the required data. The Department may elect to verify the data through on-site review of appropriate records. Data for an MRI unit approved pursuant to Section 9(1), Section 10, OR SECTION 11 shall be reported separately.

(A) FOR PURPOSES OF SECTION 11, THE DATA REPORTED SHALL INCLUDE, AT A MINIMUM, HOW OFTEN THE IMRI UNIT IS USED AND FOR WHAT TYPE OF SERVICES, I.E., INTRA-OPERATIVE OR DIAGNOSTIC.

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

(e)(i) The applicant shall provide the Department with a notice stating the first date on which the MRI unit became operational, and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules.

(ii) An applicant who is a central service coordinator shall notify the Department of any additions, deletions, or changes in the host sites of each approved mobile MRI unit within 10 days after the change(s) in host sites is made.

(2) An applicant for an MRI unit under Section 9(1) shall agree that the services provided by the MRI unit approved pursuant to Section 9(1) 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 MRI unit approved pursuant to Section 9(1) shall be charged only to a specific research account(s) and not to any patient or third-party payor.

(b) The MRI unit approved pursuant to Section 9(1) shall not be used for any purposes other than as approved by the institutional review board unless the applicant has

obtained CON approval for the MRI unit pursuant to Part 222 and these standards, other than Section 9.

(3) The agreements and assurances required by this section shall be in the form of a certification agreed to by the applicant or its authorized agent.

(4) An applicant approved to initiate a fixed MRI service pursuant to Section 3(4) of these standards shall cease operation as a host site and not become a host site for at least 12 months from the date the fixed service and its unit becomes operational.

Section 14. MRI procedure adjustments

Sec. 14. (1) The Department shall apply the following formula, as applicable, to determine the number of MRI adjusted procedures that are performed by an existing MRI service or unit:

(a) The base value for each MRI procedure is 1.0.

(b) For each MRI visit involving a pediatric patient, 0.25 shall be added to the base value.

(c) For each MRI visit involving an inpatient, 0.50 shall be added to the base value.

(d) For each MRI procedure performed on a sedated patient, 0.75 shall be added to the base value.

(e) For each MRI procedure performed on a re-sedated patient, 0.25 shall be added to the base value.

(f) For each MRI procedure performed on a special needs patient, 0.25 shall be added to the base value.

(g) For each MRI visit that involves both a clinical and research scan on a single patient in a single visit, 0.25 shall be added to the base value.

(h) For each contrast MRI procedure performed after use of a contrast agent, and not involving a procedure before use of a contrast agent, 0.35 shall be added to the base value.

(i) For each contrast MRI procedure involving a procedure before and after use of a contrast agent, 1.0 shall be added to the base value.

(j) For each MRI procedure performed at a teaching facility, 0.15 shall be added to the base value.

(k) The results of subsections (a) through (j) shall be summed, and that sum shall represent an MRI adjusted procedure.

(2) The Department shall apply not more than one of the adjustment factors set forth in this subsection, as applicable, to the number of MRI procedures adjusted in accordance with the applicable provisions of subsection (1) that are performed by an existing MRI service or unit.

(a) For a site located in a rural or micropolitan statistical area county, the number of MRI adjusted procedures shall be multiplied by a factor of 1.4.

(b) For a mobile MRI unit that serves hospitals and other host sites located in rural, micropolitan statistical area, and metropolitan statistical area counties, the number of MRI adjusted procedures for a site located in a rural or micropolitan statistical area county, shall be multiplied by a factor of 1.4 and for a site located in a metropolitan statistical area county, the number of MRI adjusted procedures shall be multiplied by a factor of 1.0.

(c) For a mobile MRI unit that serves only sites located in rural or micropolitan statistical area counties, the number of MRI adjusted procedures shall be multiplied by a factor of 2.0.

(d) For a mobile MRI unit that serves only sites located in a health service area with one or fewer fixed MRI units and one or fewer mobile MRI units, the number of MRI adjusted procedures shall be multiplied by a factor of 3.5.

(e) Subsection (2) shall not apply to an application proposing a subsequent fixed MRI unit (second, third, etc.) at the same site.

(3) The number of MRI adjusted procedures performed by an existing MRI service is the sum of the results of subsections (1) and (2).

Section 15. Documentation of actual utilization

Sec. 15. Documentation of the number of MRI procedures performed by an MRI unit shall be substantiated by the Department utilizing data submitted by the applicant in a format and media specified by the Department and as verified for the 12-month period reported on the most recently published "Available MRI Adjusted Procedures List" as of the date an application is deemed complete by the Department. The number of MRI procedures actually performed shall be documented by procedure records and not by application of the methodology required in Section 16. The Department may elect to verify the data through on-site review of appropriate records.

Section 16. Methodology for computing the number of available MRI adjusted procedures

Sec. 16. (1) The number of available MRI adjusted procedures required pursuant to Section 3 or 4(2) of these standards shall be computed in accordance with the methodology set forth in this section. In applying the methodology, the following steps shall be taken in sequence, and data for the 12-month period reported on the most recently published "Available MRI Adjusted Procedures List," as of the date an application is deemed complete by the Department, shall be used:

(a) Identify the number of actual MRI adjusted procedures performed by each existing MRI service as determined pursuant to Section 14.

(i) For purposes of computing actual MRI adjusted procedures, MRI adjusted procedures performed on MRI units used exclusively for research and approved pursuant to Section 9(1) and dedicated pediatric MRI approved pursuant to Section 10 shall be excluded.

(II) FOR PURPOSES OF COMPUTING ACTUAL MRI ADJUSTED PROCEDURES, THE MRI ADJUSTED PROCEDURES, FROM THE HOST SITE ROUTES UTILIZED TO MEET THE REQUIREMENTS OF SECTION 3(4)(D), SHALL BE EXCLUDED BEGINNING AT THE TIME THE APPLICATION IS SUBMITTED AND FOR THREE YEARS FROM THE DATE THE FIXED MRI UNIT BECOMES OPERATIONAL.

(III) FOR PURPOSES OF COMPUTING ACTUAL MRI ADJUSTED PROCEDURES, THE MRI ADJUSTED PROCEDURES UTILIZED TO MEET THE REQUIREMENTS OF SECTION 4(1) SHALL BE REDUCED BY 8,000 AND SHALL BE EXCLUDED BEGINNING AT THE TIME THE APPLICATION IS SUBMITTED AND FOR THREE YEARS FROM THE DATE THE FIXED MRI UNIT BECOMES OPERATIONAL.

(B) IDENTIFY THE NUMBER OF AVAILABLE MRI ADJUSTED PROCEDURES, IF ANY, FOR EACH EXISTING MRI SERVICE AS DETERMINED PURSUANT TO SECTION 2(1)(C).

(c) Determine the number of available MRI adjusted procedures that each referring doctor may commit from each service to an application in accordance with the following:

(i) Divide the number of available MRI adjusted procedures identified in subsection (b) for each service by the number of actual MRI adjusted procedures identified in subsection (a) for that existing MRI service.

(ii) For each doctor referring to that existing service, multiply the number of actual MRI adjusted procedures that the referring doctor made to the existing MRI service by the applicable proportion obtained by the calculation in subdivision (c)(i).

(A) For each doctor, subtract any available adjusted procedures previously committed. The total for each doctor cannot be less than zero.

(B) The total number of available adjusted procedures for that service shall be the sum of the results of (A) above.

(III) FOR EACH MRI SERVICE, THE AVAILABLE MRI ADJUSTED PROCEDURES RESULTING FROM THE CALCULATION IN (II) ABOVE SHALL BE SORTED IN DESCENDING ORDER BY THE AVAILABLE MRI ADJUSTED PROCEDURES FOR EACH DOCTOR. THEN ANY DUPLICATE VALUES SHALL BE SORTED IN DESCENDING ORDER BY THE DOCTORS' LICENSE NUMBERS (LAST 6 DIGITS ONLY).

(IV) USING THE DATA PRODUCED IN III ABOVE, SUM THE NUMBER OF AVAILABLE ADJUSTED PROCEDURES IN DESCENDING ORDER UNTIL THE SUMMATION EQUALS AT LEAST 75 PERCENT OF THE TOTAL AVAILABLE ADJUSTED PROCEDURES. THIS SUMMATION SHALL INCLUDE THE MINIMUM NUMBER OF DOCTORS NECESSARY TO REACH THE 75 PERCENT LEVEL.

(V) FOR THE DOCTORS REPRESENTING 75 PERCENT OF THE TOTAL AVAILABLE ADJUSTED PROCEDURES IN (IV) ABOVE, SUM THE AVAILABLE ADJUSTED PROCEDURES.

(VI) FOR THE DOCTORS USED IN SUBSECTION (V) ABOVE, DIVIDE THE TOTAL NUMBER OF AVAILABLE ADJUSTED PROCEDURES IDENTIFIED IN (B) ABOVE BY THE SUM OF THOSE AVAILABLE ADJUSTED PROCEDURES PRODUCED IN (V) ABOVE.

(VII) FOR ONLY THOSE DOCTORS IDENTIFIED IN (V) ABOVE, MULTIPLY THE RESULT OF (VI) ABOVE BY THE AVAILABLE ADJUSTED PROCEDURES CALCULATED IN (C)(II)(A) ABOVE.

(VIII) THE RESULT SHALL BE THE "AVAILABLE MRI ADJUSTED PROCEDURES LIST."

(2) AFTER PUBLICATION OF THE "AVAILABLE MRI ADJUSTED PROCEDURES LIST" RESULTING FROM (1) ABOVE, THE DATA SHALL BE UPDATED TO ACCOUNT FOR A) DOCTOR COMMITMENTS OF AVAILABLE MRI ADJUSTED PROCEDURES IN SUBSEQUENT MRI CON APPLICATIONS AND B) MRI ADJUSTED PROCEDURES USED IN SUBSEQUENT MRI CON APPLICATIONS RECEIVED IN WHICH APPLICANTS APPLY FOR FIXED MRI SERVICES PURSUANT TO SECTION 3(4).

Section 17. Procedures and requirements for commitments of available MRI adjusted procedures

Sec. 17. (1) If one or more host sites on a mobile MRI service are located within the planning area of the proposed site, the applicant may access available MRI adjusted procedures from the entire mobile MRI service.

(2)(a) At the time the application is submitted to the Department, the applicant shall submit a signed data commitment, on a form provided by the Department in response to the applicant's letter of intent or at the applicant's discretion, on a more current form subsequently provided by the Department, for each doctor committing available MRI adjusted procedures to that application for a new or additional MRI unit pursuant to Section 3 or Section 4(2), respectively.

(b) An applicant also shall submit, at the time the application is filed with the Department, a computer file that lists, for each MRI service from which data are being committed to the same application, the name and license number of each doctor for whom a signed and dated data commitment form is submitted.

(i) The computer file shall be provided to the Department on mutually agreed upon media and in a format prescribed by the Department.

(ii) If the doctor commitments submitted on the Departmental forms do not agree with the data on the computer file, the applicant shall be allowed to correct only the computer file data which includes adding physician commitments that were submitted at the time of application.

(C) IF THE REQUIRED DOCUMENTATION FOR THE DOCTOR COMMITMENTS SUBMITTED UNDER THIS SUBSECTION 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.

(3) The Department shall consider a data commitment, on a form provided by the Department in response to the applicant's letter of intent or at the applicant's discretion, on a more current form subsequently provided by the Department, submitted by the applicant in support of its application, that meets the requirements of each of the following, as applicable:

(a) A committing doctor certifies that 100% of his or her available MRI adjusted procedures for each specified MRI service, calculated pursuant to Section 16, is being committed and specifies the CON application number, for the new fixed or mobile MRI unit or for the additional mobile MRI unit proposed to be located within the planning area, to which the data commitment is made. A doctor shall not be required to commit available MRI adjusted procedures from all MRI services to which his or her patients are referred for MRI services but only from those MRI services specified by the doctor in the data commitment form provided by the Department and submitted by the applicant in support of its application.

(b) A committing doctor certifies that he or she does not have an ownership interest, either direct or indirect, in the applicant entity, except that this requirement shall not apply if the applicant entity is a group practice of which the committing doctor is a member.

(c) A committing doctor certifies that he or she has not been provided, or received a promise of being provided, a financial incentive to commit any of his or her available MRI adjusted procedures to the application.

(4)(a) The Department shall not consider a data commitment from a doctor for available MRI adjusted procedures from a specific MRI service if the available MRI adjusted procedures from that specific MRI service were used to support approval of an application for

a new or additional MRI unit, pursuant to Section 3 or 4(2), respectively, for which a final decision to approve has been issued by the Director of the Department until either of the following occurs:

(i) The approved CON is withdrawn or expires.

(ii) The MRI service or unit to which the data were committed has been in operation for at least 36 continuous months.

(b) The Department shall not consider a data commitment from a doctor for available MRI adjusted procedures from a specific MRI service if the available MRI adjusted procedures from that specific MRI service were used to support an application for a new fixed or mobile MRI unit or additional mobile MRI unit pursuant to Section 3 or 4(2), respectively, for which a final decision to disapprove was issued by the Director of the Department until either of the following occurs:

(i) A final decision to disapprove an application is issued by the Director and the applicant does not appeal that disapproval or

(ii) If an appeal was made, either that appeal is withdrawn by the applicant or the committing doctor withdraws his or her data commitment pursuant to the requirements of subsection (8).

(5) The Department shall not consider a data commitment from a committing doctor for available MRI adjusted procedures from the same MRI service if that doctor has submitted a signed data commitment, on a form provided by Department, for more than one (1) application for which a final decision has not been issued by the Department. If the Department determines that a doctor has submitted a signed data commitment for the same available MRI adjusted procedures from the same MRI service to more than one CON application pending a final decision for a new fixed or mobile MRI unit or additional mobile MRI unit pursuant to Section 3 or 4(2), respectively, the Department shall,

(a) if the applications were filed on the same designated application date, notify all applicants, simultaneously and in writing, that one or more doctors have submitted data commitments for available MRI adjusted procedures from the same MRI service and that the doctors' data from the same MRI service shall not be considered in the review of any of the pending applications filed on the same designated application date until the doctor notifies the Department, in writing, of the one (1) application for which the data commitment shall be considered.

(b) if the applications were filed on different designated application dates, consider the data commitment submitted in the application filed on the earliest designated application date and shall notify, simultaneously in writing, all applicants of applications filed on designated application dates subsequent to the earliest date that one or more committing doctors have submitted data commitments for available MRI adjusted procedures from the same MRI service and that the doctors' data shall not be considered in the review of the application(s) filed on the subsequent designated application date(s).

(6) The Department shall not consider any data commitment submitted by an applicant after the date an application is deemed complete unless an applicant is notified by the Department, pursuant to subsection (5), that one or more committing doctors submitted data commitments for available MRI adjusted procedures from the same MRI service. If an applicant is notified that one or more doctors' data commitments will not be considered by the

Department, the Department shall consider data commitments submitted after the date an application is deemed complete only to the extent necessary to replace the data commitments not being considered pursuant to subsection (5).

(7) In accordance with either of the following, the Department shall not consider a withdrawal of a signed data commitment

(a) during the 120-day period following the date on which the Department's review of an application commences.

(b) after a proposed decision to approve an application has been issued by the Department.

(8) The Department shall consider a withdrawal of a signed data commitment if a committing doctor submits a written notice to the Department, that specifies the CON application number and the specific MRI services for which a data commitment is being withdrawn, and if an applicant demonstrates that the requirements of subsection (7) also have been met.

Section 18. Lists of MRI adjusted procedures published by the Department

Sec. 18. (1) At a minimum, on or before May 1 and November 1 of each year, the Department shall publish the following lists:

(a) A list, known as the "MRI Service Utilization List," of all MRI services in Michigan that includes at least the following for each MRI service:

(i) The number of actual MRI adjusted procedures;

(ii) The number of available MRI adjusted procedures, if any; and

(iii) The number of MRI units, including whether each unit is a clinical unit or an MRI unit used exclusively for research.

(b) A list, known as the "Available MRI Adjusted Procedures List," that identifies each MRI service that has available MRI adjusted procedures and includes at least the following:

(i) The number of available MRI adjusted procedures;

(ii) The name, address, and license number of each referring doctor, identified in Section 16(1)(c)(v), whose patients received MRI services at that MRI service; and

(iii) The number of available MRI adjusted procedures performed on patients referred by each referring doctor, identified in Section 16(1)(c)(v), and if any are committed to an MRI service. This number shall be calculated in accordance with the requirements of Section 16(1). A referring doctor may have fractional portions of available MRI adjusted procedures.

(c) For the lists published pursuant to subsections (a) or (b), the May 1 list will report 12 months of data from the previous January 1 through December 31 reporting period, and the November 1 list will report 12 months of data from the previous July 1 through June 30 reporting period. Copies of both lists shall be available upon request.

(d) The Department shall not be required to publish a list that sorts MRI database information by referring doctor, only by MRI service.

(2) When an MRI service begins to operate at a site at which MRI services previously were not provided, the Department shall include in the MRI database, data beginning with the second full quarter of operation of the new MRI service. Data from the start-up date to the start of the first full quarter will not be collected to allow a new MRI service sufficient time to

develop its data reporting capability. Data from the first full quarter of operation will be submitted as test data but will not be reported in the lists published pursuant to this section.

(3) In publishing the lists pursuant to subsections (a) and (b), if an MRI service has not reported data in compliance with the requirements of Section 13(1)(d)(iii), the Department shall indicate on both lists that the MRI service is in violation of the requirements set forth in Section 13(1)(d)(iii), and no data will be shown for that service on either list.

(4) In the case of an MRI service at which MRI services previously were not provided, the Department may use annualized data from at least a consecutive six-month period in publishing the lists pursuant to subsections (a) and (b).

Section 19. Effect on prior CON Review Standards; Comparative reviews

Sec. 19. (1) These CON review standards supersede and replace the CON Review Standards for Magnetic Resonance Imaging Services approved by the CON Commission on SEPTEMBER 18, 2007 and effective NOVEMBER 13, 2007.

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

Section 20. Health Service Areas

Sec. 20. Counties assigned to each of the health service areas are as follows:

HSA		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

CON REVIEW STANDARDS FOR MRI 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

Michigan Department of Community Health
MEMORANDUM
Lansing, MI

DATE: August 12, 2008

TO: Irma Lopez

FROM: Andrea Moore

RE: Review of Public Hearing Testimony on the Proposed Bone Marrow Transplantation (BMT) Services Standards

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Public Hearing Testimony

Pursuant to MCL 333.22215 (3), the Certificate of Need (CON) Commission "...shall conduct a public hearing on its proposed action." The Commission took proposed action on the BMT Standards at its June 11, 2008 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed BMT Standards on July 30, 2008. Written testimony was accepted for an additional 7 days after the hearing via an electronic link on the Commission's website. Testimony was received from two organizations and is summarized as follows:

18. Blue Cross Blue Shield of Michigan
    - Supports the recommended modification.

19. Karmanos Cancer Institute
    - Supports the recommended modification.
    - Provided documentation of PPS assumption efforts and status.

Staff Analysis and Recommendations

The public hearing testimony supports the modifications to the proposed BMT Standards. Therefore, the proposed BMT Standards are recommended for final action at the September 16, 2008 Commission meeting.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS
FOR BONE MARROW TRANSPLANTATION SERVICES

(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 the approval and delivery of services for all projects approved and Certificates of Need issued under Part 222 of the Code which involve bone marrow transplantation services.

(2) A bone marrow transplantation service is a covered clinical service for purposes of Part 222 of the Code.

(3) A bone marrow transplantation service listed on the Department inventory that is located at a hospital site and initially does not perform both allogeneic and autologous procedures shall not be required to obtain separate CON approval to begin performing both autologous and allogeneic bone marrow transplant procedures.

(4) An existing bone marrow transplantation service that performs only adult procedures shall require separate CON approval in order to perform pediatric procedures. An existing bone marrow transplantation service that performs only pediatric procedures shall require separate CON approval in order to perform adult procedures.

(5) The Department shall use Sections 3, 7 & 8, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

(6) The Department shall use Sections 4, 5 & 6, 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 these standards:

(a) "Acquisition of a bone marrow transplantation service" means the acquisition (including purchase, lease, donation, or other arrangement) of an existing bone marrow transplantation service.

(b) "Adult," for purposes of these standards, means an individual age 18 or older.

(c) "Allogeneic" means transplantation between genetically nonidentical individuals of the same species.

(d) "Autologous" means transplantation in which the donor and recipient are the same individual.

(e) "Bone marrow transplantation service" means the transplantation of proliferating hematopoietic stem cells essential to the survival of a patient derived from the bone marrow, the peripheral circulation, cord blood, or any other source.

(f) "Cancer hospital" means a hospital that has been approved to participate in the Title XVIII (Medicare) program as a prospective payment system (PPS) exempt hospital in accordance with Section 1886 (d)(1)(B)(v) of the Social Security Act, as amended.

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

(h) "Comparative group" means the applications that have been grouped for the same type of
project in the same planning area and are being reviewed comparatively in accordance with the CON rules.

(i) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.

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

(k) "Department inventory of bone marrow transplantation services" means the list maintained by the Department of: (i) the bone marrow transplantation services operating pursuant to a valid CON issued under Part 222 or former Part 221; (ii) operating bone marrow transplantation services for which the operation of that service did not require a CON; and (iii) bone marrow transplantation services that are not yet operational but have a valid CON issued under Part 222. The list shall inventory adult and pediatric services separately and shall specify the site at which the bone marrow transplantation service is authorized.

(l) "Existing bone marrow transplantation service," for purposes of Section 3(5) of these standards, means any of the following: (i) a bone marrow transplantation service listed on the Department inventory, (ii) a proposed bone marrow transplantation service under appeal from a final decision of the Department, or (iii) a proposed bone marrow transplantation service that is part of a completed application under Part 222 (other than the application under review) for which a proposed decision has been issued and which is pending final decision.

(m) "Health service area" or "HSA" means the geographic area set forth in Section 9.

(n) "Implementation plan" means a plan that documents how a proposed bone marrow transplantation service will be initiated within the time period specified in these standards or the CON rules. At a minimum, the implementation plan shall identify:

(i) each component or activity necessary to begin performing the proposed bone marrow transplantation service including, but not limited to, the development of physical plant requirements, such as an intensive care unit capable of treating immuno-suppressed patients, equipment acquisitions, and recruitment and employment of all physician and support staff;

(ii) the time table for completing each component or activity specified in subsection (i); and

(iii) if the applicant previously has been approved for a bone marrow transplantation service for which either the CON expired or the service did not perform a transplant procedure during any consecutive 12-month period, what changes have or will be made to ensure that the proposed service can be initiated and provided on a regular basis.

(o) "Initiate" or "implement" for purposes of these standards, means the performance of the first transplant procedure. The term of an approved CON shall be 18 months or the extended period established by Rule 325.9403(2), if authorized by the Department.

(p) "Initiate a bone marrow transplantation service" means to begin operation of a bone marrow transplantation service at a site that does not provide either adult or pediatric bone marrow transplantation services and is not listed on the Department inventory as of the date an application is submitted to the Department. The term includes an adult service that is proposing to provide a pediatric bone marrow transplantation service, and a pediatric service that is proposing to provide an adult bone marrow transplantation service. The term does not include beginning operation of a bone transplantation service by a cancer hospital which acquires an existing bone marrow transplantation service provided that all of the staff, services, and programs required under section 3(3) are to be provided by the cancer hospital and/or by the hospital from which the bone marrow transplantation service is being acquired.

(q) "Institutional Review Board" or "IRB" means an institutional review board as defined by Public Law 93-348 which is regulated by Title 45 CFR 46.

(r) "Licensed site" means either:

(i) in the case of a single site hospital, the location of the facility 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 unit of the health facility as authorized by license and listed on that licensee's certificate of licensure.

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

(t) "Pediatric" means, for purposes of these standards, any patient 20 years of age or less or any patient with congenital conditions or diseases for which bone marrow transplantation is a treatment.

(u) "Planning area" means:

(i) for an adult bone marrow transplantation service, the state of Michigan.

(ii) for a pediatric bone marrow transplantation service, either:

(A) planning area one that includes the counties in health service areas 1, 2, 5, and 6, and the following counties in health service area 7: Alcona, Alpena, Cheboygan, Crawford, Montmorency, Oscoda, Otsego, and Presque Isle; or

(B) planning area two that includes the counties in health service areas 3, 4, and 8, and the following counties in health service area 7: Antrim, Benzie, Charlevoix, Emmet, Grand Traverse, Kalkaska, Leelanau, Manistee, Missaukee, and Wexford.

(v) "Qualifying project" means each application in a comparative group that has been reviewed individually and has been determined by the Department to have satisfied all of the requirements of Section 22225 of the Code, being Section 333.22225 of the Michigan Compiled Laws, and all other applicable requirements for approval in the Code and these standards.

(w) "Survival rate" means, for purposes of these standards, the rate calculated using the Kaplan-Meier technique and the following: (i) the date of transplantation (or, if more than one transplant is performed, the date of the first transplant) must be the starting date for calculation of the survival rate; (ii) for those dead, the date of death is used, if known. If the date of death is unknown, it must be assumed as 1 day after the date of the last ascertained survival; (iii) for those who have been ascertained as surviving within 60 days before the fiducial date (the point in time when the facility's survival rates are calculated and its experience is reported), survival is considered to be the date of the last ascertained survival, except for patients described in subsection (v); (iv) any patient who is not known to be dead, but whose survival cannot be ascertained to a date that is within 60 days before the fiducial date, must be considered as "lost to follow up" for the purposes of the survival rate calculation; (v) any patient transplanted between 61 and 120 days before the fiducial date must be considered as "lost to follow up" if he or she is not known to be dead and his or her survival has not been ascertained for at least 60 days before the fiducial date. Any patient transplanted within 60 days before the fiducial date must be considered as "lost to follow up" if he or she is not known to be dead and his or her survival has not been ascertained on the fiducial date; and (vi) the survival analyses must use the assumption that each patient in the "lost to follow up" category died 1 day after the last date of ascertained survival. However, an applicant may submit additional analyses that reflect each patient in the "lost to follow up" category as alive at the date of the last ascertained survival.

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

Section 3. Requirements for approval for applicants proposing to initiate a bone marrow transplantation service

Sec. 3. (1) An applicant proposing to initiate a bone marrow transplantation service shall specify in the application whether the proposed service will perform either or both adult and pediatric bone marrow transplant procedures.

(2) An applicant shall specify the licensed hospital site at which the bone marrow transplantation service will be provided.

(3) An applicant proposing to initiate either an adult or pediatric bone marrow transplantation service shall demonstrate that the licensed hospital site at which the transplants will be offered provides each of the following staff, services, and programs:

(a) operating rooms.

(b) continuous availability, on-site or physically connected, either immediate or on-call, of CT scanning, magnetic resonance imaging, ultrasound, angiography, and nuclear medicine services.

(c) dialysis.

(d) inpatient-outpatient social work.

(e) inpatient-outpatient psychiatry/psychology.

(f) clinical research.

(g) a microbiology and virology laboratory.

(h) a histocompatibility laboratory that meets the standards of the American Society for Histocompatibility and Immunogenetics, or an equivalent organization, either on-site or through written agreement.

(i) a hematopathology lab capable of performing cell phenotype analysis using flow cytometry.

(j) a clinical chemistry lab with the capability to monitor antibiotic and antineoplastic drug levels, available either on-site or through other arrangements that assure adequate availability.

(k) other support services, as necessary, such as physical therapy and rehabilitation medicine.

(l) continuous availability of anatomic and clinical pathology and laboratory services, including clinical chemistry, and immuno-suppressive drug monitoring.

(m) continuous availability of red cells, platelets, and other blood components.

(n) an active medical staff that includes, but is not limited to, the following board-certified or board-eligible specialists. For an applicant that is proposing to perform pediatric transplant procedures, these specialists shall be board-certified or board-eligible in the pediatric discipline of each specialty.

(i) anesthesiology.

(ii) cardiology.

(iii) critical care medicine.

(iv) gastroenterology.

(v) general surgery.

(vi) hematology.

(vii) infectious diseases.

(viii) nephrology.

(ix) neurology.

(x) oncology.

(xi) pathology, including blood banking experience.

(xii) pulmonary medicine.

(xiii) radiation oncology.

(xiv) radiology.

(xv) urology.

(o) One or more consulting physicians who are board-certified or board-eligible in each of the following specialties. For an applicant proposing to perform pediatric bone marrow transplant procedures, these specialists shall have specific experience in the care of pediatric patients.

(i) dermatology.

(ii) immunology.
(iii) neurosurgery.
(iv) orthopedic surgery.

(4) An applicant must provide an implementation plan for the proposed bone marrow transplantation service.

(5)(a) An applicant shall demonstrate that the number of existing adult bone marrow transplantation services in the planning area identified in Section 2(1)(u)(i) does not exceed three (3) adult bone marrow transplantation services and that approval of the proposed application will not result in the total number of adult bone marrow transplantation services exceeding three (3) in the planning area.

(b) An applicant shall demonstrate that the number of existing pediatric bone marrow transplantation services does not exceed two (2) pediatric bone marrow transplantation services in planning area one identified in Section 2(1)(u)(ii)(A) or one (1) pediatric bone marrow transplantation service in planning area two identified in Section 2(1)(u)(ii)(B) and that approval of the proposed application will not result in the total number of pediatric bone marrow transplantation services exceeding the need for each specific pediatric planning area.

(6)(a) An applicant proposing to initiate an adult bone marrow transplantation service that will perform only allogeneic transplants, or both allogeneic and autologous transplants, shall project that at least 10 allogeneic transplant procedures will be performed in the third 12-months of operation. An applicant proposing to initiate an adult bone marrow transplantation service that will perform only autologous procedures shall project that at least 10 autologous transplant procedures will be performed in the third 12-months of operation.

(b) An applicant proposing to initiate a pediatric bone marrow transplantation service that will perform only allogeneic transplants, or both allogeneic and autologous transplants, shall project that at least 10 allogeneic transplant procedures will be performed in the third 12-months of operation. An applicant proposing to initiate a pediatric bone marrow transplantation service that will perform only autologous procedures shall project that at least 10 autologous transplant procedures will be performed in the third 12-months of operation.

(c) An applicant proposing to initiate both an adult and a pediatric bone marrow transplantation service shall specify whether patients age 18-20 are included in the projection of adult procedures required pursuant to subsection (a) or the projection of pediatric procedures required pursuant to subsection (b). An applicant shall not include patients age 18-20 in both adult and pediatric projections required pursuant to subsections (a) and (b).

(7) An applicant shall provide megavoltage radiation therapy services, either on-site or physically connected, with a nominal beam energy of at least 6 MEV, including the capability to perform total body irradiation.

(8) An applicant shall demonstrate that the licensed hospital site at which the proposed bone marrow transplantation service is proposed has an institutional review board.

(9) An applicant proposing to initiate a pediatric bone marrow transplantation service shall demonstrate that the licensed hospital site at which the pediatric transplant procedures will be performed has each of the following:

(a) a designated pediatric inpatient oncology unit.

(b) a pediatric inpatient intensive care unit.

(c) membership status in either the Pediatric Oncology Group (POG) or the Children's Cancer Group (CCG).

(d) a pediatric tumor board that meets on a regularly scheduled basis.

(e) family support group services, provided either directly or through written agreements.

(f) a pediatric cancer program with the following staff:

(i) a director who is either a board-certified immunologist who has specific training and experience in bone marrow transplantation or a board-certified pediatric hematologist/oncologist.

(ii) nurses with training and experience in pediatric oncology.

(iii) social workers with training and experience in pediatric oncology.

(iv) pediatric psychologists.

(v) child life specialists.

(10)(a) An applicant proposing to initiate either a new adult or pediatric bone marrow transplantation service shall submit, in its application, a written consulting agreement with an existing bone marrow transplantation service, that meets each of the requirements in subsection (b).

(b) The written consulting agreement required by subsection (a) shall specify the term of the agreement and the roles and responsibilities of both the existing and proposed service, including at least the following:

(i) The term of the written consulting agreement is no less than 36 months after the proposed service begins to perform bone marrow transplant procedures.

(ii) One or more representatives of the existing bone marrow transplantation service have been designated as staff responsible for carrying out the roles and responsibilities of the existing service.

(iii) The existing service shall evaluate and make recommendations to the proposed service on policies and procedures, including time tables, for at least each of the following:

(A) nursing services.

(B) infection control.

(C) nutritional support.

(D) staff needs and training.

(E) inpatient and outpatient medical coverage.

(F) transfusion and blood bank policies.

(G) transplant treatment protocols.

(H) hematopoiesis laboratory services and personnel.
(I) data management.
(J) quality assurance program.
(iv) Specify a schedule of site visits by staff of the existing bone marrow transplantation service that, at a minimum, includes:
(A) 6 visits during the first 12-months of operation of the proposed service.
(B) 4 visits during each the second 12-months and third 12-months of operation of the proposed service.
(v) Specify that the purpose of the site visits required by subdivision (iv) is to assess the proposed service and make recommendations related to quality assurance mechanisms of the proposed service, including at least each of the following:
(A) a review of the number of patients transplanted.
(B) transplant outcomes.
(C) all infections requiring treatment or life-threatening toxicity, defined for purposes of this agreement as National Cancer Institutes grade #3 or greater toxicity, excluding hematological toxicity.
(D) all deaths occurring within 100 days from transplant.
(E) each of the requirements of subdivision (iii).
(vi) Specify that a written report and minutes of each site visit shall be completed by the existing bone marrow transplantation service and sent to the proposed service within 2 weeks of each visit, and that copies of the reports and minutes shall be available to the Department upon request. At a minimum, the written report shall address each of the items in subdivision (v).
(vii) Specify that the existing bone marrow transplantation service shall notify the Department and the proposed service immediately if it determines that the proposed service may not be in compliance with any applicable quality assurance requirements, and develop jointly with the proposed service a plan for immediate remedial actions.
(viii) Specify that the existing bone marrow transplantation service shall notify the Department immediately if the consulting agreement required pursuant to these standards is terminated and that the notification shall include a statement describing the reasons for the termination.
(c) For purposes of subsection (10), "existing bone marrow transplantation service" means a service that meets all of the following:
(i) currently is performing and is Foundation for Accreditation of Cell Therapy (FACT) accredited in, the types of transplants (allogeneic or autologous; adult or pediatric) proposed to be performed by the applicant;
(ii) currently is certified as a National Marrow Donor Program; and
(iii) is located in the United States.
(d) An applicant shall document that the existing bone marrow transplantation service meets the requirements of subsection (c)

Section 4. Additional requirements for applications included in comparative reviews

Sec. 4. (1) Any application subject to comparative review under Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, or these standards, shall be grouped and reviewed with other applications in accordance with the CON rules applicable to comparative reviews.

(2)(a) A qualifying project will have points awarded based on the number of bone marrow transplantation services, adult or pediatric, as applicable, listed on the Department inventory in the health service area in which the proposed service will be located, on the date the application is submitted to the Department, as shown in the following schedule:

Number of BMT Transplant Services (adult or pediatric, as applicable) in HSA	Points Awarded
Two or more services	0
One service	2
No services	4

(b) A qualifying project will have up to 4 points awarded based on the percentage of the medical/surgical indigent volume at the licensed hospital site at which the proposed bone marrow transplantation service will be provided in accordance with the following:

(i) For each applicant in the same comparative group, determine the medical/surgical indigent volume, rounded to the nearest whole number, for each licensed hospital site at which a bone marrow transplantation service is proposed to be provided. Determine the licensed hospital site that has the highest indigent volume in the same comparative group. Divide the medical/surgical indigent volume for that licensed hospital site by 4.0. The result is the indigent volume factor.

(ii) For each applicant in the same comparative group, divide the medical/surgical indigent volume by the indigent volume factor determined in subdivision (i). The result, to the first decimal place, is the number of points that will be awarded to each applicant pursuant to this subsection.

For purposes of this subsection, indigent volume means the ratio of a hospital's indigent charges to its total charges expressed as a percentage as determined by the Michigan Department of Community Health Medical Services Administration pursuant to Chapter VIII of the Medical Assistance Program Hospital Manual. The indigent volume data being used for rates in effect at the time the application is deemed submitted will be used by the Department in determining the number of points awarded to each qualifying project.

(c) A qualifying project will have 2 points awarded if an applicant documents that, during the 36-month period prior to the date an application is submitted to the Department, at least 15 patients received pre- and post-transplant care at the licensed hospital site at which the bone marrow transplant procedures will be performed and were referred for and received a bone marrow transplant at an existing bone marrow transplantation service, and submits documentation from the existing bone marrow transplantation service(s) of these referrals.

(3) Each application in a comparative group shall be individually reviewed to determine whether the application has satisfied all the requirements of Section 22225 of the Code being Section 333.22225 of the Michigan Compiled Laws and all other applicable requirements for approval in the Code and these standards. If the Department determines that two or more competing applications satisfy all of the requirements for approval, these projects shall be considered qualifying projects. The Department shall approve those qualifying projects which, when taken together, do not exceed the need, as defined in Section 22225(1) of the Code, and which have the highest number of points when the results of subsection (2) are totaled. If two or more qualifying projects are determined to have an identical number of points, then the Department shall approve those qualifying projects which, when taken together, do not exceed the need, in the order in which the applications were received by the Department, based on the date and time stamp placed on the applications by the Department in accordance with Rule 325.9123.

(4) No points will be awarded to an applicant under specific subsections of Section 4 if information presented is inconsistent with related information provided in other portions of the CON application.

Section 5. Requirements for approval -- all applicants

Sec. 5. 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.

Section 6. Project delivery requirements -- terms of approval for all applicants

Sec. 6. (1) An applicant shall agree that, if approved, the bone marrow transplantation service shall be delivered in compliance with the following terms of CON approval:

(a) Compliance with these standards. An applicant shall immediately report to the Department any changes in key staff or other aspects of the bone marrow transplantation service that may affect its ability to comply with these standards.

(b) Compliance with applicable safety and operating standards.

(c) Compliance with the following quality assurance standards, as applicable, no later than the date the first bone marrow transplant procedure, allogeneic or autologous, is performed:

(i) An applicant shall establish and maintain, either on-site or through written agreements, all of the following:

(A) 24-hour blood bank support, including pheresis capability, irradiated blood, products suitable for cytomegalovirus-negative transplants, and blood component therapy.

(B) a cytogenetics and/or molecular genetic laboratory.

(C) a processing and cryopreservation laboratory that meets the standards of the Foundation for Accreditation of Cell Therapy (FACT) or an equivalent organization.

(D) for a program that performs allogeneic transplants, a histocompatibility laboratory that has the capability of DNA-based HLA-typing and meets the standards of the American Society for Histocompatibility and Immunogenetics or an equivalent organization.

(E) anatomic and clinical pathology with competency in interpreting pathologic findings related to graft-v-host disease (programs performing allogeneic transplants) and other opportunistic infections in immuno-compromised hosts (programs performing allogeneic or autologous transplants).

(F) therapeutic drug monitoring.

(ii) An applicant shall establish and maintain, at the licensed hospital site at which the transplants are performed, both of the following:

(A) a protective environmental bone marrow transplant inpatient unit for immuno-suppressed patients that has an isolation policy, an infection control plan specific to that unit, and an air handling system capable of preventing nosocomial infections disseminated from central heating and cooling systems and ambient air.

(B) a specialized intensive care unit capable of treating immuno-suppressed neutropenic patients.

(iii) An applicant shall establish and maintain written policies related to outpatient care for bone marrow transplantation patients, including at least the following:

(A) the ability to evaluate and provide treatment on a 24-hour basis.

(B) nurses experienced in the care of bone marrow transplantation patients.

(C) a designated outpatient area for patients requiring long-duration infusions or the administration of multiple medications or blood product transfusions.

(iv) A bone marrow transplantation service shall establish and maintain a dedicated transplant team that includes at least the following staff:

(A) a transplant team leader, who is a physician that is board-certified in at least one of the following specialties: hematology, medical oncology, immunology, or pediatric hematology/oncology, as appropriate, and has had either at least one year of specific clinical training or two years of experience, both inpatient and outpatient, as an attending physician principally responsible for the clinical management of patients

treated with hematopoietic transplantation. If the bone marrow transplantation service performs allogeneic transplants, the team leader's experience shall include the clinical management of patients receiving an allogeneic transplant. The responsibilities of the transplant team leader shall include overseeing the medical care provided by attending physicians, reporting required data to the Department, and responsibility for ensuring compliance with the all applicable project delivery requirements.

(B) one or more attending physicians with specialized training in pediatric and/or adult, as appropriate, bone marrow transplantation. If a service performs allogeneic transplants, at least one attending physician shall have specialized training in allogeneic transplantation, adult or pediatric, as appropriate. An attending physician shall be board-certified or board-eligible in hematology, medical oncology, immunology, or pediatric hematology/oncology, as appropriate.

(C) on-site availability of board-certified or board-eligible consulting physicians, adult and/or pediatric, as appropriate, in at least the following specialities: anatomic pathology with competence in graft versus host disease (services performing allogeneic transplants) and other opportunistic diseases (services performing allogeneic or autologous transplants), cardiology, gastroenterology, infectious diseases with experience in immuno-compromised hosts, nephrology, psychiatry, pulmonary medicine, and radiation oncology with experience in total body irradiation, and an intensivist who is board-certified in critical care.

(D) a transplant team coordinator, who shall be responsible for providing pre-transplant patient evaluation and coordinating treatment and post-transplant follow-up and care.

(E) a nurse to patient ratio necessary to provide care consistent with the severity of a patient's clinical status.

(F) nurses with specialized training in pediatric and/or adult, as appropriate, bone marrow transplantation, hematology/oncology patient care, administration of cytotoxic therapies, management of infectious complications associated with compromised host-defense mechanisms, administration of blood components, the hemodynamic support of the transplant patient, and managing immuno-suppressed patients.

(G) a pharmacist experienced with the use of cytotoxic therapies, use of blood components, the hemodynamic support of the transplant patient, and the management of immuno-suppressed patients.

(H) dietary staff capable of providing dietary consultations regarding a patient's nutritional status, including total parenteral nutrition.

(I) designated social services staff.

(J) designated physical therapy staff.

(K) data management personnel designated to the bone marrow transplantation service.

(L) for an applicant performing pediatric bone marrow transplants, a child-life specialist.

(v) In addition to the dedicated transplant team required in subdivision (iv), an applicant's staff shall include a patient ombudsman, who is familiar with the bone marrow transplantation service, but who is not a member of the transplant team.

(vi) An applicant shall develop and maintain patient management plans and protocols that include the following:

(A) therapeutic and evaluative procedures for the acute and long-term management of a patient.

(B) patient management and evaluation during the waiting, in-hospital and immediate post-discharge phases of the service.

(C) long-term management and evaluation, including education of the patient, liaison with the patient's attending physician, and the maintenance of active patient records for at least 5 years.

(D) IRB approval of all clinical research protocols, or if transplantation does not require an IRB-approved clinical research protocol, written policies and procedures that include at least the following: donor, if applicable, and recipient selection, transplantation evaluations, administration of the preparative regimen, post-transplantation care, prevention and treatment of graft-versus-host disease (allogeneic transplants), and follow-up care.

(vii) An applicant shall establish and maintain a written quality assurance plan.

(viii) An applicant shall implement a program of education and training for nurses, technicians, service personnel, and other hospital staff.

(ix) An applicant shall participate actively in the education of the general public and the medical community with regard to bone marrow transplantation, and make donation literature available in public areas of the institution.

(x) An applicant shall establish and maintain an active, formal multi-disciplinary research program related to the proposed bone marrow transplantation service.

(xi) An applicant shall operate, either on-site or under its direct control, a multi-disciplinary selection committee which includes, but is not limited to, a social worker, a mental health professional, and physicians experienced in treating bone marrow transplant patients.

(xii) A pediatric bone marrow transplant service shall maintain membership status in the Children's Oncology Group (COG).

(xiii) For purposes of evaluating subsection (c), except subdivision (xii), the Department shall consider it prima facie evidence as to compliance with the applicable requirements if an applicant documents that the bone marrow transplantation service is accredited by the National Marrow Donor Program (NMDP) or the Foundation for the Accreditation of Cell Therapy (FACT).

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

(d) Compliance with the following terms of approval:

(i) An applicant shall perform the applicable required volumes as follow:

(A) An adult bone marrow transplantation service that performs only allogeneic transplants, or both allogeneic and autologous transplants, shall perform at least 10 allogeneic transplants in the third 12-months of operation. If an adult service performs only autologous transplants, the service shall perform at least 10 autologous transplants in the third 12-months of operation. After the third 12-months of operation, an applicant shall perform at least 30 adult transplants in any 36-month consecutive period, with no

fewer than 5 allogeneic in any 12-month period, beginning with the third 12-months of operation, and thereafter.

(B) A pediatric bone marrow transplantation service that performs only allogeneic transplants, or both allogeneic and autologous transplants, shall perform at least 10 allogeneic transplants in the third 12-months of operation. If a pediatric service performs only autologous transplants, the service shall perform at least 10 autologous transplants in the third 12-months of operation. After the third 12-months of operation, an applicant shall perform at least 30 pediatric transplants in any 36-month consecutive period, with no fewer than 5 allogeneic transplants in any 12-month period, beginning with the third 12-months of operation, and thereafter.

(C) A bone marrow transplantation service that performs both adult and pediatric bone marrow transplants shall specify whether each patient age 18-20 is included in the category of adult procedures or the category of pediatric procedures. An applicant shall determine for each patient age 18-20 whether to record that patient as an adult or a pediatric procedure, but an applicant shall record each patient age 18-20 in only 1 category.

(ii) 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, demographic and diagnostic information, primary and secondary diagnoses, whether the transplant procedure was a first or repeat transplant procedure, length of stay, the volume of care provided to patients from all payor sources, and other data requested by the Department and approved by the CON Commission. The applicant shall provide the required data on an individual basis for each designated licensed site; 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. In addition, an applicant shall report at least the following data for each patient:

(A) disease type.

(B) transplant type, i.e., related allogeneic, unrelated allogeneic, and autologous.

(C) source of hematopoietic stem cell, i.e., bone marrow, peripheral circulation, cord blood, etc.

(D) patient age, i.e., adult or pediatric as defined by these standards.

(E) data on 100-day, 6-month, 1-year, 2-year, and 5-year survival rates.

(F) relapse rates at 6-months, 1-year, and 5-years post-transplant.

(G) median follow-up, and patients lost-to-followup.

(H) cause(s) of death, if applicable.

(I) additional summary information, as applicable.

An applicant annually shall report for its bone marrow transplantation service annual and cumulative survival rates by type of transplant performed reported in actual number of transplants by disease category, transplant type, i.e., related allogeneic, unrelated allogeneic, and autologous; source of hematopoietic stem cell; patient age, i.e., adult or pediatric, as defined by these standards; and relapse rates at 100-days, 6-months, one year, and five years post-transplant. For purposes of these standards, procedure-related mortality is defined as death occurring within 100 days from bone marrow transplant.

(iii) The applicant shall maintain an organized institutional transplant registry for recording ongoing information on its patients being evaluated for transplant and on its transplant recipients and shall participate in the national and international registries applicable to the bone marrow transplantation service.

(iv) An applicant, to assure that the bone marrow transplantation service(s) will be utilized by all segments of the Michigan population, shall:

(A) not deny the services to any individual based on ability to pay or source of payment;

(B) provide the services to all individuals in accordance with the patient selection criteria developed by appropriate medical professionals, and approved by the Department; 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.

(v) The applicant shall provide the Department with a notice stating the date on which the first transplant procedure is performed and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules. An applicant that initially does not perform both allogeneic and autologous procedures also shall notify the Department when it begins to perform either allogeneic or autologous procedures, whichever was not performed initially by the applicant.

(vi) An applicant shall notify the Department immediately if the consulting agreement required pursuant to Section 3(10) of these standards is terminated prior to the end of the first 36-months of operation of the bone marrow transplantation service. The notification shall include a statement describing the reasons for the termination. An applicant shall have 30 days following termination of that agreement to enter into a written consulting agreement that meets the requirements of Section 3(10). An applicant shall provide the Department with a copy of that written consulting agreement.

(vii) The Department may use the information provided pursuant to Section 3(10) of these standards in evaluating compliance with the requirements of this section.

(2) The agreements and assurances required by this section, as applicable, shall be in the form of a certification authorized by the governing body of the applicant or its authorized agent.

Section 7. Documentation of projections

Sec. 7. An applicant required to project volumes of service under Section 3 shall specify how the volume projections were developed. This specification of projections shall include a description of the data source(s) used, assessments of the accuracy of these data, and the statistical method used to make the projections. Based on this documentation, the Department shall determine if the projections are reasonable.

Section 8. Requirements for approval – acquisition of a bone marrow transplantation service by a cancer hospital

(1) An applicant proposing to acquire an existing bone marrow transplantation service shall demonstrate that it meets all of the requirements of this subsection and shall not be required to be in compliance with section 3(5) and the department inventory.

(a) The total number of bone marrow transplantation services is not increased in the planning area as the result of the acquisition.

(b) As part of the acquisition of the bone marrow transplantation service, the acquisition or replacement of the cancer hospital, or for any other reasons, the location of the bone marrow transplantation service shall be located at its prior location or in space within the licensed cancer hospital site.

(c) The applicant is a cancer hospital as defined by these standards. The applicant shall, to the satisfaction of the Department, provide verification of PPS-exemption at the time of application, or shall demonstrate compliance with the following to the satisfaction of the Department:

(i) The applicant, or an affiliate of the applicant, operates a comprehensive cancer center recognized by the National Cancer Institute in conjunction with a Michigan university that is designated as a comprehensive cancer center, or the applicant is the Michigan university that is designated as a comprehensive cancer center.

(ii) The applicant commits to provide evidence, satisfactory to the Department, of approval as a PPS-exempt hospital within the time limits specified in subsection (g).

(d) The applicant demonstrates that it meets, directly or through arrangements with the hospital from which it acquires the bone marrow transplantation service, the requirements set forth under section 3(3), (6), (7), and (8), as applicable.

(e) The applicant agrees to either have a written consulting agreement as required by Section 3(10) or obtain a determination by the Department that such an agreement is not required because the existing bone marrow transplantation staff, services, and program substantially will continue to be in place after the acquisition.

(f) The applicant agrees and assures to comply, either directly or through arrangements with the hospital from which it acquires the bone marrow transplantation service, with all applicable project delivery requirements.

(g) If the applicant described in this subsection does not meet the Title XVIII requirements of the Social Security Act for exemption from PPS within 24 months after receiving CON approval under this section, the Department may extend the 24-month deadline to no later than the last session day permitted by the United States Constitution for the NEXT United States Congress in session AFTER THE EFFECTIVE DATE OF THESE STANDARDS. Extension of the deadline shall require demonstration by the applicant, to the satisfaction of the Department, that there has been progress toward achieving the changes in federal law and regulations that are required to secure the PPS exemption. If the applicant fails to meet the Title XVIII requirements for PPS exemption within the 24-month period, or its possible extension, then the CON granted pursuant to this section shall expire automatically and will not be subject to further applications for acquisition. However, prior to the final deadline for the expiration of the CON, the prior holder of the (CON/authorization) to provide the bone marrow transplantation service may apply for acquisition of the service, pursuant to all the provisions of this section, except for subsection (c).

2. Applicants proposing to acquire an existing bone marrow transplantation service under this section shall not be subject to comparative review.

Section 9. Health Service Areas

Sec. 9. Counties assigned to each health service area are as follows:

HSA		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 10. Department Inventory of Bone Marrow Transplantation Services

Sec 10. The Department shall maintain, and provide on request, a listing of the Department Inventory of bone marrow transplantation services.

Section 11. Effect on prior CON Review Standards; comparative reviews

Sec. 11. (1) These CON review standards supersede and replace the CON Review Standards for Extrarenal Transplantation Services pertaining to bone marrow transplantation services approved by the CON Commission on December 12, 2006 and effective on March 8, 2007.

(2) Projects reviewed under these standards shall be subject to comparative review.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR HOSPITAL BEDS

(By authority conferred on the CON Commission by sections 22215 and 22217 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, 333.22217, 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 (a) increasing licensed beds in a hospital licensed under Part 215 or (b) physically relocating hospital beds from one licensed site to another geographic location or (c) replacing beds in a hospital or (d) acquiring a hospital or (e) beginning operation of a new hospital.

(2) A hospital licensed under Part 215 is a covered health facility for purposes of Part 222 of the Code.

(3) An increase in licensed hospital beds is a change in bed capacity for purposes of Part 222 of the Code.

(4) The physical relocation of hospital beds from a licensed site to another geographic location is a change in bed capacity for purposes of Part 222 of the Code.

(5) An increase in hospital beds certified for long-term care is a change in bed capacity for purposes of Part 222 of the Code and shall be subject to and reviewed under the CON Review Standards for Long-Term-Care Services.

(6) The Department shall use sections 3, 4, 5, 6, 7, 8, 10, AND 16 of these standards and Section 2 of the Addendum for Projects for HIV Infected Individuals, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

(7) The Department shall use Section 9 of these standards and Section 3 of the Addendum for Projects for HIV Infected Individuals, 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 these standards:

(a) "Acquiring a hospital" means the issuance of a new hospital license as the result of the acquisition (including purchase, lease, donation, or other comparable arrangements) of a licenseD AND OPERATING HOSPITAL and which does not involve a change in bed capacity.

(b) "Alcohol and substance abuse hospital" means a licensed hospital within a long-term (acute) care hospital that exclusively provides inpatient medical detoxification and medical stabilization and related outpatient services for persons who have a primary diagnosis of substance dependence covered by DRGs 433 - 437.

(c) "Base year" means the most recent year that final MIDB data is available to the Department unless a different year is determined to be more appropriate by the Commission.

(d) "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.

(e) “Close a hospital” means an applicant will demonstrate to the satisfaction of the Department that a hospital licensed under Part 215, and whose licensed capacity for the most recent 24 months prior to
submission of the application was at least 80 percent for acute care beds, will close and surrender its acute care hospital license upon completion of the proposed project.

(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) “Common ownership or control” means a hospital that is owned by, is under common control of, or has a common parent as the applicant hospital.

(h) “Compare group” means the applications that have been grouped for the same type of project in the same subarea and are being reviewed comparatively in accordance with the CON rules.

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

(j) "Department inventory of beds" means the current list maintained for each hospital subarea on a continuing basis by the Department of (i) licensed hospital beds and (ii) hospital beds approved by a valid CON issued under either Part 221 or Part 222 of the Code that are not yet licensed. The term does not include hospital beds certified for long-term-care in hospital long-term care units.

(k) “Discharge relevance factor” (%R) means a mathematical computation where the numerator is the inpatient hospital discharges from a specific zip code for a specified hospital subarea and the denominator is the inpatient hospital discharges for any hospital from that same specific zip code.

(l) “Disproportionate share hospital payments” means the most recent payments to hospitals in the special pool for non-state government-owned or operated hospitals to assure funding for costs incurred by public facilities providing inpatient hospital services which serve a disproportionate number of low-income patients with special needs as calculated by the Medical Services Administration within the Department.

(m) "Existing hospital beds" means, for a specific hospital subarea, the total of all of the following: (i) hospital beds licensed by the Department; (ii) hospital beds with valid CON approval but not yet licensed; (iii) proposed hospital beds under appeal from a final decision of the Department; and (iv) proposed hospital beds that are part of a

completed application under Part 222 (other than the application under review) for which a proposed decision has been issued and which is pending final Department decision.

(n) “Gross hospital revenues” means the hospital’s revenues as stated on the most recent Medicare and Michigan Medicaid forms filed with the Medical Services Administration within the Department.

(o) "Health service area" OR "HSA" means the groups of counties listed in Section 18.

(p) "Hospital bed" means a bed within the licensed bed complement at a licensed site of a hospital licensed under Part 215 of the Code, excluding (i) hospital beds certified for long-term care as defined in Section 20106(6) of the Code and (ii) unlicensed newborn bassinets.

(q) "Hospital" means a hospital as defined in Section 20106(5) of the Code being Section 333.20106(5) of the Michigan Compiled Laws and licensed under Part 215 of the Code. The term does not include a hospital or hospital unit licensed or operated by the Department of Mental Health.

(r) "Hospital long-term-care unit" or "HLTCU" means a nursing care unit, owned or operated by and as part of a hospital, licensed by the Department, and providing organized nursing care and medical treatment to 7 or more unrelated individuals suffering or recovering from illness, injury, or infirmity.

(s) "Hospital subarea" or "subarea" means a cluster or grouping of hospitals and the relevant portion of the state's population served by that cluster or grouping of hospitals. For purposes of these standards, hospital subareas and the hospitals assigned to each subarea are set forth in Appendix A.

(t) “Host hospital” means a licensed AND OPERATING hospital, which delicenses hospital beds, and which leases patient care space and other space within the physical plant of the host hospital, to allow a long-term (acute) care hospital, or alcohol and substance abuse hospital, to begin operation.

(u) "Licensed site" means the location of the facility authorized by license and listed on that licensee's certificate of licensure.

(v) "Limited access area" means those geographic areas containing a population of 50,000 or more based on the planning year and not within 30 minutes drive time of an existing licensed acute care hospital with 24 hour/7 days a week emergency services utilizing the slowest route available as defined by the Michigan Department of Transportation (MDOT) and as identified in Appendix E. Limited access areas shall be redetermined when a new hospital has been approved or an existing hospital closes.

(w) "Long-term (acute) care hospital" means a hospital has been approved to participate in the Title XVIII (Medicare) program as a prospective payment system (PPS) exempt hospital in accordance with 42 CFR Part 412.

(x) “Market forecast factors” (%N) means a mathematical computation where the numerator is the number of total inpatient discharges indicated by the market survey forecasts and the denominator is the base year MIDB discharges.

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

(z) “Medicaid volume” means the number of Medicaid recipients served at the hospital as stated on the most recent Medicare and Michigan Medicaid forms filed with the Medical Services Administration within the Department.

(aa) "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 B.

(bb) "Michigan Inpatient Data Base" or "MIDB" means the data base compiled by the Michigan Health and Hospital Association or successor organization. The data base consists of inpatient discharge records from all Michigan hospitals and Michigan residents discharged from hospitals in border states for a specific calendar year.

(cc) "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 B.

(dd) "New beds in a hospital" means hospital beds that meet at least one of the following: (i) are not currently licensed as hospital beds, (ii) are currently licensed hospital beds at a licensed site in one subarea which are proposed for relocation in a different subarea as determined by the Department pursuant to Section 3 of these standards, (iii) are currently licensed hospital beds at a licensed site in one subarea which are proposed for relocation to another geographic site which is in the same subarea as determined by the Department, but which are not in the replacement zone, or (iv) are currently licensed hospital beds that are proposed to be licensed as part of a new hospital in accordance with Section 6(2) of these standards.

(ee) "New hospital" means one of the following: (i) the establishment of a new facility that shall be issued a new hospital license, (ii) for currently licensed beds, the establishment of a new licensed site that is not in the same hospital subarea as the currently licensed beds, (iii) currently licensed hospital beds at a licensed site in one subarea which are proposed for relocation to another geographic site which is in the same subarea as determined by the Department, but which are not in the replacement zone, or (iv) currently licensed hospital beds that are proposed to be licensed as part of a new hospital in accordance with section 6(2) of these standards.

(ff) "Obstetrics patient days of care" means inpatient days of care for patients in the applicant’s Michigan Inpatient Data Base data ages 15 through 44 with drgs 370 through 375 (obstetrical discharges).

(gg) "Overbedded subarea" means a hospital subarea in which the total number of existing hospital beds in that subarea exceeds the subarea needed hospital bed supply as set forth in Appendix C.

(hh) "Pediatric patient days of care" means inpatient days of care for patients in the applicant’s Michigan Inpatient Data Base data ages 0 through 14 excluding normal newborns.

(ii) "Planning year" means five years beyond the base year, established by the CON Commission, for which hospital bed need is developed, unless a different year is determined to be more appropriate by the Commission.

(jj) “Qualifying project” means each application in a comparative group which has been reviewed individually and has been determined by the Department to have satisfied all of the requirements of Section 22225 of the code, being section 333.22225 of the Michigan Compiled Laws and all other applicable requirements for approval in the Code or these Standards.

(kk) “Relevance index” or “market share factor” (%Z) means a mathematical computation where the numerator is the number of inpatient hospital patient days provided by a specified hospital subarea from a specific zip code and the denominator is the total number of inpatient hospital patient days provided by all hospitals to that specific zip code using MIDB data.

(ll) “Relocate existing licensed hospital beds" for purposes of sections 6(3) and 8 of these standards, means a change in the location of existing hospital beds from the existing licensed hospital site to a different existing licensed hospital site within the same hospital subarea or HSA. This definition does not apply to projects involving replacement beds in a hospital governed by Section 7 of these standards.

(mm) "remaining patient days of care" means total inpatient days of care in the applicant’s Michigan Inpatient Data Base data minus obstetrics patient days of care and pediatric patient days of care.

(nn) "Replacement beds in a hospital" means hospital beds that meet all of the following conditions; (i) an equal or greater number of hospital beds are currently licensed to the applicant at the licensed site at which the proposed replacement beds are currently licensed; (ii) the hospital beds are proposed for replacement in new physical plant space being developed in new construction or in newly acquired space (purchase, lease, donation, etc.); and (iii) the hospital beds to be replaced will be located in the replacement zone.

(oo) "Replacement zone" means a proposed licensed site that is (i) in the same subarea as the existing licensed site as determined by the Department in accord with Section 3 of these standards and (ii) on the same site, on a contiguous site, or on a site within 2 miles of the existing licensed site if the existing licensed site is located in a county with a population of 200,000 or more, or on a site within 5 miles of the existing licensed site if the existing licensed site is located in a county with a population of less than 200,000.

(pp) "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 regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix B.

(qq) “Uncompensated care volume” means the hospital’s uncompensated care volume as stated on the most recent Medicare and Michigan Medicaid forms filed with the Medical Services Administration within the Department.

(rr) "Utilization rate" or "use rate" means the number of days of inpatient care per 1,000 population during a one-year period.

(ss) "Zip code population" means the latest population estimates for the base year and projections for the planning year, by zip code.

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

Section 3. Hospital subareas

Sec. 3. (1)(a) Each existing hospital is assigned to a hospital subarea as set forth in Appendix A which is incorporated as part of these standards, until Appendix A is revised pursuant to this subsection.

(i) These hospital subareas, and the assignments of hospitals to subareas, shall be updated, at the direction of the Commission, starting in May 2003, to be completed no later than November 2003. Thereafter, at the direction of the Commission, the updates shall occur no later than two years after the official date of the federal decennial census, provided that:

(A) Population data at the federal zip code level, derived from the federal decennial census, are available; and final MIDB data are available to the Department for that same census year.

(b) For an application involving a proposed new licensed site for a hospital (whether new or replacement), the proposed new licensed site shall be assigned to an existing hospital subarea utilizing a market survey conducted by the applicant and submitted with the application. The market survey shall provide, at a minimum, forecasts of the number of inpatient discharges for each zip code that the proposed new licensed site shall provide service. The forecasted numbers must be for the same year as the base year MIDB data. The market survey shall be completed by the applicant using accepted standard statistical methods. The market survey must be submitted on a computer media and in a format specified by the Department. The market survey, if determined by the Department to be reasonable pursuant to Section 15, shall be used by the Department to assign the proposed new site to an existing subarea based on the methodology described by “The Specification of Hospital Service Communities in a Large Metropolitan Area” by J. William Thomas, Ph.D., John R. Griffith, and Paul Durance, April 1979 as follows:

(i) For the proposed new site, a discharge relevance factor for each of the zip codes identified in the application will be computed. Zip codes with a market forecast factor of less than .05 will be deleted from consideration.

(ii) The base year MIDB data will be used to compute discharge relevance factors (%Rs) for each hospital subarea for each of the zip codes identified in step (i) above. Hospital subareas with a %R of less than .10 for all zip codes identified in step (i) will be deleted from the computation.

(iii) The third step in the methodology is to calculate a population-weighted average discharge relevance factor $\overline{R}_j$ for the proposed hospital and existing subareas. Letting:

P_i = Population of zip code i.

d_{ij} = Number of patients from zip code i treated at hospital j.

$D_i = \sum_j d_{ij}$ = Total patients from zip code i.

$I_j = \{i \mid (d_{ij}/D_i) \geq \alpha\}$, set of zip codes for which the individual relevance factor [%R from (i) and (ii) above) values (d_{ij}/D_i) of hospital j exceeds or equals α, where α is specified $0 \leq \alpha \geq 1$.

$$\text{then } \overline{R}_j = \frac{\sum_{i \in Ij} P_i (d_{ij}/D_i)}{\sum_{i \in Ij} P_i}$$

(iv) After $\overline{R}_j$ is calculated for the applicant(s) and the included existing subareas, the hospital/subarea with the smallest $\overline{R}_j$ ($S\overline{R}_j$) is grouped with the hospital/subarea having the greatest individual discharge relevance factor in the $S\overline{R}j$'s home zip code. $S\overline{R}j$'s home zip code is defined as the zip code from $S\overline{R}j$'s with the greatest discharge relevance factor.

(v) If there is only a single applicant, then the assignment procedure is complete. If there are additional applicants, then steps (iii), and (iv) must be repeated until all applicants have been assigned to an existing subarea.

(2) The Commission shall amend Appendix A to reflect: (a) approved new licensed site(s) assigned to a specific hospital subarea; (b) hospital closures; and (c) licensure action(s) as appropriate.

(3) As directed by the Commission, new sub-area assignments established according to subsection (1)(a)(i) shall supersede Appendix A and shall be included as an amended appendix to these standards effective on the date determined by the Commission.

Section 4. Determination of the needed hospital bed supply

Sec. 4. (1) The determination of the needed hospital bed supply for a limited access area and a hospital subarea for a planning year shall be made using the MIDB and population estimates and projections by zip code in the following methodology:

(a) All hospital discharges for normal newborns (DRG 391) and psychiatric patients (ICD-9-CM codes 290 through 319 as a principal diagnosis) will be excluded.

(b) For each discharge from the selected zip codes for a limited access area or each hospital subarea discharge, as applicable, calculate the number of patient days (take the patient days for each discharge and accumulate it within the respective age group) for the following age groups: ages 0 (excluding normal newborns) through 14 (pediatric), ages 15 through 44, female ages 15 through 44 (DRGs 370 through 375 – obstetrical discharges), ages 45 through 64, ages 65 through 74, and ages 75 and older. Data from non-Michigan residents are to be included for each specific age group. For limited access areas, proceed to section 4(1)(e).

(c) For each hospital subarea, calculate the relevance index (%Z) for each zip code and for each of the following age groups: ages 0 (excluding normal newborns) through 14 (pediatric), ages 15 through 44, female ages 15 through 44 (DRGs 370 THROUGH

375 – obstetrical discharges), ages 45 through 64, ages 65 through 74, and ages 75 and older.

(d) For each hospital subarea, multiply each zip code %Z calculated in (c) by its respective base year zip code and age group specific year population. The result will be the zip code allocations by age group for each subarea.

(e) For each limited access area or hospital subarea, as applicable, calculate the subarea base year population by age group by adding together all zip code population allocations calculated in (d) for each specific age group in that subarea. For a limited access area, add together the age groups identified for the limited access area. The result will be six population age groups for each limited access area or subarea, as applicable.

(f) For each limited access area or hospital subarea, as applicable, calculate the patient day use rates for ages 0 (excluding normal newborns) through 14 (pediatric), ages 15 through 44, female ages 15 through 44 (DRGs 370 through 375 – obstetrical discharges), ages 45 through 64, ages 65 through 74, and ages 75 and older by dividing the results of (b) by the results of (e).

(g) For each hospital subarea, multiply each zip code %Z calculated in (c) by its respective planning year zip code and age group specific year population. The results will be the projected zip code allocations by age group for each subarea. For a limited access area, multiply the population projection for the plan year by the proportion of the zip code that is contained within the limited access area for each zip code age group. The results will be the projected zip code allocations by age group for each zip code within the limited access area.

(h) For each hospital subarea, calculate the subarea projected year population by age group by adding together all projected zip code population allocations calculated in (g) for each specific age group. For a limited access area, add together the zip code allocations calculated in (g) by age group identified for the limited access area. The result will be six population age groups for each limited access area or subarea, as applicable.

(i) For each limited access area or hospital subarea, as applicable, calculate the limited access area or hospital subarea, as applicable, projected patient days for each age group by multiplying the six projected populations by age group calculated in step (h) by the age specific use rates identified in step (f).

(j) For each limited access area or hospital subarea, as applicable, calculate the adult medical/surgical limited access area or hospital subarea, as applicable, projected patient days by adding together the following age group specific projected patient days calculated in (i): ages 15 through 44, ages 45 through 64, ages 65 through 74, and ages 75 and older. The 0 (excluding normal newborns) through 14 (pediatric) and female ages 15 through 44 (DRGs 370 through 375 – obstetrical discharges) age groups remain unchanged as calculated in (i).

(k) For each limited access area or hospital subarea, as applicable, calculate the limited access area or hospital subarea, as applicable, projected average daily census (ADC) for three age groups: Ages 0 (excluding normal newborns) through 14 (pediatric), female ages 15 through 44 (DRGs 370 through 375 – obstetrical discharges), and adult medical surgical by dividing the results calculated in (j) by 365 (or

366 if the planning year is a leap year). Round each ADC to a whole number. This will give three ADC computations per limited access area or subarea, as applicable.

(l) For each limited access area or hospital subarea, as applicable, and age group, select the appropriate occupancy rate from the occupancy rate table in Appendix D.

(m) For each limited access area or hospital subarea, as applicable, and age group, calculate the limited access area or subarea, as applicable, projected bed need number of hospital beds for the limited access area or subarea, as applicable, by age group by dividing the ADC calculated in (k) by the appropriate occupancy rate determined in (l). To obtain the total limited access area or hospital, as applicable, bed need, add the three age group bed projections together. Round any part of a bed up to a whole bed.

Section 5. Bed Need

Sec. 5. (1) The bed-need numbers incorporated as part of these standards as Appendix C shall apply to projects subject to review under these standards, except where a specific CON review standard states otherwise.

(2) The Commission shall direct the Department, effective November 2004 and every two years thereafter, to re-calculate the acute care bed need methodology in Section 4, within a specified time frame.

(3) The Commission shall designate the base year and the future planning year which shall be utilized in applying the methodology pursuant to subsection (2).

(4) When the Department is directed by the Commission to apply the methodology pursuant to subsection (2), the effective date of the bed-need numbers shall be established by the Commission.

(5) As directed by the Commission, new bed-need numbers established by subsections (2) and (3) shall supersede the bed-need numbers shown in Appendix C and shall be included as an amended appendix to these standards.

Section 6. Requirements for approval -- new beds in a hospital

Sec. 6. (1) An applicant proposing new beds in a hospital, except an applicant meeting the requirements of subsection 2, 3, 4, or 5 shall demonstrate that it meets all of the following:

(a) The new beds in a hospital shall result in a hospital of at least 200 beds in a metropolitan statistical area county or 50 beds in a rural or micropolitan statistical area county. This subsection may be waived by the Department if the Department determines, in its sole discretion, that a smaller hospital is necessary or appropriate to assure access to health-care services.

(b) The total number of existing hospital beds in the subarea to which the new beds will be assigned does not currently exceed the needed hospital bed supply as set forth in Appendix C. The Department shall determine the subarea to which the beds will be assigned in accord with Section 3 of these standards.

(c) Approval of the proposed new beds in a hospital shall not result in the total number of existing hospital beds, in the subarea to which the new beds will be assigned, exceeding the needed hospital bed supply as set forth in Appendix C. The Department shall determine the subarea to which the beds will be assigned in accord with Section 3 of these standards.

(2) An applicant proposing to begin operation as a new long-term (acute) care hospital or alcohol and substance abuse hospital within an existing licensed, host hospital shall demonstrate that it meets all of the requirements of this subsection:

(a) If the long-term (acute) care hospital applicant described in this subsection does not meet the Title XVIII requirements of the Social Security Act for exemption from PPS as a long-term (acute) care hospital within 12 months after beginning operation, then it may apply for a six-month extension in accordance with R325.9403 of the CON rules. If the applicant fails to meet the Title XVIII requirements for PPS exemption as a long-term (acute) care hospital within the 12 or 18-month period, then the CON granted pursuant to this section shall expire automatically.

(b) The patient care space and other space to establish the new hospital is being obtained through a lease arrangement AND RENEWAL OF A LEASE between the applicant and the host hospital. The initial, renewed, or any subsequent lease shall specify at least all of the following:

(i) That the host hospital shall delicense the same number of hospital beds proposed by the applicant for licensure in the new hospital OR ANY SUBSEQUENT APPLICATION TO ADD ADDITIONAL BEDS.

(ii) That the proposed new beds shall be for use in space currently licensed as part of the host hospital.

(iii) That upon non-renewal and/or termination of the lease, upon termination of the license issued under Part 215 of the act to the applicant for the new hospital, or upon noncompliance with the project delivery requirements or any other applicable requirements of these standards, the beds licensed as part of the new hospital must be disposed of by one of the following means:

(A) Relicensure of the beds to the host hospital. The host hospital must obtain a CON to acquire the long-term (acute) care hospital. In the event that the host hospital applies for a CON to acquire the long-term (acute) care hospital [including the beds leased by the host hospital to the long-term (acute) care hospital] within six months following the termination of the lease with the long-term (acute) care hospital, it shall not be required to be in compliance with the hospital bed supply set forth in Appendix C if the host hospital proposes to add the beds of the long-term (acute) care hospital to the host hospital's medical/surgical licensed capacity and the application meets all other applicable project delivery requirements. The beds must be used for general medical/surgical purposes. Such an application shall not be subject to comparative review and shall be processed under the procedures for non-substantive review (as this will not be considered an increase in the number of beds originally licensed to the applicant at the host hospital);

(B) Delicensure of the hospital beds; or

(C) Acquisition by another entity that obtains a CON to acquire the new hospital in its entirety and that entity must meet and shall stipulate to the requirements specified in Section 6(2).

(c) The applicant or the current licensee of the new hospital shall not apply, initially or subsequently, for CON approval to initiate any other CON covered clinical services; provided, however, that this section is not intended, and shall not be construed in a manner which would prevent the licensee from contracting and/or billing for medically necessary covered clinical services required by its patients under arrangements with its host hospital or any other CON approved provider of covered clinical services.

(d) The new licensed hospital shall remain within the host hospital.

(e) The new hospital shall be assigned to the same subarea as the host hospital.

(f) The proposed project to begin operation of a new hospital, under this subsection, shall constitute a change in bed capacity under Section 1(3) of these standards.

(g) The lease will not result in an increase in the number of licensed hospital beds in the subarea.

(H) APPLICATIONS PROPOSING A NEW HOSPITAL UNDER THIS SUBSECTION SHALL NOT BE SUBJECT TO COMPARATIVE REVIEW.

(3) AN APPLICANT PROPOSING TO ADD NEW HOSPITAL BEDS, AS THE RECEIVING LICENSED HOSPITAL UNDER SECTION 8, SHALL DEMONSTRATE THAT IT MEETS ALL OF THE REQUIREMENTS OF THIS SUBSECTION AND SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH THE NEEDED HOSPITAL BED SUPPLY SET FORTH IN APPENDIX C IF THE APPLICATION MEETS ALL OTHER APPLICABLE CON REVIEW STANDARDS AND AGREES AND ASSURES TO COMPLY WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS.

(A) THE APPROVAL OF THE PROPOSED NEW HOSPITAL BEDS SHALL NOT RESULT IN AN INCREASE IN THE NUMBER OF LICENSED HOSPITAL BEDS AS FOLLOWS:

(I) IN THE SUBAREA, OR

(II) IN THE HSA PURSUANT TO SECTION 8(2)(B).

(A) THE RECEIVING HOSPITAL SHALL MEET THE REQUIREMENTS OF SECTION 6(4)(B) OF THESE STANDARDS.

(B) THE PROPOSED PROJECT TO ADD NEW HOSPITAL BEDS, UNDER THIS SUBSECTION, SHALL CONSTITUTE A CHANGE IN BED CAPACITY UNDER SECTION 1(3) OF THESE STANDARDS.

(C) APPLICANTS PROPOSING TO ADD NEW HOSPITAL BEDS UNDER THIS SUBSECTION SHALL NOT BE SUBJECT TO COMPARATIVE REVIEW.

(4) AN APPLICANT MAY APPLY FOR THE ADDITION OF NEW BEDS IF ALL OF THE FOLLOWING SUBSECTIONS ARE MET. FURTHER, AN APPLICANT PROPOSING NEW BEDS AT AN EXISTING LICENSED HOSPITAL SITE SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH THE NEEDED HOSPITAL BED SUPPLY SET FORTH IN APPENDIX C IF THE APPLICATION MEETS ALL OTHER APPLICABLE CON REVIEW STANDARDS AND AGREES AND ASSURES TO COMPLY WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS.

(A) THE BEDS ARE BEING ADDED AT THE EXISTING LICENSED HOSPITAL SITE.

(B) THE HOSPITAL AT THE EXISTING LICENSED HOSPITAL SITE HAS OPERATED AT AN ADJUSTED OCCUPANCY RATE OF 80 PERCENT OR ABOVE FOR THE PREVIOUS, CONSECUTIVE 24 MONTHS BASED ON ITS LICENSED AND APPROVED HOSPITAL BED CAPACITY. THE ADJUSTED OCCUPANCY RATE SHALL BE CALCULATED AS FOLLOWS:

(i) Combine all pediatric patient days of care and obstetrics patient days of care provided during the most recent, consecutive 24-month period for which verifiable data are available to the Department and multiply that number by 1.1.

(ii) Add remaining patient days of care provided during the most recent, consecutive 24-month period for which verifiable data are available to the Department to the number calculated in (i) above. This is the adjusted patient days.

(iii) Divide the number calculated in (ii) above by the total possible patient days [licensed and approved hospital beds multiplied by 730 (or 731 if including a leap year)]. This is the adjusted occupancy rate.

(C) THE NUMBER OF BEDS THAT MAY BE APPROVED PURSUANT TO THIS SUBSECTION SHALL BE THE NUMBER OF BEDS NECESSARY TO REDUCE THE ADJUSTED OCCUPANCY RATE FOR THE HOSPITAL TO 75 PERCENT. THE NUMBER OF BEDS SHALL BE CALCULATED AS FOLLOWS:

(i) Divide the number of adjusted patient days calculated in subsection (b)(ii) by .75 to determine licensed bed days at 75 percent occupancy;

(II) DIVIDE THE RESULT OF STEP (I) BY 730 (OR 731 IF INCLUDING A LEAP YEAR) AND ROUND THE RESULT UP TO THE NEXT WHOLE NUMBER;

(III) SUBTRACT THE NUMBER OF LICENSED AND APPROVED HOSPITAL BEDS AS DOCUMENTED ON THE "DEPARTMENT INVENTORY OF BEDS" FROM THE RESULT OF STEP (II) AND ROUND THE RESULT UP TO THE NEXT WHOLE NUMBER TO DETERMINE THE MAXIMUM NUMBER OF BEDS THAT MAY BE APPROVED PURSUANT TO THIS SUBSECTION.

(D) A LICENSED ACUTE CARE HOSPITAL THAT HAS RELOCATED ITS BEDS, AFTER THE EFFECTIVE DATE OF THESE STANDARDS, SHALL NOT BE APPROVED FOR HOSPITAL BEDS UNDER THIS SUBSECTION FOR FIVE YEARS FROM THE EFFECTIVE DATE OF THE RELOCATION OF BEDS.

(E) APPLICANTS PROPOSING TO ADD NEW HOSPITAL BEDS UNDER THIS SUBSECTION SHALL NOT BE SUBJECT TO COMPARATIVE REVIEW.

(F) APPLICANTS PROPOSING TO ADD NEW HOSPITAL BEDS UNDER THIS SUBSECTION SHALL DEMONSTRATE TO THE DEPARTMENT THAT THEY HAVE PURSUED A GOOD FAITH EFFORT TO RELOCATE ACUTE CARE BEDS FROM OTHER LICENSED ACUTE CARE HOSPITALS WITHIN THE hsa. AT THE TIME AN APPLICATION IS SUBMITTED TO THE DEPARTMENT, THE APPLICANT SHALL DEMONSTRATE THAT CONTACT WAS MADE BY ONE CERTIFIED MAIL RETURN RECEIPT FOR EACH ORGANIZATION CONTACTED.

(5) AN APPLICANT PROPOSING A NEW HOSPITAL IN A LIMITED ACCESS AREA SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH THE NEEDED HOSPITAL BED SUPPLY SET FORTH IN APPENDIX C IF THE APPLICATION MEETS ALL OTHER APPLICABLE con REVIEW STANDARDS, AGREES AND ASSURES TO COMPLY WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS, AND ALL OF THE FOLLOWING SUBSECTIONS ARE MET.

(A) THE PROPOSED NEW HOSPITAL, UNLESS A CRITICAL ACCESS HOSPITAL, SHALL HAVE 24 HOUR/7 DAYS A WEEK EMERGENCY SERVICES, OBSTETRICAL SERVICES, SURGICAL SERVICES, AND LICENSED ACUTE CARE BEDS.

(B) THE DEPARTMENT SHALL ASSIGN THE PROPOSED NEW HOSPITAL TO AN EXISTING SUBAREA BASED ON THE CURRENT MARKET USE PATTERNS OF EXISTING SUBAREAS.

(C) APPROVAL OF THE PROPOSED NEW BEDS IN A HOSPITAL IN A LIMITED ACCESS AREA SHALL NOT EXCEED THE BED NEED FOR THE LIMITED ACCESS AREA AS DETERMINED BY THE BED NEED METHODOLOGY IN SECTION 4 AND AS SET FORTH IN APPENDIX E.

(D) THE NEW BEDS IN A HOSPITAL IN A LIMITED ACCESS AREA SHALL RESULT IN A HOSPITAL OF AT LEAST 100 BEDS IN A METROPOLITAN STATISTICAL AREA COUNTY OR 50

BEDS IN A RURAL OR MICROPOLITAN STATISTICAL AREA COUNTY. IF THE BED NEED FOR A LIMITED ACCESS AREA, AS SHOWN IN APPENDIX E, IS LESS, THEN THAT WILL BE THE MINIMUM NUMBER OF BEDS FOR A NEW HOSPITAL UNDER THIS PROVISION. IF AN APPLICANT FOR NEW BEDS IN A HOSPITAL UNDER THIS PROVISION SIMULTANEOUSLY APPLIES FOR STATUS AS A CRITICAL ACCESS HOSPITAL, THE MINIMUM HOSPITAL SIZE SHALL BE THAT NUMBER ALLOWED UNDER STATE/FEDERAL CRITICAL ACCESS HOSPITAL DESIGNATION.

(E) APPLICANTS PROPOSING TO CREATE A NEW HOSPITAL UNDER THIS SUBSECTION SHALL NOT BE APPROVED, FOR A PERIOD OF FIVE YEARS AFTER BEGINNING OPERATION OF THE FACILITY, OF THE FOLLOWING COVERED CLINICAL SERVICES: (I) OPEN HEART SURGERY, (II) THERAPEUTIC CARDIAC CATHETERIZATION, (III) FIXED POSITRON EMISSION TOMOGRAPHY (pet) SERVICES, (IV) ALL TRANSPLANT SERVICES, (V) NEONATAL INTENSIVE CARE SERVICES/BEDS, AND (VI) FIXED URINARY EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY (ueswl) SERVICES.

(F) APPLICANTS PROPOSING TO ADD NEW HOSPITAL BEDS UNDER THIS SUBSECTION SHALL BE PROHIBITED FROM RELOCATING THE NEW HOSPITAL BEDS FOR A PERIOD OF 10 YEARS AFTER BEGINNING OPERATION OF THE FACILITY.

(G) AN APPLICANT PROPOSING TO ADD A NEW HOSPITAL PURSUANT TO THIS SUBSECTION SHALL LOCATE THE NEW HOSPITAL AS FOLLOWS:

(I) IN A METROPOLITAN STATISTICAL AREA COUNTY, AN APPLICANT PROPOSING TO ADD A NEW HOSPITAL PURSUANT TO THIS SUBSECTION SHALL LOCATE THE NEW HOSPITAL WITHIN THE LIMITED ACCESS AREA AND SERVE A POPULATION OF 50,000 OR MORE INSIDE THE LIMITED ACCESS AREA AND WITHIN 30 MINUTES DRIVE TIME FROM THE PROPOSED NEW HOSPITAL.

(II) IN A RURAL OR MICROPOLITAN STATISTICAL AREA COUNTY, AN APPLICANT PROPOSING TO ADD A NEW HOSPITAL PURSUANT TO THIS SUBSECTION SHALL LOCATE THE NEW HOSPITAL WITHIN THE LIMITED ACCESS AREA AND SERVE A POPULATION OF 50,000 OR MORE INSIDE THE LIMITED ACCESS AREA AND WITHIN 60 MINUTES DRIVE TIME FROM THE PROPOSED NEW HOSPITAL.

Section 7. Requirements for approval -- replacement beds in a hospital in a replacement zone

Sec. 7. (1) If the application involves the development of a new licensed site, an applicant proposing replacement beds in a hospital in the replacement zone shall demonstrate that the new beds in a hospital shall result in a hospital of at least 200 beds in a metropolitan statistical area county or 50 beds in a rural or micropolitan statistical area county. This subsection may be waived by the Department if the Department determines, in its sole discretion, that a smaller hospital is necessary or appropriate to assure access to health-care services.

(2) In order to be approved, the applicant shall propose to (i) replace an equal or lesser number of beds currently licensed to the applicant at the licensed site at which the proposed replacement beds are located, and (ii) that the proposed new licensed site is in the replacement zone.

(3) An applicant proposing replacement beds in the replacement zone shall not be required to be in compliance with the needed hospital bed supply set forth in Appendix

C if the application meets all other applicable CON review standards and agrees and assures to comply with all applicable project delivery requirements.

Section 8. Requirements for approval of an applicant proposing to relocate existing licensed hospital beds

SEC 8. (1) THE PROPOSED PROJECT TO RELOCATE BEDS, UNDER THIS SECTION, SHALL CONSTITUTE A CHANGE IN BED CAPACITY UNDER SECTION 1(4) OF THESE STANDARDS.

(2) Any existing licensed acute care hospital may relocate all or a portion of its beds to another existing licensed acute care hospital as follows:

(a) The licensed acute care hospitals are located within the same subarea, or

(b) the licensed acute care hospitals are located within the same HSA if the receiving hospital meets the requirements of Section 6(4)(b) of these standards.

(3) The hospital from which the beds are being relocated, and the hospital receiving the beds, shall not require any ownership relationship.

(4) The relocated beds shall be licensed to the receiving hospital and will be counted in the inventory for the applicable subarea.

(5) The relocation of beds under this section shall not be subject to a mileage limitation.

Section 9. Project delivery requirements -- terms of approval for all applicants

Sec. 9. (1) An applicant shall agree that, if approved, the project shall be delivered in compliance with the following terms of CON approval:

(a) Compliance with these standards.

(b) Compliance with applicable operating standards.

(i) An applicant approved pursuant to Section 6(4) must achieve a minimum occupancy of 75 percent over the last 12-month period in the three years after the new beds are put into operation, and for each subsequent calendar year, or the number of new licensed beds shall be reduced to achieve a minimum of 75 percent average annual occupancy for the revised licensed bed complement.

(ii) The applicant must submit documentation acceptable and reasonable to the Department, within 30 days after the completion of the 3-year period, to substantiate the occupancy rate for the last 12-month period after the new beds are put into operation and for each subsequent calendar year, within 30 days after the end of the year.

(c) Compliance with the following quality assurance standards:

(i) The applicant shall provide the Department with a notice stating the date the hospital beds are placed in operation and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules.

(II) THE APPLICANT SHALL ASSURE COMPLIANCE WITH SECTION 20201 OF THE CODE, BEING SECTION 333.20201 OF THE MICHIGAN COMPILED LAWS.

(iii) 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 and demographic, diagnostic, morbidity, and mortality information, as well as the volume of care provided to patients from all payor sources. The applicant shall provide the required data on a separate basis for each licensed site; 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.

(A) The applicant shall participate and submit data to the Michigan Inpatient Data Base (MIDB). The data shall be submitted to the Department or its designee.

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

(d) The applicant, to assure appropriate utilization by all segments of the Michigan population, shall:

(i) Not deny services to any individual based on ability to pay or source of payment.

(II) MAINTAIN INFORMATION BY SOURCE OF PAYMENT TO INDICATE THE VOLUME OF CARE FROM EACH PAYOR AND NON-PAYOR SOURCE PROVIDED ANNUALLY.

(III) PROVIDE SERVICES TO ANY INDIVIDUAL BASED ON CLINICAL INDICATIONS OF NEED FOR THE SERVICES.

(2) The agreements and assurances required by this section shall be in the form of a certification AGREED TO by the applicant or its authorized agent.

Section 10. Rural, micropolitan statistical area, and metropolitan statistical area Michigan counties

Sec. 10. Rural, micropolitan statistical area, and metropolitan statistical area Michigan counties, for purposes of these standards, are incorporated as part of these standards as Appendix B. The Department may amend Appendix B as appropriate to reflect changes by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget.

Section 11. Department inventory of beds

Sec. 11. The Department shall maintain and provide on request a listing of the Department inventory of beds for each subarea.

Section 12. Effect on prior planning policies; comparative reviews

Sec. 12. (1) These CON review standards supersede and replace the CON standards for hospital beds approved by the CON Commission on DECEMBER 12, 2006 and effective MARCH 8, 2007.

(2) Projects reviewed under these standards shall be subject to comparative review except those projects meeting the requirements of Section 7 involving the replacement

of beds in a hospital within the replacement zone and projects involving acquisition (including purchase, lease, donation or comparable arrangements) of a hospital.

Section 13. Additional requirements for applications included in comparative reviews

Sec. 13. (1) Except for those applications for limited access areas, any application for hospital beds, that is subject to comparative review under Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, or under these standards shall be grouped and reviewed comparatively with other applications in accordance with the CON rules.

(2) Each application in a comparative review group shall be individually reviewed to determine whether the application is a qualifying project. If the Department determines that two or more competing applications are qualifying projects, it shall conduct a comparative review. The Department shall approve those qualifying projects which, when taken together, do not exceed the need, as defined in Section 22225(1) of the Code, and which have the highest number of points when the results of subsection (3) are totaled. If two or more qualifying projects are determined to have an identical number of points, then the Department shall approve those qualifying projects that, when taken together, do not exceed the need in the order in which the applications were received by the Department based on the date and time stamp placed on the applications by the department in accordance with rule 325.9123.

(3)(a) A qualifying project will be awarded points based on the percentile ranking of the applicant's uncompensated care volume and as measured by percentage of gross hospital revenues as set forth in the following table. The applicant's uncompensated care volume will be the cumulative of all currently licensed Michigan hospitals under common ownership or control with the applicant that are located in the same health service area as the proposed hospital beds. If a hospital under common ownership or control with the applicant has not filed a Cost Report, then the related applicant shall receive a score of zero. The source document for the calculation shall be the most recent Cost Report filed with the Department for purposes of calculating disproportionate share hospital payments.

Percentile Ranking	Points Awarded
90.0 – 100	25 pts
80.0 – 89.9	20 pts
70.0 – 79.9	15 pts
60.0 – 69.9	10 pts
50.0 – 59.9	5 pts

Where an applicant proposes to close a hospital(s) as part of its application, data from the hospital(s) to be closed shall be excluded from this calculation.

(b) A qualifying project will be awarded points based on the health service area percentile rank of the applicant's Medicaid volume as measured by percentage of gross hospital revenues as set forth in the following table. For purposes of scoring, the applicant's Medicaid volume will be the cumulative of all currently licensed Michigan hospitals under common ownership or control with the applicant that are located in the same health service area as the proposed hospital beds. If a hospital under common ownership or control with the applicant has not filed a Cost Report, then the related applicant shall receive a score of zero. The source document for the calculation shall be the most recent Cost Report filed with the department for purposes of calculating disproportionate share hospital payments.

percentile rank	points awarded
87.5 – 100	20 pts
75.0 – 87.4	15 pts
62.5 – 74.9	10 pts
50.0 – 61.9	5 pts
less than 50.0	0 pts

Where an applicant proposes to close a hospital(s) as part of its application, data from the hospital(s) to be closed shall be excluded from this calculation.

(c) A qualifying project shall be awarded points as set forth in the following table in accordance with its impact on inpatient capacity. If an applicant proposes to close a hospital(s), points shall only be awarded if (i) closure of that hospital(s) does not create a bed need in any subarea as a result of its closing; (ii) the applicant stipulates that the hospital beds to be closed shall not be transferred to another location or facility; and (iii) the utilization (as defined by the average daily census over the previous 24-month period prior to the date that the application is submitted) of the hospital to be closed is at least equal to 50 percent of the size of the proposed hospital (as defined by the number of proposed new licensed beds).

Impact on Capacity	Points Awarded
Closure of hospital(s)	25 pts
Closure of hospital(s) which creates a bed need	-15 pts

(d) A qualifying project will be awarded points based on the percentage of the applicant's historical market share of inpatient discharges of the population in an area which will be defined as that area circumscribed by the proposed hospital locations defined by all of the applicants in the comparative review process under consideration. This area will include any zip code completely within the area as well as any zip code which touches, or is touched by, the lines that define the area included within the figure that is defined by the geometric area resulting from connecting the proposed locations. In the case of two locations or one location or if the exercise in geometric definition does not include at least ten zip codes, the market area will be defined by the zip codes within the county (or counties) that includes the proposed site (or

sites). Market share used for the calculation shall be the cumulative market share of the population residing in the set of above-defined zip codes of all currently licensed Michigan hospitals under common ownership or control with the applicant**,** which are in the same health service area.

Percent	Points Awarded
% of market share served x 30	
	(total pts. awarded)

The source for calculations under this criterion is the MIDB.

Section 14. Review standards for comparative review of a limited access area

Sec. 14. (1) Any application subject to comparative review, under Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, or under these standards, shall be grouped and reviewed comparatively with other applications in accordance with the CON rules.

(2) Each application in a comparative group shall be individually reviewed to determine whether the application has satisfied all the requirements of Section 22225 of the Code, being Section 333.22225 of the Michigan Compiled Laws and all other applicable requirements for approval in the Code and these standards. If the Department determines that two or more competing applications satisfy all of the requirements for approval, these projects shall be considered qualifying projects. The Department shall approve those qualifying projects which, when taken together, do not exceed the need, as defined in Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws, and which have the highest number of points when the results of subsection (3) are totaled. If two or more qualifying projects are determined to have an identical number of points, then the Department shall approve those qualifying projects, when taken together, that do not exceed the need, as defined in Section 22225(1) in the order in which the applications were received by the Department based on the date and time stamp placed on the application by the Department when the application is filed.

(3)(a) A qualifying project will be awarded points based on the percentile ranking of the applicant's uncompensated care volume as measured by percentage of gross hospital revenues as set forth in the following table. For purposes of scoring, the applicant's uncompensated care will be the cumulative of all currently licensed Michigan hospitals under common ownership or control with the applicant. The source document for the calculation shall be the most recent Cost Report submitted to MDCH for purposes of calculating disproportionate share hospital payments. If a hospital under common ownership or control with the applicant has not filed a Cost Report, then the related applicant shall receive a score of zero.

Percentile Ranking	Points Awarded
90.0 – 100	25 pts

80.0 – 89.9	20 pts
70.0 – 79.9	15 pts
60.0 – 69.9	10 pts
50.0 – 59.9	5 pts

Where an applicant proposes to close a hospital as part of its application, data from the closed hospital shall be excluded from this calculation.

(b) A qualifying project will be awarded points based on the statewide percentile rank of the applicant's Medicaid volume as measured by percentage of gross hospital revenues as set forth in the following table. For purposes of scoring, the applicant's Medicaid volume will be the cumulative of all currently licensed Michigan hospitals under common ownership or control with the applicant. The source documents for the calculation shall be the Cost Report submitted to MDCH for purposes of calculating disproportionate share hospital payments. If a hospital under common ownership or control with the applicant has not filed a Cost Report, then the related applicant shall receive a score of zero.

Percentile Rank	Points Awarded
87.5 – 100	20 pts
75.0 – 87.4	15 pts
62.5 – 74.9	10 pts
50.0 – 61.9	5 pts
Less than 50.0	0 pts

Where an applicant proposes to close a hospital as part of its application, data from the closed hospital shall be excluded from this calculation.

(c) A qualifying project shall be awarded points as set forth in the following table in accordance with its impact on inpatient capacity in the health service area of the proposed hospital site.

Impact on Capacity	Points Awarded
Closure of hospital(s)	15 pts
Move beds	0 pts
Adds beds (net)	-15 pts
or	
Closure of hospital(s)	
or delicensure of beds	
which creates a bed need	
or	
Closure of a hospital	
which creates a new Limited Access Area	

(d) A qualifying project will be awarded points based on the percentage of the applicant's market share of inpatient discharges of the population in the limited access

area as set forth in the following table. Market share used for the calculation shall be the cumulative market share of Michigan hospitals under common ownership or control with the applicant.

Percent	Points Awarded
% of market share	% of market share served x 15 (total pts awarded)

The source for calculations under this criterion is the MIDB.

(e) A qualifying project will be awarded points based on the percentage of the limited access area's population within a 30 minute travel time of the proposed hospital site if in a metropolitan statistical area county, or within 60 minutes travel time if in a rural or micropolitan statistical area county as set forth in the following table.

Percent	Points Awarded
% of population within 30 (or 60) minute travel time of proposed site	% of population covered x 15 (total pts awarded)

(f) All applicants will be ranked in order according to their total project costs as stated in the CON application divided by its proposed number of beds in accordance with the following table.

Cost Per Bed	Points Awarded
Lowest cost	10 pts
2nd Lowest cost	5 pts
All other applicants	0 pts

Section 15. Documentation of market survey

Sec. 15. An applicant required to conduct a market survey under Section 3 shall specify how the market survey was developed. This specification shall include a description of the data source(s) used, assessments of the accuracy of these data, and the statistical method(s) used. Based on this documentation, the Department shall determine if the market survey is reasonable.

Section 16. Requirements for approval -- acquisition of a hospital

Sec. 16. (1) An applicant proposing to acquire a hospital shall not be required to be in compliance with the needed hospital bed supply set forth in Appendix C for the subarea in which the hospital subject to the proposed acquisition is assigned if the applicant demonstrates that all of the following are met:

(a) the acquisition will not result in a change in bed capacity,

(b) the licensed site does not change as a result of the acquisition,

(c) the project is limited solely to the acquisition of a hospital with a valid license, and

(d) if the application is to acquire a hospital, which was proposed in a prior application to be established as a long-term (acute) care hospital (LTAC) and which received CON approval, the applicant also must meet the requirements of Section 6(2). Those hospitals that received such prior approval are so identified in Appendix A.

Section 17. Requirements for approval – all applicants

Sec. 17. 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 18. Health service areas

Sec. 18. Counties assigned to each of the health service areas are as follows:

HSA	COUNTIES		
1 - Southeast	Livingston	Monroe	St. Clair
	Macomb	Oakland	Washtenaw
	Wayne		
2 - Mid-Southern	Clinton	Hillsdale	Jackson
	Eaton	Ingham	Lenawee
3 - Southwest	Barry	Calhoun	St. Joseph
	Berrien	Cass	Van Buren
	Branch	Kalamazoo	
4 - West	Allegan	Mason	Newaygo
	Ionia	Mecosta	Oceana
	Kent	Montcalm	Osceola
	Lake	Muskegon	Ottawa
5 - GLS	Genesee	Lapeer	Shiawassee
6 - East	Arenac	Huron	Roscommon
	Bay	Iosco	Saginaw
	Clare	Isabella	Sanilac
	Gladwin	Midland	Tuscola
	Gratiot	Ogemaw	
7 - Northern Lower	Alcona	Crawford	Missaukee
	Alpena	Emmet	Montmorency
	Antrim	Gd Traverse	Oscoda

		Benzie	Kalkaska	Otsego
		Charlevoix	Leelanau	Presque Isle
		Cheboygan	Manistee	Wexford
	8 - Upper Peninsula	Alger	Gogebic	Mackinac
		Baraga	Houghton	Marquette
		Chippewa	Iron	Menominee
		Delta	Keweenaw	Ontonagon
	DICKINSON		*LUCE*	
	SCHOOLCRAFT			

APPENDIX A

CON REVIEW STANDARDS
FOR HOSPITAL BEDS

Hospital Subarea Assignments

REVISED 9/2/08

Health Service Area	Sub Area	Hospital Name	City
1 - Southeast			
	1A	North Oakland Med Center (Fac #63-0110)	Pontiac
	1A	Pontiac Osteopathic Hospital (Fac #63-0120)	Pontiac
	1A	St. Joseph Mercy – Oakland (Fac #63-0140)	Pontiac
	1A	Select Specialty Hospital - Pontiac (LTAC - FAC #63-0172)*	Pontiac
	1A	Crittenton Hospital (Fac #63-0070)	Rochester
	1A	Huron Valley – Sinai Hospital (Fac #63-0014)	Commerce Township
	1A	Wm Beaumont Hospital (Fac #63-0030)	Royal Oak
	1A	Wm Beaumont Hospital – Troy (Fac #63-0160)	Troy
	1A	Providence Hospital & MEDICAL CENTER (Fac #63-0130)	Southfield
	1A	OAKLAND REGIONAL Hospital (Fac #63-0013)	Southfield
	1A	Straith Hospital for Special Surg (Fac #63-0150)	Southfield
	1A	MI Orthopaedic Specialty Hospital (Fac #63-0060)	Madison Heights
	1A	St. John MACOMB – Oakland Hospital – OAKLAND (Fac #63-0080)	Madison Heights
	1A	Southeast Michigan Surgical Hospital (Fac #50-0100)	Warren
	1A	HENRY FORD WEST BLOOMFIELD HOSPITAL (FAC #63-0176)	WEST BLOOMFIELD
	1A	PROVIDENCE MED CTR-PROVIDENCE PARK (FAC #63-0177)	NOVI
	1B	HENRY FORD Bi-County Hospital (Fac #50-0020)	Warren
	1B	St. John Macomb – OAKLAND Hospital – MACOMB (Fac #50-0070)	Warren
	1C	Oakwood HospITAL and Medical Center (Fac #82-0120)	Dearborn
	1C	Garden City Hospital (Fac #82-0070)	Garden City
	1C	Henry Ford –Wyandotte Hospital (Fac #82-0230)	Wyandotte
	1C	Select Specialty Hosp – DOWNRIVER (LTAC - Fac #82-0272)*	Wyandotte
	1C	Oakwood Annapolis Hospital (Fac #82-0010)	Wayne
	1C	Oakwood Heritage Hospital (Fac #82-0250)	Taylor
	1C	Riverside Osteopathic Hospital (Fac #82-0160)	Trenton
	1C	Oakwood Southshore Medical Center (Fac #82-0170)	Trenton

	1C	VIBRA OF SOUTHEASTERN MICHIGAN (Fac #82-0130)	Lincoln Park
	1D	Sinai-Grace Hospital (Fac #83-0450)	Detroit
	1D	Rehabilitation Institute of Michigan (Fac #83-0410)	Detroit
	1D	Harper University Hospital (Fac #/83-0220)	Detroit
	1D	Henry Ford Hospital (Fac #83-0190)	Detroit
	1D	St. John Hospital & Medical Center (Fac #83-0420)	Detroit
	1D	Children's Hospital of Michigan (Fac #83-0080)	Detroit
	1D	Detroit Receiving Hospital & Univ Hlth (Fac #83-0500)	Detroit
	1D	KARMANOS CANCER CENTER (Fac #83-0520)	Detroit
	1D	TRIUMPH Hospital Detroit (LTAC - Fac #83-0521)*	Detroit

*This is a hospital that must meet the requirement(s) of Section 16(1)(d) - LTAC.

APPENDIX A (continued)

Health Service Area	Sub Area	Hospital Name	City
1 – Southeast (continued)			
	1D	DETROIT HOPE HospITAL (Fac #83-0390)	Detroit
	1D	United Community Hospital (Fac #83-0490)	Detroit
	1D	Hutzel WOMEN'S Hospital (Fac #83-0240)	Detroit
	1D	Select Specialty Hosp–NW Detroit (LTAC - Fac #83-0523)*	Detroit
	1D	BEAUMONT Hospital, GROSSE POINTE (Fac #82-0030)	Grosse Pointe Farm
	1D	HENRY FORD Cottage Hospital (Fac #82-0040)	Grosse Pointe
	1D	SELECT SPECIALTY HOSPITAL – GROSSE POINTE (LTAC - Fac #82-0276)*	GROSSE POINTE
	1E	Botsford Hospital (Fac #63-0050)	Farmington Hills
	1E	St. Mary Mercy Hospital (Fac #82-0190)	Livonia
	1F	Mount Clemens REGIONAL MEDICAL CENTER (Fac #50-0060)	Mt. Clemens
	1F	Select Specialty Hosp – Macomb Co. (FAC #50-0111)*	Mt. Clemens
	1F	St. John North Shores Hospital (Fac #50-0030)	Harrison Twp.
	1F	HENRY FORD MACOMB HospITAL (Fac #50-0110)	Clinton Township
	1F	HENRY FORD MACOMB Hospital - MT. CLEMENS (Fac #50-0080)	Mt. Clemens
	1G	Mercy Hospital (Fac #74-0010)	Port Huron

	1G	Port Huron Hospital (Fac #74-0020)	Port Huron
	1H	St. Joseph Mercy Hospital (Fac #81-0030)	Ann Arbor
	1H	University of Michigan Health System (Fac #81-0060)	Ann Arbor
	1H	Select Specialty Hosp–Ann Arbor (LTAC - Fac #81-0081)*	YPSILANTI
	1H	Chelsea Community Hospital (Fac #81-0080)	Chelsea
	1H	Saint Joseph Mercy Livingston Hosp (Fac #47-0020)	Howell
	1H	Saint Joseph Mercy Saline Hospital (Fac #81-0040)	Saline
	1H	Forest Health Medical Center (Fac #81-0010)	Ypsilanti
	1H	Brighton Hospital (Fac #47-0010)	Brighton
	1I	St. John River District Hospital (Fac #74-0030)	East China
	1J	Mercy Memorial Hospital SYSTEM (Fac #58-0030)	Monroe

2 - Mid-Southern

	2A	Clinton Memorial Hospital (Fac #19-0010)	St. Johns
	2A	Eaton Rapids Medical Center (Fac #23-0010)	Eaton Rapids
	2A	Hayes Green Beach Memorial Hosp (Fac #23-0020)	Charlotte
	2A	Ingham RegIONAL MedICAL CEntEr (Greenlawn) (Fac #33-0020)	Lansing
	2A	Ingham RegIONAL ORTHOPEDIC HOSPITAL (Fac #33-0010)	Lansing
	2A	Edward W. Sparrow Hospital (Fac #33-0060)	Lansing
	2A	Sparrow HEALTH SYSTEM – St. Lawrence Campus (Fac #33-0050)	Lansing
	2A	SPARROW SPECIALTY HOSPITAL (LTAC - FAC #33-0061)*	Lansing

*This is a hospital that must meet the requirement(s) of Section 16(1)(d) - LTAC.

2 – Mid-Southern (continued)

Health Service Area	Sub Area	Hospital Name	City
	2B	Carelink of Jackson (LTAC Fac #38-0030)*	Jackson
	2B	W. A. Foote Memorial Hospital (Fac #38-0010)	Jackson
	2C	Hillsdale Community Health Center (Fac #30-0010)	Hillsdale
	2D	Emma L. Bixby Medical Center (Fac #46-0020)	Adrian
	2D	Herrick Memorial Hospital (Fac #46-0052)	Tecumseh

3 – Southwest

3A	Borgess Medical Center (Fac #39-0010)	Kalamazoo
3A	Bronson Methodist Hospital (Fac #39-0020)	Kalamazoo
3A	Borgess-Pipp Health Center (Fac #03-0031)	Plainwell
3A	BRONSON Lakeview Hospital (Fac #80-0030)	Paw Paw
3A	Bronson Vicksburg Hospital (Fac #39-0030)	Vicksburg
3A	Pennock Hospital (Fac #08-0010)	Hastings
3A	Three Rivers HEALTH (Fac #75-0020)	Three Rivers
3A	Sturgis Hospital (Fac #75-0010)	Sturgis
3A	SELECT SPECIALTY Hospital – KALAMAZOO (LTAC - Fac #39-0032)*	Kalamazoo
3B	Battle Creek Health System (Fac #13-0031)	Battle Creek
3B	SW REGIONAL RehabILITATION CENTER (Fac #13-0100)	Battle Creek
3B	Oaklawn Hospital (Fac #13-0080)	Marshall
3C	Community Hospital (Fac #11-0040)	Watervliet
3C	Lakeland Hospital, St. Joseph (Fac #11-0050)	St. Joseph
3C	Lakeland Specialty Hospital (LTAC - Fac #11-0080)*	Berrien Center
3C	South Haven Community Hospital (Fac #80-0020)	South Haven
3D	Lakeland Hospital, Niles (Fac #11-0070)	Niles
3D	BORGESS-Lee Memorial Hospital (A) (Fac #14-0010)	Dowagiac
3E	Community HEALth CENtEr of Branch CoUNTY (Fac #12-0010)	Coldwater

4 – WEST

4A	Memorial Medical Center of West MI (Fac #53-0010)	Ludington
4B	SPECTRUM HEALTH UNITED MEMORIAL – Kelsey (A) (Fac #59-0050)	Lakeview

*This is a hospital that must meet the requirement(s) of Section 16(1)(d) - LTAC.

(A) This is a hospital that has state/federal critical access hospital designation.

APPENDIX A (continued)

Health Service Area	Sub Area	Hospital Name	City
4 – West (continued)			
	4B	Mecosta County MEDICAL CENTER (Fac #54-0030)	Big Rapids
	4C	Spectrum HEAlth-Reed City Campus (Fac #67-0020)	Reed City
	4D	Lakeshore Community Hospital (Fac #64-0020)	Shelby
	4E	Gerber Memorial Hospital (Fac #62-0010)	Fremont
	4F	Carson City Hospital (Fac #59-0010)	Carson City
	4F	Gratiot MEDICAL CENTER (Fac #29-0010)	Alma
	4G	Hackley Hospital (Fac #61-0010)	Muskegon
	4G	Mercy GenERAL HEAlth Partners (Sherman) (Fac #61-0020)	Muskegon
	4G	Mercy GenERAL HEAlth Partners (Oak) (Fac #61-0030)	Muskegon
	4G	Lifecare Hospitals of Western MI (LTAC - Fac #61-0052)*	Muskegon
	4G	Select SpecIALTY HospITAL – Western MI (LTAC - Fac #61-0051)*	Muskegon
	4G	North Ottawa Community Hospital (Fac #70-0010)	Grand Haven
	4H	Spectrum HEAlth – Blodgett Campus (Fac #41-0010)	E. Grand Rapids
	4H	Spectrum HEAlth – Butterworth Campus (Fac #41-0040)	Grand Rapids
	4H	Spectrum HEAlth – Kent CommUNITY Campus (Fac #41-0090)	Grand Rapids
	4H	Mary Free Bed Hospital & Rehab Ctr (Fac #41-0070)	Grand Rapids
	4H	METRO HEALTH Hospital (Fac #41-0060)	WYOMING
	4H	Saint Mary's HEALTH CARE (Fac #41-0080)	Grand Rapids
	4I	Sheridan Community Hospital (A) (Fac #59-0030)	Sheridan
	4I	SPECTRUM HEALTH United Memorial – UNITED CAMPUS (Fac #59-0060)	Greenville
	4J	Holland Community Hospital (Fac #70-0020)	Holland
	4J	Zeeland Community Hospital (Fac #70-0030)	Zeeland
	4K	Ionia County Memorial Hospital (A) (Fac #34-0020)	Ionia
	4L	Allegan General Hospital (A) (Fac #03-0010)	Allegan

APPENDIX A (continued)

5 – GLS

5A	Memorial Healthcare (Fac #78-0010)	Owosso
5B	Genesys RegIONAL MedICAL CENtEr – HEAlth Park (Fac #25-0072)	Grand Blanc
5B	Hurley Medical Center (Fac #25-0040)	Flint
5B	Mclaren Regional Medical Center (Fac #25-0050)	Flint
5B	Select Specialty Hospital-Flint (LTAC - Fac #25-0071)*	Flint

*This is a hospital that must meet the requirement(s) of Section 16(1)(d) - LTAC.

(A) This is a hospital that has state/federal critical access hospital designation.

APPENDIX A (continued)

Health Service Area	Sub Area	Hospital Name	City
5 – GLS (continued)			
	5C	Lapeer Regional MEDICAL CENTER (Fac #44-0010)	Lapeer
6 – East			
	6A	West Branch Regional Medical CEntEr (Fac #65-0010)	West Branch
	6A	Tawas St. Joseph Hospital (Fac #35-0010)	Tawas City
	6B	Central Michigan Community HospITAL (Fac #37-0010)	Mt. Pleasant
	6C	MidMichigan Medical Center-Clare (Fac #18-0010)	Clare
	6D	Mid-Michigan Medical CEntEr - Gladwin (A) (Fac #26-0010)	Gladwin
	6D	Mid-Michigan Medical CEntEr - Midland (Fac #56-0020)	Midland
	6E	Bay Regional Medical Center (Fac #09-0050)	Bay City
	6E	Bay Regional Medical CENtEr - West (Fac #09-0020)	Bay City
	6E	Bay Special Care (LTAC - Fac #09-0010)*	Bay City
	6E	ST. MARY'S Standish Community Hospital (A) (Fac #06-0020)	Standish
	6F	Select Specialty HospITAL – Saginaw (LTAC - Fac #73-0062)*	Saginaw
	6F	Covenant Medical Center – COOPER (Fac #73-0040)	Saginaw
	6F	Covenant Medical CEntEr – N Michigan (Fac #73-0030)	Saginaw
	6F	Covenant Medical CEntEr – N Harrison (Fac #73-0020)	Saginaw
	6F	Healthsource Saginaw (Fac #73-0060)	Saginaw
	6F	St. Mary's OF MICHIGAN Medical Center (Fac #73-0050)	Saginaw
	6F	Caro Community Hospital (Fac #79-0010)	Caro
	6F	Hills And Dales General Hospital (Fac #79-0030)	Cass City
	6G	Harbor Beach Community HospITAL (A) (Fac #32-0040)	Harbor Beach
	6G	Huron Medical Center (Fac #32-0020)	Bad Axe
	6G	Scheurer Hospital (A) (Fac #32-0030)	Pigeon
	6H	Deckerville Community Hospital (A) (Fac #76-0010)	Deckerville
	6H	Mckenzie Memorial Hospital (A) (Fac #76-0030)	Sandusky
	6I	Marlette REGIONAL Hospital (Fac #76-0040)	Marlette

7 - Northern Lower

7A	Cheboygan Memorial Hospital (Fac #16-0020)	Cheboygan
7B	Charlevoix Area Hospital (Fac #15-0020)	Charlevoix
7B	Mackinac Straits Hospital (A) (Fac #49-0030)	St. Ignace

*This is a hospital that must meet the requirement(s) of Section 16(1)(d) - LTAC.

(A) This is a hospital that has state/federal critical access hospital designation.

APPENDIX A (continued)

Health Service Area	Sub Area	Hospital Name	City
7 - Northern Lower (continued)			
	7B	Northern Michigan Hospital (Fac #24-0030)	Petoskey
	7C	Rogers City Rehabilitation Hospital (Fac #71-0030)	Rogers City
	7D	Otsego Memorial Hospital (Fac #69-0020)	Gaylord
	7E	Alpena General Hospital (Fac #04-0010)	Alpena
	7F	Kalkaska Memorial Health Center (A) (Fac #40-0020)	Kalkaska
	7F	Munson Medical Center (Fac #28-0010)	Traverse City
	7F	Paul Oliver Memorial Hospital (A) (Fac #10-0020)	Frankfort
	7G	Mercy Hospital - Cadillac (Fac #84-0010)	Cadillac
	7H	Mercy Hospital - Grayling (Fac #20-0020)	Grayling
	7I	West Shore Medical Center (Fac #51-0020)	Manistee
8 - Upper Peninsula			
	8A	Grand View Hospital (Fac #27-0020)	Ironwood
	8B	ASPIRUS Ontonagon Hospital, INC. (A) (Fac #66-0020)	Ontonagon
	8C	Iron County COMMUNITY Hospital (Fac #36-0020)	Iron River
	8D	Baraga County Memorial Hospital (A) (Fac #07-0020)	L'anse
	8E	Keweenaw Memorial Medical Center (Fac #31-0010)	Laurium
	8E	Portage Health HOSPITAL (Fac #31-0020)	Hancock
	8F	Dickinson County Memorial Hospital (Fac #22-0020)	Iron Mountain
	8G	Bell Memorial Hospital (Fac #52-0010)	Ishpeming
	8G	Marquette General Hospital (Fac #52-0050)	Marquette
	8H	St. Francis Hospital (Fac #21-0010)	Escanaba

8I	Munising Memorial Hospital (A) (Fac #02-0010)	Munising
8J	Schoolcraft Memorial Hospital (A) (Fac #77-0010)	Manistique
8K	Helen Newberry Joy Hospital (A) (Fac #48-0020)	Newberry
8L	Chippewa CoUNTY War Memorial HospITAL (Fac #17-0020)	Sault Ste Marie

(A) This is a hospital that has state/federal critical access hospital designation.

APPENDIX B

CON REVIEW STANDARDS FOR HOSPITAL BEDS

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

APPENDIX C

CON REVIEW STANDARDS
FOR HOSPITAL BEDS

The hospital bed need for purposes of these standards, effective September 19, 2006, and until otherwise changed by the Commission are as follows:

Health Service Area	SA No.	Bed Need
1 - SOUTHEAST		
	1A	2946
	1B	480
	1C	1481
	1D	2979
	1E	495
	1F	700
	1G	267
	1H	1648
	1I	53
	1J	177
2 - MID-SOUTHERN		
	2A	889
	2B	306
	2C	59
	2D	117
3 – SOUTHWEST		
	3A	890
	3B	281
	3C	282
	3D	89
	3E	71
4 – WEST		
	4A	65
	4B	52
	4C	19
	4D	13
	4E	38
	4F	133
	4G	373
	4H	1400
	4I	48
	4J	157
	4K	18
	4L	30

5 - GLS		
	5A	78
	5B	1163
	5C	109

APPENDIX C (Continued)

Health Service Area	SA No.	Bed Need
6 - EAST		
	6A	96
	6B	62
	6C	42
	6D	181
	6E	321
	6F	820
	6G	48
	6H	16
	6I	22
7 - NORTHERN LOWER		
	7A	38
	7B	200
	7C	19
	7D	35
	7E	102
	7F	392
	7G	64
	7H	59
	7I	36
8 - UPPER PENINSULA		
	8A	30
	8B	12
	8C	22
	8D	12
	8E	54
	8F	93
	8G	226
	8H	53
	8I	7
	8J	9
	8K	11
	8L	51

APPENDIX D

OCCUPANCY RATE TABLE

Adult Medical/Surgical

ADC >=	ADC<	Occup	Beds Start	Beds Stop
	30	0.60		<=50
31	32	0.60	52	52
32	34	0.61	53	56
35	37	0.62	57	60
38	41	0.63	61	65
42	46	0.64	66	72
47	50	0.65	73	77
51	56	0.66	78	85
57	63	0.67	86	94
64	70	0.68	95	103
71	79	0.69	104	114
80	89	0.70	115	126
90	100	0.71	127	140
101	114	0.72	141	157
115	130	0.73	158	177
131	149	0.74	178	200
150	172	0.75	201	227
173	200	0.76	228	261
201	234	0.77	262	301
235	276	0.78	302	350
277	327	0.79	351	410
328	391	0.80	411	484
392	473	0.81	485	578
474	577	0.82	579	696
578	713	0.83	697	850
714	894	0.84	851	894
895		0.85	>=1054	

Pediatric Beds

ADC >	ADC<=	Occup	Beds Start	Beds Stop
	30	0.50		<=50
30	33	0.50	61	66
34	40	0.51	67	79
41	46	0.52	80	88
47	53	0.53	89	100
54	60	0.54	101	111
61	67	0.55	112	121
68	74	0.56	122	131
75	80	0.57	132	139
81	87	0.58	140	149
88	94	0.59	150	158
95	101	0.60	159	167
102	108	0.61	168	175
109	114	0.62	176	182
115	121	0.63	183	190
122	128	0.64	191	198
129	135	0.65	199	206
136	142	0.66	207	213
143	149	0.67	214	220
150	155	0.68	221	226
156	162	0.69	227	232
163	169	0.70	233	239
170	176	0.71	240	245
177	183	0.72	246	252
184	189	0.73	253	256
190	196	0.74	257	262
197		0.75	>=263	

Obstetric Beds

ADC >	ADC<=	Occup	Beds Start	Beds Stop
	30	0.50		<=50
30	33	0.50	61	66
34	40	0.51	67	79
41	46	0.52	80	88
47	53	0.53	89	100
54	60	0.54	101	111

Obstetric Beds cont.

ADC >	ADC<=	Occup	Beds Start	Beds Stop
115	121	0.63	183	190
122	128	0.64	191	198
129	135	0.65	199	206
136	142	0.66	207	213
143	149	0.67	214	220
150	155	0.68	221	226

61	67	0.55	112	121	156	162	0.69	227	232
68	74	0.56	122	131	163	169	0.70	233	239
75	80	0.57	132	139	170	176	0.71	240	245
81	87	0.58	140	149	177	183	0.72	246	252
88	94	0.59	150	158	184	189	0.73	253	256
95	101	0.60	159	167	190	196	0.74	257	262
102	108	0.61	168	175	197		0.75	>=263	
109	114	0.62	176	182					

1450

APPENDIX E

LIMITED ACCESS AREAS

Limited access areas and the hospital bed need, effective May 27, 2005, for each of those areas are identified below. The hospital bed need for limited access areas shall be changed by the department in accordance with section 2(1)(V) of these standards, and this appendix shall be updated accordingly.

HEALTH SERVICE AREA	ACCESS AREA	LIMITED POPULATION FOR NEED	BED PLANNING YEAR
7	Alpena/Plus 1204	358	66946
8	Upper Peninsula 1204	415	135,215

Sources:

1) Michigan State University
Department of Geography
Hospital Site Selection Final Report
November 3, 2004, as amended

2) Section 4 of these standards

MICHIGAN DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH AND MEDICAL AFFAIRS

CON REVIEW STANDARDS FOR HOSPITAL BEDS
-- ADDENDUM FOR PROJECTS FOR HIV INFECTED INDIVIDUALS --

(By authority conferred on the CON Commission by sections 22215 and 22217 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, 333.2217, 24.207, and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability; definitions

Sec. 1. (1) This addendum supplements the CON Review Standards for Hospital Beds and may be used for determining the need for projects established to meet the needs of HIV infected individuals.

(2) Except as provided by sections 2 and 3 below, these standards supplement and do not supercede the requirements and terms of approval required by the CON Review Standards for Hospital Beds.

(3) The definitions that apply to the CON Review Standards for Hospital Beds apply to these standards.

(4) "HIV infected" means that term as defined in Section 5101 of the Code.

(5) Planning area for projects for HIV infected individuals means the State of Michigan.

Section 2. Requirements for approval; change in bed capacity

Sec. 2. (1) A project which, if approved, will increase the number of licensed hospital beds in an overbedded subarea or will result in the total number of existing hospital beds in a subarea exceeding the needed hospital bed supply as determined under the CON Review Standards for Hospital Beds may, nevertheless, be approved pursuant to subsection (3) of this addendum.

(2) Hospital beds approved as a result of this addendum shall be included in the Department inventory of existing beds in the subarea in which the hospital beds will be located. Increases in hospital beds approved under this addendum shall cause subareas currently showing a current surplus of beds to have that surplus increased.

(3) In order to be approved under this addendum, an applicant shall demonstrate all of the following:

(a) The Director of the Department has determined that action is necessary and appropriate to meet the needs of HIV infected individuals for quality, accessible and efficient health care.

(b) The hospital will provide services only to HIV infected individuals.

(c) The applicant has obtained an obligation, enforceable by the Department, from existing licensed hospital(s) in any subarea of this state to voluntarily delicense a number of hospital beds equal to the number proposed in the application. The effective date of the delicensure action will be the date the beds approved pursuant to this addendum are licensed. The beds delicensed shall not be beds already subject to delicensure under a bed reduction plan.

(d) The application does not result in more than 20 beds approved under this addendum in the State.

(4) In making determinations under Section 22225(2)(a) of the Code, for projects under this addendum, the Department shall consider the total cost and quality outcomes for overall community health systems for services in a dedicated portion of an existing facility compared to a separate aids facility and has determined that there exists a special need, and the justification of any cost increases in terms of important quality/access improvements or the likelihood of future cost reductions, or both.

Section 3. Project delivery requirements--additional terms of approval for projects involving HIV infected individuals approved under this addendum.

Sec. 3. (1) An applicant shall agree that, if approved, the services provided by the beds for HIV infected individuals shall be delivered in compliance with the following terms of CON approval:

(a) The license to operate the hospital will be limited to serving the needs of patients with the clinical spectrum of HIV infection and any other limitations established by the Department to meet the purposes of this addendum.

(b) The hospital shall be subject to the general license requirements of Part 215 of the Code except as waived by the Department to meet the purposes of this addendum.

(c) The applicant agrees that the Department shall revoke the license of the hospital if the hospital provides services to inpatients other than HIV infected individuals.

Section 4. Comparative reviews

Sec. 4. (1) Projects proposed under Section 3 shall be subject to comparative review.

Attachment K

STATUS REPORT OF MDCH WORK GROUP MEETINGS
Certificate of Need (CON) Standard
Specialized Computed Tomography (CT) Scanners
CON Commission Meeting – September 16, 2008

At the request of the CON Commission, the Department has held workgroup meetings on the topic of CT mini-scanners. Two specific issues that the workgroup has discussed are the ear, nose and throat (ENT) mini-scanner and the dental scanner.

The group has met four (4) times; May 13th, July 30th, August 21st, and September 3rd. At the September 3, 2008, meeting, the group decided that they had made significant progress in their discussions and that it will be possible to develop language to present to the Commission at its December meeting. A final meeting for the purpose of reviewing draft language will be scheduled in September or early October.

Overall : There was consensus agreement on a conceptual framework for how to deal with emerging specialty CTs (copy attached), subject to agreement on the all important specifics in the Standards language.

- There should be a separate section in the CT Standards for specialty CTs.
- The language affecting all such CTs, should first list the overall requirements. Then subsections indicating the specific requirements for particular types of imaging equipment (e.g., minimum volume, which professions able to have which types of units, etc.). Currently this would be separate subsections for dental CTs and ENT CTs.

Workgroup Participants' Agreement on Some Specific Items:

1. **A requirement for accreditation by recognized national organizations for new applicants for CTs – full body and specialty use:** This follows what was in the Medicare legislation that the Congress just passed. This gradually will be required for existing units as they upgrade/replace out-of-date equipment.
2. **A methodology for projecting that the applicant will reach the minimum volume level:** Follow the approach already established for the first specialty use CT equipment – dental CTs. No use of data commitments based on prior referrals to existing CT units. Instead, applicant would demonstrate from their own billing records for the most recent 12-month data that they treated patients with the specific listed conditions for that type of equipment.
3. **Workgroup objective: Develop draft language:** Language was drafted based on the concepts agreed to at the 7/30/08 discussion. Discussion of the draft language occurred on August 21st and September 3rd 3 and further suggested language will be incorporated into the next draft.

Key Issues Still to be Resolved:

1. **Minimum annual volume:** Prior discussions lead to a suggestion of 1,500 annual minimum volume. At the September 3rd meeting, two different numbers were suggested: 1,000 and 150. The Department has tried to obtain data from national organizations to determine whether it is possible to identify a "reasonable" volume requirement but has not been able to obtain this. The Department's annual survey was also considered as a potential information source, however, the data is not broken down by physician specialty**.**

2. **Specified patient diagnoses/treatments justifying specialty use ENT CT unit:** List on the conceptual document distributed at the meeting (copy attached) was only illustrative; clearly there are other conditions. These would be specified by verbal descriptions of CPT and/or diagnostic codes, along with numeric ranges. That allows refinement of those codes to be automatically included in the list of approved conditions/treatments.

Comment: I show this as not in agreement as to whether or not there should be a list.

3. **Dental CT for orthodontics:** There remains the question of whether or not orthodontics should be included in the definition of "dental procedures."

4. **Need criteria vs. maintenance criteria:** The workgroup members discussed the need to identify the requirements needed to first obtain the equipment, and secondly to identify the criteria needed to maintain the CON. An issue needing further discussion is whether it is appropriate to identify the specific medical procedures for which the units can be used; from both a CON perspective and from a clinical judgment perspective.

DRAFT DISCUSSION ISSUES
CON Template for Use of Emerging Specialty CT Scanners

(e.g., ENT CT machines)

1. **Who** can get the CT: Board-certified or eligible doctor. In this case an ENT doctor. Are there other specialists that should be included? If so, why?

2. **What** services can be provided: Specific uses need to be identified in the standard like there is for Dental CT. Here is a list of possible uses for an ENT machine:
   - **Sinus disease**
   - **Sinus nasal polyps**
   - **Sinus tumours**
   - **Nasal nasoplarysogel masses**

3. **Projecting volume** according to the number of cases that the applicant (which we presume to be a group practice) treated with that confirmed diagnosis PLUS those other patients suspected of that diagnosis that the applicant referred for a CT.

4. **Projected delivery required volume:** After __ years (We are suggesting 2), applicant must have been doing X number of CT images.

5. **Required training:**
   a. **Physician:** certification of training in reading CT scans.

   b. **Staff:** certification by some appropriate source in running the CT and maintaining it.

CERTIFICATE OF NEED

Compliance Activity Report to the CON Commission

September 16, 2008

This quarterly report is designed to update the Commission on the Department's activity in monitoring compliance with all Certificates of Need issued as required by Section 22247 of the Public Health Code. This report details activities from April 1 through June 30, 2008.

MCL 333.22247

(1) The department shall monitor compliance with all certificates of need issued under this part and shall investigate allegations of noncompliance with a certificate of need or this part.

(2) If the department determines that the recipient of a certificate of need under this part is not in compliance with the terms of the certificate of need or that a person is in violation of this part or the rules promulgated under this part, the department shall do 1 or more of the following:
(a) Revoke or suspend the certificate of need.
(b) Impose a civil fine of not more than the amount of the billings for the services provided in violation of this part.
(c) Take any action authorized under this article for a violation of this article or a rule promulgated under this article, including, but not limited to, issuance of a compliance order under section 20162(5), whether or not the person is licensed under this article.
(d) Request enforcement action under section 22253.
(e) Take any other enforcement action authorized by this code.
(f) Publicize or report the violation or enforcement action, or both, to any person.
(g) Take any other action as determined appropriate by the department.

(3) A person shall not charge to, or collect from, another person or otherwise recover costs forservices provided or for equipment or facilities that are acquired in violation of this part. If a person has violated this subsection, in addition to the sanctions provided under subsection (2), the person shall, upon request of the person from whom the charges were collected, refund those charges, either directly or through a credit on a subsequent bill.

Activity Report

Follow Up: In accordance with Administrative Rules 325.9403 and 325.9417, the Department performs follow up checks on approved CONs to determine if proposed projects have been implemented in accordance with Part 222 of the Code. For the 3rd quarter of FY 2008, the following actions have occurred:

- 503 follow-up letters mailed (Year to Date: 1,022)
- 187 projects deemed 100% complete and operational (Year to Date: 471)
- 88 CON approvals expired due to noncompliance with Part 222, not meeting required time frames to implement projects (Year to Date: 211)

Compliance Report to CON Commission
September 16, 2008

Compliance: In accordance with Section 22247 and Rule 9419, the Department performs compliance checks on approved and operational Certificates of Need to determine if projects have been implemented in accordance with Part 222 of the Code. For the 3rd quarter of FY 2008, the following action has occurred:

- A statewide review was performed to assure nursing homes approved under the pilot program in the CON Review Standards for Nursing Home Beds are compliant with the requirement to participate in an annual survey process (My InnerView). Actions below are outside reporting period, but provided for the Commission's information.

- Department has worked with numerous licensed health facilities to return unused hospital, psychiatric and nursing home beds to the applicable bed inventories. Numerous beds have been returned or agreed to be returned to the State pools; however, final numbers will be reported in the next report as these beds were or will be returned after June 2008.

- The Department continues to receive surveys that were deemed delinquent for 2007

CERTIFICATE OF NEED

Quarterly Program Section Activity Report to the CON Commission

October 1, 2007 through June 30, 2008 (FY 2008)

This quarterly report is designed to assist the CON Commission in monitoring and assessing the operations and effectiveness of the CON Program Section in accordance with Section 22215(1)(e) of the Public Health Code, 1978 PA 368.

Measures

Administrative Rule R325.9201 requires the Department to process a Letter of Intent within 15 days upon receipt of a Letter of Intent.

Activity	Most Recent Quarter	Year-to-Date
Letters of Intent Received	126	400
Letters of Intent Processed within 15 days	125	398

Administrative Rule R325.9201 requires the Department to request additional information from an applicant within 15 days upon receipt of an application, if additional information is needed.

Activity	Most Recent Quarter	Year-to-Date
Applications Received	88	298
Applications Processed within 15 Days	87	297
Applications Incomplete/More Information Needed	62	213

Administrative rules R325.9206 and R325.9207 require the Department to issue a proposed decision for completed applications within 45 days for nonsubstantive, 120 days for substantive, and 150 days for comparative reviews.

Activity	Most Recent Quarter		Year-to-Date	
	Issued on Time	Not Issued on Time	Issued on Time	Not Issued on Time
Nonsubstantive Applications	36	1	129	2
Substantive Applications	37	1	129	2
Comparative Review Applications	14	3	37	3

Note: Data in this table may not total/correlate with application received table because receive and processed dates may carry over into next month/next quarter.

Administrative Rule R325.9227 requires the Department to determine if an emergency application will be reviewed pursuant to Section 22235 of the Public Health Code within 10 working days upon receipt of the emergency application request.

Source: Certificate of Need Program Review Section, Division of Health Facilities and Services, Bureau of Health Systems, Michigan Department of Community Health.

Measures – continued

Activity	Most Recent Quarter	Year-to-Date
Emergency Applications Received	1	3
Decisions Issued within 10 workings Days	1	2*

* One emergency application submitted was not eligible for review under this provision.

Administrative Rule R325.9413 requires the Department to process amendment requests within the same review period as the original application.

Activity	Most Recent Quarter		Year-to-Date	
	Issued on Time	Not Issued on Time	Issued on Time	Not Issued on Time
Amendments	14	4	32	13

Note: CON Program Section has taken steps to address this requirement to assure timely issuance of decisions on amendments, including weakly monitoring of due dates and assigning additional staff to reviews.

Section 22231(10) of the Public Health Code requires the Department to issue a refund of the application fee, upon written request, if the Director exceeds the time set forth in this section for a final decision for other than good cause as determined by the Commission.

Activity	Most Recent Quarter	Year-to-Date
Refunds Issued Pursuant to Section 22231	0	0

Other Measures

Activity	Most Recent Quarter	Year-to-Date
FOIA Requests Received	56	121
FOIA Requests Processed on Time	56	121
Number of Applications Viewed Onsite	18	33

FOIA – Freedom of Information Act.

Source: Certificate of Need Program Review Section, Division of Health Facilities and Services, Bureau of Health Systems, Michigan Department of Community Health.

CERTIFICATE OF NEED LEGAL ACTION

(09/10/08)

Case Name	*Date Opened*	*Case Description*	
Mobile Diagnostic Ingham County Circuit Docket No: 08-461-AA CON Application #06-0031	04/07/08	Appeal to Circuit Court of Denial of application for CON (Docket No: 2007-1870 CON) by Administrative Law Judge Lisa Gigliotti.	D 9
Regency on the Lake-Novi, LLC Admin Tribunal Docket No.: 2007-1988 CON	04/02/07	Appeal of Denial of CON application. Comparative Review decision including Maple Drake Real Estate, Maple Manor Rehabilitation Center Status.	A D S cl w to S
Maple Drake Real Estate, LLC Admin Tribunal Docket No: 2007-2263 CON	05/24/07	Appeal of Comparative Review of CON application. Comparative Review proposed decision including Maple Manor Rehabilitation Center and Regency on the Lake.	A D S cl w to S
Maple Manor Rehabilitation Center Admin Tribunal Docket No.: 2007-2263 CON	05/24/07	Appeal of Comparative Review of CON application. Approval with Regency on the Lake and Maple Drake Real Estate.	A D S cl w to S
MediLodge of Milford, LLC (AG#20073000935) Admin Tribunal Docket No.: 2007-3545 CON	07/17/07	Appeal of denial of CON application.	S w th A a A

CERTIFICATE OF NEED LEGAL ACTION

(09/10/08)

Case Name	*Date Opened*	*Case Description*	
Maple Manor Rehabilitation Center Admin Tribunal Docket No: 2008-17098 CON CON Application No: 08-0018	5/28/08	Appeal of Proposed Decision of Disapproval dated 4/16/08. Proposed project to acquire an 82 bed nursing home and replace 22 beds disapproved.	9 D E 1
Fountainbleu, LLC Admin Tribunal Docket No: 2008-10920 CON	3/20/08	Appeal of proposed CON decision dated February 22, 2008.	P f c

s: chd; assign control; special; CON Leg Action; report 9/10/08

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

CERTIFICATE OF NEED (CON) COMMISSION WORK PLAN

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

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 c
D - Discussion
F - Final Commission action, Transmittal to Governor/Legislature for
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 comi

For Approval September 16, 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 Depar
egulation & 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.