MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES (MDHHS)
CERTIFICATE OF NEED (CON) COMMISSION MEETING

Wednesday March 16, 2016

Grand Tower Building
235 S. Grand Ave,
1st Floor, Dempsey Conference Room
Lansing, MI 48933

APPROVED MINUTES

I. Call to Order & Introductions

Chairperson Keshishian called the meeting to order at 9:35 a.m. Chairperson Keshishian introduced new Commissioner Debra Guido-Allen. Commissioners and staff introduced themselves.

Chairperson Keshishian read the Certificate for outgoing Commissioner Landstrom.

A. Members Present:

Denise Brooks-Williams
Kathleen Cowling, DO
James B. Falahee, Jr., JD
Debra Guido-Allen, RN
Robert Hughes
Marc Keshishian, MD, Chairperson
Jessica Kochin
Suresh Mukherji, MD, Vice- Chairperson
Luis Tomatis, MD

B. Members Absent:

Gail J. Clarkson, RN
Thomas Mittelbrun

C. Department of Attorney General Staff:

Joseph Potchen

D. Michigan Department of Health and Human Services Staff Present:

Tulika Bhattacharya
Amber Myers
Beth Nagel
Tania Rodriguez
Brenda Rogers

II. Review of Agenda

Motion by Commissioner Kochin, seconded by Commissioner Mukherji, to approve the agenda as presented. Motion carried.

III. Declaration of Conflicts of Interests

None.

IV. Review of Minutes of January 28, 2016

Motion by Commissioner Brooks-Williams, seconded by Commissioner Kochin, to approved the minutes as presented. Motion carried.

V. Magnetic Resonance Imaging (MRI) Services – February 4, 2016 Public Hearing Summary & Report

Ms. Rogers gave an overview of the public hearing summary and the Department's recommendations (see Attachment A).

A. Public Comment

None.

B. Commission Discussion

None.

C. Commission Action

Motion made by Tomatis seconded by Cowling to take final action on the language (see Attachment B) as presented and move the standards forward to the Joint Legislative Committee (JLC) and Governor for the 45-day review period; Motion carried in a vote of 9 - Yes, 0 - No, and 0-Abstained.

VI. MRI Services – Common Ownership

Ms. Rogers gave an overview of the draft language. (see Attachment C).

A. Public Comment

None.

B. Commission Discussion

None.

C. Commission Action

Motion by Commissioner Falahee, seconded by Commissioner Cowling to take proposed action on the MRI standards (see Attachment C) as presented and move to a Public Hearing and forward to the JLC. Motion carried in a vote of 9 - Yes, 0 - No, and 0- Abstained.

VII. Nursing Home and Hospital Long-Term-Care Unit (HLTCU) Bed Need Effective Date – Action Delayed from December 10, 2015 CON Commission Meeting

Ms. Rogers gave an overview.

A. Public Comment

1. Pat Anderson, Health Care Association of Michigan (HCAM)

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Falahee, seconded by Commissioner Hughes to set effective date of the new bed need numbers (see Attachment D) for March 16, 2016. Motion carried in a vote of 9 - Yes, 0 - No, and 0 - Abstained.

VIII. Psychiatric Beds and Services Workgroup Final Report Follow-up

Commissioner Cowling provided an overview of the Psychiatric Beds and Services workgroup's work, and Ms. Rogers gave an overview of the draft standards (see Attachment E).

A. Public Comment
1. Arlene Elliott, Arbor Advisors
2. Nancy List, McLaren

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Falahee, seconded by Commissioner Brooks-Williams to take proposed action on the standards and addendum language (see Attachment E) as presented and move to a Public Hearing and forward to the JLC. Motion carried in a vote of 9 - Yes, 0- No, and 0- Abstained.

IX. Bone Marrow Transplantation (BMT) Services Standards Advisory Committee (SAC) – Interim Report (Written only – see Attachment F)

A. Public Comment

1. Susan Grant, Beaumont

X. Legislative Report

Ms. Nagel gave a verbal update on legislative activity.

XI. Administrative Update

B. Planning and Access to Care Section Update

Ms. Nagel gave a verbal update of the section.

C. CON Evaluation Section Update

1. Compliance Report (see Attachment G)

   Ms. Bhattacharya gave a summary of the compliance report.

2. Quarterly Performance Measures (see Attachment H)

   Ms. Bhattacharya gave a summary of the quarterly performance report.

3. FY2015 CON Annual Activity Report (See Attachment I)

   Ms. Bhattacharya gave a summary of the annual report.

XII. Legal Activity Report

Mr. Potchen stated that there is no active CON litigation to report.

XIII. Future Meeting Dates – June 11, 2015, September 24, 2015, and December 10, 2015

XIV. Public Comment

None.

XV. Review of Commission Work Plan

Ms. Rogers gave an overview of the Work Plan (see Attachment J) including today's actions.

A. Commission Discussion

None.

B. Commission Action

Motion by Commissioner Falahee, seconded by Commissioner Hughes to accept the work plan as presented. Motion Carried in a vote of 9 - Yes, 0 - No, and 0 - Abstained.

XVI. Election of Officers

Motion by Commissioner Tomatis, seconded by Commissioner Cowling to nominate and re-elect Commissioner Keshishian as Chairperson and Commissioner Mukherji as the Vice-Chairperson of the Commission. Motion Carried in a vote of 9 - Yes, 0 - No, and 0 - Abstained.

XVII. Adjournment

Motion by Commissioner Brooks-Williams, seconded by Commissioner Hughes to adjourn the meeting at 11:07 a.m. Motion Carried in a vote of 9 - Yes, 0 - No, and 0 - Abstained.

Michigan Department of Health and Human Services (MDHHS or Department)
MEMORANDUM
Lansing, MI

Date: February 18, 2016

TO: The Certificate of Need (CON) Commission

FROM: Brenda Rogers, Special Assistant to the Commission, Planning and Access to Care Section, MDHHS

RE: Summary of Public Hearing Comments on Magnetic Resonance Imaging (MRI) 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 MRI Services Standards at its December 10, 2015 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed MRI Services Standards on February 4, 2016. Written testimony was accepted for an additional seven days after the hearing via an electronic link on the Commission's website. Testimony was received from one organization.

Written Testimony:

1.) Sue Durso, MRI of Southfield

- Supports the proposed changes to the MRI CON Standards specifically regarding the elimination of the volume requirement for replacement of an existing MRI unit.

Department Recommendation:

The Department supports the language as presented at the December 10, 2015 CON Commission meeting.

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. These standards are requirements for the approval of the initiation, expansion, replacement, or acquisition of MRI services and the delivery of services under Part 222 of the Code. Pursuant to Part 222 of the Code, MRI is a covered clinical service. The Department shall use these standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and 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" or "MRI adjusted procedures," means the number of MRI procedures, adjusted in accordance with the applicable provisions of Section 15, 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 "MRI Service Utilization List," as of the date an application is deemed submitted by the Department.

(c) "Available MRI adjusted procedures" 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 submitted by the Department.

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).

(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 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 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" 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 21.

(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 replacement of an existing fixed MRI service to a new site 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" 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) "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.

(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 the location of the hospital authorized by license and listed on that licensee's certificate of licensure.

(y) "Magnetic resonance imaging" or "MRI" 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) "MRI adjusted procedure" means an MRI visit, at an existing MRI service, that has been adjusted in accordance with the applicable provisions of Section 15.

(aa) "MRI database" means the database, maintained by the Department pursuant to Section 14 of these standards, that collects information about each MRI visit at MRI services located in Michigan.

(bb) "MRI-guided electrophysiology intervention" or "MRI-guided EPI" means equipment specifically designed for the integrated use of MRI technology for the purposes of electrophysiology interventional procedures within a cardiac catheterization lab.

(cc) "MRI procedure" means a procedure conducted by an MRI unit approved pursuant to sections 3, 4, 5, 6, 7, or 9 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 IRB. 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 7.

(dd) "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.

(ee) "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 including FDA-approved positron emission tomography (PET)/MRI scanner hybrids if used for MRI only procedures. The term does not include MRI simulators used solely for treatment planning purposes in conjunction with a Megavoltage Radiation Therapy (MRT) unit.

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

(gg) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396 to 1396g and 1396i to 1396u.

(hh) "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.

(ii) "Ownership interest, direct or indirect" 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.

(jj) "Pediatric patient" means a patient who is 12 years of age or less, except for Section 8.

(kk) "Planning area" 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.

(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 15(2)(d), the health service area in which all the proposed mobile host sites will be located.

(ll) "Referring doctor" 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.

(mm) "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 4, or (ii) a change in the parties to the lease.

(nn) "Research scan" means an MRI scan administered under a research protocol approved by the applicant’s IRB.

(oo) "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.

(pp) "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).

(qq) "Site" 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.

(rr) "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, IMPLANTABLE CARDIAC DEVICES (ICDS), and other conditions that make the patient unable to comply with the positional requirements of the exam OR IS UNABLE TO COMPLY WITH THE MOTIONLESS REQUIREMENTS AND WHOSE RESULTING MOVEMENTS RESULT IN NON-DIAGNOSTIC QUALITY IMAGES THEREFORE REQUIRING THE TECHNOLOGIST TO REPEAT THE SAME SEQUENCE IN AN ATTEMPT TO OBTAIN A DIAGNOSTIC QUALITY IMAGE.

(ss) "Teaching facility" 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.

(tt) "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 15.

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

Section 3. Requirements to initiate an MRI service

Sec. 3. An applicant proposing to initiate an MRI service or a host site shall demonstrate the following requirements, as applicable:

(1) An applicant proposing to initiate a fixed MRI service shall demonstrate 6,000 available MRI adjusted procedures per proposed fixed MRI unit from within the same planning area as the proposed service/unit.

(2) An applicant proposing to initiate a fixed MRI service that meets the following requirements shall not be required to be in compliance with subsection (1):

(a) The applicant is currently an existing host site.

(b) The applicant has received in aggregate, one of the following:

(i) At least 6,000 MRI adjusted procedures.

(ii) At least 4,000 MRI adjusted procedures 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.

(iii) At least 3,000 MRI adjusted procedures and the applicant meets all of the following:

(A) The proposed site is a hospital licensed under Part 215 of the Code.

(B) The applicant hospital operates an emergency room that provides 24-hour emergency care services and at least 20,000 visits within the most recent 12-month period for which data, verifiable by the Department, is available.

(c) All of the MRI adjusted procedures from the mobile MRI service referenced in Section 3(2)(b) shall be utilized even if the aggregated data exceeds the minimum requirements.

(d) The applicant shall install the fixed MRI unit at the same site as the existing host site or within the relocation zone. If applying pursuant to Section 3(2)(b)(iii), the applicant shall install the fixed MRI unit at the same site as the existing host site.

(e) The applicant 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.

(3) An applicant proposing to initiate a mobile MRI service shall demonstrate 5,500 available MRI adjusted procedures from within the same planning area as the proposed service/unit, and the applicant shall meet the following:
(a) Identify the proposed route schedule and procedures for handling emergency situations.
(b) Submit copies of all proposed contracts for the proposed host site related to the mobile MRI service.
(c) Identify a minimum of two (2) host sites for the proposed service.

(4) An applicant, whether the central service coordinator or the host site, proposing to initiate a host site on a new or existing mobile MRI service shall demonstrate the following, as applicable:
(a) 600 available MRI adjusted procedures, from within the same planning area as the proposed service/unit, for a proposed host site that is not located in a rural or micropolitan statistical area county, or
(b) 400 available MRI adjusted procedures from within the same planning area for a proposed host site that is located in a rural or micropolitan statistical area county, and
(c) The proposed host site 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.

(5) An applicant proposing to add or change service on an existing mobile MRI service that meets the following requirements shall not be required to be in compliance with subsection (4):
(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) Submit copies of all proposed contracts for the proposed host site related to the mobile MRI service.

(6) The applicant shall demonstrate that the available MRI adjusted procedures from the "Available MRI Adjusted Procedures List" or the adjusted procedures from the "MRI Service Utilization List," as applicable, are from the most recently published MRI lists as of the date an application is deemed submitted by the Department.

Section 4. Requirements to replace an existing MRI unit

Sec. 4. Replace an existing MRI unit means (i) any equipment change involving a change in, or replacement of, the entire MRI unit 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 that involves a capital expenditure of $750,000 or more in any consecutive 24-month period or (iii) the renewal of a lease. Replacement also means the relocation of an MRI service or unit to a new site. The term does not include the replacement of components of the MRI system, including the magnet, under an existing service contract or required maintenance to maintain the system to operate within manufacturer specifications. The term does not include an upgrade to an existing MRI unit or repair 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) have been met.

(1) "Upgrade an existing MRI unit" means any equipment change that
(i) does not involve a change in, or replacement of, the entire MRI unit, 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 related to the MRI equipment of less than $750,000 in any consecutive 24-month period.

(2) “Repair an existing MRI unit” means restoring the ability of the system to operate within the manufacturer’s specifications by replacing or repairing the existing components or parts of the system, including the magnet, pursuant to the terms of an existing maintenance agreement WITH THE MANUFACTURER OF THE MRI UNIT that does not result in a change in the strength of the MRI unit.

(3) An applicant proposing to replace an existing MRI unit shall demonstrate the following requirements~~, as applicable~~:

(a) ~~An applicant shall demonstrate that the applicable MRI adjusted procedures are from the most recently published MRI Service Utilization List as of the date an application is deemed submitted by the Department. An applicant proposing to replace an existing MRI unit that is below 1 tesla with an MRI unit that is a 1 tesla or higher, shall be exempt once, as of September 18, 2013, from the minimum volume requirements for replacement:~~

~~(i) Each existing mobile MRI unit on the network has performed at least an average of 5,500 MRI adjusted procedures per MRI unit.~~

~~(ii) Each existing fixed MRI unit at the current site has performed at least an average of 6,000 MRI adjusted procedures per MRI unit unless the applicant demonstrates compliance with one of the following:~~

~~(A) The existing fixed MRI unit initiated pursuant to Section 3(2)(b)(ii) has performed at least 4,000 MRI adjusted procedures and is the only fixed MRI unit at the current site.~~

~~(B) The existing fixed MRI unit initiated pursuant to Section 3(2)(b)(iii) has performed at least 3,000 MRI adjusted procedures and is the only fixed MRI unit at the current site.~~

~~(iii) Each existing dedicated pediatric MRI unit at the current site has performed at least an average of 3,500 MRI adjusted procedures per MRI unit.~~

~~(b)~~ 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.

(~~c~~b) The replacement unit shall be located at the same site.

(~~d~~c) 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.

(4) An applicant proposing to replace an existing mobile MRI host site to a new location shall demonstrate the following:

(a) The applicant currently operates the MRI mobile host site to be relocated.

(b) The MRI mobile host site to be relocated has been in operation ~~for at least 36 months~~ as of the date an application is submitted to the Department.

(c) The proposed new site is within a 5-mile radius of the existing site for a metropolitan statistical area county or within a 10-mile radius for a rural or micropolitan statistical area county.

~~(d) The mobile MRI host site to be relocated performed at least the applicable minimum number of MRI adjusted procedures set forth in Section 14 based on the most recently published MRI Service Utilization List as of the date an application is deemed submitted by the Department.~~

(~~e~~d) The relocation will not involve a change in the current central service coordinator unless the requirements of Section 3(5) are met.

(5) An applicant proposing to replace an existing fixed MRI service and its unit(s) to a new site shall demonstrate the following:

(a) The existing MRI service and its unit(s) to be replaced has been in operation for at least 36 months as of the date an application is submitted to the Department UNLESS THE APPLICANT MEETS THE REQUIREMENT IN SUBSECTION (c)(i) OR (ii).

(b) The proposed new site is within a 10-mile radius of the existing site.

(c) Each existing MRI unit to be relocated performed at least the applicable minimum number of MRI adjusted procedures set forth in Section 14 based on the most recently published MRI Service Utilization List as of the date an application is deemed submitted by the Department,UNLESS ONE OF THE FOLLOWING REQUIRMENTS ARE MET~~.~~:

(i) THE OWNER OF THE BUILDING WHERE THE SITE IS LOCATED HAS INCURRED A FILING FOR BANKRUPTCY UNDER CHAPTER SEVEN (7) WITHIN THE LAST THREE YEARS;

(ii) THE OWNERSHIP OF THE BUILDING WHERE THE SITE IS LOCATED HAS CHANGED WITHIN 24 MONTHS OF THE DATE OF THE SERVICE BEING OPERATIONAL; OR

(iii) THE MRI SERVICE BEING REPLACED IS PART OF THE REPLACEMENT OF AN ENTIRE HOSPITAL TO A NEW GEOGRAPHIC SITE AND HAS ONLY ONE (1) MRI UNIT.

(6) An applicant proposing to replace a fixed MRI unit of an existing MRI service to a new site shall demonstrate the following:

(a) The applicant currently operates the MRI service from which the unit will be relocated.

(b) 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.

(c) The proposed new site is within a 10-mile radius of the existing site.

(d) 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 14 based on the most recently published MRI Service Utilization List as of the date an application is deemed submitted by the Department.

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

Section 5. Requirements to expand an existing MRI service

Sec. 5. An applicant proposing to expand an existing MRI service shall demonstrate the following:

(1) An applicant shall demonstrate that the applicable MRI adjustable procedures are from the most recently published MRI Service Utilization List as of the date of an application is deemed submitted by the Department:

(a) Each existing MRI unit on the network has performed at least an average of 9,000 MRI adjusted procedures per MRI unit.

(b) Each existing fixed MRI unit at the current site has performed at least an average of 11,000 MRI adjusted procedures per MRI unit.

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

(2) The additional fixed unit shall be located at the same site unless the requirements of the replacement section have been met.

Section 6. Requirements to acquire an existing MRI service or an existing MRI unit(s)

Sec. 6. ~~(1)~~ An applicant proposing to acquire an existing fixed or mobile MRI service and its unit(s) shall demonstrate the following:

(~~a~~1) 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 14 of these standards in the second 12 months after the effective date of the acquisition, and annually thereafter.

(~~b~~2)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 (a), 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 14 of these standards applicable to an existing MRI service on the date the application is submitted to the Department.

(~~2~~3) 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, AS APPLICABLE:

(a) AN APPLICANT SHALL DEMONSTRATE THAT THE APPLICABLE MRI ADJUSTABLE PROCEDURES ARE FROM THE MOST RECENTLY PUBLISHED MRI SERVICE UTILIZATION LIST AS OF THE DATE OF AN APPLICATION IS DEEMED SUBMITTED BY THE DEPARTMENT:

(i) THE FIXED MRI UNIT(S) TO BE ACQUIRED PERFORMED AT LEAST 6,000 MRI ADJUSTED PROCEDURES PER FIXED MRI UNIT.

(ii) THE MOBILE MRI UNIT(S) TO BE ACQUIRED PERFORMED AT LEAST 5,500 MRI ADJUSTED PROCEDURES PER MOBILE MRI UNIT.

(b) The project will not change the number of MRI units at the site ~~of the MRI service~~FROM WHICH THE NUMBER OF UNITS ARE being acquired, subject to the applicable requirements under Section 4(6), unless the applicant demonstrates that the project is in compliance with the requirements of the initiation or expansion Section, as applicable.

(~~b~~c) 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 the replacement section have been met.

Section 7. Requirements to establish a dedicated research MRI unit

Sec. 7. An applicant proposing an MRI unit to be used exclusively for research shall demonstrate the following:

(1) The applicant agrees that the dedicated research MRI unit will be used primarily (70% or more of the procedures) for research purposes only.

(2) Submit copies of documentation demonstrating that 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.

(3) Submit copies of documentation demonstrating that the MRI unit shall operate under a protocol approved by the applicant's IRB.

(4) An applicant meeting the requirements of this section shall be exempt from meeting the requirements of sections to initiate and replace.

(5) THE DEDICATED RESEARCH MRI UNIT APPROVED UNDER THIS SECTION MAY NOT UTILIZE MRI ADJUSTED PROCEDURES PERFORMED ON THE DEDICATED MRI UNIT TO DEMONSTRATE NEED OR TO SATISFY MRI CON REVIEW STANDARDS REQUIREMENTS.

Section 8. Requirements to establish a dedicated pediatric MRI unit

Sec. 8. An applicant proposing to establish dedicated pediatric MRI shall demonstrate all of the following:

(1) The applicant shall have experienced at least 7,000 pediatric (< 18 years old) discharges (excluding normal newborns) in the most recent year of operation.

(2) The applicant shall have performed at least 5,000 pediatric (< 18 years old) surgeries in the most recent year of operation.

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

(a) pediatric radiology (at least two)

(b) pediatric anesthesiology

(c) pediatric cardiology
(d) pediatric critical care
(e) pediatric gastroenterology
(f) pediatric hematology/oncology
(g) pediatric neurology
(h) pediatric neurosurgery
(i) pediatric orthopedic surgery
(j) pediatric pathology
(k) pediatric pulmonology
(l) pediatric surgery
(m) neonatology

(4) The applicant shall have in operation the following pediatric specialty programs:
(a) pediatric bone marrow transplant program
(b) established pediatric sedation program
(c) pediatric open heart program

(5) An applicant meeting the requirements of this section shall be exempt from meeting the requirements of Section 5 of these standards.

Section 9. Requirements for all applicants proposing to initiate, replace, or acquire a hospital based IMRI

Sec. 9. An applicant proposing to initiate, replace, or acquire a hospital based IMRI service shall demonstrate each of the following, as applicable to the proposed project.

(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 has achieved 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 or a room adjoining an operating room allowing for transfer of the patient between the operating room and this adjoining 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.

Section 10. Requirements for all applicants proposing to initiate, replace, or acquire a hospital based MRI-guided EPI service

Sec. 10. An applicant proposing to initiate, replace, or acquire a hospital based MRI-guided EPI service shall demonstrate each of the following, as applicable to the proposed project.

(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 therapeutic cardiac catheterization service and is meeting its minimum volume requirements pursuant to the CON review standards for cardiac catheterization services and open heart surgery services.

(4) The proposed MRI-guided EPI unit must be located in a cardiac catheterization lab containing a flouroscopy unit with an adjoining room containing an MRI scanner. The rooms shall contain a patient transfer system allowing for transfer of the patient between the cardiac catheterization lab and the MRI unit, utilizing one of the following:

(a) moving the patient to the MRI scanner, or

(b) installing the MRI scanner on a sliding gantry to allow the patient to remain stationary.

(5) Non-cardiac MRI diagnostic studies shall not be performed in an MRI-guided EPI 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 as follows:

(i) is in need of general anesthesia or deep sedation as defined by the American Society of Anesthesiologists, or

(ii) has an implantable cardiac device.

(6) The approved MRI-guided EPI unit shall not be subject to MRI volume requirements.

(7) The applicant shall not utilize the procedures performed on the MRI-guided EPI unit to demonstrate need or to satisfy MRI CON review standards requirements.

Section 11. Requirements for all applicants proposing to initiate, replace, or acquire an MRI simulator that will not be used solely for MRT treatment planning purposes

Sec. 11. MRI simulation is the use of MRI to help simulate (or plan) a patient's MRT treatment and to incorporate superior delineation of soft tissues for MRT treatment plans. An applicant proposing to initiate, replace, or acquire an MRI simulator shall demonstrate each of the following, as applicable to the proposed project.

(1) 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.

(2) The proposed site has an existing and operational MRT service and is meeting its minimum volume requirements pursuant to the CON review standards for MRT services/units.

(3) MRI diagnostic studies shall not be performed using an MRI simulator 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.

(4) The approved MRI simulator will not be subject to MRI volume requirements.

(5) The applicant shall not utilize the procedures performed on the MRI simulator to demonstrate need or to satisfy MRI CON review standards requirements.

Section 12. Requirements for approval of an FDA-approved PET/MRI scanner hybrid for initiation, expansion, replacement, and acquisition

Sec. 12. An applicant proposing to initiate, expand, replace, or acquire an FDA-approved PET/MRI scanner hybrid shall demonstrate that it meets all of the following:

(1) There is an approved PET CON for the FDA-approved PET/MRI hybrid, and the FDA-approved PET/MRI scanner hybrid is in compliance with all applicable project delivery requirements as set forth in the CON review standards for PET.

(2) The applicant agrees to operate the FDA-approved PET/MRI scanner hybrid in accordance with all applicable project delivery requirements set forth in Section 14 of these standards.

(3) The approved FDA-approved PET/MRI scanner hybrid shall not be subject to MRI volume requirements.

(4) An FDA-approved PET/MRI scanner hybrid approved under the CON review standards for PET scanner services and the review standards for MRI scanner services may not utilize MRI procedures performed on an FDA-approved PET/MRI scanner hybrid to demonstrate need or to satisfy MRI CON review standards requirements.

Section 13. Requirements for all applicants

Sec. 13. 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 14. Project delivery requirements – terms of approval

Sec. 14. An applicant shall agree that, if approved, MRI services, whether fixed or mobile, shall be delivered and maintained in compliance with the following:

(1) Compliance with these standards.

(2) Compliance with the following quality assurance standards:

(a) 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.

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

(c) 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:

(i) 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.

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

(iii) An MRI physicist/engineer available as a team member on a full-time, part-time, or contractual basis.

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

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

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

(B) 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 (1), (2), or (3):

(1) 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.

(2) 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.

(3) 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.

(C) 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.

(D) The physician complies with the "American College of Radiology (ACR) Practice ~~Guideline~~ PARAMETER for Performing and Interpreting Magnetic Resonance Imaging (MRI)."

(ii) 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.

(iii) 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) 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.

(3) Compliance with the following access to care requirements:

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

(a) provide MRI 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.

(c) 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 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).

(4) Compliance with the following monitoring and reporting requirements:

(a) MRI units shall be operating at a minimum average annual utilization during the second 12 months of operation, and annually thereafter, as applicable:

(i) 6,000 MRI adjusted procedures per unit for fixed MRI services unless compliant with (~~1~~A) or (~~2~~B),

(A) 4,000 MRI adjusted procedures for the fixed MRI unit initiated pursuant to Section 3(2)(b)(ii) and is the only fixed MRI unit at the current site,

(B) 3,000 MRI adjusted procedures for the fixed MRI unit initiated pursuant to Section 3(2)(b)(iii) and is the only fixed MRI unit at the hospital site licensed under part 215 of the code,

(ii) 5,500 MRI adjusted procedures per unit for mobile MRI services.

(iii) 3,500 MRI adjusted procedures per unit for dedicated pediatric MRI units.

(iv) 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.

(v) 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 7 or for an IMRI unit approved pursuant to Section 9.

(b) 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, operating 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. The Department may elect to verify the data through on-site review of appropriate records. Data for an MRI unit approved pursuant to Section 7, Section 8, Section 9, Section 10, or Section 11 shall be reported separately.
For purposes of Section 9, 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. For purposes of Section 10, the data reported shall include, at a minimum, how often the MRI-guided EPI unit is used and for what type of services, i.e., electrophysiology or diagnostic. For purposes of Section 11, the data reported shall include, at a minimum, how often the MRI simulator is used and for what type of services, i.e., treatment plans or diagnostic services.

(c) 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.

(d) 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.

(5) An applicant for an MRI unit approved under Section 7 shall agree that the services provided by the MRI unit are delivered in compliance with the following terms.

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

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

(c) The dedicated research MRI unit will be used primarily (70% or more of the procedures) for research purposes only.

(6) The dedicated pediatric MRI unit approved under Section 8 shall include at least 80% of the MRI procedures that are performed on patients under 18 years of age.

(7) 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 15. MRI procedure adjustments

Sec. 15. (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. For functional MRI (fMRI) procedures, MRI-guided interventions, and cardiac MRI procedures, the base value is 2.0.

(i) fMRI means brain activation studies.

(ii) MRI-guided interventions means any invasive procedure performed requiring MRI guidance performed in the MRI scanner.

(iii) Cardiac MRI Procedure means dedicated MRI performed of the heart done for the sole purpose of evaluation of cardiac function, physiology, or viability.

(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 16. Documentation of actual utilization

Sec. 16. 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 "MRI Service Utilization List" as of the date an application is deemed submitted 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 17. The Department may elect to verify the data through on-site review of appropriate records.

Section 17. Methodology for computing the number of available MRI adjusted procedures

Sec. 17. (1) The number of available MRI adjusted procedures required pursuant to Section 3 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 submitted 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 15.

(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 7 and dedicated pediatric MRI approved pursuant to Section 8 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(2)(c), 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 5(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 (c)(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 (c)(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 (c)(iv) above, sum the available adjusted procedures.

(vi) For the doctors used in subsection (c)(v) above, divide the total number of available adjusted procedures identified in (c)(ii)(B) above by the sum of those available adjusted procedures produced in (c)(v) above.

(vii) For only those doctors identified in (c)(v) above, multiply the result of (c)(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(2).

Section 18. Procedures and requirements for commitments of available MRI adjusted procedures

Sec. 18. (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 for each doctor committing available MRI adjusted procedures to that application for a new MRI unit that requires doctor commitments.

(b) An applicant also shall submit, at the time the application is submitted to 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 submitted on the first applicable designated application date after all required documentation is received by the Department.

(3) The Department shall consider a signed and dated data commitment on a form provided by the Department in response to the applicant's letter of intent 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 17, is being committed and specifies the CON application number for the MRI unit 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 ownership interest, either direct or indirect, in the applicant entity. Indirect ownership includes ownership in an entity that has ownership interest in the applicant entity. This requirement shall not apply if the applicant entity is a group practice of which the committing doctor is a member. Group practice 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.

(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, 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, 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~~THE ~~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, the Department shall,

(a) if the applications were submitted 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 submitted 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 submitted on different designated application dates, consider the data commitment in the application submitted on the earliest designated application date and shall notify, simultaneously in writing, all applicants of applications submitted 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) submitted 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 submitted 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 submitted only to the extent necessary to replace the data commitments not being considered pursuant to subsection (5).

(a) The applicant shall have 30 days to submit replacement of doctor commitments as identified by the Department in this Section.

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

~~(a)~~ on or after the date an application is deemed submitted by the Department.

~~(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 BEFORE THE APPLICATION IS DEEMED SUBMITTED, 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 19. Lists published by the Department

Sec. 19. (1) 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, research, or dedicated pediatric.

(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 17(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 17(1)(c)(v), and if any are committed to an MRI service. This number shall be calculated in accordance with the requirements of Section 17(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 14, the Department shall indicate on both lists that the MRI service is in violation of the requirements set forth in Section 14, and no data will be shown for that service on either list.

Section 20. Effect on prior CON Review Standards; Comparative reviews

Sec. 20. (1) These CON review standards supersede and replace the CON Review Standards for MRI Services approved by the CON Commission on ~~June 13, 2013~~September 25, 2014 and effective ~~September 18, 2013~~December 22, 2014.

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

Section 21. Health Service Areas

Sec. 21. 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

APPENDIX A

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

75 F.R., p. 37245 (June 28, 2010)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget

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. These standards are requirements for the approval of the initiation, expansion, replacement, or acquisition of MRI services and the delivery of services under Part 222 of the Code. Pursuant to Part 222 of the Code, MRI is a covered clinical service. The Department shall use these standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and 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" or "MRI adjusted procedures," means the number of MRI procedures, adjusted in accordance with the applicable provisions of Section 15, 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 "MRI Service Utilization List," as of the date an application is deemed submitted by the Department.

(c) "Available MRI adjusted procedures" 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 submitted by the Department.

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).

(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 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 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" 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 21.

(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 replacement of an existing fixed MRI service to a new site 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" 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) "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.

(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 the location of the hospital authorized by license and listed on that licensee's certificate of licensure.

(y) "Magnetic resonance imaging" or "MRI" 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) "MRI adjusted procedure" means an MRI visit, at an existing MRI service, that has been adjusted in accordance with the applicable provisions of Section 15.

(aa) "MRI database" means the database, maintained by the Department pursuant to Section 14 of these standards, that collects information about each MRI visit at MRI services located in Michigan.

(bb) "MRI-guided electrophysiology intervention" or "MRI-guided EPI" means equipment specifically designed for the integrated use of MRI technology for the purposes of electrophysiology interventional procedures within a cardiac catheterization lab.

(cc) "MRI procedure" means a procedure conducted by an MRI unit approved pursuant to sections 3, 4, 5, 6, 7, or 9 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 IRB. 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 7.

(dd) "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.

(ee) "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 including FDA-approved positron emission tomography (PET)/MRI scanner hybrids if used for MRI only procedures. The term does not include MRI simulators used solely for treatment planning purposes in conjunction with a Megavoltage Radiation Therapy (MRT) unit.

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

(gg) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396 to 1396g and 1396i to 1396u.

(hh) "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.

(ii) "Ownership interest, direct or indirect" 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.

(jj) "Pediatric patient" means a patient who is 12 years of age or less, except for Section 8.

(kk) "Planning area" 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.

(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 15(2)(d), the health service area in which all the proposed mobile host sites will be located.

(ll) "Referring doctor" 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.

(mm) "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 4, or (ii) a change in the parties to the lease.

(nn) "Research scan" means an MRI scan administered under a research protocol approved by the applicant's IRB.

(oo) "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.

(pp) "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).

(qq) "Site" 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.

(rr) "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.

(ss) "Teaching facility" 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.

(tt) "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 15.

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

Section 3. Requirements to initiate an MRI service

Sec. 3. An applicant proposing to initiate an MRI service or a host site shall demonstrate the following requirements, as applicable:

(1) An applicant proposing to initiate a fixed MRI service shall demonstrate 6,000 available MRI adjusted procedures per proposed fixed MRI unit from within the same planning area as the proposed service/unit.

(2) An applicant proposing to initiate a fixed MRI service that meets the following requirements shall not be required to be in compliance with subsection (1):

(a) The applicant is currently an existing host site.

(b) The applicant has received in aggregate, one of the following:

(i) At least 6,000 MRI adjusted procedures.

(ii) At least 4,000 MRI adjusted procedures 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.

(iii) At least 3,000 MRI adjusted procedures and the applicant meets all of the following:

(A) The proposed site is a hospital licensed under Part 215 of the Code.

(B) The applicant hospital operates an emergency room that provides 24-hour emergency care services and at least 20,000 visits within the most recent 12-month period for which data, verifiable by the Department, is available.

(c) All of the MRI adjusted procedures from the mobile MRI service referenced in Section 3(2)(b) shall be utilized even if the aggregated data exceeds the minimum requirements.

(d) The applicant shall install the fixed MRI unit at the same site as the existing host site or within the relocation zone. If applying pursuant to Section 3(2)(b)(iii), the applicant shall install the fixed MRI unit at the same site as the existing host site.

(e) The applicant 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.

(3) An applicant proposing to initiate a mobile MRI service shall demonstrate 5,500 available MRI adjusted procedures from within the same planning area as the proposed service/unit, and the applicant shall meet the following:

(a) Identify the proposed route schedule and procedures for handling emergency situations.

(b) Submit copies of all proposed contracts for the proposed host site related to the mobile MRI service.

(c) Identify a minimum of two (2) host sites for the proposed service.

(4) An applicant, whether the central service coordinator or the host site, proposing to initiate a host site on a new or existing mobile MRI service shall demonstrate the following, as applicable:
(a) 600 available MRI adjusted procedures, from within the same planning area as the proposed service/unit, for a proposed host site that is not located in a rural or micropolitan statistical area county, or
(b) 400 available MRI adjusted procedures from within the same planning area for a proposed host site that is located in a rural or micropolitan statistical area county, and
(c) The proposed host site 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.

(5) An applicant proposing to add or change service on an existing mobile MRI service that meets the following requirements shall not be required to be in compliance with subsection (4):
(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) Submit copies of all proposed contracts for the proposed host site related to the mobile MRI service.

(6) The applicant shall demonstrate that the available MRI adjusted procedures from the "Available MRI Adjusted Procedures List" or the adjusted procedures from the "MRI Service Utilization List," as applicable, are from the most recently published MRI lists as of the date an application is deemed submitted by the Department.

Section 4. Requirements to replace an existing MRI unit

Sec. 4. Replace an existing MRI unit means (i) any equipment change involving a change in, or replacement of, the entire MRI unit 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 that involves a capital expenditure of $750,000 or more in any consecutive 24-month period or (iii) the renewal of a lease. Replacement also means the relocation of an MRI service or unit to a new site. The term does not include the replacement of components of the MRI system, including the magnet, under an existing service contract or required maintenance to maintain the system to operate within manufacturer specifications. The term does not include an upgrade to an existing MRI unit or repair 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) have been met.

(1) "Upgrade an existing MRI unit" means any equipment change that
(i) does not involve a change in, or replacement of, the entire MRI unit, 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 related to the MRI equipment of less than $750,000 in any consecutive 24-month period.

(2) “Repair an existing MRI unit” means restoring the ability of the system to operate within the manufacturer’s specifications by replacing or repairing the existing components or parts of the system, including the magnet, pursuant to the terms of an existing maintenance agreement that does not result in a change in the strength of the MRI unit.

(3) An applicant proposing to replace an existing MRI unit shall demonstrate the following requirements, as applicable:
(a) An applicant shall demonstrate that the applicable MRI adjusted procedures are from the most recently published MRI Service Utilization List as of the date an application is deemed submitted by the Department. An applicant proposing to replace an existing MRI unit that is below 1 tesla with an MRI unit

that is a 1 tesla or higher, shall be exempt once, as of September 18, 2013, from the minimum volume requirements for replacement:

(i) Each existing mobile MRI unit on the network has performed at least an average of 5,500 MRI adjusted procedures per MRI unit.

(ii) Each existing fixed MRI unit at the current site has performed at least an average of 6,000 MRI adjusted procedures per MRI unit unless the applicant demonstrates compliance with one of the following:

(A) The existing fixed MRI unit initiated pursuant to Section 3(2)(b)(ii) has performed at least 4,000 MRI adjusted procedures and is the only fixed MRI unit at the current site.

(B) The existing fixed MRI unit initiated pursuant to Section 3(2)(b)(iii) has performed at least 3,000 MRI adjusted procedures and is the only fixed MRI unit at the current site.

(iii) Each existing dedicated pediatric MRI unit at the current site has performed at least an average of 3,500 MRI adjusted procedures per MRI unit.

(b) 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.

(c) The replacement unit shall be located at the same site.

(d) 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.

(4) An applicant proposing to replace an existing mobile MRI host site to a new location shall demonstrate the following:

(a) The applicant currently operates the MRI mobile host site to be relocated.

(b) The MRI mobile host site to be relocated has been in operation for at least 36 months as of the date an application is submitted to the Department.

(c) The proposed new site is within a 5-mile radius of the existing site for a metropolitan statistical area county or within a 10-mile radius for a rural or micropolitan statistical area county.

(d) The mobile MRI host site to be relocated performed at least the applicable minimum number of MRI adjusted procedures set forth in Section 14 based on the most recently published MRI Service Utilization List as of the date an application is deemed submitted by the Department.

(e) The relocation will not involve a change in the current central service coordinator unless the requirements of Section 3(5) are met.

(5) An applicant proposing to replace an existing fixed MRI service and its unit(s) to a new site shall demonstrate the following:

(a) The existing MRI service and its unit(s) to be replaced 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 is within a 10-mile radius of the existing site.

(c) Each existing MRI unit to be relocated performed at least the applicable minimum number of MRI adjusted procedures set forth in Section 14 based on the most recently published MRI Service Utilization List as of the date an application is deemed submitted by the Department.

(6) An applicant proposing to replace a fixed MRI unit of an existing MRI service to a new site shall demonstrate the following:

(a) The applicant currently operates the MRI service from which the unit will be relocated.

(b) 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.

(c) The proposed new site is within a 10-mile radius of the existing site.

(d) 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 14 based on the most recently published MRI Service Utilization List as of the date an application is deemed submitted by the Department.

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

Section 5. Requirements to expand an existing MRI service

Sec. 5. An applicant proposing to expand an existing MRI service shall demonstrate the following:

(1) An applicant shall demonstrate that the applicable MRI adjustable procedures are from the most recently published MRI Service Utilization List as of the date of an application is deemed submitted by the Department:

(a) Each existing MRI unit on the network has performed at least an average of 9,000 MRI adjusted procedures per MRI unit.

(b) Each existing fixed MRI unit at the current site has performed at least an average of 11,000 MRI adjusted procedures per MRI unit.

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

(2) The additional fixed unit shall be located at the same site unless the requirements of the replacement section have been met.

Section 6. Requirements to acquire an existing MRI service or an existing MRI unit(s)

Sec. 6. ~~(1)~~ An applicant proposing to acquire an existing fixed or mobile MRI service and its unit(s) shall demonstrate the following:

(~~a~~1) ~~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~~ THE APPLICANT shall not be required to be in compliance with the volume requirements applicable to a seller/lessor on the date the acquisition occurs IF THE PROPOSED PROJECT MEETS ONE OF THE FOLLOWING:

(a) ~~For~~IT IS the first application proposing to acquire ~~an~~THE existing fixed or mobile MRI service AND ITS UNIT(S) on or after July 1, 1997~~, the existing MRI service and its unit(s) to be acquired~~.

(b) THE EXISTING FIXED OR MOBILE MRI SERVICE IS OWNED BY, IS UNDER COMMON CONTROL OF, OR HAS A COMMON PARENT AS THE APPLICANT, AND THE MRI SERVICE AND ITS UNIT(S) SHALL REMAIN AT THE SAME SITE. ~~The MRI service shall be operating at the applicable volume requirements set forth in Section 14 of these standards in the second 12 months after the effective date of the acquisition, and annually thereafter.~~

(~~b~~2) For any application proposing to acquire an existing fixed or mobile MRI service and its unit(s), except ~~the first~~AN application approved pursuant to subsection (~~a~~1), 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 14 of these standards applicable to an existing MRI service on the date the application is submitted to the Department.

(~~2~~3) 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 4(6), unless the applicant demonstrates that the project is in compliance with the requirements of the initiation or expansion Section, 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 the replacement section have been met.

(4) The MRI service AND ITS UNIT(S) shall be operating at the applicable volume requirements set forth in Section 14 of these standards in the second 12 months after the effective date of the acquisition, and annually thereafter.

Section 7. Requirements to establish a dedicated research MRI unit

Sec. 7. An applicant proposing an MRI unit to be used exclusively for research shall demonstrate the following:

(1) The applicant agrees that the dedicated research MRI unit will be used primarily (70% or more of the procedures) for research purposes only.

(2) Submit copies of documentation demonstrating that 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.

(3) Submit copies of documentation demonstrating that the MRI unit shall operate under a protocol approved by the applicant's IRB.

(4) An applicant meeting the requirements of this section shall be exempt from meeting the requirements of sections to initiate and replace.

Section 8. Requirements to establish a dedicated pediatric MRI unit

Sec. 8. An applicant proposing to establish dedicated pediatric MRI shall demonstrate all of the following:

(1) The applicant shall have experienced at least 7,000 pediatric (< 18 years old) discharges (excluding normal newborns) in the most recent year of operation.

(2) The applicant shall have performed at least 5,000 pediatric (< 18 years old) surgeries in the most recent year of operation.

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

(a) pediatric radiology (at least two)
(b) pediatric anesthesiology
(c) pediatric cardiology
(d) pediatric critical care
(e) pediatric gastroenterology
(f) pediatric hematology/oncology
(g) pediatric neurology
(h) pediatric neurosurgery
(i) pediatric orthopedic surgery
(j) pediatric pathology
(k) pediatric pulmonology
(l) pediatric surgery
(m) neonatology

(4) The applicant shall have in operation the following pediatric specialty programs:

(a) pediatric bone marrow transplant program
(b) established pediatric sedation program
(c) pediatric open heart program

(5) An applicant meeting the requirements of this section shall be exempt from meeting the requirements of Section 5 of these standards.

Section 9. Requirements for all applicants proposing to initiate, replace, or acquire a hospital based IMRI

Sec. 9. An applicant proposing to initiate, replace, or acquire a hospital based IMRI service shall demonstrate each of the following, as applicable to the proposed project.

(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 has achieved 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 or a room adjoining an operating room allowing for transfer of the patient between the operating room and this adjoining 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.

Section 10. Requirements for all applicants proposing to initiate, replace, or acquire a hospital based MRI-guided EPI service

Sec. 10. An applicant proposing to initiate, replace, or acquire a hospital based MRI-guided EPI service shall demonstrate each of the following, as applicable to the proposed project.

(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 therapeutic cardiac catheterization service and is meeting its minimum volume requirements pursuant to the CON review standards for cardiac catheterization services and open heart surgery services.

(4) The proposed MRI-guided EPI unit must be located in a cardiac catheterization lab containing a flouroscopy unit with an adjoining room containing an MRI scanner. The rooms shall contain a patient transfer system allowing for transfer of the patient between the cardiac catheterization lab and the MRI unit, utilizing one of the following:

(a) moving the patient to the MRI scanner, or

(b) installing the MRI scanner on a sliding gantry to allow the patient to remain stationary.

(5) Non-cardiac MRI diagnostic studies shall not be performed in an MRI-guided EPI 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 as follows:

(i) is in need of general anesthesia or deep sedation as defined by the American Society of Anesthesiologists, or

(ii) has an implantable cardiac device.

(6) The approved MRI-guided EPI unit shall not be subject to MRI volume requirements.

(7) The applicant shall not utilize the procedures performed on the MRI-guided EPI unit to demonstrate need or to satisfy MRI CON review standards requirements.

Section 11. Requirements for all applicants proposing to initiate, replace, or acquire an MRI simulator that will not be used solely for MRT treatment planning purposes

Sec. 11. MRI simulation is the use of MRI to help simulate (or plan) a patient's MRT treatment and to incorporate superior delineation of soft tissues for MRT treatment plans. An applicant proposing to initiate, replace, or acquire an MRI simulator shall demonstrate each of the following, as applicable to the proposed project.

(1) 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.

(2) The proposed site has an existing and operational MRT service and is meeting its minimum volume requirements pursuant to the CON review standards for MRT services/units.

(3) MRI diagnostic studies shall not be performed using an MRI simulator 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.

(4) The approved MRI simulator will not be subject to MRI volume requirements.

(5) The applicant shall not utilize the procedures performed on the MRI simulator to demonstrate need or to satisfy MRI CON review standards requirements.

Section 12. Requirements for approval of an FDA-approved PET/MRI scanner hybrid for initiation, expansion, replacement, and acquisition

Sec. 12. An applicant proposing to initiate, expand, replace, or acquire an FDA-approved PET/MRI scanner hybrid shall demonstrate that it meets all of the following:

(1) There is an approved PET CON for the FDA-approved PET/MRI hybrid, and the FDA-approved PET/MRI scanner hybrid is in compliance with all applicable project delivery requirements as set forth in the CON review standards for PET.

(2) The applicant agrees to operate the FDA-approved PET/MRI scanner hybrid in accordance with all applicable project delivery requirements set forth in Section 14 of these standards.

(3) The approved FDA-approved PET/MRI scanner hybrid shall not be subject to MRI volume requirements.

(4) An FDA-approved PET/MRI scanner hybrid approved under the CON review standards for PET scanner services and the review standards for MRI scanner services may not utilize MRI procedures performed on an FDA-approved PET/MRI scanner hybrid to demonstrate need or to satisfy MRI CON review standards requirements.

Section 13. Requirements for all applicants

Sec. 13. 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 14. Project delivery requirements – terms of approval

Sec. 14. An applicant shall agree that, if approved, MRI services, whether fixed or mobile, shall be delivered and maintained in compliance with the following:

(1) Compliance with these standards.

(2) Compliance with the following quality assurance standards:

(a) 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.

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

(c) 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:

(i) 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.

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

(iii) An MRI physicist/engineer available as a team member on a full-time, part-time, or contractual basis.

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

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

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

(B) 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 (1), (2), or (3):

(1) 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.

(2) 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.

(3) 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.

(C) 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.

(D) The physician complies with the "American College of Radiology (ACR) Practice Guideline for Performing and Interpreting Magnetic Resonance Imaging (MRI)."

(ii) 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.

(iii) 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) 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.

(3) Compliance with the following access to care requirements:

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

(a) provide MRI 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.

(c) 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 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).

(4) Compliance with the following monitoring and reporting requirements:

(a) MRI units shall be operating at a minimum average annual utilization during the second 12 months of operation, and annually thereafter, as applicable:

(i) 6,000 MRI adjusted procedures per unit for fixed MRI services unless compliant with (1) or (2),

(A) 4,000 MRI adjusted procedures for the fixed MRI unit initiated pursuant to Section 3(2)(b)(ii) and is the only fixed MRI unit at the current site,

(B) 3,000 MRI adjusted procedures for the fixed MRI unit initiated pursuant to Section 3(2)(b)(iii) and is the only fixed MRI unit at the hospital site licensed under part 215 of the code,

(ii) 5,500 MRI adjusted procedures per unit for mobile MRI services.
(iii) 3,500 MRI adjusted procedures per unit for dedicated pediatric MRI units.
(iv) 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.
(v) 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 7 or for an IMRI unit approved pursuant to Section 9.

(b) 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, operating 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. The Department may elect to verify the data through on-site review of appropriate records. Data for an MRI unit approved pursuant to Section 7, Section 8, Section 9, Section 10, or Section 11 shall be reported separately.
For purposes of Section 9, 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. For purposes of Section 10, the data reported shall include, at a minimum, how often the MRI-guided EPI unit is used and for what type of services, i.e., electrophysiology or diagnostic. For purposes of Section 11, the data reported shall include, at a minimum, how often the MRI simulator is used and for what type of services, i.e., treatment plans or diagnostic services.
(c) 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.
(d) 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.

(5) An applicant for an MRI unit approved under Section 7 shall agree that the services provided by the MRI unit are delivered in compliance with the following terms.
(a) The capital and operating costs relating to the research use of the MRI unit shall be charged only to a specific research account(s) and not to any patient or third-party payor.
(b) The MRI unit shall not be used for any purposes other than as approved by the IRB unless the applicant has obtained CON approval for the MRI unit pursuant to Part 222 and these standards, other than Section 7.
(c) The dedicated research MRI unit will be used primarily (70% or more of the procedures) for research purposes only.

(6) The dedicated pediatric MRI unit approved under Section 8 shall include at least 80% of the MRI procedures that are performed on patients under 18 years of age.

(7) 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 15. MRI procedure adjustments

Sec. 15. (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. For functional MRI (fMRI) procedures, MRI-guided interventions, and cardiac MRI procedures, the base value is 2.0.

(i) fMRI means brain activation studies.

(ii) MRI-guided interventions means any invasive procedure performed requiring MRI guidance performed in the MRI scanner.

(iii) Cardiac MRI Procedure means dedicated MRI performed of the heart done for the sole purpose of evaluation of cardiac function, physiology, or viability.

(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 16. Documentation of actual utilization

Sec. 16. 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 "MRI Service Utilization List" as of the date an application is deemed submitted 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 17. The Department may elect to verify the data through on-site review of appropriate records.

Section 17. Methodology for computing the number of available MRI adjusted procedures

Sec. 17. (1) The number of available MRI adjusted procedures required pursuant to Section 3 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 submitted 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 15.

(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 7 and dedicated pediatric MRI approved pursuant to Section 8 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(2)(c), 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 5(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 (c)(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 (c)(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 (c)(iv) above, sum the available adjusted procedures.

(vi) For the doctors used in subsection (c)(v) above, divide the total number of available adjusted procedures identified in (c)(ii)(B) above by the sum of those available adjusted procedures produced in (c)(v) above.

(vii) For only those doctors identified in (c)(v) above, multiply the result of (c)(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(2).

Section 18. Procedures and requirements for commitments of available MRI adjusted procedures

Sec. 18. (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 for each doctor committing available MRI adjusted procedures to that application for a new MRI unit that requires doctor commitments.

(b) An applicant also shall submit, at the time the application is submitted to 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 submitted on the first applicable designated application date after all required documentation is received by the Department.

(3) The Department shall consider a signed and dated data commitment on a form provided by the Department in response to the applicant’s letter of intent 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 17, is being committed and specifies the CON application number for the MRI unit 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 ownership interest, either direct or indirect, in the applicant entity. Indirect ownership includes ownership in an entity that has ownership interest in the applicant entity. This requirement shall not apply if the applicant entity is a group practice of which the committing doctor is a member. Group practice 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.

(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, 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, 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, the Department shall,

(a) if the applications were submitted 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 submitted 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 submitted on different designated application dates, consider the data commitment in the application submitted on the earliest designated application date and shall notify, simultaneously in writing, all applicants of applications submitted 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) submitted 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 submitted 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 submitted only to the extent necessary to replace the data commitments not being considered pursuant to subsection (5).

(a) The applicant shall have 30 days to submit replacement of doctor commitments as identified by the Department in this Section.

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

(a) on or after the date an application is deemed submitted by the Department.

(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 19. Lists published by the Department

Sec. 19. (1) 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, research, or dedicated pediatric.

(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 17(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 17(1)(c)(v), and if any are committed to an MRI service. This number shall be calculated in accordance with the requirements of Section 17(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 14, the Department shall indicate on both lists that the MRI service is in violation of the requirements set forth in Section 14, and no data will be shown for that service on either list.

Section 20. Effect on prior CON Review Standards; Comparative reviews

Sec. 20. (1) These CON review standards supersede and replace the CON Review Standards for MRI Services approved by the CON Commission on ~~June 13, 2013~~SEPTEMBER 25, 2014 and effective ~~September 18, 2013~~DECEMBER 22, 2014.

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

Section 21. Health Service Areas

Sec. 21. 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

APPENDIX A

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

75 F.R., p. 37245 (June 28, 2010)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget

Nursing Home Bed Need (Base Year-2013; Planning Year-2018)

Planning Area	Total Proj Days	ADC	Adj Fac	Adj ADC	AdjADC (ceiling) [New Bede Need]	Current Bed Need	Difference in Bed Need	Current CON Bed Inventory	Unmet Bed Need
Alcona	26552.85	72.748	0.9	80.831	**81**	91	(10)	78	3
Alger	17287.59	47.363	0.9	52.626	**53**	58	(5)	106	(53)
Allegan	144705.15	396.452	0.95	417.318	**418**	449	(31)	539	(121)
Alpena	51067.35	139.911	0.95	147.274	**148**	168	(20)	185	(37)
Antrim	41490.20	113.672	0.95	119.655	**120**	135	(15)	133	(13)
Arenac	28302.46	77.541	0.9	86.157	**87**	95	(8)	113	(26)
Baraga	13002.89	35.624	0.9	39.583	**40**	45	(5)	59	(19)
Barry	86035.69	235.714	0.95	248.120	**249**	263	(14)	267	(18)
Bay	168174.14	460.751	0.95	485.001	**486**	545	(59)	654	(168)
Benzie	35736.84	97.909	0.9	108.788	**109**	112	(3)	117	(8)
Berrien	242136.39	663.387	0.95	698.302	**699**	786	(87)	787	(88)
Branch	61086.74	167.361	0.95	176.169	**177**	194	(17)	283	(106)
Calhoun	191739.73	525.314	0.95	552.962	**553**	621	(68)	796	(243)
Cass	80744.90	221.219	0.95	232.862	**233**	247	(14)	188	45
Charlevoix	44618.18	122.242	0.95	128.675	**129**	141	(12)	159	(30)
Cheboygan	52106.76	142.758	0.95	150.272	**151**	163	(12)	182	(31)
Chippewa	52226.83	143.087	0.95	150.618	**151**	166	(15)	165	(14)
Clare	54376.50	148.977	0.95	156.818	**157**	170	(13)	163	(6)
Clinton	106328.07	291.310	0.95	306.642	**307**	320	(13)	331	(24)
Crawford	25827.44	70.760	0.9	78.622	**79**	83	(4)	111	(32)
Delta	70705.47	193.714	0.95	203.909	**204**	228	(24)	282	(78)
Dickinson	42558.90	116.600	0.95	122.737	**123**	148	(25)	245	(122)
Eaton	163102.19	446.855	0.95	470.374	**471**	496	(25)	513	(42)
Emmet	55767.19	152.787	0.95	160.828	**161**	175	(14)	220	(59)
Genesee	586648.18	1607.255	0.95	1691.848	**1692**	1847	(155)	1915	(223)
Gladwin	48349.20	132.464	0.95	139.435	**140**	153	(13)	170	(30)
Gogebic	31359.98	85.918	0.9	95.464	**96**	107	(11)	174	(78)
Grand Traverse	139095.87	381.085	0.95	401.142	**402**	431	(29)	505	(103)
Gratiot	61678.63	168.983	0.95	177.876	**178**	200	(22)	530	(352)
Hillsdale	74405.95	203.852	0.95	214.581	**215**	232	(17)	209	6
Houghton and Keweenaw	54783.00	150.090	0.95	157.990	**158**	180	(22)	365	(207)
Huron	64408.07	176.460	0.95	185.748	**186**	214	(28)	293	(107)
Ingham	300969.33	824.574	0.95	867.972	**868**	953	(85)	1084	(216)
Ionia	73467.91	201.282	0.95	211.876	**212**	226	(14)	235	(23)
Iosco	56523.43	154.859	0.95	163.009	**164**	183	(19)	211	(47)
Iron	30610.27	83.864	0.9	93.182	**94**	109	(15)	249	(155)
Isabella	74409.14	203.861	0.95	214.590	**215**	232	(17)	300	(85)
Jackson	220624.63	604.451	0.95	636.264	**637**	706	(69)	717	(80)
Kalamazoo	333475.52	913.632	0.95	961.717	**962**	1051	(89)	1032	(70)

Nursing Home Bed Need (Base Year-2013; Planning Year-2018)

Planning Area	Total Proj Days	ADC	Adj Fac	Adj ADC	AdjADC (ceiling) [New Bede Need]	Current Bed Need	Difference in Bed Need	Current CON Bed Inventory	Unmet Bed Need
Kalkaska	26803.90	73.435	0.9	81.595	**82**	85	(3)	104	(22)
Kent	725056.92	1986.457	0.95	2091.008	**2092**	2291	(199)	2477	(385)
Lake	23220.41	63.618	0.9	70.686	**71**	76	(5)	79	(8)
Lapeer	118043.79	323.408	0.95	340.429	**341**	354	(13)	368	(27)
Leelanau	55253.30	151.379	0.95	159.346	**160**	169	(9)	188	(28)
Lenawee	142408.84	390.161	0.95	410.696	**411**	449	(38)	490	(79)
Livingston	232293.49	636.421	0.95	669.916	**670**	689	(19)	689	(19)
Luce	11235.59	30.782	0.9	34.203	**35**	38	(3)	22	13
Mackinac	19726.79	54.046	0.9	60.051	**61**	69	(8)	48	13
Macomb	1269987.16	3479.417	0.95	3662.544	**3663**	4044	(381)	4210	(547)
Manistee	45252.05	123.978	0.95	130.503	**131**	145	(14)	107	24
Marquette	103654.78	283.986	0.95	298.932	**299**	327	(28)	441	(142)
Mason	49459.85	135.506	0.95	142.638	**143**	158	(15)	169	(26)
Mecosta	61178.97	167.614	0.95	176.435	**177**	189	(12)	200	(23)
Menominee	41240.63	112.988	0.95	118.935	**119**	135	(16)	133	(14)
Midland	130083.98	356.394	0.95	375.152	**376**	409	(33)	422	(46)
Missaukee	23627.13	64.732	0.9	71.924	**72**	79	(7)	95	(23)
Monroe	211652.28	579.869	0.95	610.389	**611**	660	(49)	679	(68)
Montcalm	87030.72	238.440	0.95	250.990	**251**	273	(22)	272	(21)
Montmorency	22229.55	60.903	0.9	67.670	**68**	77	(9)	74	(6)
Muskegon	223194.64	611.492	0.95	643.676	**644**	720	(76)	792	(148)
Newaygo	72328.49	198.160	0.95	208.590	**209**	222	(13)	245	(36)
Oakland	1646138.05	4509.967	0.95	4747.334	**4748**	5235	(487)	5620	(872)
Oceana	37509.08	102.765	0.95	108.173	**109**	121	(12)	120	(11)
Ogemaw	41580.39	113.919	0.95	119.915	**120**	131	(11)	172	(52)
Ontonagon	13349.61	36.574	0.9	40.638	**41**	47	(6)	46	(5)
Osceola	36046.20	98.757	0.9	109.730	**110**	114	(4)	50	60
Oscoda	14528.93	39.805	0.9	44.228	**45**	50	(5)	62	(17)
Otsego	41504.12	113.710	0.95	119.695	**120**	129	(9)	148	(28)
Ottawa	335308.65	918.654	0.95	967.004	**968**	1035	(67)	1022	(54)
Presque Isle	32734.76	89.684	0.9	99.649	**100**	106	(6)	106	(6)
Roscommon	54063.49	148.119	0.95	155.915	**156**	176	(20)	179	(23)
Saginaw	302033.43	827.489	0.95	871.041	**872**	965	(93)	1142	(270)
Saint Clair	230191.35	630.661	0.95	663.854	**664**	729	(65)	789	(125)
Saint Joseph	86548.17	237.118	0.95	249.598	**250**	276	(26)	369	(119)
Sanilac	67134.02	183.929	0.95	193.609	**194**	218	(24)	227	(33)
Schoolcraft	17010.70	46.605	0.9	51.783	**52**	58	(6)	50	2
Shiawassee	96912.40	265.513	0.95	279.488	**280**	309	(29)	316	(36)
Tuscola	77793.35	213.132	0.95	224.350	**225**	248	(23)	256	(31)

Nursing Home Bed Need (Base Year-2013; Planning Year-2018)									
Planning Area	Total Proj Days	ADC	Adj Fac	Adj ADC	AdjADC (ceiling) [New Bede Need]	Current Bed Need	Difference in Bed Need	Current CON Bed Inventory	Unmet Bed Need
Van Buren	95587.53	261.884	0.95	275.667	**276**	301	(25)	330	(54)
Washtenaw	402002.85	1101.378	0.95	1159.345	**1160**	1217	(57)	1217	(57)
Wexford	50608.45	138.653	0.95	145.951	**146**	161	(15)	133	13
Southwest Wayne County	515830.55	1413.234	0.95	1487.615	**1488**	1663	(175)	1788	(300)
Northwest Wayne County	875045.70	2397.385	0.95	2523.564	**2524**	2839	(315)	3024	(500)
Detroit	850229.43	2329.396	0.95	2451.995	**2452**	2832	(380)	4107	(1655)
STATEWIDE	*13621144.00*	*37318.203*		*39354.288*	***39391***	43341	(3950)		

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR PSYCHIATRIC BEDS AND 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. These standards are requirements for the approval under Part 222 of the Code that involve (a) beginning operation of a new psychiatric service, (b) replacing licensed psychiatric beds or physically relocating licensed psychiatric beds from one licensed site to another geographic location, or (c) increasing licensed psychiatric beds within a psychiatric hospital or unit licensed under the Mental Health Code, 1974 PA 258, or (d) acquiring a psychiatric service pursuant to Part 222 of the Code. A psychiatric hospital or unit is a covered health facility. The Department shall use these standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and Section 22225(2)(c) of the code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

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

(3) 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.

Section 2. Definitions

Sec. 2. (1) For purposes of these standards:

(a) "Acquisition of a psychiatric hospital or unit" means the issuance of a new license as the result of the acquisition (including purchase, lease, donation, or other comparable arrangement) of an existing licensed psychiatric hospital or unit and which does not involve a change in the number of licensed psychiatric beds at that health facility.

(b) “Adult” means any individual aged 18 years or older.

(c) "Base year" means the most recent year for which verifiable data are collected by the Department and are available separately for the population age cohorts of 0 to 17 and 18 and older.

(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) "Child/adolescent" means any individual less than 18 years of age.

(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) "Community mental health board" or "board" or "CMH" means the board of a county(s) community mental health board as referenced in the provisions of MCL 330.1200 to 330.1246.

(h) "Comparative group" means the applications which have been grouped for the same type of project in the same planning area OR STATEWIDE SPECIAL POPULATION GROUP 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 planning area on a continuing basis by the Department which includes:

(i) licensed adult and child/adolescent psychiatric beds; and

(ii) adult and child/adolescent psychiatric beds approved by a valid CON, which are not yet licensed. A separate inventory will be maintained for child/adolescent beds and adult beds.

(k) "Existing adult inpatient psychiatric beds" or "existing adult beds" means:

(i) all adult beds in psychiatric hospitals or units licensed by the Department pursuant to the Mental Health Code;

(ii) all adult beds approved by a valid CON, which are not yet licensed;

(iii) proposed adult beds under appeal from a final Department decision, or pending a hearing from a proposed decision; and

(iv) proposed adult beds that are part of a completed application (other than the application or applications in the comparative group under review) which are pending final Department decision.

(l) "Existing child/adolescent inpatient psychiatric beds" or "existing child/adolescent beds" means:

(i) all child/adolescent beds in psychiatric hospitals or units licensed by the Department pursuant to the Mental Health Code;

(ii) all child/adolescent beds approved by a valid CON, which are not yet licensed;

(iii) proposed child/adolescent beds under appeal from a final Department decision, or pending a hearing from a proposed decision; and

(iv) proposed child/adolescent beds that are part of a completed application (other than the application or applications in the comparative group under review) which are pending final Department decision.

(m) "Flex bed" means an existing adult psychiatric bed converted to a child/adolescent psychiatric bed in an existing child/adolescent psychiatric service to accommodate during peak periods and meet patient demand.

(n) "Initiation of service" means the establishment of an inpatient psychiatric unit with a specified number of beds at a site not currently providing psychiatric services.

(o) "Involuntary commitment status" means a hospital admission effected pursuant to the provisions of MCL 330.1423 to 330.1429.

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

(q) "Medicaid" means title XIX of the Social Security Act, chapter 531, 49 Stat. 620, 1396 to 1396g and 1396i to 1396u.

(r) "Mental Health Code" means Act 258 of the Public Acts of 1974, as amended, being Sections 330.1001 to 330.2106 of the Michigan Compiled Laws.

(s) "Mental health professional" means an individual who is trained and experienced in the area of mental illness or developmental disabilities and who is any 1 of the following:

(i) a physician who is licensed to practice medicine or osteopathic medicine and surgery in Michigan and who has had substantial experience with mentally ill, mentally retarded, or developmentally disabled clients for 1 year immediately preceding his or her involvement with a client under administrative rules promulgated pursuant to the Mental Health Code;

(ii) a psychologist who is licensed in Michigan pursuant to the provisions of MCL 333.16101 to 333.18838;

(iii) a licensed master’s social worker licensed in Michigan Pursuant to the provisions of MCL 333.16101 to 333.18838;

(iv) a registered nurse who is licensed in Michigan pursuant to the provisions of MCL 333.16101 to 333.18838;

(v) a licensed professional counsel or licensed in Michigan pursuant to the provisions of MCL 333.16101 to 333.18838;

(vi) a marriage and family therapist licensed in Michigan pursuant to the provisions of MCL 333.16101 to 333.18838;

(vii) a professional person, other than those defined in the administrative rules promulgated pursuant to the Mental Health Code, who is designated by the Director of the Department or a director of a facility operated by the Department in written policies and procedures. This mental health professional shall have a degree in his or her profession and shall be recognized by his or her respective professional association as being trained and experienced in the field of mental health. The term does not include non-clinical staff, such as clerical, fiscal or administrative personnel.

(t) "Mental health service" means the provision of mental health care in a protective environment with mental illness or mental retardation, including, but not limited to, chemotherapy and individual and group therapies pursuant to MCL 330.2001.

(u) "Non-renewal or revocation of license" means the Department did not renew or revoked the psychiatric hospital's or unit's license based on the hospital's or unit's failure to comply with state licensing standards.

(v) "Non-renewal or termination of certification" means the psychiatric hospital's or unit's Medicare and/or Medicaid certification was terminated or not renewed based on the hospital's or unit's failure to comply with Medicare and/or Medicaid participation requirements.

(w) "Offer" means to provide inpatient psychiatric services to patients.

(x) "Physician" means an individual licensed in Michigan to engage in the practice of medicine or osteopathic medicine and surgery pursuant to MCL 333.16101 to 333.18838.

(y) "Planning area" means the geographic boundaries of the groups of counties shown in Section 17.

(z) "Planning year" means a year in the future, at least 3 years but no more than 7 years, for which inpatient psychiatric bed needs are developed. The planning year shall be a year for which official population projections from the Department of Technology, Management and Budget or its designee are available.

(aa) "Psychiatric hospital" means an inpatient program operated by the Department for the treatment of individuals with serious mental illness or serious emotional disturbance or a psychiatric hospital or psychiatric unit licensed under pursuant to MCL 330.1137.

(bb) "Psychiatrist" means 1 or more of the following, pursuant to MCL 330.1100c:

(i) a physician who has completed a residency program in psychiatry approved by the Accreditation Council for Graduate Medical Education or The American Osteopathic Association, or who has completed 12 months of psychiatric rotation and is enrolled in an approved residency program;

(ii) a psychiatrist employed by or under contract with the Department or a community health services program on March 28, 1996;

(iii) a physician who devotes a substantial portion of his or her time to the practice of psychiatry and is approved by the Director.

(cc) "Psychiatric unit" means a unit of a general hospital that provides inpatient services for individuals with serious mental illness or serious emotional disturbances pursuant to MCL 330.1100c.

(dd) "Psychologist" means an individual licensed to engage in the practice of psychology, who devotes a substantial portion of his or her time to the diagnosis and treatment of individuals with serious mental illness, serious emotional disturbance, or developmental disability, pursuant to MCL 333.16101 to 333.18838.

(ee) "Public patient" means an individual approved for mental health services by a CMH or an individual who is admitted as a patient under the Mental Health Code, Act No. 258 of the Public Acts of 1974, being Sections 330.1423, 330.1429, and 330.1438 of the Michigan Compiled Laws.

(ff) "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 and these standards.

(gg) "Registered professional nurse" or "R.N." means an individual licensed in Michigan pursuant to the provisions of MCL 333.16101 to 333.18838.

(hh) "Relocate existing licensed inpatient psychiatric beds" means a change in the location of existing inpatient psychiatric beds from the existing licensed psychiatric hospital site to a different existing licensed psychiatric hospital site within the same planning area. This definition does not apply to projects involving replacement beds in a psychiatric hospital or unit governed by Section 7 of these standards.

(ii) "Replace beds" means a change in the location of the licensed psychiatric hospital or unit, or the replacement of a portion of the licensed beds at the same licensed site. The beds will be in new physical plant space being developed in new construction or in newly acquired space (purchase, lease, donation, etc.) within the replacement zone.

(jj) "Replacement zone" means a proposed licensed site that is:

(i) in the same planning area as the existing licensed site; and

(ii) on the same site, on a contiguous site, or on a site within 15 miles of the existing licensed site.

(kk) "Social worker" means an individual registered in Michigan to engage in social work under the provisions of MCL 333.18501.

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

Section 3. Determination of needed inpatient psychiatric bed supply

Sec. 3. (1) Until changed by the Commission in accordance with Section 5, the use rate for the base year for the population age 0-17 is set forth in Appendix B.

(2) The number of child/adolescent inpatient psychiatric beds needed in a planning area shall be determined by the following formula:

(a) Determine the population for the planning year for each separate planning area for the population age 0-17.

(b) Multiply the population by the use rate established in Appendix B. The resultant figure is the total patient days.

(c) Divide the total patient days obtained in subsection (b) by 365 (or 366 for leap years) to obtain the projected average daily census (ADC).

(d) Divide the ADC by 0.75.

(e) For each planning area, all psychiatric hospitals or units with an average occupancy of 60% or less for the previous 24 months will have the ADC, for the previous 24 months, multiplied by 1.7. The net decrease from the current licensed beds will give the number to be added to the bed need.

(f) The adjusted bed need for the planning area is the sum of the results of subsections (d) and (e). round up to the nearest whole number.

(3) The number of needed adult inpatient psychiatric beds shall be determined by multiplying the population aged 18 years and older for the planning year for each planning area by either:

(a) The ratio of adult beds per 10,000 adult population set forth in Appendix A; or

(b) The statewide ratio of adult beds per 10,000 adult population set forth in Appendix A, whichever is lower; and dividing the result by 10,000. If the ratio set forth in Appendix A for a specific planning area is "0", the statewide ratio of adult beds per 10,000 adult population shall be used to determine the number of needed adult inpatient psychiatric beds.

(c) For each planning area, an addition to the bed need will be made for low occupancy facilities. All psychiatric hospitals or units with an average occupancy of 60% or less for the previous 24 months will have the ADC, for the previous 24 months, multiplied by 1.5. The net decrease from the current licensed beds will give the number to be added to the bed need.

(d) The adjusted bed need for the planning area is the sum of the results of subsections (b) and (c).

Section 4. Bed need for inpatient psychiatric beds

Sec. 4. (1) The bed need numbers determined pursuant to Section 3 shall apply to projects subject to review under these standards, except where a specific CON review standard states otherwise.

(2) The Department shall apply the bed need methodologies in Section 3 on a biennial basis.

(3) The effective date of the bed need numbers shall be established by the Commission.

(4) New bed need numbers shall supercede previous bed need numbers and shall be posted on the State of Michigan CON web site as part of the Psychiatric Bed Inventory.

(5) Modifications made by the Commission pursuant to this Section 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 5. Modification of the child/adolescent use rate by changing the base year

Sec. 5. (1) The Commission may modify the base year based on data obtained from the Department and presented to the Commission. The Department shall calculate the use rate for the population age 0-17 and biennially present the revised use rate based on the most recent base year information available biennially to the CON Commission.

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

(3) Modifications made by the Commission pursuant to subsection (1) 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 6. Requirements for approval to initiate service

Sec. 6. An applicant proposing the initiation of an adult or child/adolescent psychiatric service shall demonstrate or provide the following:

(1) The number of beds proposed in the CON application shall not result in the number of existing adult or child/adolescent psychiatric beds, as applicable, in the planning area exceeding the bed need. However, an applicant may request and be approved for up to a maximum of 10 beds if, when the total number of existing adult beds or existing child/adolescent beds is subtracted from the bed need for the planning area, the difference is equal to or more than 1 or less than 10.

(2) A written recommendation, from the Department or the CMH that serves the county in which the proposed beds or service will be located, shall include an agreement to enter into a contract to meet the needs of the public patient. At a minimum, the letter of agreement shall specify the number of beds to be allocated to the public patient and the applicant's intention to serve patients with an involuntary commitment status.

(3) The number of beds proposed in the CON application to be allocated for use by public patients shall not be less than 50% of the beds proposed in the CON application. Applications proposed in direct response to a Department plan pursuant to subsection (5) shall allocate not less than 80% of the beds proposed in the CON application.

(4) The minimum number of beds in a psychiatric unit shall be at least 10 beds. If a psychiatric unit has or proposes to operate both adult and child/adolescent beds, each unit shall have a minimum of 10 beds. The Department may approve an application for a unit of less than 10 beds, if the applicant demonstrates to the satisfaction of the Department, that travel time to existing units would significantly limit access to care.

(5) An applicant shall not be required to be in compliance with subsection (1) if the applicant demonstrates that the application meets both of the following:

(a) The Director of the Department determines that an exception to subsection (1) should be made and certifies in writing that the proposed project is a direct response to a Department plan for reducing the use of public institutions for acute mental health care through the closure of a state-owned psychiatric hospital; and

(b) The proposed beds will be located in the area currently served by the public institution that will be closed, as determined by the Department.

Section 7. Requirements for approval to replace beds

Sec. 7. An applicant proposing to replace beds shall not be required to be in compliance with the needed bed supply if the applicant demonstrates all of the following:

(1) The applicant shall specify whether the proposed project is to replace the existing licensed psychiatric hospital or unit to a new site or to replace a portion of the licensed psychiatric beds at the existing licensed site.

(2) The proposed licensed site is in the replacement zone.

(3) Not less than 50% of the beds proposed to be replaced shall be allocated for use by public patients.

(4) Previously made commitments, if any, to the Department or CMH to serve public patients have been fulfilled.

(5) Proof of current contract or documentation of contract renewal, if current contract is under negotiation, with the CMH or its designee that serves the planning area in which the proposed beds or service will be located.

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

Sec. 8. (1) The proposed project to relocate beds, under this section, shall constitute a change in bed capacity under Section 1(3) of these standards.

(2) Any existing licensed inpatient psychiatric hospital or unit may relocate all or a portion of its beds to another existing licensed inpatient psychiatric hospital or unit located within the same planning area.

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

(4) The relocated beds shall be licensed to the receiving inpatient psychiatric hospital or unit and will be counted in the inventory for the applicable planning area.

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

(6) The relocation of beds under this section shall not result in initiation of a new adult or child/adolescent service.

Section 9. Requirements for approval to increase beds

Sec. 9. An applicant proposing an increase in the number of adult or child/adolescent beds shall demonstrate or provide the following:

(1) The number of beds proposed in the CON application will not result in the number of existing adult or child/adolescent psychiatric beds, as applicable, in the planning area exceeding the bed need. However, an applicant may request and be approved for up to a maximum of 10 beds if, when the total

number of existing adult beds or existing child/adolescent beds is subtracted from the bed need for the planning area, the difference is equal to or more than 1 or less than 10.

(2) The average occupancy rate for the applicant's facility, where the proposed beds are to be located, was at least 70% for adult or child/adolescent beds, as applicable, during the most recent, consecutive 12-month period, as of the date of the submission of the application, for which verifiable data are available to the Department. For purposes of this section, average occupancy rate shall be calculated as follows:
(a) Divide the number of patient days of care provided by the total number of patient days, then multiply the result by 100.

(3) Subsections (1) and (2) shall not apply if all of the following are met:
(a) The number of existing adult or child/adolescent psychiatric beds in the planning area is equal to or exceeds the bed need.
(b) The beds are being added at the existing licensed site.
(c) The average occupancy rate for the applicant's facility was at least 75% for facilities with 19 beds or less and 80% for facilities with 20 beds or more, as applicable, during the most recent, consecutive 12-month period, as of the date of the submission of the application, for which verifiable data are available to the Department.
(i) For a facility with flex beds,
(A) calculate the average occupancy rate as follows:
(1) For adult beds:
(a) Adult bed days are the number of licensed adult beds multiplied by the number of days they were licensed during the most recent consecutive 12-month period.
(b) Flex bed days are the number of licensed flex beds multiplied by the number of days the beds were used to serve a child/ adolescent patient.
(c) Subtract the flex bed days from the adult bed days and divide the adult patient days of care by this number, then multiply the result by 100.
(2) For child/adolescent beds:
(a) Child/adolescent bed days are the number of licensed child/adolescent beds multiplied by the number of days they were licensed during the most recent 12-month period.
(b) Flex bed days are the number of licensed flex beds multiplied by the number of days the beds were used to serve a child/ adolescent patient.
(c) Add the flex bed days to the child/adolescent bed days and divide the child/adolescent patient days of care by this number, then multiply the result by 100.
(d) The number of beds to be added shall not exceed the results of the following formula:
(ii) Multiply the facility's average daily census for the most recent, consecutive 12-month period, as of the date of the submission of the application, for which verifiable data are available to the Department by 1.5 for adult beds and 1.7 for child/adolescent beds.
(iii) Subtract the number of currently licensed beds from the number calculated in (ii) above. This is the maximum number of beds that may be approved pursuant to this subsection.

(4) Proof of current contract or documentation of contract renewal, if current contract is under negotiation, with at least one CMH or its designee that serves the planning area in which the proposed beds or service will be located.

(5) Previously made commitments, if any, to the Department or CMH to serve public patients have been fulfilled.

(6) The number of beds proposed in the CON application to be allocated for use by public patients shall not be less than 50% of the beds proposed in the CON application. Applications proposed in direct response to a Department plan pursuant to subsection (9) shall allocate not less than 80% of the beds proposed in the CON application.

(7) The minimum number of beds in a psychiatric unit shall be at least 10 beds. If a psychiatric unit has or proposes to operate both adult and child/adolescent beds, then each unit shall have a minimum of 10 beds. The Department may approve an application for a unit of less than 10 beds, if the applicant demonstrates, to the satisfaction of the Department, that travel time to existing units would significantly impair access to care.

(8) Subsection (2) shall not apply if the Director of the Department has certified in writing that the proposed project is a direct response to a Department plan for reducing the use of public institutions for acute mental health care through the closure of a state-owned psychiatric hospital.

(9) An applicant shall not be required to be in compliance with subsection (1) if the applicant demonstrates that the application meets both of the following:

(a) The Director of the Department determines that an exception to subsection (1) should be made and certifies in writing that the proposed project is a direct response to a Department plan for reducing the use of public institutions for acute mental health care through the closure of a state-owned psychiatric hospital; and

(b) The proposed beds will be located in the area currently served by the public institution that will be closed as determined by the Department.

(10) An applicant proposing to add new adult and/or child/adolescent psychiatric beds, as the receiving licensed inpatient psychiatric hospital or unit 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 bed need 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 inpatient psychiatric beds shall not result in an increase in the number of licensed inpatient psychiatric beds in the planning area.

(b) The applicant meets the requirements of subsections (4), (5), (6), and (7) above.

(c) The proposed project to add new adult and/or child adolescent psychiatric beds, under this subsection, shall constitute a change in bed capacity under Section 1(2) of these standards.

(d) Applicants proposing to add new adult and/or child/adolescent psychiatric beds under this subsection shall not be subject to comparative review.

Section 10. Requirements for approval for flex beds

Sec. 10. An applicant proposing flex beds shall demonstrate the following as applicable to the proposed project:

(1) The applicant has existing adult psychiatric beds and existing child/adolescent psychiatric beds.

(2) The number of flex beds proposed in the CON application shall not result in the existing adult psychiatric unit to become non-compliant with the minimum size requirements within Section 6(4).

(3) The applicant shall meet all applicable sections of the standards.

(4) The facility shall be in compliance and meet all design standards of the most recent Minimum Design Standards for Health Care Facilities in Michigan.

(5) The applicant shall convert the beds back to adult inpatient psychiatric beds if the bed has not been used as a flex bed serving a child/adolescent patient for a continuous 12-month period or if the CON application is withdrawn.

Section 11. Requirements for approval for acquisition of a psychiatric hospital or unit

Sec. 11. An applicant proposing to acquire a psychiatric hospital or unit shall not be required to be in compliance with the needed bed supply, for the planning area in which the psychiatric hospital or unit subject to the proposed acquisition is located, if the applicant demonstrates that all of the following are met:

(1) The acquisition will not result in a change in the number of licensed beds or beds designated for a child/adolescent specialized psychiatric program.

(2) The licensed site does not change as a result of the acquisition.

Section 12. Additional requirements for applications included in comparative review

Sec. 12. (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 ~~applicable to comparative review~~.

(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, 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 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.

(3)(a) A qualifying project application will be awarded 5 points if, within six months of beginning operation and annually thereafter, 100% of the licensed psychiatric beds (both existing and proposed) at the facility will be Medicaid certified.

(b) A qualifying project will have 4 points deducted if, on or after November 26, 1995, the records maintained by the Department document that the applicant was required to enter into a contract with either the Department or a CMH to serve the public patient and did not do so.

(c) A qualifying project will have 5 points deducted if, on or after November 26, 1995, the records maintained by the Department document that the applicant entered into a contract with MDCH or CMH but never admitted any public patients referred pursuant to that contract.

(d) A qualifying project will have 5 points deducted if, on or after November 26, 1995, the records maintained by the Department document that an applicant agreed to serve patients with an involuntary commitment status but has not admitted any patients referred with an involuntary commitment status.

(e) A qualifying project will be awarded 3 points if the applicant presents, in its application, a plan, acceptable to the Department, for the treatment of patients requiring long-term treatment. For purposes of this subsection, long-term treatment is defined to mean an inpatient length of stay in excess of 45 days.

(f) A qualifying project will be awarded 3 points if the applicant currently provides a partial hospitalization psychiatric program, outpatient psychiatric services, or psychiatric aftercare services, or the applicant includes any of these services as part of their proposed project, as demonstrated by site plans and service contracts.

(g) A qualifying project will have 4 points deducted if the Department has issued, within three years prior to the date on which the CON application was deemed submitted, a temporary permit or provisional

license due to a pattern of licensure deficiencies at any psychiatric hospital or unit owned or operated by the applicant in this state.

(h) A qualifying project will have points awarded based on the percentage of the hospital's indigent volume as set forth in the following table.

Hospital Indigent Volume	Points Awarded
0 - <6%	1
6 - <11%	2
11 - <16%	3
16 - <21%	4
21 - <26%	5
26 - <31%	6
31 - <36%	7
36 - <41%	8
41 - <46%	9
46% +	10

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 Department pursuant to Chapter VIII of the Medical Assistance Program 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.

(i) A qualifying project will have points deducted based on the applicant's record of compliance with applicable safety and operating standards for any psychiatric hospital or unit owned and/or operated by the applicant in this state. Points shall be deducted in accordance with the following schedule if, on or after November 26, 1995, the Department records document any non-renewal or revocation of license for cause or non-renewal or termination of certification for cause of any psychiatric hospital or unit owned or operated by the applicant in this state.

Psychiatric Hospital/Unit Compliance Action	Points Deducted
Non-renewal or revocation of license	4
Non-renewal or termination of:	
Certification - Medicare	4
Certification - Medicaid	4

(4) Submission of conflicting information in this section may result in a lower point award. If an application contains conflicting information which could result in a different point value being awarded in this section, the Department will award points based on the lower point value that could be awarded from the conflicting information. For example, if submitted information would result in 6 points being awarded, but other conflicting information would result in 12 points being awarded, then 6 points will be awarded. If the conflicting information does not affect the point value, the Department will award points accordingly. For example, if submitted information would result in 12 points being awarded and other conflicting information would also result in 12 points being awarded, then 12 points will be awarded.

Section 13. Requirements for approval -- all applicants

Sec. 13. (1) 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.

(2) The applicant certifies all outstanding debt obligations owed to the State of Michigan for Quality Assurance Assessment Program (QAAP) or Civil Monetary Penalties (CMP) have been paid in full.

(3) The applicant certifies that the health facility for the proposed project has not been cited for a state or federal code deficiency within the 12 months prior to the submission of the application. If a code deficiency has been issued, then the applicant shall certify that a plan of correction for cited state or federal code deficiencies at the health facility has been submitted and approved by the Bureau of Health Systems within the Department or, as applicable, the Centers for Medicare and Medicaid Services. If code deficiencies include any unresolved deficiencies still outstanding with the Department or the Centers for Medicare and Medicaid Services that are the basis for the denial, suspension, or revocation of an applicant's health facility license, poses an immediate jeopardy to the health and safety of patients, or meets a federal conditional deficiency level, the proposed project cannot be approved without approval from the Bureau of Health Systems.

Section 14. Project delivery requirements - terms of approval for all applicants

Sec. 14. An applicant shall agree that, if approved, the project shall be delivered in compliance with the following terms of CON approval:

(1) Compliance with these standards.

(2) Compliance with the following applicable quality assurance standards:

(a) The proposed licensed psychiatric beds shall be operated in a manner that is appropriate for a population with the ethnic, socioeconomic, and demographic characteristics including the developmental stage of the population to be served.

(b) The applicant shall establish procedures to care for patients who are disruptive, combative, or suicidal and for those awaiting commitment hearings, and the applicant shall establish a procedure for obtaining physician certification necessary to seek an order for involuntary treatment for those persons that, in the judgment of the professional staff, meet the Mental Health Code criteria for involuntary treatment.

(c) The applicant shall develop a standard procedure for determining, at the time the patient first presents himself or herself for admission or within 24 hours after admission, whether an alternative to inpatient psychiatric treatment is appropriate.

(d) The inpatient psychiatric hospital or unit shall provide clinical, administrative, and support services that will be at a level sufficient to accommodate patient needs and volume, and will be provided seven days a week to assure continuity of services and the capacity to deal with emergency admissions.

(3) Compliance with the following access to care requirements:

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

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

(i) not deny acute inpatient mental health services to any individual based on ability to pay, source of payment, age, race, handicap, national origin, religion, gender, sexual orientation or commitment status;

(ii) provide acute inpatient mental health services to any individual based on clinical indications of need for the services; and

(iii) 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.

(4) Compliance with the following monitoring and reporting requirements:

(a) The average occupancy rate for all licensed beds at the psychiatric hospital or unit shall be at least 60 percent (%) for adult beds and 40 percent (%) for child/adolescent beds for the second 12 months of operation, and annually thereafter.

(i) Calculate average occupancy rate for adult beds as follows:

(A) Add the number of adult patient days of care to the number of child/adolescent patient days of care provided in the flex beds; divide this number by the adult bed days, then multiply the result by 100.

(ii) Calculate average occupancy rate for child/adolescent beds as follows:

(A) Subtract the number of child/adolescent patient days of care provided in the flex beds from the number of child adolescent patient days of care; divide this number by the child/adolescent bed days, then multiply the result by 100.

(b) Flex beds approved under section 10 shall be counted as existing adult inpatient psychiatric beds. (c) After the second 12 months of operation, if the average occupancy rate is below 60% for adult beds or 40% for child/adolescent beds, the number of beds shall be reduced to achieve a minimum of 60% average annual occupancy for adult beds or 40% annual average occupancy for child/adolescent beds for the revised licensed bed complement. However, the psychiatric hospital or unit shall not be reduced to less than 10 beds.

(d) 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, 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.

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

(f) An applicant required to enter into a contract with a CMH(s) or the Department pursuant to these standards shall have in place, at the time the approved beds or services become operational, a signed contract to serve the public patient. The contract must address a single entry and exit system including discharge planning for each public patient. The contract shall specify that at least 50% or 80% of the approved beds, as required by the applicable sections of these standards, shall be allocated to the public patient, and shall specify the hospital's or unit's willingness to admit patients with an involuntary commitment status. The contract need not be funded.

(5) Compliance with this Section shall be determined by the Department based on a report submitted by the applicant and/or other information available to the Department.

(6) NOTHING IN THIS SECTION PROHIBITS THE DEPARTMENT FROM TAKING COMPLIANCE ACTION UNDER MCL 333.22247.

(~~6~~7) 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 15. Project delivery requirements - additional terms of approval for child/adolescent service

Sec. 15. (1) In addition to the provisions of Section ~~12~~14, an applicant for a child/adolescent service shall agree to operate the program in compliance with the following terms of CON approval, as applicable:

(a) There shall be at least the following child and adolescent mental health professionals employed, either directly or by contract, by the hospital or unit, each of whom must have been involved in the delivery of child/adolescent mental health services for at least 2 years within the most recent 5 years:

(i) a child/adolescent psychiatrist;

(ii) a child psychologist;

(iii) a psychiatric nurse;

(iv) a psychiatric social worker;

(v) an occupational therapist or recreational therapist; and

(b) There shall be a recipient rights officer employed by the hospital or the program.

(c) The applicant shall identify a staff member(s) whose assigned responsibilities include discharge planning and liaison activities with the home school district(s).

(d) There shall be the following minimum staff employed either on a full time basis or ACCESS TO on a consulting basis AS NEEDED:

(i) a pediatrician;

(ii) a child neurologist;

(iii) a neuropsychologist;

(iv) a speech and language therapist;

(v) an audiologist; and

(vi) a dietician.

(e) A child/adolescent service shall have the capability to determine that each inpatient admission is the appropriate treatment alternative consistent with Section 498e of the Mental Health Code, being Section 330.1498e of the Michigan Compiled Laws.

(f) The child/adolescent service shall develop and maintain a coordinated relationship with the home school district of any patient to ensure that all public education requirements are met.

(g) The applicant shall demonstrate that the child/adolescent service is integrated within the continuum of mental health services available in its planning area by establishing a formal agreement with the CMH(s) serving the planning area in which the child/adolescent specialized psychiatric program is located. The agreement shall address admission and discharge planning issues which include, at a minimum, specific procedures for referrals for appropriate community services and for the exchange of information with the CMH(s), the probate court(s), the home school district, the Michigan Department of Human Services, the parent(s) or legal guardian(s) and/or the patient's attending physician.

(2) Compliance with this Section shall be determined by the Department based on a report submitted by the program and/or other information available to the Department.

(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.

Section 16. Department inventory of beds

Sec. 16. The Department shall maintain, and provide on request, a listing of the Department Inventory of Beds for each adult and child/adolescent planning area.

Section 17. Planning areas

Sec. 17. The planning areas for inpatient psychiatric beds are the geographic boundaries of the groups of counties as follows.

Planning Areas	Counties
1	Livingston, Macomb, Monroe, Oakland, St. Clair, Washtenaw, Wayne
2	Clinton, Eaton, Hillsdale, Ingham, Jackson, Lenawee
3	Barry, Berrien, Branch, Calhoun, Cass, Kalamazoo, St. Joseph, Van Buren
4	Allegan, Ionia, Kent, Lake, Mason, Montcalm, Muskegon, Newaygo, Oceana, Ottawa
5	Genesee, Lapeer, Shiawassee
6	Arenac, Bay, Clare, Gladwin, Gratiot, Huron, Iosco, Isabella, Midland, Mecosta, Ogemaw, Osceola, Oscoda, Saginaw, Sanilac, Tuscola
7	Alcona, Alpena, Antrim, Benzie, Charlevoix, Cheboygan, Crawford, Emmet, Grand Traverse, Kalkaska, Leelanau, Manistee, Missaukee, Montmorency, Otsego, Presque Isle, Roscommon, Wexford
8	Alger, Baraga, Chippewa, Delta, Dickinson, Gogebic, Houghton, Iron, Keweenaw, Luce, Mackinac, Marquette, Menominee, Ontonagon, Schoolcraft

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

Sec. 18. (1) These CON review standards supercede and replace the CON Review Standards for Psychiatric Beds and Services, approved by the CON Commission on ~~September 10~~DECEMBER 13, ~~2009~~ 2012 and effective on ~~November 5~~MARCH 22, ~~2009~~2013.

(2) Projects involving replacement beds, relocation of beds, flex beds under Section 10, or an increase in beds, approved pursuant to Section 7(3), are reviewed under these standards and shall not be subject to comparative review.

(3) Projects involving initiation of services or an increase in beds, approved pursuant to Section ~~7~~6(1), are reviewed under these standards and shall be subject to comparative review.

APPENDIX A

RATIO OF ADULT INPATIENT PSYCHIATRIC BEDS PER 10,000 ADULT POPULATION

The ratio per 10,000 adult population, for purposes of these standards, EFFECTIVE APRIL 1, 2015, AND until otherwise changed by the Commission, is as follows:

PLANNING AREA	ADULT BEDS PER 10,000 ADULT POPULATION
1	3.09143~~3.0808~~
2	2.40602~~2.4282~~
3	2.44460~~2.4604~~
4	2.39174~~2.5284~~
5	3.07912~~3.0698~~
6	1.75052~~1.5558~~
7	0.83839~~1.2570~~
8	2.26654~~2.2756~~
STATE	2.64279~~2.6633~~

APPENDIX B

CON REVIEW STANDARDS
FOR CHILD/ADOLESCENT INPATIENT PSYCHIATRIC BEDS

The use rate per 1000 population age 0-17, for purposes of these standards, EFFECTIVE APRIL 1, 2015, AND until otherwise changed by the Commission, is ~~22.8146~~25.664.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CON REVIEW STANDARDS
FOR PSYCHIATRIC BEDS AND SERVICES
--ADDENDUM FOR SPECIAL POPULATION GROUPS

(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; DEFINITIONS

SEC. 1. (1) THIS ADDENDUM SUPPLEMENTS THE CON REVIEW STANDARDS FOR PSYCHIATRIC BEDS AND SERVICES AND SHALL BE USED FOR DETERMINING THE NEED FOR PROJECTS ESTABLISHED TO BETTER MEET THE NEEDS OF SPECIAL POPULATION GROUPS WITHIN THE MENTAL HEALTH POPULATIONS.

(2) EXCEPT AS PROVIDED IN SECTIONS 2, 3, 4, 5, 6, AND 7 OF THIS ADDENDUM, THESE STANDARDS SUPPLEMENT, AND DO NOT SUPERSEDE, THE REQUIREMENTS AND TERMS OF APPROVAL REQUIRED BY THE CON REVIEW STANDARDS FOR PSYCHIATRIC BEDS AND SERVICES.

(3) THE DEFINITIONS WHICH APPLY TO THE CON REVIEW STANDARDS FOR PSYCHIATRIC BEDS AND SERVICES SHALL APPLY TO THESE STANDARDS.

(4) FOR PURPOSES OF THIS ADDENDUM, THE FOLLOWING TERMS ARE DEFINED:
(a) "DEVELOPMENTAL DISABILITY UNIT" MEANS A UNIT DESIGNED FOR PSYCHIATRIC PATIENTS (ADULT OR CHILD/ADOLESCENT AS APPLICABLE) WHO HAVE BEEN DIAGNOSED WITH A SEVERE, CHRONIC DISABILITY AS OUTLINED IN SECTION 102, 42 USC 15002, OF THE DEVELOPMENTAL DISABILITIES ASSISTANCE AND BILL OF RIGHTS ACT OF 2000 (DD ACT) AND ITS UPDATE OR FUTURE GUIDELINE CHANGES.
(b) "GERIATRIC PSYCHIATRIC UNIT" MEANS A UNIT DESIGNED FOR PSYCHIATRIC PATIENTS AGED 65 AND OVER.
(c) "MEDICAL PSYCHIATRIC UNIT" MEANS A UNIT DESIGNED FOR PSYCHIATRIC PATIENTS (ADULT OR CHILD/ADOLESCENT AS APPLICABLE) WHO HAVE ALSO BEEN DIAGNOSED WITH A MEDICAL ILLNESS REQUIRING HOSPITILIZATION, E.G., PATIENTS WHO MAY BE ON DIALYSIS, REQUIRE WOUND CARE OR NEED INTRAVENOUS OR TUBE FEEDING.

SECTION 2. REQUIREMENTS FOR APPROVAL -- APPLICANTS PROPOSING TO INCREASE PSYCHIATRIC BEDS -- SPECIAL USE EXCEPTIONS

SEC. 2. A PROJECT TO INCREASE PSYCHIATRIC BEDS IN A PLANNING AREA WHICH, IF APPROVED, WOULD OTHERWISE CAUSE THE TOTAL NUMBER OF PSYCHIATRIC BEDS IN THAT PLANNING AREA TO EXCEED THE NEEDED PSYCHIATRIC BED SUPPLY OR CAUSE AN INCREASE IN AN EXISTING EXCESS AS DETERMINED UNDER THE APPLICABLE CON REVIEW STANDARDS FOR PSYCHIATRIC BEDS AND SERVICES, MAY NEVERTHELESS BE APPROVED PURSUANT TO THIS ADDENDUM.

SECTION 3. STATEWIDE POOL FOR THE NEEDS OF SPECIAL POPULATION GROUPS WITHIN THE MENTAL HEALTH POPULATIONS

SEC. 3. (1) A STATEWIDE POOL OF ADDITIONAL PSYCHIATRIC BEDS CONSISTS OF 170 BEDS NEEDED IN THE STATE IS ESTABLISHED TO BETTER MEET THE NEEDS OF SPECIAL POPULATION GROUPS WITHIN THE MENTAL HEALTH POPULATIONS. THE NUMBER OF BEDS IN THE POOL IS BASED ON TWO PERCENT OF THE STATEWIDE BED NEED FOR PSYCHIATRIC INPATIENT BEDS ROUNDED UP TO THE NEXT TEN. BEDS IN THE POOL SHALL BE DISTRIBUTED AS FOLLOWS AND SHALL BE REDUCED IN ACCORDANCE WITH SUBSECTION (2):

(a) DEVELOPMENTAL DISABILITY BEDS WILL BE ALLOCATED 50 ADULT BEDS AND 10 CHILD/ADOLESCENT BEDS.

(b) GERIATRIC PSYCHIATRIC BEDS WILL BE ALLOCATED 50 ADULT BEDS.

(c) MEDICAL PSYCHIATRIC BEDS WILL BE ALLOCATED 50 ADULT BEDS AND 10 CHILD/ADOLESCENT BEDS.

(2) BY SETTING ASIDE THESE BEDS FROM THE TOTAL STATEWIDE POOL, THE COMMISSION'S ACTION APPLIES ONLY TO APPLICANTS SEEKING APPROVAL OF PSYCHIATRIC BEDS PURSUANT TO SECTIONS 4, 5, AND 6. IT DOES NOT PRECLUDE THE CARE OF THESE PATIENTS IN UNITS OF HOSPITALS, PSYCHIATRIC HOSPITALS, OR OTHER HEALTH CARE SETTINGS IN COMPLIANCE WITH APPLICABLE STATUTORY OR CERTIFICATION REQUIREMENTS.

(3) INCREASES IN PSYCHIATRIC BEDS APPROVED UNDER THIS ADDENDUM FOR SPECIAL POPULATION GROUPS SHALL NOT CAUSE PLANNING AREAS CURRENTLY SHOWING AN UNMET BED NEED TO HAVE THAT NEED REDUCED OR PLANNING AREAS SHOWING A CURRENT SURPLUS OF BEDS TO HAVE THAT SURPLUS INCREASED.

(4) THE COMMISSION MAY ADJUST THE NUMBER OF BEDS AVAILABLE IN THE STATEWIDE POOL FOR THE NEEDS OF SPECIAL POPULATION GROUPS WITHIN THE MENTAL HEALTH POPULATIONS CONCURRENT WITH THE BIENNIAL RECALCUATION OF THE STATEWIDE PSYCHIATRIC INPATIENT BED NEED. MODIFYING THE NUMBER OF BEDS AVAILABLE IN THE STATEWIDE POOL FOR THE NEEDS OF SPECIAL POPULATION GROUPS WITHIN THE MENTAL HEALTH POPULATIONS PURSUANT TO THIS SECTION SHALL NOT REQURE A PUBLIC HEARING OR SUBMITTAL OF THE STANDARD TO THE LEGISLATURE AND THE GOVERNOR IN ORDER TO BECOME EFFECTIVE.

SECTION 4. REQUIREMENTS FOR APPROVAL FOR BEDS FROM THE STATEWIDE POOL FOR SPECIAL POPULATION GROUPS ALLOCATED TO DEVELOPMENTAL DISABILITY PATIENTS

SEC. 4. THE CON COMMISSION DETERMINES THERE IS A NEED FOR BEDS FOR APPLICATIONS DESIGNED TO DETERMINE THE EFFICIENCY AND EFFECTIVENESS OF SPECIALIZED PROGRAMS FOR THE CARE AND TREATMENT OF DEVELOPMENTAL DISABILITY PATIENTS AS COMPARED TO SERVING THESE NEEDS IN GENERAL PSYCHIATRIC UNIT(S).

(1) AN APPLICANT PROPOSING TO ADD BEDS TO AN EXISTING ADULT OR CHILD/ADOLESCENT PSYCHIATRIC SERVICE UNDER THIS SECTION SHALL DEMONSTRATE WITH CREDIBLE DOCUMENTATION TO THE SATISFACTION OF THE DEPARTMENT EACH OF THE FOLLOWING:

(a) THE APPLICANT SHALL SUBMIT EVIDENCE OF ACCREDITATION AS FOLLOWS:

(i) DOCUMENTATION OF ITS EXISTING DEVELOPMENTAL DISABILITY PROGRAM BY THE NATIONAL ASSOCIATION FOR THE DUALLY DIAGNOSED (NADD) OR ANOTHER NATIONALLY-RECOGNIZED ACCREDITATION ORGANIZATION FOR DEVELOPMENTAL DISABILITY CARE AND SERVICES; OR

(ii) WITHIN 24-MONTHS OF ACCEPTING ITS FIRST PATIENT, THE APPLICANT SHALL OBTAIN NADD OR ANOTHER NATIONALLY-RECOGNIZED ACCREDITATION ORGANIZATION FOR THE DEVELOPMENTAL DISABILITY BEDS PROPOSED UNDER THIS SUBSECTION.

(b) THE APPLICANT PROPOSES PROGRAMS TO PROMOTE A CULTURE WITHIN THE FACILITY THAT IS APPROPRIATE FOR DEVELOPMENTAL DISABILITY PATIENTS.
(c) STAFF WILL BE SPECIALLY TRAINED IN TREATMENT OF DEVELOPMENTAL DISABILITY PATIENTS.
(d) THE PROPOSED BEDS WILL SERVE ONLY DEVELOPMENTAL DISABILITY PATIENTS.

(2) ALL BEDS APPROVED PURSUANT TO THIS SUBSECTION SHALL BE CERTIFIED FOR MEDICAID.

SECTION 5. REQUIREMENTS FOR APPROVAL FOR BEDS FROM THE STATEWIDE POOL FOR SPECIAL POPULATION GROUPS ALLOCATED TO GERIATRIC PSYCHIATRIC PATIENTS

SEC. 5. THE CON COMMISSION DETERMINES THERE IS A NEED FOR BEDS FOR APPLICATIONS DESIGNED TO DETERMINE THE EFFICIENCY AND EFFECTIVENESS OF SPECIALIZED PROGRAMS FOR THE CARE AND TREATMENT OF GERIATRIC PSYCHIATRIC PATIENTS AS COMPARED TO SERVING THESE NEEDS IN GENERAL PSYCHIATRIC UNIT(S).

(1) AN APPLICANT PROPOSING TO ADD BEDS TO AN EXISTING ADULT PSYCHIATRIC SERVICE UNDER THIS SECTION SHALL DEMONSTRATE WITH CREDIBLE DOCUMENTATION TO THE SATISFACTION OF THE DEPARTMENT EACH OF THE FOLLOWING:
(a) THE APPLICANT SHALL SUBMIT EVIDENCE OF ACCREDITATION AS FOLLOWS:
(i) DOCUMENTATION OF ITS EXISTING GERIATRIC PSYCHIATRIC PROGRAM BY THE COMMISSION ON ACCREDITATION OF REHABILITATION FACILITIES (CARF) OR ANOTHER NATIONALLY-RECOGNIZED ACCREDITATION ORGANIZATION FOR GERIATRIC PSYCHIATRIC CARE AND SERVICES; OR
(ii) WITHIN 24-MONTHS OF ACCEPTING ITS FIRST PATIENT, THE APPLICANT SHALL OBTAIN CARF OR ANOTHER NATIONALLY-RECOGNIZED ACCREDITATION ORGANIZATION FOR THE GERIATRIC PSYCHIATRIC BEDS PROPOSED UNDER THIS SUBSECTION.
(b) THE APPLICANT PROPOSES PROGRAMS TO PROMOTE A CULTURE WITHIN THE FACILITY THAT IS APPROPRIATE FOR GERIATRIC PSYCHIATRIC PATIENTS.
(c) STAFF WILL BE SPECIALLY TRAINED IN TREATMENT OF GERIATRIC PSYCHIATRIC PATIENTS.
(d) THE PROPOSED BEDS WILL SERVE ONLY GERIATRIC PSYCHIATRIC PATIENTS.

(2) ALL BEDS APPROVED PURSUANT TO THIS SUBSECTION SHALL BE DUALLY CERTIFIED FOR MEDICARE AND MEDICAID.

SECTION 6. REQUIREMENTS FOR APPROVAL FOR BEDS FROM THE STATEWIDE POOL FOR SPECIAL POPULATION GROUPS ALLOCATED TO MEDICAL PSYCHIATRIC PATIENTS

SEC. 6. THE CON COMMISSION DETERMINES THERE IS A NEED FOR BEDS FOR APPLICATIONS DESIGNED TO DETERMINE THE EFFICIENCY AND EFFECTIVENESS OF SPECIALIZED PROGRAMS FOR THE CARE AND TREATMENT OF MEDICAL PSYCHIATRIC PATIENTS AS COMPARED TO SERVING THESE NEEDS IN GENERAL PSYCHIATRIC UNIT(S).

(1) AN APPLICANT PROPOSING TO ADD BEDS TO AN EXISTING ADULT OR CHILD/ADOLESCENT PSYCHIATRIC SERVICE UNDER THIS SECTION SHALL DEMONSTRATE WITH CREDIBLE DOCUMENTATION TO THE SATISFACTION OF THE DEPARTMENT EACH OF THE FOLLOWING:
(a) THE BEDS WILL BE OPERATED AS PART OF A SPECIALIZED PROGRAM EXCLUSIVELY FOR ADULT OR CHILD/ADOLESCENT MEDICAL PSYCHIATRIC PATIENTS, AS APPLICABLE, WITHIN A LICENSED HOSPITAL LICENSED UNDER PART 215 OF THE CODE.
(b) THE APPLICANT SHALL SUBMIT EVIDENCE OF ACCREDITATION AS FOLLOWS:

(i) DOCUMENTATION OF ITS EXISTING MEDICAL PSYCHIATRIC PROGRAM BY CARF OR ANOTHER NATIONALLY-RECOGNIZED ACCREDITATION ORGANIZATION FOR MEDICAL PSYCHIATRIC CARE AND SERVICES; OR

(ii) WITHIN 24-MONTHS OF ACCEPTING ITS FIRST PATIENT, THE APPLICANT SHALL OBTAIN CARF OR ANOTHER NATIONALLY-RECOGNIZED ACCREDITATION ORGANIZATION FOR THE MEDICAL PSYCHIATRIC BEDS PROPOSED UNDER THIS SUBSECTION.

(c) THE APPLICANT PROPOSES PROGRAMS TO PROMOTE A CULTURE WITHIN THE FACILITY THAT IS APPROPRIATE FOR MEDICAL PSYCHIATRIC PATIENTS.

(d) STAFF WILL BE SPECIALLY TRAINED IN TREATMENT OF MEDICAL PSYCHIATRIC PATIENTS.

(e) THE PROPOSED BEDS WILL SERVE ONLY MEDICAL PSYCHIATRIC PATIENTS.

(2) ALL BEDS APPROVED PURSUANT TO THIS SUBSECTION SHALL BE CERTIFIED FOR MEDICAID.

SECTION 7. ACQUISITION OF PSYCHIATRIC BEDS APPROVED PURSUANT TO THIS ADDENDUM

SEC. 7. (1) AN APPLICANT PROPOSING TO ACQUIRE PSYCHIATRIC BEDS FROM THE STATEWIDE POOL FOR SPECIAL POPULATION GROUPS ALLOCATED TO DEVELOPMENTAL DISABILITY SHALL MEET THE FOLLOWING:

(a) THE APPLICANT SHALL SUBMIT EVIDENCE OF ACCREDITATION OF THE EXISTING DEVELOPMENTAL DISABILITY PROGRAM BY THE NATIONAL ASSOCIATION FOR THE DUALLY DIAGNOSED (NADD) OR ANOTHER NATIONALLY-RECOGNIZED ACCREDITATION ORGANIZATION FOR DEVELOPMENTAL DISABILITY CARE AND SERVICES.

(b) WITHIN 24-MONTHS OF ACCEPTING ITS FIRST PATIENT, THE APPLICANT SHALL OBTAIN NADD OR ANOTHER NATIONALLY-RECOGNIZED ACCREDITATION ORGANIZATION FOR THE DEVELOPMENTAL DISABILITY BEDS PROPOSED UNDER THIS SUBSECTION.

(c) THE APPLICANT PROPOSES PROGRAMS TO PROMOTE A CULTURE WITHIN THE FACILITY THAT IS APPROPRIATE FOR DEVELOPMENTAL DISABILITY PATIENTS.

(d) STAFF WILL BE SPECIALLY TRAINED IN TREATMENT OF DEVELOPMENTAL DISABILITY PATIENTS.

(e) THE PROPOSED BEDS WILL SERVE ONLY DEVELOPMENTAL DISABILITY PATIENTS.

(f) ALL BEDS APPROVED PURSUANT TO THIS SUBSECTION SHALL BE CERTIFIED FOR MEDICAID.

(2) AN APPLICANT PROPOSING TO ACQUIRE PSYCHIATRIC BEDS FROM THE STATEWIDE POOL FOR SPECIAL POPULATION GROUPS ALLOCATED TO GERIATRIC PSYCHIATRIC SHALL MEET THE FOLLOWING:

(a) THE APPLICANT SHALL SUBMIT EVIDENCE OF ACCREDITATION OF THE EXISTING GERIATRIC PSYCHIATRIC PROGRAM BY CARF OR ANOTHER NATIONALLY-RECOGNIZED ACCREDITATION ORGANIZATION FOR GERIATRIC PSYCHIATRIC CARE AND SERVICES.

(b) WITHIN 24-MONTHS OF ACCEPTING ITS FIRST PATIENT, THE APPLICANT SHALL OBTAIN CARF OR ANOTHER NATIONALLY-RECOGNIZED ACCREDITATION ORGANIZATION FOR THE GERIATRIC PSYCHIATRIC BEDS PROPOSED UNDER THIS SUBSECTION.

(c) THE APPLICANT PROPOSES PROGRAMS TO PROMOTE A CULTURE WITHIN THE FACILITY THAT IS APPROPRIATE FOR GERIATRIC PSYCHIATRIC PATIENTS.

(d) STAFF WILL BE SPECIALLY TRAINED IN TREATMENT OF GERIATRIC PSYCHIATRIC PATIENTS.

(e) THE PROPOSED BEDS WILL SERVE ONLY GERIATRIC PSYCHIATRIC PATIENTS.

(f) ALL BEDS APPROVED PURSUANT TO THIS SUBSECTION SHALL BE DUALLY CERTIFIED FOR MEDICARE AND MEDICAID.

(3) AN APPLICANT PROPOSING TO ACQUIRE PSYCHIATRIC BEDS FROM THE STATEWIDE POOL FOR SPECIAL POPULATION GROUPS ALLOCATED TO MEDICAL PSYCHIATRIC SHALL MEET THE FOLLOWING:

(a) THE APPLICANT SHALL SUBMIT EVIDENCE OF ACCREDITATION OF THE EXISTING MEDICAL PSYCHIATRIC PROGRAM BY CARF OR ANOTHER NATIONALLY-RECOGNIZED ACCREDITATION ORGANIZATION FOR MEDICAL PSYCHIATRIC CARE AND SERVICES.

(b) WITHIN 24-MONTHS OF ACCEPTING ITS FIRST PATIENT, THE APPLICANT SHALL OBTAIN CARF OR ANOTHER NATIONALLY-RECOGNIZED ACCREDITATION ORGANIZATION FOR THE MEDICAL PSYCHIATRIC BEDS PROPOSED UNDER THIS SUBSECTION.

(c) THE APPLICANT PROPOSES PROGRAMS TO PROMOTE A CULTURE WITHIN THE FACILITY THAT IS APPROPRIATE FOR MEDICAL PSYCHIATRIC PATIENTS.

(d) STAFF WILL BE SPECIALLY TRAINED IN TREATMENT OF MEDICAL PSYCHIATRIC PATIENTS.

(e) THE PROPOSED BEDS WILL SERVE ONLY MEDICAL PSYCHIATRIC PATIENTS.

(f) ALL BEDS APPROVED PURSUANT TO THIS SUBSECTION SHALL BE CERTIFIED FOR MEDICAID.

SECTION 8. PROJECT DELIVERY REQUIREMENTS -- TERMS OF APPROVAL FOR ALL APPLICANTS SEEKING APPROVAL UNDER SECTION 3(1) OF THIS ADDENDUM

SEC. 8. (1) AN APPLICANT SHALL AGREE THAT IF APPROVED, THE SERVICES SHALL BE DELIVERED IN COMPLIANCE WITH THE TERMS OF APPROVAL REQUIRED BY THE CON REVIEW STANDARDS FOR PSYCHIATRIC BEDS AND SERVICES.

(2) AN APPLICANT FOR BEDS FROM THE STATEWIDE POOL FOR SPECIAL POPULATION GROUPS ALLOCATED TO DEVELOPMENTAL DISABILITY PATIENTS SHALL AGREE THAT, IF APPROVED, ALL BEDS APPROVED PURSUANT TO THAT SUBSECTION SHALL BE OPERATED IN ACCORDANCE WITH THE FOLLOWING TERMS OF CON APPROVAL:

(a) THE APPLICANT SHALL DOCUMENT, AT THE END OF THE THIRD YEAR FOLLOWING INITIATION OF BEDS APPROVED AN ANNUAL AVERAGE OCCUPANCY RATE OF 80 PERCENT OR MORE. IF THIS OCCUPANCY RATE HAS NOT BEEN MET, THE APPLICANT SHALL REDUCE BEDS TO A NUMBER OF BEDS NECESSARY TO RESULT IN A 80 PERCENT AVERAGE ANNUAL OCCUPANCY FOR THE THIRD FULL YEAR OF OPERATION AND ANNUALLY THEREAFTER. THE NUMBER OF BEDS REDUCED SHALL REVERT TO THE TOTAL STATEWIDE POOL ESTABLISHED FOR DEVELOPMENTAL DISABILITY BEDS.

(b) AN APPLICANT SHALL STAFF THE PROPOSED UNIT FOR DEVELOPMENTAL DISABILITY PATIENTS WITH EMPLOYEES THAT HAVE BEEN TRAINED IN THE CARE AND TREATMENT OF SUCH INDIVIDUALS.

(c) AN APPLICANT SHALL MAINTAIN NADD CERTIFICATION OR ANOTHER NATIONALLY-RECOGNIZED ACCREDITATION ORGANIZATION FOR DEVELOPMENTAL DISABILITY CARE AND SERVICES.

(d) AN APPLICANT SHALL ESTABLISH AND MAINTAIN WRITTEN POLICIES AND PROCEDURES FOR EACH OF THE FOLLOWING:

(i) PATIENT ADMISSION CRITERIA THAT DESCRIBE MINIMUM AND MAXIMUM CHARACTERISTICS FOR PATIENTS APPROPRIATE FOR ADMISSION TO THE DEVELOPMENTAL DISABILITY UNIT.

(ii) THE TRANSFER OF PATIENTS REQUIRING CARE AT OTHER HEALTH CARE FACILITIES.

(iii) UPON ADMISSION AND PERIODICALLY THEREAFTER, A COMPREHENSIVE NEEDS ASSESSMENT, A TREATMENT PLAN, AND A DISCHARGE PLAN THAT AT A MINIMUM ADDRESSES THE CARE NEEDS OF A PATIENT FOLLOWING DISCHARGE.

(e) THE SPECIALIZED PROGRAM SHALL BE ATTACHED OR GEOGRAPHICALLY ADJACENT TO A LICENSED PSYCHIATRIC SERVICE THAT IS MEETING VOLUME REQUIREMENTS OUTLINED IN SECTION 14 OF THE CON REVIEW STANDARDS FOR PSYCHIATRIC BEDS AND SERVICES.

(f) THE DEVELOPMENTAL DISABILITY UNIT SHALL HAVE A DAY/DINING AREA WITHIN, OR IMMEDIATELY ADJACENT TO, THE UNIT(S), WHICH IS SOLELY FOR THE USE OF DEVELOPMENTAL DISABILITY PATIENTS.

(g) THE DEVELOPMENTAL DISABILITY UNIT SHALL HAVE DIRECT ACCESS TO A SECURE OUTDOOR OR INDOOR AREA AT THE FACILITY APPROPRIATE FOR SUPERVISED ACTIVITY.

(h) THE APPLICANT SHALL MAINTAIN PROGRAMS TO PROMOTE A CULTURE WITHIN THE FACILITY THAT IS APPROPRIATE FOR DEVELOPMENTAL DISABILITY PATIENTS.

(3) AN APPLICANT FOR BEDS FROM THE STATEWIDE POOL FOR SPECIAL POPULATION GROUPS ALLOCATED TO GERIATRIC PSYCHIATRIC PATIENTS SHALL AGREE THAT IF APPROVED, ALL BEDS APPROVED PURSUANT TO THAT SUBSECTION SHALL BE OPERATED IN ACCORDANCE WITH THE FOLLOWING TERMS OF CON APPROVAL:

(a) THE APPLICANT SHALL DOCUMENT, AT THE END OF THE THIRD YEAR FOLLOWING INITIATION OF BEDS APPROVED AN ANNUAL AVERAGE OCCUPANCY RATE OF 80 PERCENT OR MORE. IF THIS OCCUPANCY RATE HAS NOT BEEN MET, THE APPLICANT SHALL REDUCE BEDS TO A NUMBER OF BEDS NECESSARY TO RESULT IN A 80 PERCENT AVERAGE ANNUAL OCCUPANCY FOR THE THIRD FULL YEAR OF OPERATION AND ANNUALLY THEREAFTER. THE NUMBER OF BEDS REDUCED SHALL REVERT TO THE TOTAL STATEWIDE POOL ESTABLISHED FOR GERIATRIC PSYCHIATRIC BEDS.

(b) AN APPLICANT SHALL STAFF THE PROPOSED UNIT FOR GERIATRIC PSYCHIATRIC PATIENTS WITH EMPLOYEES THAT HAVE BEEN TRAINED IN THE CARE AND TREATMENT OF SUCH INDIVIDUALS.

(c) AN APPLICANT SHALL MAINTAIN CARF CERTIFICATION OR ANOTHER NATIONALLY-RECOGNIZED ACCREDITATION ORGANIZATION FOR GERIATRIC PSYCHIATRIC CARE AND SERVICES.

(d) AN APPLICANT SHALL ESTABLISH AND MAINTAIN WRITTEN POLICIES AND PROCEDURES FOR EACH OF THE FOLLOWING:

(i) PATIENT ADMISSION CRITERIA THAT DESCRIBE MINIMUM AND MAXIMUM CHARACTERISTICS FOR PATIENTS APPROPRIATE FOR ADMISSION TO THE GERIATRIC PSYCHIATRIC UNIT.

(ii) THE TRANSFER OF PATIENTS REQUIRING CARE AT OTHER HEALTH CARE FACILITIES.

(iii) UPON ADMISSION AND PERIODICALLY THEREAFTER, A COMPREHENSIVE NEEDS ASSESSMENT, A TREATMENT PLAN, AND A DISCHARGE PLAN THAT AT A MINIMUM ADDRESSES THE CARE NEEDS OF A PATIENT FOLLOWING DISCHARGE.

(e) THE SPECIALIZED PROGRAM SHALL BE ATTACHED OR GEOGRAPHICALLY ADJACENT TO A LICENSED PSYCHIATRIC SERVICE THAT IS MEETING VOLUME REQUIREMENTS OUTLINED IN SECTION 14 OF THE CON REVIEW STANDARDS FOR PSYCHIATRIC BEDS AND SERVICES.

(f) THE GERIATRIC PSYCHIATRIC UNIT SHALL HAVE A DAY/DINING AREA WITHIN, OR IMMEDIATELY ADJACENT TO, THE UNIT(S), WHICH IS SOLELY FOR THE USE OF GERIATRIC PSYCHIATRIC PATIENTS.

(g) THE GERIATRIC PSYCHIATRIC UNIT SHALL HAVE DIRECT ACCESS TO A SECURE OUTDOOR OR INDOOR AREA AT THE FACILITY APPROPRIATE FOR SUPERVISED ACTIVITY.

(h) THE APPLICANT SHALL MAINTAIN PROGRAMS TO PROMOTE A CULTURE WITHIN THE FACILITY THAT IS APPROPRIATE FOR GERIATRIC PSYCHIATRIC PATIENTS.

(4) AN APPLICANT FOR BEDS FROM THE STATEWIDE POOL FOR SPECIAL POPULATION GROUPS ALLOCATED TO MEDICAL PSYCHIATRIC PATIENTS SHALL AGREE THAT, IF APPROVED, ALL BEDS APPROVED PURSUANT TO THAT SUBSECTION SHALL BE OPERATED IN ACCORDANCE WITH THE FOLLOWING CON TERMS OF APPROVAL.

(a) THE APPLICANT SHALL DOCUMENT, AT THE END OF THE THIRD YEAR FOLLOWING INITIATION OF BEDS APPROVED AN ANNUAL AVERAGE OCCUPANCY RATE OF 80 PERCENT OR MORE. IF THIS OCCUPANCY RATE HAS NOT BEEN MET, THE APPLICANT SHALL REDUCE BEDS TO A NUMBER OF BEDS NECESSARY TO RESULT IN A 80 PERCENT AVERAGE ANNUAL

OCCUPANCY FOR THE THIRD FULL YEAR OF OPERATION AND ANNUALLY THEREAFTER. THE NUMBER OF BEDS REDUCED SHALL REVERT TO THE TOTAL STATEWIDE POOL ESTABLISHED FOR MEDICAL PSYCHIATRIC BEDS.

(b) AN APPLICANT SHALL STAFF THE PROPOSED UNIT FOR MEDICAL PSYCHIATRIC PATIENTS WITH EMPLOYEES THAT HAVE BEEN TRAINED IN THE CARE AND TREATMENT OF SUCH INDIVIDUALS.

(c) AN APPLICANT SHALL MAINTAIN CARF CERTIFICATION OR ANOTHER NATIONALLY-RECOGNIZED ACCREDITATION ORGANIZATION FOR MEDICAL PSYCHIATRIC CARE AND SERVICES.

(d) AN APPLICANT SHALL ESTABLISH AND MAINTAIN WRITTEN POLICIES AND PROCEDURES FOR EACH OF THE FOLLOWING:

(i) PATIENT ADMISSION CRITERIA THAT DESCRIBE MINIMUM AND MAXIMUM CHARACTERISTICS FOR PATIENTS APPROPRIATE FOR ADMISSION TO THE MEDICAL PSYCHIATRIC UNIT.

(ii) THE TRANSFER OF PATIENTS REQUIRING CARE AT OTHER HEALTH CARE FACILITIES.

(iii) UPON ADMISSION AND PERIODICALLY THEREAFTER, A COMPREHENSIVE NEEDS ASSESSMENT, A TREATMENT PLAN, AND A DISCHARGE PLAN THAT AT A MINIMUM ADDRESSES THE CARE NEEDS OF A PATIENT FOLLOWING DISCHARGE.

(e) THE SPECIALIZED PROGRAM SHALL BE ATTACHED OR GEOGRAPHICALLY ADJACENT TO A LICENSED PSYCHIATRIC SERVICE THAT IS MEETING VOLUME REQUIREMENTS OUTLINED IN SECTION 14 OF THE CON REVIEW STANDARDS FOR PSYCHIATRIC BEDS AND SERVICES.

(f) THE MEDICAL PSYCHIATRIC UNIT SHALL HAVE A DAY/DINING AREA WITHIN, OR IMMEDIATELY ADJACENT TO, THE UNIT(S), WHICH IS SOLELY FOR THE USE OF MEDICAL PSYCHIATRIC PATIENTS.

(g) THE MEDICAL PSYCHIATRIC UNIT SHALL HAVE DIRECT ACCESS TO A SECURE OUTDOOR OR INDOOR AREA AT THE FACILITY APPROPRIATE FOR SUPERVISED ACTIVITY.

(h) THE APPLICANT SHALL MAINTAIN PROGRAMS TO PROMOTE A CULTURE WITHIN THE FACILITY THAT IS APPROPRIATE FOR MEDICAL PSYCHIATRIC PATIENTS.

SECTION 9. COMPARATIVE REVIEWS, EFFECT ON PRIOR CON REVIEW STANDARDS

SEC. 9. (1) PROJECTS PROPOSED UNDER SECTION 4 SHALL BE CONSIDERED A DISTINCT CATEGORY AND SHALL BE SUBJECT TO COMPARATIVE REVIEW ON A STATEWIDE BASIS.

(2) PROJECTS PROPOSED UNDER SECTION 5 SHALL BE CONSIDERED A DISTINCT CATEGORY AND SHALL BE SUBJECT TO COMPARATIVE REVIEW ON A STATEWIDE BASIS.

(3) PROJECTS PROPOSED UNDER SECTION 6 SHALL BE CONSIDERED A DISTINCT CATEGORY AND SHALL BE SUBJECT TO COMPARATIVE REVIEW ON A STATEWIDE BASIS.

March 8, 2016

Since my last communication of November 18, 2015, the Bone Marrow Standards Advisory Committee has met three times. At the December meeting, building on the discussion from the previous SAC, the members reviewed and discussed various articles from the literature including Dr. Delamater's "Geographic Access to Bone Marrow Transplant Services" and three articles on Chimeric Antigen Receptor T Cells which some experts believe will supplant or obviate BM transplants for many oncological indications. Charge 4 was reviewed in detail and members voiced their opinion on trends in CON regulation and consistency of that with the regulation of other covered clinical services. Some members offered their willingness to research and present other states CON regulation of Bone Marrow Transplants if they could be found. The committee then discussed Charge 5 and the grids that the MDHHS had developed to evaluate the effect of continued CON regulation of BM transplants on cost, quality, and access and to begin thinking about information to include in these charts. Public comment was received from two persons. Charges 1 and 2 were deferred till the next meeting

At the January meeting Charges 1 and 2 were discussed. Committee members were asked to formulate their views on cost, quality, and access and to present these views in the form of "bullet comments" which were then populated into the appropriate fields of the MDHHS-developed grids. Thereafter, votes were taken on these charges. Charge 1 received an affirmative vote of 10-2 to continue to regulate Autologous BM transplants. Charge 2 received an affirmative vote of 10-2 to continue to regulate Allogeneic BM transplants. Charge 3 was discussed and members were asked to think about and propose an objective methodology for determining the appropriate number of BM transplant services in Michigan. One member had reviewed 5 other states methodology for CON regulation of BMT services but could find no objective description of their methodology. Public comment was received from one person.

At the February meeting, Beaumont presented a "BMT Needs Methodology" that would allow a new institution to begin providing BM transplant services based on its institutional-specific tumor registries demonstrating a sufficient volume of malignancies calculated to progress and then require BMT services. The new institution could also use tumor registry volume from other hospitals that would "commit" to send their patients requiring BM transplants to the new applicant. Current CON requires at least 30 transplants per year and so any new institution desirous of becoming a BMT services provider would have to prove that volume from both its own and "committed" referral institutions. Discussion ensued on this methodology and then the committee referred this to Dr. Delamater for his evaluation of the impact of this proposed methodology. Thereafter the committee discussed and populated the grid for charge 3, again making their comments in bullet fashion, to address how maintaining a cap on BMT services impacts cost, quality, and access in Michigan. The chair then informed the committee that he would like the committee to reflect on the three constructed grids from both the previous and current meeting and vote as to whether they were in agreement or not with the "bulleted comments" in the grids. The Department will send these completed grids with instructions on how to vote before the next meeting. The Department will provide a tally at the March meeting. There was no public comment.

CERTIFICATE OF NEED

1st Quarter Compliance Report to the CON Commission

October 1, 2015 through September 30, 2016 (FY 2016)

This report is to update the Commission on Department activities to monitor compliance of all Certificates of Need recipients as required by Section 22247 of the Public Health Code.

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 for services 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 tracks approved Certificates of Need to determine if proposed projects have been implemented in accordance with Part 222. By rule, applicants are required to either implement a project within one year of approval or execute an enforceable contract to purchase the covered equipment or start construction, as applicable. In addition, an applicant must install the equipment or start construction within two years of approval.

Activity	1st Quarter	Year-to-Date
Approved projects requiring 1-year follow up	72	72
Approved projects contacted on or before anniversary date	48	48
Approved projects completed on or before 1-year follow up	67%	
CON approvals expired	11	11
Total follow up correspondence sent	195	195
Total approved projects still ongoing	359	

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, or if other applicable requirements have been met, in accordance with Part 222 of the Code.

- After a statewide review of Open Heart Surgery data based on the 2013 Annual Survey, the Department opened five additional compliance investigations of Open Heart Surgery programs not meeting the approved volume requirement. The Department has investigated and conducted meetings with all five hospitals and determined proposed compliance actions. The settlement proposals have been offered to all five hospitals with open compliance investigations. The Department has finalized settlement agreements with three hospitals and has worked to finalize settlement agreements with the two remaining hospitals.

- After a statewide review of Air Ambulance Services data based on the 2013 Annual Survey, the Department opened one compliance investigation for an Air Ambulance service to verify the service was meeting the approved project delivery requirements. The investigation is still open.

- After a statewide review of Urinary Extracorporeal Shock Wave Lithotripsy Services data based on the 2013 Annual Survey, the Department is opening 11 compliance investigations for 10 host site facilities to verify that the facilities are meeting the approved project delivery requirements and one mobile route for not meeting the approved volume requirement.

- For 2016 statewide compliance reviews, the Department has selected Cardiac Catheterization Services and Megavoltage Radiation Therapy Services/Units utilizing 2014 Annual Survey data. The Department is in the process of evaluating annual survey data, review standard requirements, and CON approved facilities for these selected services to identify the facilities for compliance investigations. The finding of the statewide compliance reviews will be reported to the CON Commission at a later date.

- Beaumont West Bloomfield Surgery Center – Referred from the Department of Licensing and Regulatory Affairs for use of a procedure room on the sterile corridor that was previously decommissioned as an operating room. The facility was required to remove the procedure room from use and paid a civil fine of $35,000.

Source: Certificate of Need Evaluation Section, Michigan Department of Health and Human Services.

CERTIFICATE OF NEED

1st Quarter Program Activity Report to the CON Commission

October 1, 2015 through September 30, 2016 (FY 2016)

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	1st Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Letters of Intent Received	104	N/A	104	N/A
Letters of Intent Processed within 15 days	104	100%	104	100%
Letters of Intent Processed Online	104	100%	104	100%

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	1st Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Applications Received	96	N/A	96	N/A
Applications Processed within 15 Days	96	100%	96	100%
Applications Incomplete/More Information Needed	69	72%	69	72%
Applications Filed Online*	92	100%	92	100%
Application Fees Received Online*	18	20%	18	20%

* Number/percent is for only those applications eligible to be filed online, potential comparative and comparative applications are not eligible to be filed online, and emergency applications have no fee.

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	1st Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Nonsubstantive Applications	51	100%	51	100%
Substantive Applications	28	100%	28	100%
Comparative Applications	0	N/A	0	N/A

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.

Measures – continued

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.

Activity	1st Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Emergency Applications Received	1	N/A	1	N/A
Decisions Issued within 10 workings Days	0*	N/A	0*	N/A

*Emergency CON Request was withdrawn by applicant before a decision was issued.

Administrative Rule R325.9413 requires the Department to process amendment requests within the same review period as the original application.

Activity	1st Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Amendments	24	96%	24	96%

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	1st Quarter	Year-to-Date
Refunds Issued Pursuant to Section 22231	0	0

Other Measures

Activity	1st Quarter		Year-to-Date	
	No.	Percent	No.	Percent
FOIA Requests Received	41	N/A	41	N/A
FOIA Requests Processed on Time	41	100%	41	100%
Number of Applications Viewed Onsite	1	N/A	1	N/A

FOIA – Freedom of Information Act.

Source: Certificate of Need Evaluation Section, Michigan Department of Health and Human Services.

Attachment I

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

CERTIFICATE OF NEED (CON) PROGRAM

ANNUAL ACTIVITY REPORT

October 2014 through September 2015
(FY2015)

MDHHS
Michigan Department of Health & Human Services
RICK SNYDER, GOVERNOR | NICK LYON, DIRECTOR

http://www.michigan.gov/con

MDHHS is an Equal Opportunity Employer, Services and Program Provider

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EXECUTIVE SUMMARY

One of the Michigan Department of Health and Human Services (MDHHS or Department) duties under Part 222 of the Public Health Code, MCL 333.22221(b), is to report to the Certificate of Need (CON) Commission annually on the Department's performance under this Part. This is the Department's 27th report to the Commission and covers the period beginning October 1, 2014, through September 30, 2015 (FY 2015). Data contained in this report may differ from prior reports due to updates subsequent to each report's publishing date.

Administration

The Department through its Policy and Legislative Administration provides support for the CON Commission (Commission) and its Standards Advisory Committees (SAC). The Commission is responsible for setting review standards and designating the list of covered services. The Commission may utilize a SAC to assist in the development of proposed CON review standards, which consists of a 2/3 majority of experts in the subject area. Further, the Commission, if determined necessary, may submit a request to the Department to engage the services of consultants or request the Department to contract with an organization for professional and technical assistance and advice or other services to assist the Commission in carrying out its duties and functions.

The Department, through its CON Evaluation Section, manages and reviews all incoming Letters of Intent, applications and amendments. These functions include determining if a CON is required for a proposed project as well as providing the necessary application materials, when applicable. In addition, the Section is responsible for monitoring implementation of approved projects, as well as the compliance with the terms and conditions of approvals.

During FY 2015, the Department has continued to make process improvements in both the Policy and Evaluation Sections. The Department successfully completed the performance audit of the CON Program by the Office of Auditor General (OAG) without any material findings and three reportable conditions. Since the completion of the audit the Policy and Evaluation Sections have developed policies and procedures to address the issues.

The Evaluation Section developed processes to implement the revised CON Review Standards for Cardiac Catheterization (CC) Services that includes elective percutaneous coronary intervention (PCI) services without on-site open heart surgery (OHS) services. The Section established new forms, review processes and accreditation criteria, and worked with both departmental and external subject matter experts to ensure proper review of elective PCI services. The Section also facilitated webinars and seminars to reach out to the providers regarding implementation plans for the CC Services standards. The Section completed enhancements to the CON Annual Survey tool for proper submission and validation of physician level data for CT, surgery and MRT services. The Section also established a statewide compliance schedule for covered services and streamlined procedures for follow-up.

The Policy Section assisted the Commission to make the necessary modifications to the CON Review standards to allow for elective PCI services without on-site OHS services and added specific quality measures to the standards; added inpatient rehabilitation facility (IRF) hospitals to the Hospital Beds standards; updated equivalent treatment visits (ETVs) and other parts of the Megavoltage Radiation Therapy (MRT) services standards to better reflect current practice; modified the comparative review requirements for Nursing Homes and Hospital Long-Term Care Unit (NH-HLTCU) Beds standards to better reflect current practice and assure quality; and updated the metropolitan statistical area, micropolitan statistical area, and rural counties in all impacted standards based on the 2010 Census data.

These initiatives have greatly increased the availability of CON information and data to improve and streamline the review process, better inform policy makers and enhance community knowledge about Michigan's healthcare system.

CON Required

In accordance with MCL 333.22209, a person or entity is required to obtain a Certificate of Need, unless elsewhere specified in Part 222, for any of the following activities:

- Acquire an existing health facility or begin operation of a health facility
- Make a change in the bed capacity of a health facility
- Initiate, replace, or expand a covered clinical service
- Make a covered capital expenditure.

CON Application Process

To apply for a CON, the following steps must be completed:

- Letter of Intent filed and processed prior to submission of an application
- CON application filed on appropriate date as defined in the CON Administrative Rules
- Application reviewed by the Evaluation Section
- Issuance of Proposed Decision by the Policy and Legislative Administration
    - Appeal if applicant disagrees with the Proposed Decision issued
- Issuance of the Final Decision by the MDHHS Director.

There are three types of CON review: nonsubstantive, substantive individual, and comparative. The Administrative Rules for the CON program establish time lines by which the Department must issue a proposed decision on each CON application. The proposed decision for a nonsubstantive review must be issued within 45 days of the date the review cycle begins, 120 days for substantive individual, and 150 days for comparative reviews.

FY 2015 in Review

In FY 2015, there were 435 Letters of Intent received resulting in 326 applications filed for CON review and approval, including three (3) emergency applications. In addition, the Department received 84 amendments to previously approved applications. In total, the Department approved 314 proposed projects resulting in approximately $2,317,168,916 of new capital expenditures into Michigan's healthcare system. The Department also surveyed 1,221 facilities and collected statistical data.

As required by Administrative Rules, the Department was timely in processing Letters of Intent, pending CON applications and issuing its decisions on pending applications. These measures, along with the other information contained in this report, aid the Commission in its duties as set forth in Part 222 of the Public Health Code.

The CON Commission also reviewed and revised 10 different CON review standards including: Cardiac Catheterization Services, Computed Tomography (CT) Services, Hospital Beds, Magnetic Resonance Imaging (MRI) Services, Megavoltage Radiation Therapy (MRT) Services/Units, Neonatal Intensive Care Services/Beds (NICU) and Special Newborn Nursing Services, Nursing Home and Hospital Long-Term Care Unit (NH-HLTCU) Beds and Addendum for Special Population Groups, Positron Emission Tomography (PET) Scanner Services, Surgical Services, and Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services/Units.

This report is filed by the Department in accordance with MCL 333.2221(f). The report presents information about the nature of these CON applications and decisions, as well as the Commission's actions during the reporting period. Several tables include benchmarks for timely processing of applications and issuing decisions as set forth in the CON Administrative Rules. Note that the data in the report represents some applications that were carried over from last fiscal year while others may be carried over into next fiscal year.

HISTORICAL OVERVIEW OF MICHIGAN'S CERTIFICATE OF NEED PROGRAM

1972 Legislation was introduced in the Michigan legislature to enact the Certificate of Need (CON) program. The Michigan CON program became effective on April 1, 1973.

1974 Congress passed the National Health Planning and Resources Development Act (PL 93-641) including funding incentives that encouraged states to establish a CON program. The purpose of the act was to facilitate recommendations for a national health planning policy. It encouraged state planning for health services, manpower, and facilities. And, it authorized financial assistance for the development of resources to implement that policy. Congress repealed PL 93-641 and certificate of need in 1986. At that time, federal funding of the program ceased and states became totally responsible for the cost of maintaining CON.

1988 Michigan's CON Reform Act of 1988 was passed to develop a clear, systematic standards development process and reduce the number of services requiring a CON.

Prior to the 1988 CON Reform Act, the Department found that the program was not serving the needs of the state optimally. It became clear that many found the process to be excessively unclear and unpredictable. To strengthen CON, the 1988 Act established a specific process for developing and approving standards used in making CON decisions. The review standards establish how the need for a proposed project must be demonstrated. Applicants know before filing an application what specific requirements must be met.

The Act also created the CON Commission. The CON Commission, whose membership is appointed by the Governor, is responsible for approving CON review standards. The Commission also has the authority to revise the list of covered clinical services subject to CON review. However, the CON sections inside the Department are responsible for day-to-day operations of the program, including supporting the Commission and making decisions on CON applications consistent with the review standards.

1993 Amendments to the 1988 Act required ad hoc committees to be appointed by the Commission to provide expert assistance in the formation of the review standards.

2002 Amendments to the 1988 Act expanded the CON Commission to 11 members, eliminated the previous ad hoc committees, and established the use of Standard Advisory Committees or other private consultants/organizations for professional and technical assistance.

Present The CON standards now allow applicants to reasonably assess requirements for approval, before filing an application. As a result, there are far fewer appeals of Department decisions. Moreover, the 1988 amendments appear to have reduced the number of unnecessary applications, i.e., those involving projects for which a need cannot be demonstrated.

The standards development process now provides a public forum and involves organizations representing purchasers, payers, providers, consumers, and experts in the subject matter. The process has resulted in CON review standards that are legally enforceable, while assuring that standards can be revised promptly in response to the changing healthcare environment.

ADMINISTRATION OF THE CERTIFICATE OF NEED PROGRAM

Commission The Commission is an 11-member body. The Commission, appointed by the Governor and confirmed by the Senate, is responsible for approving CON review standards used by the Department to make decisions on individual CON applications. The Commission also has the authority to revise the list of covered clinical services subject to CON review. Appendix I is a list of the CON Commissioners for FY2015.

NEWTAC The New Technology Advisory Committee is a standing committee responsible for advising the Commission on the new technologies, including medical equipment and services that have not yet been approved by the federal Food and Drug Administration for commercial use.

SAC A Standards Advisory Committee (SAC) may be appointed by and report to the CON Commission. The SACs advise the Commission regarding creation of, or revisions to the standards. The Committees are composed of a 2/3 majority of experts in the subject matter and include representatives of organizations of healthcare providers, professionals, purchasers, consumers, and payers.

MDHHS The Michigan Department of Health and Human Services is responsible for administering the CON program and providing staffing support for the Commission. This includes promulgating applicable rules, processing and rendering decisions on applications, and monitoring and enforcing the terms and conditions of approval. These functions are within the Policy and Legislative Administration.

Policy Section The Policy Section within the Administration provides professional and support staff assistance to the Commission and its committees in the development of new and revised standards. Staff support includes researching issues related to specific standards, preparing draft standards, and performing functions related to both Commission and Committee meetings.

Evaluation Section The Evaluation Section, also within the Administration, has operational responsibility for the program, including providing assistance to applicants prior to and throughout the CON process. The Section is responsible for reviewing all Letters of Intent and applications as prescribed by the Administrative Rules. Staff determines if a proposed project requires a CON. If a CON is required, staff identifies the appropriate application forms for completion by the applicant and submission to the Department. The application review process includes the assessment of each application for compliance with all applicable statutory requirements and CON review standards, and preparation of a Program Report and Finance Report documenting the analysis and findings. These findings are used by the Director to make a final decision to approve or deny a project.

In addition to the application reviews, the Section reviews requests for amendments to approved CONs as allowed by the Rules. Amendment requests involve a variety of circumstances, including changes in how an approved project is financed and authorization for cost overruns. The Section is also responsible for monitoring the implementation of approved projects, as well as the long-term compliance with the terms and conditions of approvals.

The Section also provides the Michigan Finance Authority (MFA) with information when healthcare entities request financing through MFA bond issues and Hospital Equipment Loan Program (HELP) loans. This involves advising on whether a CON is required for the item(s) that will be bond financed.

CERTIFICATE OF NEED PROCESS

The following discussion briefly describes the steps an applicant follows in order to apply for a Certificate of Need.

Letter of Intent — An applicant must file an LOI with the Department and, if applicable, the regional CON review agency. The CON Evaluation Section identifies for an applicant all the necessary application forms required based on the information contained in the LOI.

Application — On or before the designated application date, an applicant files an application with the Department and the regional review agency, if applicable. The Evaluation Section reviews an application to determine if it is complete. If not complete, additional information is requested. The review cycle starts after an application is deemed complete or received in accordance with the Administrative Rules.

Review Types and Time Frames — There are three review types: nonsubstantive, substantive individual and comparative. Nonsubstantive reviews involve projects such as replacement of covered equipment or changes in ownership that do not require a full review. Substantive individual reviews involve projects that require a full review but are not subject to comparative review as specified in the applicable CON review standards. Comparative reviews involve situations where two or more applicants are competing for a resource limited by a CON review standard, such as hospital and nursing home beds. The maximum review time frames for each review type, from the date an application is deemed complete or received until a proposed decision is issued, are: 45 days for nonsubstantive, 120 for substantive individual and 150 days for comparative reviews. The comparative review time frame includes an additional 30-day period for determining if a comparative review is necessary. Whenever this determination is made, the review cycle begins for comparative reviews.

Review Process — The Evaluation Section reviews the application. Each application is reviewed separately unless part of a comparative review. Each application review includes a program and finance report documenting the Department's analysis and findings of compliance with the statutory review criteria, as set forth in Section 22225 of the Public Health Code and the applicable CON review standards.

Proposed Decision — The Policy and Legislative Administration in which the Evaluation Section resides issues a proposed decision to the applicant within the required time frame. This decision is binding unless reversed by the Department Director or appealed by the applicant. The applicant must file an appeal within 15 days of receipt of the proposed decision if the applicant disagrees with the proposed decision or its terms and conditions. In the case of a comparative review, a single decision is issued for all applications in the same comparative group.

Final Decision — If the proposed decision is not appealed, a final decision is made by the Director of the Department in accordance with MCL 333.22231. If a hearing on the proposed decision is requested, the final decision by the Director is not issued until completion of the hearing and any filing of exceptions to the proposed decision by the Michigan Administrative Hearing System. A final decision by the Director may be appealed to the applicable circuit court.

LETTERS OF INTENT

The CON Administrative Rules, specifically Rule 9201, provides that Letters of Intent (LOI) must be processed within 15 days of receipt. Processing an LOI includes entering data in the management information system, verifying historical facility information, and obtaining proof of authorization to do business in Michigan. This information determines the type of review for the proposed project, and the Department then notifies the applicant of applicable application forms to be completed.

Table 1 provides an overview of the number of LOIs received and processed in accordance with the above-referenced Rule.

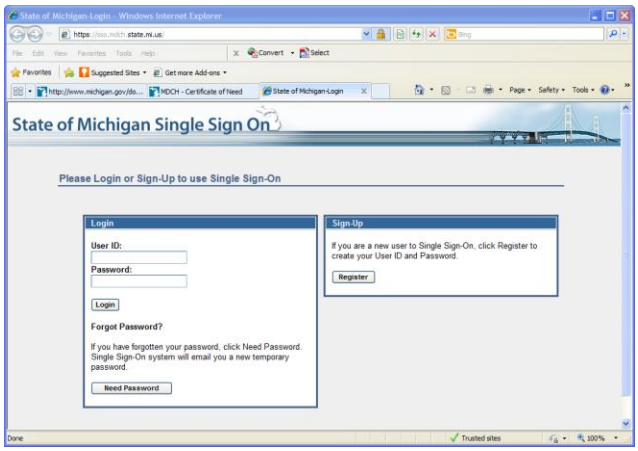
TABLE 1
LETTERS OF INTENT RECEIVED AND PROCESSED WITHIN 15 DAYS
FY2011 FY2015

	LOIs Received	Processed within 15 Days	Percent Processed within 15 Days	Waivers Processed*
FY2011	441	438	99%	51
FY2012	422	422	100%	43
FY2013	440	438	99%	61
FY2014	333	332	99%	39
FY2015	435	434	99%	44

* Waivers are proposed projects that do not require CON review, but an LOI was submitted for Department's guidance/confirmation.

In FY 2015, LOIs were processed in a timely manner as required by Administrative Rule and available for public viewing on the online application system. The online system allows for faster processing of LOIs and subsequent applications by the Evaluation Section, as well as modifying these applications by applicants when needed.

In 2006, Michigan became the first state to have an online application and information system. Today 100% of all LOIs and applicable applications are submitted online.



http://www.mi.gov/con

TYPES OF CERTIFICATE OF NEED APPLICATION REVIEWS

The Administrative Rules also establish three types of project reviews: nonsubstantive, substantive individual, and comparative. The Rules specify the time frames by which the Bureau (Evaluation Section) must issue its proposed decision related to a CON application. The time allowed varies based on the type of review.

Nonsubstantive

Nonsubstantive reviews involve projects that are subject to CON review but do not warrant a full review. The following describes types of projects that are potentially eligible for nonsubstantive review:

- Acquire an existing health facility
- Replace a health facility within the replacement zone and below the covered capital expenditure

- Add a host site to an existing mobile network/route that does not require data commitments
- Replace or upgrade a covered clinical equipment
- Acquire or relocate an existing freestanding covered clinical service.

The Rules allow the Bureau (Evaluation Section) up to 45 days from the date an application is deemed complete to issue a proposed decision. Reviewing these types of proposed projects on a nonsubstantive basis allows an applicant to receive a decision in a timely fashion while still being required to meet current CON requirements, including quality assurance standards.

Substantive Individual

Substantive individual review projects require a full review but are not subject to comparative review and not eligible for nonsubstantive review. An example of a project reviewed on a substantive individual basis is the initiation of a covered clinical service such as Computed Tomography (CT) scanner services. The Bureau (Evaluation Section) must issue its proposed decision within 120 days of the date a substantive individual application is deemed complete or received.

Comparative

Comparative reviews involve situations where two or more applications are competing for a limited resource such as hospital or nursing home beds. A proposed decision for a comparative review project must be issued by the Bureau (Evaluation Section) no later than 120 days after the review cycle begins. The cycle begins when the determination is made that the project requires comparative review. According to the Rules, the Department has the additional 30 days to determine if, in aggregate, all of the applications submitted on a window date exceed the current need. A comparative window date is one of the three dates during the year on which projects subject to comparative review must be filed. Those dates are the first working day of February, June, and October.

Section 22229 established the covered services and beds that were subject to comparative review. Pursuant to Part 222, the CON Commission may change the list subject to comparative review.

Figure 1 delineates services/beds subject to comparative review.

FIGURE 1 *Services/Beds Subject to Comparative Review in FY2015*	
Neonatal Intensive Care Unit	Nursing Home/HLTCU Beds
Hospital Beds	Nursing Home Beds for Special Population Groups
Psychiatric Beds	
Transplantations	

Note: See individual CON review standards for more information.

Table 2 shows the number of applications received by the Department by review type.

TABLE 2
APPLICATIONS RECEIVED BY REVIEW TYPE
FY2011 FY2015

	FY2011	FY2012	FY2013	FY2014	FY2015
Nonsubstantive*	166	160	161	117	194
Substantive Individual	122	135	152	114	129
Comparative	28	10	8	2	0
TOTALS	316	305	321	233	323

Note: Does not include three (3) emergency CON applications.

* Includes swing bed applications.

Table 3 provides a summary of applications received and processed in accordance with Rule 9201. The Rule requires the Evaluation Section to determine if additional information is needed within 15 days of receipt of an application. Processing of applications includes: updating the management information system, verifying submission of required forms, and determining if other information is needed in response to applicable Statutes and Standards.

TABLE 3
APPLICATIONS RECEIVED AND PROCESSED WITHIN 15 DAYS
FY2011 FY2015

	FY2011	FY2012	FY2013	FY2014	FY2015
Applications Received	318	305	326	235	326
Processed within 15 Days	315	290	326	235	324
Percent Processed within 15 Days	99%	95%	100%	100%	99%

Note: Includes emergency CON and swing bed applications.

Table 4 provides an overview of the average number of days taken by the Evaluation Section to complete reviews by type.

TABLE 4
AVERAGE NUMBER OF DAYS IN REVIEW CYCLE BY REVIEW TYPE
FY2011 FY2015

	FY2011	FY2012	FY2013	FY2014	FY2015
Nonsubstantive	31	41	38	40	42
Substantive Individual	110	114	117	117	112
Comparative	117	117	119	116	N/A

Note: Average review cycle accounts for extensions requested by applicants.

EMERGENCY CERTIFICATES OF NEED

Table 5 shows the number of emergency CONs issued. The Department is authorized by Section 22235 of the Public Health Code to issue emergency CONs when applicable. Rule 9227 permits up to 10 working days to determine if an emergency application is eligible for review under Section 22235. Although it is not required by Statute, the Bureau (Evaluation Section) attempts to issue emergency CON decisions to the Director for final review and approval within 10 days from receipt of request.

TABLE 5
EMERGENCY CON DECISIONS ISSUED
FY2011 FY2015

	FY2011	FY2012	FY2013	FY2014	FY2015
Emergency CONs Issued	2	2	5	2	2*
Percent Issued within 10 Working Days	100%	100%	100%	100%	100%

*One emergency con application was withdrawn before a decision was issued.

PROPOSED DECISIONS

Part 222 establishes a 2-step decision making process for CON applications that includes both a proposed decision and final decision. After an application is deemed complete and reviewed by the Evaluation Section, a proposed decision is issued by the Bureau (Evaluation Section) to the applicant and the Department Director according to the timeframes established in the Rules.

Table 6 shows the number of proposed decisions by type, issued within the applicable timeframes set forth in the Administrative Rules 325.9206 and 325.9207: 45 days for nonsubstantive, 120 days for substantive individual, and 150 days for comparative reviews, or any requested extension(s) to the review cycle.

TABLE 6
PROPOSED DECISIONS ISSUED
FY2011 FY2015

	Nonsubstantive		Substantive Individual		Comparative	
	Issued	Issued on Time	Issued	Issued on Time	Issued	Issued on Time
FY2011	180	100%	129	100%	34	100%
FY2012	155	100%	115	100%	3	100%
FY2013	147	100%	145	100%	9	100%
FY2014	119	100%	130	100%	6	100%
FY2015	195	100%	118	100%	0	N/A

Note: Table 6 does not include two (2) emergency proposed decisions.

Table 7 compares the number of proposed decisions by decision type made.

TABLE 7
COMPARISON OF PROPOSED DECISIONS BY DECISION TYPE
FY2011 FY2015

	Approved	Approved w/ Conditions	Disapproved	Percent Disapproved	TOTAL
FY2011	298	30	15	6%	343
FY2012	244	19	10	4%	243
FY2013	261	35	10	3%	306
FY2014	222	28	7	3%	257
FY2015	261	53	1	0.3%	315

Note: Not all proposed decisions issued in a given year will have a final decision in the same year.

If a proposed decision is disapproved, an applicant may request an administrative hearing that suspends the time frame for issuing a final decision. After a proposed disapproval is issued, an applicant may also request that the Department consider new information. The Administrative Rules allow an applicant to submit new information in response to the areas of noncompliance identified by the Department's analysis of an application and the applicable Statutory requirements to satisfy the requirements for approval.

FINAL DECISIONS

The Director issues a final decision on a CON application following either a proposed decision or the completion of a hearing, if requested, on a proposed decision. Pursuant to Section 22231(1) of the Public Health Code, the Director may issue a decision to approve an application, disapprove an application, or approve an application with conditions or stipulations. If an application is approved with conditions, the conditions must be explicit and relate to the proposed project. In addition, the conditions must specify a time period within which the conditions shall be met, and that time period cannot exceed one year after the date the decision is rendered. If approved with stipulations, the requirements must be germane to the proposed project and agreed to by the applicant.

This section of the report provides a series of tables summarizing final decisions for each of the review thresholds for which a CON is required. It should be noted that some tables will not equal other tables, as many applications fall into more than one category.

Table 8 and **Figure 2** display the number of final decisions issued.

TABLE 8 *FINAL DECISIONS ISSUED FY2011 FY2015*	
FY2011	323
FY2012	283
FY2013	309
FY2014	256
FY2015	316

FIGURE 2
FY 2015 FINAL DECISIONS ISSUED BY HEALTH SERVICE AREAS

Note: Figure 2 does not include 2 out-state decision.

Table 9 summarizes final decisions by review categories defined in MCL 333.22209(1) and as summarized below:

Acquire, Begin Operation of, or Replace a Health Facility
Under Part 222, a health facility is defined as a general hospital, hospital long-term care unit, psychiatric hospital or unit, nursing home, freestanding surgical outpatient facility (FSOF), and health maintenance organization under limited circumstances. This category includes projects to construct or replace a health facility, as well as projects involving the acquisition of an existing health facility through purchase or lease.

Change in Bed Capacity
This category includes projects to increase in the number of licensed hospital, nursing home, or psychiatric beds; change the licensed use; and relocate existing licensed beds from one geographic location to another without an increase in the total number of beds.

Covered Clinical Services
This category includes projects to initiate, replace, or expand a covered clinical service: neonatal intensive care services, open heart surgery, extrarenal organ transplantation, extracorporeal shock wave lithotripsy, megavoltage radiation therapy, positron emission tomography, surgical services, cardiac catheterization, magnetic resonance imaging services, computed tomography scanner services, and air ambulance services.

Covered Capital Expenditures
This category includes capital expenditure project in a clinical area of a licensed health facility that is equal to or above the threshold set forth in Part 222. Typical examples of covered capital expenditure projects include construction, renovation, or the addition of space to accommodate increases in patient treatment or care areas not already covered. In 2014 the covered capital expenditure threshold was $3,160,000 and as of January 1, 2015, the covered capital expenditure threshold was increased to $3,197,500. The threshold is updated in January of every year.

TABLE 9 FINAL DECISIONS ACTIVITY CATEGORY FY2011 FY2015					
Approved	**FY2011**	**FY2012**	**FY2013**	**FY2014**	**FY2015**
Acquire, Begin, or Replace a Health Facility	43	25	38	47	68
Change in Bed Capacity	54	57	52	46	34
Covered Clinical Services	212	188	241	191	214
Covered Capital Expenditures	78	55	44	47	33
Disapproved					
Acquire, Begin, or Replace a Health Facility	0	9	2	4	0
Change in Bed Capacity	0	12	5	5	1
Covered Clinical Services	1	2	0	0	1
Covered Capital Expenditures	0	10	3	5	1

Note: Totals above may not match Final Decision totals because one application may include multiple categories.

Table 10 provides a comparison of the total number of final decisions and total project costs by decision type.

TABLE 10 COMPARISON OF FINAL DECISIONS BY DECISION TYPE FY2011 FY2015				
	Approved	**Approved With Conditions**	**Disapproved**	**Totals**
Number of Final Decisions				
FY2011	229	25	1	325
FY2012	245	24	14	283
FY2013	268	36	5	309
FY2014	223	28	5	256
FY2015	261	53	2	316
Total Project Costs				
FY2011	$ 4,237,317,904	$ 78,451,908	$ 96,000	$ 4,315,865,812
FY2012	$ 1,018,583,923	$ 61,902,640	$ 119,186,198	$ 1,199,672,761
FY2013	$ 724,546,360	$ 239,908,373	$ 321,167,591	$ 1,285,622,324
FY2014	$ 904,329,614	$ 196,996,469	$ 39,529,999	$ 1,140,856,082
FY2015	$ 2,077,265,073	$ 239,911,843	$ 5,554,114	$ 2,322,741,030

Note: Final decisions include emergency CON applications.

In FY2015, two (2) CON applications received final decision of disapproval from the Department. These projects included an addition of nursing home beds to an existing facility and an emergency application for the temporary use of mobile MRI.

CERTIFICATE OF NEED ACTIVITY SUMMARY COMPARISON

Table 11 provides a comparison for various stages of the CON process.

TABLE 11 *CON ACTIVITY COMPARISON FY2011 FY2015*				
	Number of Applications	**Difference from Previous Year**	**Total Project Costs**	**Difference from Previous Year**
Letters of Intent Processed				
FY2011	441	1%	$4,104,907,789	144%
FY2012	422	(4%)	$1,969,641,919	(52%)
FY2013	440	4%	$1,661,621,556	(16%)
FY2014	333	(24%)	$1,282,834,192	(23%)
FY2015	435	31%	$2,894,486,078	126%
Applications Submitted				
FY2011	318	5%	$3,896,990,034	159%
FY2012	307	(3%)	$1,351,924,859	(65%)
FY2013	326	6%	$1,539,877,626	14%
FY2014	235	(28%)	$ 904,601,983	(41%)
FY2015	326	39%	$2,526,962,926	179%
Final Decisions Issued				
FY2011	325	21%	$4,315,865,812	418%
FY2012	283	(13%)	$1,199,672,761	(72%)
FY2013	309	9%	$1,285,622,324	7%
FY2014	256	(17%)	$1,140,856,082	(11%)
FY2015	316	23%	$2,322,741,030	104%

Note: Applications submitted and final decisions Issued include Emergency CONs and swing bed applications.

AMENDMENTS

The Rules allow an applicant to request to amend an approved CON for projects that are not complete. The Department has the authority to decide when an amendment is appropriate or when the proposed change is significant enough to require a separate application. Typical reasons for requesting amendments include:

- **Cost overruns -** The Rules allow the actual cost of a project to exceed the approved amount by 15 percent of the first $1 million and 10 percent of all costs over $1 million. Fluctuations in construction costs can cause projects to exceed approved amounts

- **Changes in the scope of a project -** An example is the addition of construction or renovation required by regulatory agencies to correct existing code violations that an applicant did not anticipate in planning the project or a change in covered clinical equipment.

- **Changes in financing -** Applicants may decide to pursue a financing alternative better than the financing that was approved in the CON.

- **Change in construction start date** – The Rules allow an Applicant to request an extension to start construction/renovation for an approved project.

Table 12 provides a summary of amendment requests received by the Department and the time required to process and issue a decision. Rule 9413 permits that the review period for a request to amend a CON-approved project be no longer than the original review period.

TABLE 12
AMENDMENTS RECEIVED AND DECISIONS ISSUED
FY2011 FY2015

	FY2011	FY2012	FY2013	FY2014	FY2015
Amendments Received	83	68	73	63	84
Amendment Decisions Issued	76	66	84	60	88
Percent Issued within Required Time Frame	99%	100%	100%	99%	100%

NEW CERTIFICATE OF NEED CAPACITY

Table 13 provides a comparison of existing covered services, equipment and facilities already operational to new capacity approved in FY 2015. One hundred and two (102) of the 314 CON approvals in FY 2015 were for new or additional capacity. The remaining approvals were for replacement equipment, relocation of existing services, acquisitions, renovations and other capital expenditures.

TABLE 13
COVERED CLINICAL SERVICES AND BEDS
FY2015

Covered Clinical Services/Beds	Existing Sites	Existing Units/Beds	New Sites	New Units/Beds
Air Ambulances	14	17	1	3
Cardiac Catheterization Services	68	219	1	5
Primary PCI *	14	N/A	1	N/A
Open Heart Surgical Services	34	N/A	0	N/A
Surgical Services	264	1,430	6	16
CT Scanners Services	435	526	34	35
MRI Services	324	242	5	6
PET Services	88	27	2	1
Lithotripsy Services	96	11	5	6
MRT Services	67	133	0	1
Transplant Services	8	N/A	0	N/A
Hospitals	183	26,440	1	0
NICU Services	22	632	0	0
SCN Services *	0	N/A	13	N/A
Extended Care Services Program (Swing Beds)	34	314	2	12
Nursing Homes/HLTCU	505	52,366	3	171
Psychiatric Hospitals/Units	63	2,525	0	20
Psychiatric Flex Beds *	3	28	0	16

Note: Table 13 does not account for facilities closed, services or equipment no longer operational, or beds delicensed and returned to the various bed pools. New sites include mobile host sites for CT, Lithotripsy, MRI and PET services.
** New service categories*

COMPLIANCE ACTIONS

Table 14 shows there were 350 projects requiring follow-up for FY 2015 based on the Department's Monthly Follow-up/Monitoring Report as shown below.

TABLE 14 *FOLLOW UP AND COMPLIANCE ACTIONS FY2011 FY2015*					
	FY2011	**FY2012**	**FY2013**	**FY2014**	**FY2015**
Projects Requiring 1-yr Follow-up	341	386	340	350	251
Approved CONs Expired	80	69	127	97	95
Compliance Orders Issued	0	2	1	6	30

Note: CONs are expired due to non-compliance with terms and conditions of approval or when the recipient has notified the Department that either the approved-project was not implemented or the site is no longer providing the covered service/beds. Compliance Orders include orders issued by the Department under MCL 333.22247 or remedies for non-compliance. The Department completed a statewide review of compliance of open heart and psychiatric services.

ANALYSIS OF CERTIFICATE OF NEED PROGRAM FEES AND COSTS

Section 20161(3) sets forth the fees to be collected for CON applications. **Figure 3A** shows the application fees that are based on total project costs effective until October 14, 2013.

FIGURE 3A *PREVIOUS CON APPLICATION FEES*	
Total Project Costs	**CON Application Fee**
$0 to $500,000	$1,500
$500,001 to $4,000,000	$5,500
$4,000,001 and above	$8,500

Figure 3B shows the application fees based on total projects costs and additional fees per the new fee structure, effective October 15, 2013, approved under House Bill No. 4787.

FIGURE 3B *CURRENT CON APPLICATION FEES*	
Total Project Costs	**CON Application Fee**
$0 to $500,000	$3,000
$500,001 to $3,999,999	$8,000
$4,000,000 to $9,999,999	$11,000
$10,000,000 and above	$15,000
Additional Fee Category	**Additional Fee**
Complex Projects (i.e. Comparative Review, Acquisition or replacement of a licensed health facility with two or more covered clinical services.)	$3,000
Expedited Review - Applicant Request	$1,000
Letter of Intent (LOI) Resulting in a Waiver	$500
Amendment Request to Approved CON	$500
CON Annual Survey	$100 per Covered Clinical Service

Table 15A, 15B analyzes the number of applications by fee assessed.

TABLE 15A
NUMBER OF CON APPLICATIONS BY FEE
FY2011 FY2014

CON Fee	FY2011	FY2012	FY2013	FY2014
$ 0*	2	2	6	0
$1,500	104	147	139	5
$5,500	101	96	97	8
$8,500	110	62	84	7
TOTAL	317	307	326	20

TABLE 15B
NUMBER OF CON APPLICATIONS BY FEE
FY2014 FY2015

CON Fee	FY2014	FY 2015
$ 0*	3	6
$3,000	103	146
$8,000	70	91
$11,000	23	36
$15,000	16	47
TOTAL	215	326

Note: Table 15A and 15B may not match fee totals in Table 16, as Table 16 accounts for refunds, overpayments, MFA funding, etc.
** No fees are required for emergency CON and swing beds applications.*

Table 15C analyzes the fees collected for the additional fee categories. More than one fee category may be assessed for one application.

TABLE 15C
NUMBER OF ADDITIONAL CON APPLICATIONS FEES
FY2014 FY2015

CON Fee Category	FY2014	FY 2015
Complex Project	8	3
Expedited Review	27	38
LOI Waiver*	37	34
Amendment*	32	44
Annual Survey (Facilities)	1,191	1,099
TOTAL		

*Note: Some waivers and amendments do not require a fee based on the type of change requested.

Table 16 provides information on CON program costs and source of funds.

TABLE 16
CON PROGRAM
COST AND REVENUE SOURCES FOR FY2011 FY2015

	FY2011	FY2012	FY2013	FY2014	FY2015
Program Cost	$1,902,658	$1,802,307	$1,785,688	$1,967,395	$2,115,182
Fees/Funding	$1,715,588	$1,298,504	$1,508,118	$1,823,772	$2,620,083
Fees % of Costs	90%	72%	84%	93%	100%+

Source: MDCH Budget and Finance Administration.

CERTIFICATE OF NEED COMMISSION ACTIVITY

During FY2015, the CON Commission revised the review standards for Cardiac Catheterization Services, Computed Tomography (CT) Services, Hospital Beds, Magnetic Resonance Imaging (MRI) Services, Megavoltage Radiation Therapy (MRT) Services/Units, Neonatal Intensive Care Services/Beds (NICU) and Special Newborn Nursing Services, Nursing Home and Hospital Long-Term Care Unit (NH-HLTCU) Beds and Addendum for Special Population Groups, Positron Emission Tomography (PET) Scanner Services, Surgical Services, and Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services/Units.

The revisions to the CON Review Standards for Cardiac Catheterization Services received final approval by the CON Commission on June 11, 2015 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective September 14, 2015. The final language changes include the following:

- Section 2: Definitions have been modified, and new definitions have been added as follows:
  - "Cardiac catheterization service" means the provision of one or more of the following types of procedures: adult diagnostic cardiac catheterizations; adult therapeutic cardiac catheterizations; and pediatric cardiac catheterizations. This definition was updated.
  - “Elective percutaneous coronary intervention (PCI)” means a PCI procedure performed on a non-emergent basis. Definition added to allow for elective PCI without on-site open heart surgery.
  - “Elective PCI services without on-site open heart surgery (OHS)” means performing PCI, percutaneous transluminal coronary angioplasty (PTCA), and coronary stent implantation on an organized, regular basis in a hospital having a diagnostic cardiac catheterization service and a primary PCI service but not having OHS on-site and adhering to patient selection as outlined in the SCAI/ACC/AHA Expert Consensus Document: 2014 Updated on PCI Without On-Site Surgical Backup and published in circulation 2014, 129:2610-2626 and its update or further guideline changes. Definition added to allow for elective PCI without on-site open heart surgery.
  - “Primary percutaneous coronary intervention (PCI)” means a PCI performed on an acute myocardial infarction (AMI) patient with confirmed ST elevation or new left bundle branch block on an emergent basis. This definition was updated.
  - “Primary PCI service without on-site OHS” means performing primary PCI on an emergent basis in a hospital having a diagnostic cardiac catheterization service. Definition added for clarity.
  - "Therapeutic cardiac catheterization service" means providing therapeutic cardiac catheterizations on an organized, regular basis in a laboratory to treat and resolve anatomical and/or physiological problems in the heart. Procedures include PCI, PTCA, atherectomy, stent, laser, cardiac valvuloplasty, balloon atrial septostomy, catheter ablation, cardiac permanent pacemaker, ICD device implantations, transcatheter valve, other structural heart disease procedures, PTCA with coronary stent implantation and left sided arrhythmia therapeutic procedures. The term does not include the intra coronary administration of drugs where that is the only therapeutic intervention. This definition was updated.
- Section 3(3): Revised consistent with current practice.
- Section 4: New section that provides the requirements to initiate primary PCI service without on-site OHS (previously included in Section 3) or elective PCI services without

on-site OHS services (new to standards). To be considered for an elective PCI service without on-site OHS services, the applicant shall have operated a primary PCI service for one year prior to the date of application. If the applicant was not approved as a primary PCI service prior to the effective date of the new standards, then, in addition, the applicant shall demonstrate that there is no PCI or OHS service within 60 radius miles or 60 minutes travel time from the proposed site.

- Section 7: Modified the language consistent with other CON review standards to clarify that any acquisition of a cardiac catheterization service, after the first acquisition, on or after February 27, 2012, must be meeting volume requirements to be acquired.
- Section 10(2): Revised consistent with current practice and national guidelines. Included a requirement for applicant hospitals providing therapeutic cardiac catheterization services, primary PCI services without on-site OHS service, or elective PCI services without on-site OHS service to participate with a data registry administered by the Department or its designee (currently BMC2) that monitors quality and risk adjusted outcomes.
- Section 10(4): Revised language for consistency with other changes in the standards as well as consistency with other CON review standards.
- Section 10(5): Updated the quality reporting criteria for primary and elective PCI for hospitals providing therapeutic cardiac catheterization services, primary PCI services without on-site OHS services, or elective PCI services without on-site OHS service.
- Section 10(6) and (7): Added for administrative feasibility and consistent with other CON review standards.
- Section 12: Added requirements for documentation of projections for applicants proposing to initiate an elective PCI service without on-site OHS services.
- Appendix A: Updated the counties based on the 2010 Census data.
- Other technical edits.

The revisions to the CON Review Standards for CT Services received final approval by the CON Commission on September 25, 2014 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective December 22, 2014. The final language changes include the following:

- Section 24: Technical edit.
- Appendix B: Updated the counties based on the 2010 Census data.

The revisions to the CON Review Standards for Hospital Beds received final approval by the CON Commission on December 11, 2014 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective March 20, 2015. The final language changes include the following:

- Section 2: Definitions have been modified consistent with other CON review standards, and new definitions have been added as follows:
    - "Inpatient rehabilitation facility hospital" or "IRF hospital" means a hospital that has been approved to participate in the Title XVIII (Medicare) program as a prospective payment system (PPS) exempt inpatient rehabilitation hospital in accordance with 42 CFR Part 412 Subpart P. Definition added to allow for IRF Hospitals the same considerations as LTAC Hospitals.
    - "Replace beds" means a change in the location of the licensed hospital, the replacement of a portion of the licensed beds at the same licensed site, or the one-time replacement of less than 50% of the licensed beds to a new site within 250 yards of the building on the licensed site containing more than 50% of the

licensed beds, which may include a new site across a highway(s) or street(s) as defined in MCL 257.20 and excludes a new site across a limited access highway as defined in MCL 257.26. The hospital beds will be in new physical plant space being developed in new construction or in newly acquired space (purchase, lease, donation, etc.) within the replacement zone. Definition modified to allow for a one-time replacement of beds to property separated by a road(s).

- Section 5: Modified consistent with other CON review standards.
- Section 6(2): Modified to allow for IRF Hospitals the same considerations as LTAC Hospitals.
- Section 7(2): Modified to allow for the one-time replacement of beds to property separated by a road(s). This includes the same additional language as added in the definition of "replace beds."
- Removal of Previous Section 10: Technical edit consistent with other CON Review Standards.
- Appendix B: Updated the counties based on the 2010 Census data.
- Other technical edits.

The revisions to the CON Review Standards for MRI Services received final approval by the CON Commission on September 25, 2014 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective December 22, 2014. The final language changes include the following:

- Previous Section 2(1)(hh), (ii) and (rr): Technical edit consistent with other CON Review Standards.
- Section 20: Technical edit.
- Appendix A: Updated the counties based on the 2010 Census data.

The revisions to the CON Review Standards for Hospital Beds received final approval by the CON Commission on March 18, 2014 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective June 2, 2014. The final language changes include the following:

- Section 4: Modified for the CD-9-CM to ICD-10-CM Code translation.
- Appendix E: Added new Appendix for the ICD-9-CM to ICD-10-CM Code translation.
- Other technical edits.

The revisions to the CON MRT Services/Units received final approval by the CON Commission on June 11, 2015 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective September 14, 2015. The final language changes include the following:

- Section 2: Definitions have been modified, moved, and/or deleted if no longer needed, and new definitions have been added as follows:
    - "Dedicated stereotactic radiosurgery unit" means an MRT unit for which more than 90 percent of cases will be treated with radiosurgery. The term wasn't previously defined.
    - "Megavoltage radiation therapy" or "MRT" means a clinical modality in which patients with cancer, other neoplasms, cerebrovascular system abnormalities, or certain benign conditions are treated with radiation which is delivered by a MRT unit. This definition was updated.
    - "Simulation" means the precise mock-up of a patient treatment with an apparatus

that uses a diagnostic x-ray tube, magnetic resonance imaging device, or computed tomography scanner, which is used in reproducing the two-dimensional or three-dimensional internal or external geometry of the patient, for use in treatment planning and delivery. This definition was updated.
    - "Special purpose MRT unit" or "special purpose unit" or "special unit" means any of the following types of MRT units: (i) dedicated stereotactic radiosurgery unit, (ii) dedicated total body irradiator (TBI), or (iii) an OR-based IORT unit. This definition was updated.
    - "Treatment visit" means one patient encounter during which MRT is administered and billed. 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. Definition updated for clarification.
- Section 4(1)(a) and (d): Updated language to allow for replacement of a special purpose unit with a non-special purpose unit . The site at which a special purpose unit is replaced shall continue to operate a non-special purpose unit.
- Section 5(2)(a): Updated language to reflect that if expanding an existing MRT service with a special purpose MRT unit, that the applicant shall demonstrate that the existing and approved special purpose MRT units are averaging 1,000 ETVs in the most recent 12-month period in addition to the non-special MRT units averaging 8,000 ETVs in the most recent 12-month period.
- Section 6: Modified the language consistent with other CON review standards to clarify that any acquisition of an MRT service, after the first acquisition, on or after November 21, 2011, must be meeting volume requirements to be acquired.
- Section 10 Table 1 Equivalent Treatments: Updated to better reflect current practice.
- Section 11(2)(e)(ii): Revised as the American College of Radiology (ACR) and the American Society for Radiation Oncology (ASTRO) are no longer one organization, but two separate organizations.
- Other technical edits.

The revisions to the CON Review Standards for NICU and Special Newborn Nursing Services received final approval by the CON Commission on September 25, 2014 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective December 22, 2014. The final language changes include the following:

- Section 14: Technical edit.
- Appendix A: Updated the counties based on the 2010 Census data.

The revisions to the CON Review Standards for NH-HLTCU Beds and Addendum for Special Population Groups received final approval by the CON Commission on December 11, 2014 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective March 20, 2015. The final language changes include the following:

- Section 1: Modified for consistency with other CON review standards.
- Section 2: Definitions have been modified, moved, and/or deleted if no longer needed, and a new definition has been added as follows:
    - “Applicant’s cash” has been revised to include contributions designated for the project from the landlord to reflect the investment by the lease holder.
    - “Proposed licensed site” means the physical location and address (or legal description of property) of the proposed project or within 250 yards of the physical

location and address (or legal description of property) and within the same planning area of the proposed project that will be authorized by license and will be listed on that licensee's certificate of licensure. This definition would allow for 250 yards of movement, if necessary, when a CON application has been approved, but the specific site cannot be used for new construction.

- Section 6(1)(a)(vi) and other applicable sections: Changed "outstanding" to "delinquent" to meet the intent and aid in administering this requirement.
- Section 6(1)(d)(ii) and 6(1)(d)(iii)(B): The Staffing/Bed Utilization Ratios Report is no longer available. The CON Annual Survey will now be used.
- Section 6(2)(c) and other applicable sections: Revised consistent with change under comparative review criteria in Section 10(7).
- Section 7(1)(b) and (c): Language revised consistent with the proposed new definition for "proposed licensed site."
- Section 7(3)(c)(i): Removed three mile radius language as it is no longer necessary. This was originally drafted for the pilot programs (new design model) in 2008, and all pilot programs are now CON approved.
- Section 8(1): Removed the restrictions of relocating no more than 50% of a nursing home's beds and the seven year restriction making it consistent with HLTCUs and added that relocation of beds shall not increase the number of rooms with three or more bed wards at the receiving facility
- Section 10(2): Updated to reduce redundancy and to simplify while maintaining the high consideration of Medicaid access.
- Old Section 10(3): Removed the points for Medicare participation within the most recent 12 months based on the modifications made to Section 10(2).
- New Section 10(3): Removed redundant special focus nursing home/HLTCU language.
- Section 10(4): Revised points. Qualifying projects that already participate or plan to participate in a culture change model will receive three points. They will receive an additional 5 points if the culture change model is a Department approved model.
- Old Section 10(6): Removed the requirement for sprinklers as this became Federal law in 2013.
- New Section 10(6): Revised to award points if there is climate control for the entire facility.
- Section 10(7): Revised language and points for facility design to create a more homelike environment for the resident while recognizing that there is still a need for semi-private rooms too.
- Old Section 10(11): Removed for redundancy as this is a requirement in the Administrative Rules.
- Section 10(10): Revised to award points if the entire facility will have no more than double occupancy rooms at completion of the project to help with improved quality of care.
- Section 10(11): Points revised to balance the points of comparative review based on the relevance of care to the resident.
- Section 10(12): Revised to reflect technology Innovations to better reflect on changes in healthcare, i.e. wireless nurse call/paging system for the proposed project; wireless internet with resident access to related equipment/device in entire facility; integrated electronic medical records system for the entire facility; a backup generator for the proposed project.
- Section 10(13): Added points if the proposed project includes bariatric rooms to ensure access for the bariatric resident.
- Section 11: Divided requirements into distinct groups consistent with other standards: quality assurance, access to care, and monitoring and reporting.
    - Under subsection (1), added clarifying language that an applicant approved

pursuant to Section 10 will be held accountable for complying with the requirements agreed to in the awarding of beds for the approved project.
    - Under new subsection (3), added access to care requirements consistent with other CON review standards.
- Other technical edits.

The revisions to the CON Review Standards for PET Scanner Services received final approval by the CON Commission on June 11, 2015 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective September 14, 2015. The final language changes include the following:

- Section 6(1) and (2): Updated acquisition language for clarity consistent with other CON review standard.
- Section 11(4)(a): Technical edit.
- Section 19: Technical edit.
- Appendix C: Updated the counties based on the 2010 Census data.

The revisions to the CON Review Standards for UESWL Services/Units received final approval by the CON Commission on September 25, 2014 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective December 22, 2014. The final language changes include the following:

- Section 12: Technical edit.
- Appendix C: Updated the counties based on the 2010 Census data.

APPENDIX I - CERTIFICATE OF NEED COMMISSION

Marc D. Keshishian, MD, CON Commission Chairperson
Suresh Mukherji, MD, CON Commission Vice-Chairperson
Denise Brooks-Williams
Gail J. Clarkson, RN, NHA
Kathleen Cowling, DO
James B. Falahee, Jr., JD
Charles M. Gayney (Appointment expired and replaced by Thomas Mittlebrun, III)
Robert L. Hughes
Jessica A. Kochin
Gay L. Landstrom, RN
Thomas Mittlebrun, III (Replaced Charles M. Gayney)
Luis A. Tomatis, MD

For a list and contact information of the current CON Commissioners, please visit our web site at **www.michigan.gov/con**.

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

Attachment J

DRAFT CERTIFICATE OF NEED (CON) COMMISSION WORK PLAN

	2015												2016											
	J*	F	M*	A	M	J*	J	A	S*	O	N	D*	J*	F	M*	A	M	J*	J	A	S*	O	N	D*
Bone Marrow Transplantation (BMT) Services**	• R A		D A	•	•	• S	•S	•S	•S	•S	▮	▮	▮	▮	▮	▮	▮	• R—	•P	•	•▲ F			
Computed Tomography (CT) Scanner										PC	•	•	• R A	•	•	•	•	• R—						
Magnetic Resonance Imaging (MRI) Services**	• R A	•	•	•	•	•	•	•	•	•	•	• R—	•	•P	•▲ F R—	•	•P	•▲ F						
Neonatal Intensive Care Services/Beds and Special Newborn Nursing Services										PC	•	•	• R A	•	•	•	•	• R—						
Nursing Home and Hospital Long-Term-Care Unit (NH-HLTCU) Beds										PC	•	•A	• R A	•	• A	•	•	•	•	•	•	•	•	•
Psychiatric Beds and Services**	• R A	•	•	•	•	•	•	•	•	•	•	• R	•	•	• R—	• P	•	•▲ F						
Urinary Extracorporeal Shock Wave Lithotripsy Services										PC	•	•	• R A	•	•	•	•	•	•	•	•	•	•	•
New Medical Technology Standing Committee	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M
Commission & Department Responsibilities	•M		•M			•M			•M			•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 clinical services requiring CON approva
D - Discussion
F - Final Commission action, Transmittal to Governor/Legislature for 45-day review period
M - Monitor service or new technology for changes
P - Commission public hearing/Legislative comment period
PC - Public Comment Period for initial comments on review standards for review in the upcoming year
R - Receipt of report
S - Solicit nominations for standard advisory committee or standing committee membership

For Approval March 16, 2016

Updated March 7, 2016

The CON Commission may revise this work plan at each meeting. For information about the CON Commission work plan or how to be notified of CON Commission meetings, contact the Michigan Department of Health and Human Services (MDHHS), Office of Health Policy and Innovation, Planning and Access to Care Section, 15th Floor Grand Tower Bldg., 235 S. Grand Ave., Lansing, MI 48933, 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 2, 2014	2019
Bone Marrow Transplantation Services	September 29, 2014	2018
Cardiac Catheterization Services	September 14, 2015	2017
Computed Tomography (CT) Scanner Services	December 22, 2014	2019
Heart/Lung and Liver Transplantation Services	September 28, 2012	2018
Hospital Beds	March 20, 2015	2017
Magnetic Resonance Imaging (MRI) Services	December 22, 2014	2018
Megavoltage Radiation Therapy (MRT) Services/Units	September 14, 2015	2017
Neonatal Intensive Care Services/Beds (NICU)	December 22, 2014	2019
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups	March 20, 2015	2019
Open Heart Surgery Services	June 2, 2014	2017
Positron Emission Tomography (PET) Scanner Services	September 14, 2015	2017
Psychiatric Beds and Services	March 22, 2013	2018
Surgical Services	December 22, 2014	2017
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	December 22, 2014	2019

*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 Comment Period 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.