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

Wednesday June 15, 2016

South Grand Building
333 S. Grand Ave,
1st Floor, Conference Rooms 1K and 1L
Lansing, MI 48933

APPROVED MINUTES

I. Call to Order & Introductions

Chairperson Keshishian called the meeting to order at 9:40 a.m.

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
Thomas Mittelbrun
Suresh Mukherji, MD, Vice- Chairperson
Luis Tomatis, MD

B. Members Absent:

Gail J. Clarkson, RN

C. Department of Attorney General Staff:

None

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

Tulika Bhattacharya
Elizabeth Hertel
Amber Myers
Beth Nagel
Tania Rodriguez
Brenda Rogers

II. Review of Agenda

Motion by Commissioner Falahee, seconded by Commissioner Cowling, to approve the agenda as presented. Motion carried.

III. Declaration of Conflicts of Interests

None.

IV. Review of Minutes of March 16, 2016

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

V. Magnetic Resonance Imaging (MRI) Services – Common Ownership – April 21, 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 Commissioner Tomatis, seconded by Commissioner Mittelbrun 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 10 - Yes, 0 - No, and 0- Abstained.

VI. Psychiatric Beds and Services – April 21, 2016 Public Hearing Summary & Report

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

A. Public Comment

1. Saju George, Garden City Hospital (see Attachment D)
2. Bob Nykamp, Pine Rest
3. David Walker, Spectrum Health

B. Commission Discussion

Ms. Bhattacharya provided an overview of the Psychiatric beds and Services Compliance Project Overview (see Attachment E).

Discussion followed.

C. Commission Action

Motion by Commissioner Falahee, seconded by Commissioner Cowling to take proposed action on the language as presented (including the amendments – see Attachment F) and move to a second Public Hearing and forward to the JLC. Motion carried in a vote of 10 - Yes, 0 - No, and 0- Abstained.

Motion by Commissioner Falahee, seconded by Commissioner Kochin to have the Department and Commissioner Cowling work together to draft a letter to the Legislature that includes additional items as related to Psychiatric Beds and Services that the Commission and/or Department think would be appropriate to be considered by the Legislature. This can be a separate letter or as part of the Commission's Biennial report to the JLC. Motion carried in a vote of 10 - Yes, 0 - No, and 0- Abstained.

VII. Computed Tomography (CT) Scanner Services – Workgroup Final Report

Commissioner Mukherji provided the report (see Attachment G).

Discussion followed.

A. Public Comment

1. Mark Johnston, Michigan Dental Association
2. Brent Garvin, Planmeca Imaging
3. Michael Kasotakis, Michigan Radiology Society
4. Robert Langlais, University of Texas HSC at San Antonio (see Attachment H)

B. Commission Discussion

Discussion continued.

1. Gaurang Shah, University of Michigan

C. Commission Action

Motion by Commissioner Brooks-Williams, seconded by Commissioner Cowling to take proposed action on the language as presented (see Attachment I) and move to Public Hearing and forward to the JLC. Motion carried in a vote of 9 - Yes, 1 - No, and 0 - Abstained.

Recessed at 11:32 a.m. and reconvened at 11:44 a.m.

VIII. Neonatal Intensive Care Services/Beds (NICU) & Special Newborn Nursing Services – Draft Language

Ms. Rogers gave an overview of the draft standards (see Attachment J).

A. Public Comment

None.

B. Commission Discussion

None.

C. Commission Action

Motion by Commissioner Tomatis, seconded by Commissioner Hughes to take proposed action on the language (see Attachment J) as presented and move to a Public Hearing and forward to the JLC. Motion carried in a vote of 10 - Yes, 0- No, and 0- Abstained.

IX. Bone Marrow Transplantation (BMT) Services Standards Advisory Committee (SAC) – Final Report

Bruce Carl, MD, BMTSAC Chairperson, provided the report (see Attachment K).

Discussion followed.

B. Public Comment

1. Brett Jackson, Economic Alliance of Michigan (EAM)
2. Edward Peres, MD, Henry Ford Health System
3. Joseph Uberti, MD, Karmanos Cancer Center
4. David Walker, Spectrum Health
5. Gregory Yanik, MD, University of Michigan (see Attachment L)
6. Adil Akhtar, MD, Beaumont Health
7. Patrick O'Donovan, Beaumont Health

B. Commission Discussion

Discussion continued.

C. Commission Action

Motion by Commissioner Falahee, seconded by Commissioner Hughes to instruct the Department to work with an independent entity to analyze the methodologies that were presented to the SAC, to look at the strengths

and weaknesses of those or the administrative issues with those. If there are issues that mean either one or both of them aren't adequate or enforceable, that the Department work with that independent entity to come up with a new methodology that would be presented to us at our next meeting in September if possible. Motion carried in a vote of 10 - Yes, 0- No, and 0- Abstained.

X. Legislative Report

Ms. Hertel gave a verbal update on legislative activity.

XI. Administrative Update

A. Planning and Access to Care Section Update

Ms. Nagel gave a verbal update of the section.

B. CON Evaluation Section Update

1. Compliance Report (see Attachment M)

Ms. Bhattacharya gave a summary of the compliance report.

2. Quarterly Performance Measures (see Attachment N)

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

XII. Legal Activity Report

Written report only (see Attachment O).

XIII. Future Meeting Dates – 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 P) including today's actions.

A. Commission Discussion

None.

B. Commission Action

Motion by Commissioner Hughes, seconded by Commissioner Mukherji to accept the work plan as presented including today's modifications. Motion Carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

XVI. Adjournment

Motion by Commissioner Falahee, seconded by Commissioner Brooks-Williams to adjourn the meeting at 1:37 p.m. Motion Carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

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

Date: May 17, 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 March 16, 2016 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed MRI Services Standards on April 21, 2016. Written testimony was accepted for an additional seven days after the hearing via an electronic link on the Commission's website. No testimony was received.

Department Recommendation:

The Department supports the language as presented at the March 16, 2016 CON Commission meeting.

MICHIGAN DEPARTMENT OF ~~COMMUNITY~~ HEALTH AND HUMAN SERVICES

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 AND HUMAN SERVICES (~~MDCH~~MDHHS).

(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:

(a) 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.

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

(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 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 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 requirements are met:

(i) the owner of the building where the site is located has incurred a filing for bankruptcy under chapter 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. An applicant proposing to acquire an existing fixed or mobile MRI service and its unit(s) shall demonstrate the following:

(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.~~

(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.

(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 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.

(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.

(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.

(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 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 (A) or (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 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 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 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, the appeal is withdrawn by the applicant.

(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) The Department shall not consider a withdrawal of a signed data commitment on or after the date an application is deemed submitted 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.

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 ~~September 25, 2014~~MARCH 16, 2016 and effective ~~December 22, 2014~~MAY 27, 2016.

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

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

Date: May 17, 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 Psychiatric Beds and 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 Psychiatric Beds and Services Standards at its March 16, 2016 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed Psychiatric Beds and Services Standards on April 21, 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 and Verbal Testimony:

1.) Robert L. Nykamp, Pine Rest

- States that "the workgroup has only heard anecdotal evidence of an acute inpatient psychiatric access problem in the State of Michigan for care of developmental disabilities, geriatric care and patients with medical needs. It would be of critical importance to collect specific demand information on these three specialty populations."
- States that "further data is needed to determine patients who are represented in anecdotal information regarding psychiatric boarding in Emergency Departments meet inpatient criteria, or if respite care, residential care, partial hospitalization care or intensive outpatient care is more appropriate to meet the needs of these special populations of patients."
- States that "determine why current Medicaid funding and CON standards have not been able to influence hospitals to expand or open new units based on available bed inventories."
- States that "adult psychiatric beds can currently be utilized for the three proposed specialty populations."
- States that occupancy rates per the 2014 MI CON Annual Survey is 69.2% for adult psych beds and 70.1% for child & adolescent psych beds.

- It was suggested to re-evaluate health services areas; develop a Medicaid Psychiatric Inpatient Intensive Care per diem payment code to off-set the anticipated staffing costs to manage (estimated at an additional $500 - $1,000 per day) these proposed special populations; and state-wide incentives for loan forgiveness for psychiatrists moving into Michigan or deciding to stay in Michigan post residency.

Department Recommendation:

The Department supports the language as presented at the March 16, 2016 CON Commission meeting with the following proposed amendment:

Additional language to allow for an existing hospital licensed under Part 215 of the Code that does not currently provide adult or child/adolescent psychiatric services to begin operation of a new adult or child/adolescent psychiatric service for medical psychiatric patients in an over bedded area using special population beds to provide better access to care for the medical psychiatric patient.

DIST adm mtg 6-15-16
Attachment D

Garden City Hospital

Compassion. Community. Quality.

6/15/16

Testimony regarding the Certificate of Need Review Standards for Psychiatric Beds and Services

Good Morning. My name is Saju George and I am the CEO of Garden City Hospital. We really appreciate the time and effort put forth by the workgroup on Psychiatric Beds and Services and supports the direction the Commission has taken to create a statewide pool for both geriatric psychiatric patients as well as medical psychiatric patients. We also support the recommendations of the Department to expand the pool to include new applicant facilities as well.

As a community provider, Garden City Hospital sees approximately 6 to 8 patients per day in our ER that requires inpatient psychiatric services. Many of the psychiatric patients that we see in our ER are seniors. Often we have difficulty placing these patients, and in some cases these patients stay in our ER for as long as 7-10 days. This situation is not ideal for the patient, their families or the acute care providers. Further, in many instances patients are sent to a facility a long distance away putting further burden on the patient and their loved ones.

Studies shows, majority of adults with a mental illness have at least one medical condition. Comorbidity is associated with elevated symptom burden, functional impairment, decreased length and quality of life, and increased costs. The pathways causing comorbidity are complex and bidirectional. Medical disorders may lead to mental disorders, mental conditions may place a person at risk for medical disorders, and mental and medical disorders may share common risk factors.

Recognition of the needs of this patient population is essential to our community and population health management. Our community would benefit greatly from the initiation of both a medical and geriatric program. We hope to provide Geropsychiatric treatment services at Garden City Hospital that encompasses a greater demographic than traditional geriatric programming, which limits programming capacity for patients who are age 65 and above.

According to a report prepared by Milliman, Inc. for the American Psychiatric Association, integrated treatment models such as the Geropsychiatric programming proposed at Garden City Hospital are a cost-effective approach to healthcare delivery for complex patients. After tracking total healthcare costs for a four year period, researchers determined that collaborative care patient costs were, on average, $70 million less than the costs of those receiving usual care. This represents approximately a 10 percent Medicare cost savings in total healthcare costs. The report indicated that collaborative care had lowered costs in every

category that was observed. Ultimately, a patient in a collaborative care program was 87 percent more likely to have lower total healthcare costs than those receiving usual care.

The creation of a statewide pool for both geriatric psychiatric patients and medical psychiatric patients by the Commission, as well as the inclusion of new applicant facilities will benefit communities throughout Michigan. Adopting the proposed rules will increase eligibility and decrease healthcare costs, benefitting patients, providers, and other stakeholders.

Thank you for your time and consideration.

CON Psychiatric Beds and Services

Denial of Service Pilot Compliance Program Update

As part of a collaborative effort, the Department of Health and Human Services (MDHHS) has initiated a compliance program to monitor the denial of treatment for inpatient psychiatric patients and collect information from the Prepaid Inpatient Health Plans (PIHP). The PIHP is responsible for reporting denial data to Certificate of Need (CON) on a weekly basis. This is a Pilot program expected to run through September 2016. The PIHP participating in the pilot is Region 5, Mid-State Health Network, and the Community Mental Health Boards (CMH) functioning in that region.

This pilot program is part of the department's evaluation of the mental health services and related issues in order to propose policy changes to enhance access to care. Specifically, the assessments of the reasons for denial are being monitored and verified through this pilot program. Additionally, if the denial of service complaint is based on a reason contained within the CON Standards for Psychiatric Beds and Services, the department may take appropriate compliance actions as authorized by law.

The PIHP provides basic information about the patient, the date and time the hospital denied service, the hospital that denied service, the reason service was denied, and if the patient had comorbidities. The department started collecting information as of March 2016. To date, the PIHP reported 3,047 denials for 360 individual patients. The patients' age range from 7 to 73 years with 18% being child/adolescent patients and 82% being adult patients. When evaluated by gender, male patients account for 1,890 denials (62%) and female patients account for 1,157 denials (38%).

Using a straight calculation, average number of denials per patient (3,047 denials / 360 unique patients) is 8 denials per patient before that patient is admitted to an inpatient psych bed. Unfortunately, the average is a little misleading when the data is evaluated further. Patients are receiving denials over several consecutive dates prior to placement and also, over several non-consecutive dates, indicating multiple different events for seeking psychiatric treatment or readmission. For the 360 unique patients, 60 of the patients received denials over 2 consecutive dates, 12 patients received denials over 3 consecutive dates, 3 patients received denials over 4 consecutive dates, and 1 patient received denials over 5 consecutive dates. Additionally, 15 patients received denials over non-consecutive dates indicating multiple different events of seeking psychiatric treatment. The maximum number of denials a single patient received prior to admission was 62 denials over a 4-day period.

Peaks and valleys are being analyzed in the number of denials submitted on a weekly basis. The maximum number reported in a week was 390; with the minimum weekly total of 170. This same variance is noted when looking at denials on a daily basis; with a daily peak of more than 90 denials on a single date to valleys of less than 10 denials on other dates.

There are established categories for the classification of the denial. Currently, 70% of the denials are associated with 'the facility being at capacity' (70%). Next, 'failure to return a phone call' (8%) and 'patient did not fit milieu of the unit' (8%) were the categories with the next highest frequency. Finally, the 'other' category accounts for 7% of the denials.

At this point, the department continues to collect data and monitor the denial of psych services to be able to analyze trends and identify areas of concerns.

MICHIGAN DEPARTMENT OF ~~COMMUNITY~~ HEALTH AND HUMAN SERVICES

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 AND HUMAN SERVICES (~~MDCH~~MDHHS).

(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 AND HUMAN SERVICES

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 BEGIN OPERATION OF A NEW ADULT OR CHILD/ADOLESCENT PSYCHIATRIC SERVICE OR 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 BEGIN OPERATION OF A NEW ADULT PSYCHIATRIC SERVICE OR 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 BEGIN OPERATION OF A NEW ADULT OR CHILD/ADOLESCENT PSYCHIATRIC SERVICE OR 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.

CT CON Workgroup Report

Suresh K. Mukherji, M.D., M.B.A., F.A.C.R.

Certificate of Need Commission

June, 15, 2016

CHARGE

Should Dental CT be deregulated?

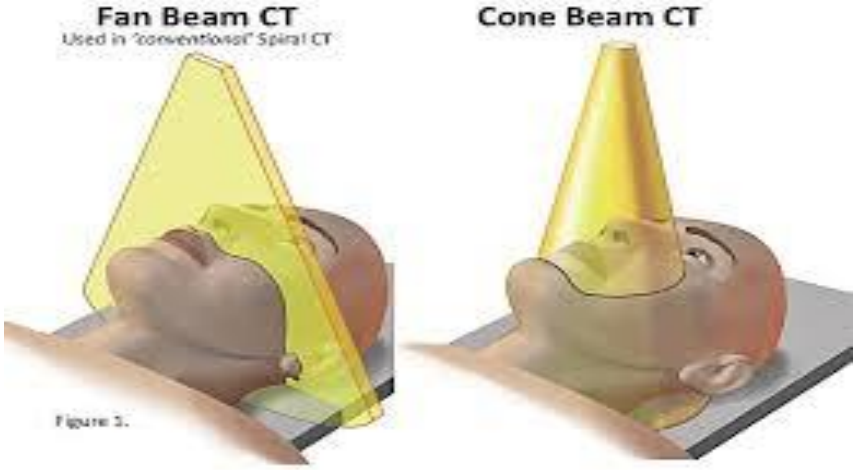
INTRODUCTION

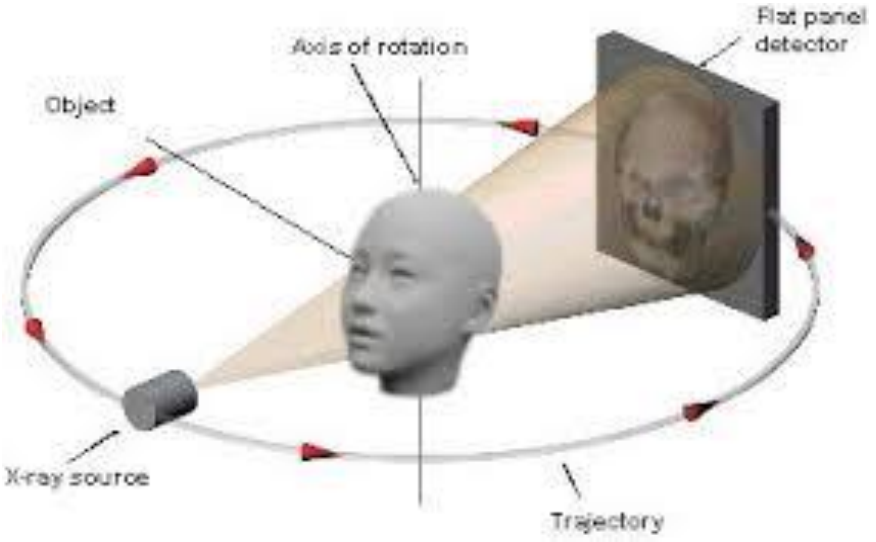
“Fixed Unit”

“Dental CT”

INTRODUCTION

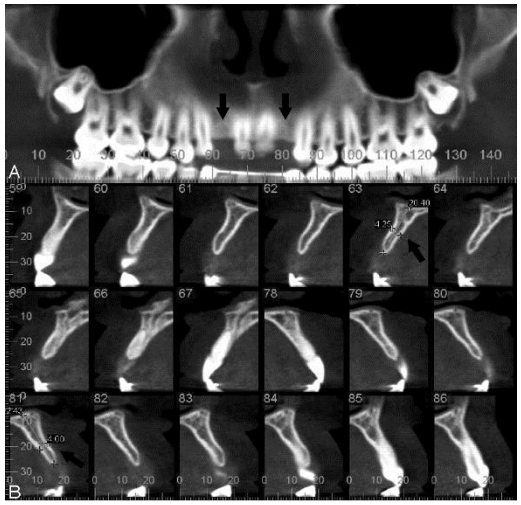
"Cone Beam CT"

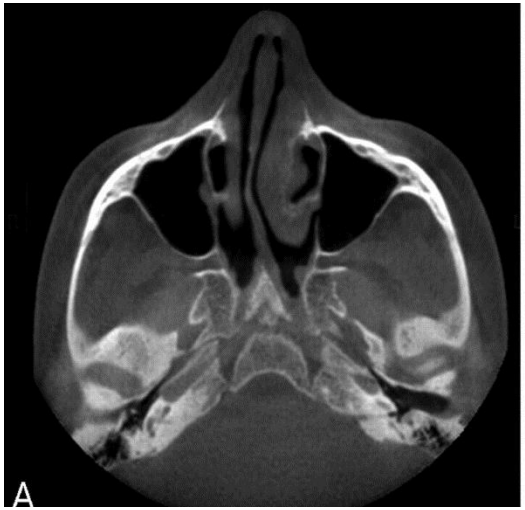




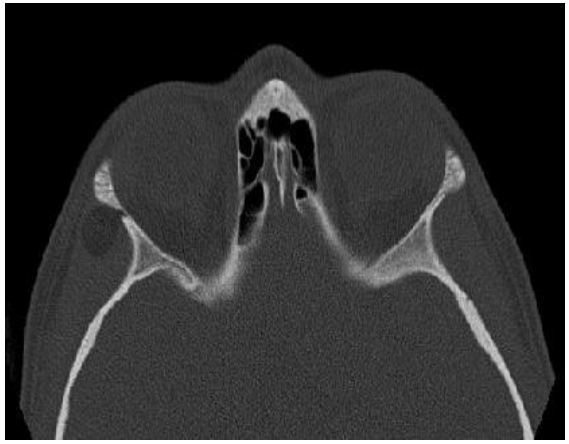
INTRODUCTION

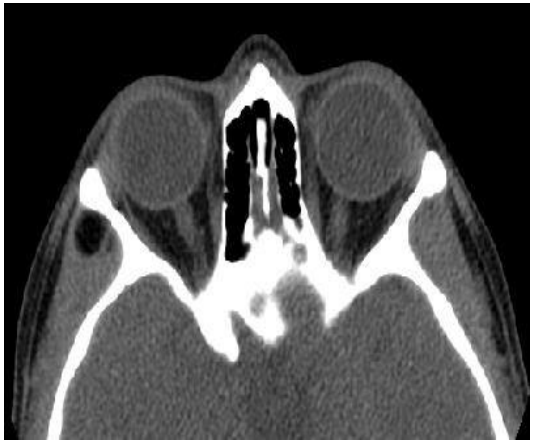
"Dental CT"
"Cone Beam"





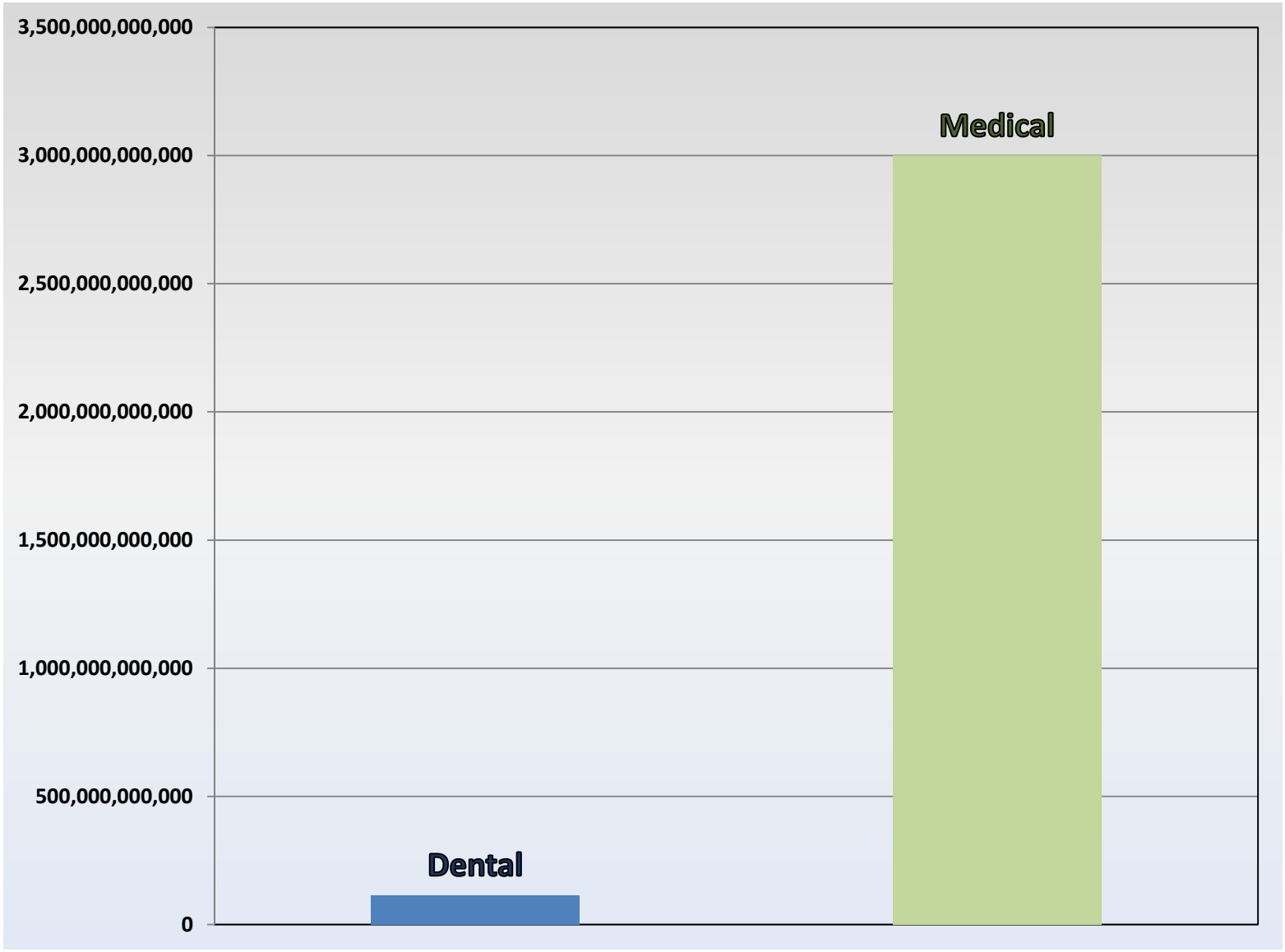
"Fixed Unit CT"





2014

Attachment G



Attendees

- Kent Albrecht
- Umbrin Ateequi
- Tulika Bhattacharya
- Karen Burgess
- Mark Burton
- Jim Cavanagh
- Melissa Cupp
- Larry DeGroat
- Brent Garvin
- Sean Gehle
- Bret Jackson
- Mark Johnston
- Michael Kasotakis
- Josh Kluzak
- Suresh Mukherji
- Amber Myers
- Beth Nagel
- James Pienkowski
- Brenda Rogers
- Matt Rowell
- Gaurang Shah
- Brian Smiley
- Bill Sullivan
- Steven Szelag
- Matthew Usher
- Michael Warren
- Matt Weaver
- Mark Weiss
- Ralph Lieto
- Nancy List
- Matt LaMaster

Cost

Attachment G

"Pros"

- Progressive reduction in cost of machine
- Uncovered benefit
- Patient cost is determined by each provider
- No substantial increase in overall health care costs for hospitals or payers

"Cons"

- Unclear if reduced cost is transferred to patient
- Cost born by patient
- No standardized fee schedule for CMS or insurance
- Increase individual cost

Access

Attachment G

"Pros"

- Cumbersome application process
- Eliminate restrictions on access to technology
- 20% - 30% of dentists have these in other states
- Improved access for all citizens of the state
- More convenient for patients to have scanners in dentist offices
- Improves access to CBCT for Dentists

"Cons"

- No applications have been denied
- Accessibility increased by 300% over 3 years
- 2% currently in Michigan
- Eliminate CON provisions for requiring dentists to treat Medicaid patients
- Self-referral; no pre-authorization as for other advanced imaging (self-pay)
- Prevents access to CBCT for other providers who manage and treat patients with maxillofacial disorders

Quality

Attachment G

"Pros"

- Majority of scanners and utilization performed by subspecialists
- Better visualization of bone thickness prior to implants over panorex
- Better outcomes for orthodontics
- More available for dental students
- Is this considered a CT or upgraded panorex?

"Cons"

- Permit dentists currently not performing certain procedures to perform these procedures
- ? Sinuses, TMJ, tumors? (Hospital-based)
- Debatable; no randomized prospective trials
- Currently available in dental schools in the state (UM)
- Historically considered a CT when initially covered

Workgroup Recommendations

Dental CT Deregulation: 12

Continued Regulation: 9

Questions?

PRESENTATION BY:

Robert Langlais BA, DDS, MS, PhD
Professor Emeritus Univ. Texas HSC at San Antonio, TX
Board Certified Oral & Maxillofacial Radiologist
Licensed to practice dentistry in Texas

Presentation Title:
CBCT applications and how CBCT enhances treatment outcomes:

1. **Accuracy of CBCT measurements:** Here are some examples:
   Linear measurements:
   Assess the length of the jaw vs. the combined width of unerupted teeth. These teeth may or may not fit in the jaw.

   Curvilinear measurements:
   Root canals are often curved; accurate length measurements are critical for successful treatment.

   Angular measurements:
   These are used to plan treatment of malaligned teeth.

   Volumetric measurements:
   Supply bone graft material for a bone deficient area to receive an implant or build up bone loss due to chronic gum disease.

2. **Treatment tools as developed from the CBCT volume:**
   Here are some examples:

   Implant specifications:
   Implant size and shape as determined with the CBCT scan and software

   Implant selection:
   This is done from the implant library in the CBCT software.

   Manufacture of surgical guides:
   These devices are important for the accurate placement of implants in the jaws

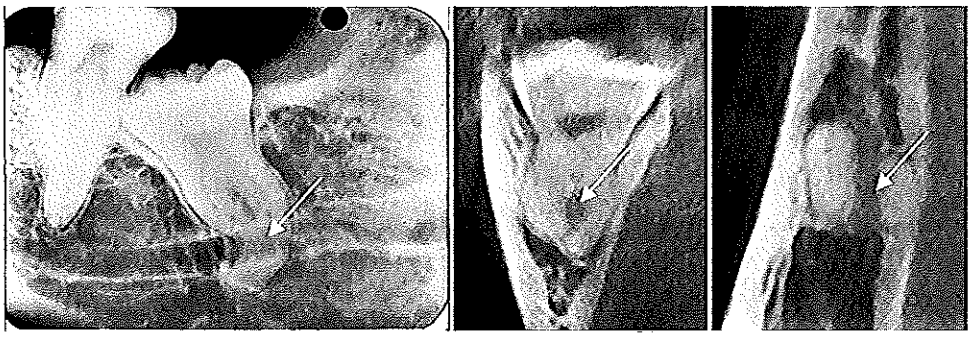
   Third molar applications:
   Measure the jaw space available to allow the tooth to erupt into the mouth vs. extraction.

   Advanced orthodontic treatment:
   This treatment makes use of a sequential series of preplanned and manufactured acrylic-based appliances which must snap onto the teeth in their new position.

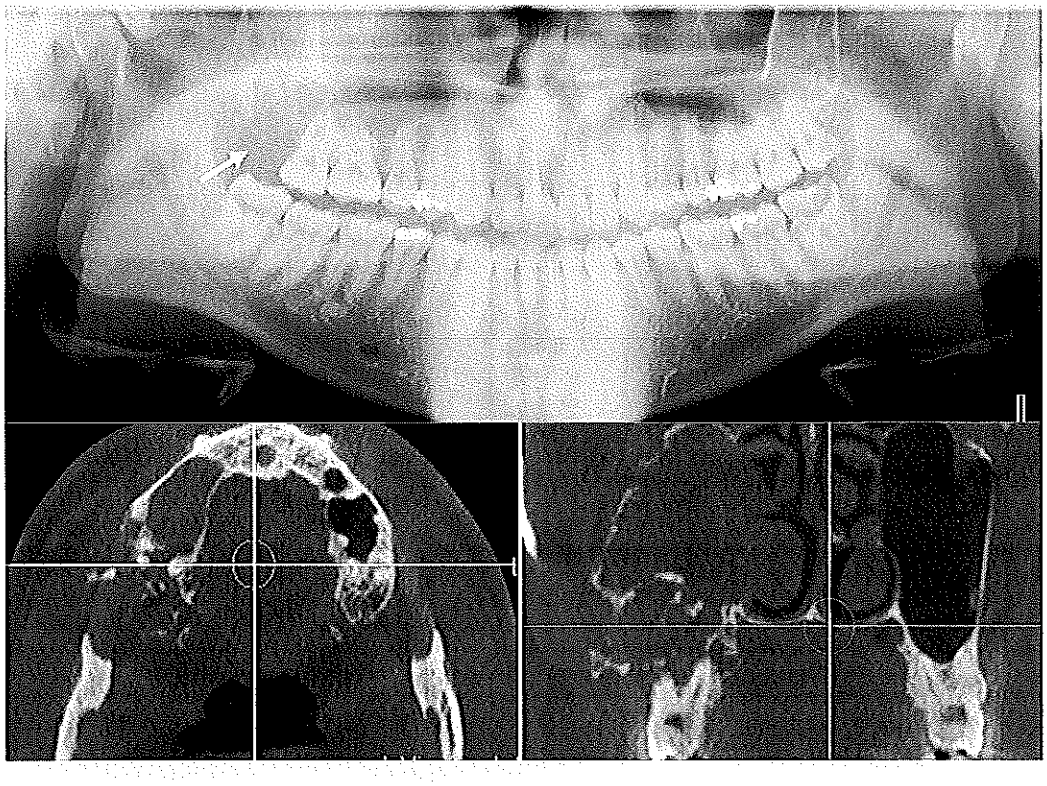
3. **Orthodontic treatment planning:**
   This procedure is traditionally planned with several 2D head plate x-ray images; with CBCT a more advanced 3D orthodontic treatment planning analysis is possible.

4. **Extent and distribution of abnormal findings:**
   Surgical planning:
   The extent of disease cannot always be fully determined from current 2D imaging modalities. As a result, surgery cannot always be accurately planned.

   Inflammatory disease:
   This may extend much further than is visible in the 2D images.



Case 3: Identifying and preventing a serious surgical complication:
Patient A left: Impacted 3rd molar root and mandibular canal are superimposed in standard 2D image, the relationship of these structures is not clear; patient B middle & right: CBCT image of mandibular canal containing major artery, vein & nerve pass between the roots of the impacted 3rd molar; improper removal of this tooth may result in severe bleeding and permanent sensory nerve damage to the lip and gums.



Case 4. Visualizing the full extent of a lesion:
Standard 2D panoramic imaging (top) does not fully indicate a cause for the patient's continuing symptoms after the upper right 3rd molar was extracted (arrow); axial and coronal CBCT (bottom left & right) demonstrates the extent of the lesion which was a large ossifying fibroma, a benign but destructive tumor extending into the maxillary sinus and eroding into the nose.

CONCLUSION:

CBCT adds a new and greater dimension to the effectiveness of dental diagnoses and treatments at very low doses of radiation. Which would folks rather have: a dentist with this equipment or one without this technology?

MICHIGAN DEPARTMENT OF ~~COMMUNITY~~ HEALTH AND HUMAN SERVICES

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR COMPUTED TOMOGRAPHY (CT) SCANNER 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 CT services and the delivery of services under Part 222 of the Code. Pursuant to Part 222 of the Code, CT 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 CT scanner service" means obtaining possession or control of an existing fixed or mobile CT scanner service or existing CT scanner(s) by contract, ownership, or other comparable arrangement. For proposed projects involving mobile CT scanners, this applies to the central service coordinator and/or host facility.

(b) "Billable procedure" means a CT procedure billed as a single unit and performed in Michigan.

(c) "Body scans" include all spinal CT scans and any CT scan of an anatomical site below and including the neck.

(d) “Bundled body scan” means two or more body scans billed as one CT procedure.

(e) "Central service coordinator" means the organizational unit which has operational responsibility for a mobile CT scanner and which is a legal entity authorized to do business in the state of Michigan.

(f) "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.

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

(h) "Computed tomography" or "CT" means the use of radiographic and computer techniques to produce cross-sectional images of the head or body.

(i) “CT-angio hybrid unit” means an integrated system comprised of both CT and angiography equipment sited in the same room that is designed specifically for interventional radiology or cardiac procedures. The CT unit is a guidance mechanism and is intended to be used as an adjunct to the procedure. The CT unit shall not be used for diagnostic studies unless the patient is currently undergoing a CT-angio hybrid procedure and is in need of a secondary diagnostic study.

(j) "CT equivalents" means the resulting number of units produced when the number of billable procedures for each category is multiplied by its respective conversion factor tabled in Section 22.

(k) "CT scanner" means x-ray CT scanning systems capable of performing CT scans of the head, other body parts, or full body patient procedures including Positron Emission Tomography (PET)/CT scanner hybrids if used for CT only procedures. The term does not include emission-computed tomographic systems utilizing internally administered single-photon gamma ray emitters, positron annihilation CT systems, magnetic resonance, ultrasound computed tomographic systems, CT simulators used solely for treatment planning purposes in conjunction with an MRT unit, ~~and~~ non-diagnostic, intra-operative guidance tomographic units, AND DENTAL CT SCANNERS THAT generate a peak power of 5 kilowatts or less as certified by the manufacturer, AND specifically designed to generate CT images to facilitate dental procedures BY A LICENSED DENTIST UNDER THE PRACTICE OF DENTISTRY.

(l) "CT scanner services" means the CON-approved utilization of a CT scanner(s) at one site in the case of a fixed CT scanner service or at each host site in the case of a mobile CT scanner service.

(m) "Dedicated pediatric CT" means a fixed CT scanner on which at least 70% of the CT procedures are performed on patients under 18 years of age.

~~(n) "Dental CT examinations" means use of a CT scanner specially designed to generate CT images to facilitate dental procedures.~~

~~(o) "Dental procedures" means dental implants, wisdom teeth surgical procedures, mandibular or maxillary surgical procedures, or temporal mandibular joint evaluations.~~

(p) "Department" means the Michigan Department of ~~Community~~ Health AND HUMAN SERVICES (MD~~C~~HHS).

(q) "Emergency room" means a designated area physically part of a licensed hospital and recognized by the Department as having met the staffing and equipment requirements for the treatment of emergency patients.

(r) "Excess CT Equivalents" means the number of CT equivalents performed by an existing CT scanner service in excess of 10,000 per fixed CT scanner and 4,500 per mobile CT scanner or either an existing fixed or mobile CT scanner service, the number of CT scanners used to compute excess CT equivalents shall include both existing and approved but not yet operational CT scanners. In the case of a CT scanner service that operates or has a valid CON to operate that has more than one fixed CT scanner at the same site, the term means number of CT equivalents in excess of 10,000 multiplied by the number of fixed CT scanners at the same site. For example, if a CT scanner service operates, or has a valid CON to operate, two fixed CT scanners at the same site, the excess CT equivalents is the number that is in excess of 20,000 (10,000 x 2) CT equivalents. In the case of an existing mobile CT scanner service, the term means the sum of all CT equivalents performed by the same mobile CT scanner service at all of the host sites combined that is in excess of 4,500. For example, if a mobile CT scanner service serves five host sites with 1 mobile CT scanner, the term means the sum of CT equivalents for all five host sites combined that is in excess of 4,500 CT equivalents.

(s) "Existing CT scanner service" means the utilization of a CON-approved and operational CT scanner(s) at one site in the case of a fixed CT scanner service or at each host site in the case of a mobile CT scanner service.

(t) "Existing CT scanner" means a CON-approved and operational CT scanner used to provide CT scanner services.

(u) "Existing mobile CT scanner service" means a CON-approved and operational CT scanner and transporting equipment operated by a central service coordinator serving two or more host sites.

(v) "Expand an existing CT scanner service" means the addition of one or more CT scanners at an existing CT scanner service.

(w) "Head scans" include head or brain CT scans; including the maxillofacial area; the orbit, sella, or posterior fossa; or the outer, middle, or inner ear; or any other CT scan occurring above the neck.

(x) "Health Service Area" or "HSA" means the groups of counties listed in Appendix A.

(y) "HIPAA" means the Health Insurance Portability and Accountability Act of 1996.

(z) "Hospital-based portable CT scanner or portable CT scanner" means a CT scanner capable of being transported into patient care areas (i.e., ICU rooms, operating rooms, etc.) to provide high-quality imaging of critically ill patients.

(aa) "Host site" means the site at which a mobile CT scanner is authorized to provide CT scanner services.

(bb) "Initiate a CT scanner service" means to begin operation of a CT scanner, whether fixed or mobile, at a site that does not perform CT scans as of the date an application is submitted to the Department. The term does not include the acquisition or replacement of an existing CT scanner service at the existing site or to a different site or the renewal of a lease.

(cc) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396 to 1396w-5.

(dd) "Mobile CT scanner service" means a CT scanner and transporting equipment operated by a central service coordinator and which must serve two or more host facilities.

(ee) "Mobile CT scanner network" means the route (all host facilities) the mobile CT scanner is authorized to serve.

(ff) “Pediatric patient” means any patient less than 18 years of age.

(gg) "Replace an existing CT scanner" means an equipment change of an existing CT scanner, that requires a change in the radiation safety certificate, proposed by an applicant which results in that applicant operating the same number of CT scanners before and after project completion, at the same geographic location. The term also includes relocating an existing CT scanner or CT scanner service from an existing site to a different site.

(hh) “Sedated patient” means a patient that meets all of the following:

(i) Patient undergoes procedural sedation and whose level of consciousness is either moderate 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 requires observation by personnel, other than technical employees routinely assigned to the CT unit, who are trained in cardiopulmonary resuscitation (CPR) and pediatric advanced life support (PALS).

(ii) “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.

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

Section 3. Requirements for approval for applicants proposing to initiate a CT scanner service

Sec. 3. An applicant proposing to initiate a CT scanner service, other than a ~~dental CT scanner service or a~~ hospital-based portable CT scanner service, shall demonstrate the following, as applicable:

(1) A hospital proposing to initiate its first fixed CT scanner service shall demonstrate each of the following:

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

(b) The hospital operates an emergency room that provides 24-hour emergency care services as authorized by the local medical control authority to receive ambulance runs.

(2) An applicant, other than an applicant meeting all of the applicable requirements of subsection (1), proposing to initiate a fixed CT scanner service shall project an operating level of at least 7,500 CT equivalents per year for the second 12-month period after beginning operation of the CT scanner.

(3) An applicant proposing to initiate a mobile CT scanner service shall project an operating level of at least 3,500 CT equivalents per year for the second 12-month period after beginning operation of the CT scanner.

(4) An applicant proposing to initiate CT scanner services as an existing host site on a different mobile CT scanner service shall demonstrate the following:

(a) The applicant provides a proposed route schedule.

(b) The applicant provides a draft contract for services between the proposed host site and central service coordinator.

~~**Section 4. Requirements for approval for applicants proposing to initiate a dental CT scanner service**~~

~~Sec. 4. An applicant proposing to initiate a fixed or mobile dental CT scanner service shall demonstrate each of the following, as applicable:~~

~~(1) An applicant is proposing a dental CT scanner service for the sole purpose of performing dental CT examinations.~~

~~(2) The CT scanner generates a peak power of 5 kilowatts or less as certified by the manufacturer.~~

~~(3) An applicant proposing to initiate a dental CT scanner service, other than an applicant that is proposing a dental CT scanner service in HSA 8, shall project an operating level of at least 200 dental CT examinations per year for the second 12-month period after beginning operation of the dental CT scanner.~~

~~(4) The applicant has demonstrated to the satisfaction of the Department that the person(s) (e.g., technician, dentist) operating the dental CT scanner has been appropriately trained and/or certified by one of the following groups, as recognized by the Department: a dental radiology program in a certified dental school, an appropriate professional society, or a dental continuing education program accredited by the American Dental Association.~~

~~(5) The applicant has demonstrated to the satisfaction of the Department that the dental CT examinations generated by the proposed dental CT scanner will be interpreted by a licensed dentist(s) trained and/or certified by one of the following groups, as recognized by the Department: a dental radiology program in a certified dental school, an appropriate professional society, or a dental continuing education program accredited by the American Dental Association.~~

~~(6) An applicant proposing to initiate mobile dental CT scanner services as an existing host site on a different mobile dental CT scanner service shall demonstrate the following:~~
~~(a) The applicant provides a proposed route schedule.~~
~~(b) The applicant provides a draft contract for services between the proposed host site and central service coordinator.~~

Section 5. Requirements for approval for applicants proposing to expand an existing CT scanner service

Sec. 5. An applicant proposing to expand an existing CT scanner service, other than a ~~dental CT scanner service or a~~ hospital-based portable CT scanner service, shall demonstrate the following, as applicable:

(1) An applicant proposing to expand an existing fixed CT scanner service shall demonstrate that all of the applicant's fixed CT scanners, excluding CT scanners approved pursuant to sections 6, 13, 14, and 18, have performed an average of at least 10,000 CT equivalents per fixed CT scanner for the most recent continuous 12-month period preceding the applicant's request. In computing this average, the Department will divide the total number of CT equivalents performed by the applicant's total number of fixed CT scanners, including both operational and approved but not operational fixed CT scanners.

(2) An applicant proposing to expand an existing fixed CT scanner service approved pursuant to Section 18 shall demonstrate that all of the applicant’s dedicated pediatric CT scanners have performed an average of at least 3,000 CT equivalents per dedicated pediatric CT scanner for the most recent continuous 12-month period preceding the applicant’s request. In computing this average, the Department will divide the total number of CT equivalents performed by the applicant’s total number of dedicated pediatric CT scanners, including both operational and approved but not operational dedicated pediatric CT scanners.

(3) If an applicant proposes to expand an existing mobile CT scanner service, the applicant shall demonstrate that all of the applicant's mobile CT scanners have performed an average of at least 5,500 CT equivalents per mobile CT scanner for the most recent continuous 12-month period preceding the applicant's request. In computing this average, the Department will divide the total number of CT

equivalents performed by the applicant's total number of mobile CT scanners, including both operational and approved but not operational mobile CT scanners.

~~**Section 6. Requirements for approval for applicants proposing to expand an existing dental CT scanner service**~~

~~Sec. 6. An applicant proposing to expand an existing fixed or mobile dental CT scanner service shall demonstrate that all of the applicant's dental CT scanners have performed an average of at least 300 dental CT examinations per fixed or mobile dental CT scanner for the most recent continuous 12-month period preceding the applicant's request. In computing this average, the Department will divide the total number of dental CT examinations performed by the applicant's total number of fixed or mobile dental CT scanners, including both operational and approved but not operational fixed or mobile dental CT scanners.~~

Section 7. Requirements for approval for applicants proposing to replace an existing CT scanner

Sec. 7. An applicant proposing to replace an existing CT scanner or service, other than a ~~dental CT scanner service or a~~ hospital-based portable CT scanner service, shall demonstrate the following, as applicable:

(1) An applicant proposing to replace an existing fixed, mobile, or dedicated pediatric CT scanner shall demonstrate all of the following:

(a) The replacement CT scanner will be located at the same site as the CT scanner to be replaced.

(b) The existing CT scanner(s) proposed to be replaced is fully depreciated according to generally accepted accounting principles, or, that the existing equipment clearly poses a threat to the safety of the public, or, that the proposed replacement CT scanner offers technological improvements which enhance quality of care, increase efficiency, and/or reduce operating costs and patient charges.

(2) An applicant proposing to replace an existing fixed CT scanner service to a different site shall demonstrate that the proposed project meets all of the following:

(a) The existing fixed CT scanner service 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)(ii) OR (iii).

(b) The proposed new site is within a 10-mile radius of a site at which an existing fixed CT scanner service is located if an existing fixed CT scanner service is located in a metropolitan statistical area county, or a 20-mile radius if an existing fixed CT scanner service is located in a rural or micropolitan statistical area county.

(c) The CT scanner service to be replaced performed at least an average of 7,500 CT equivalents per fixed scanner in the most recent 12-month period for which the Department has verifiable data~~,~~ UNLESS ONE OF THE FOLLOWING REQUIRMENTS ARE MET:

(i) ~~except for a~~An applicant ~~that~~ meets all of the requirements of Section 3(1).

(ii) 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;

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

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

(d) The applicant agrees to operate the CT scanner service in accordance with all applicable project delivery requirements set forth in Section 20 of these standards.

(3) An applicant proposing to replace a fixed CT scanner(s) of an existing CT scanner service to a different site shall demonstrate that the proposed project meets all of the following:

(a) The existing CT scanner service from which the CT scanner(s) is 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 a site at which an existing fixed CT scanner service is located if an existing fixed CT scanner service is located in a metropolitan statistical area county, or a 20-mile radius if an existing fixed CT scanner service is located in a rural or micropolitan statistical area county..

(c) Each existing CT scanner at the service from which a scanner is to be replaced performed at least an average of 7,500 CT equivalents per fixed scanner in the most recent 12-month period for which the Department has verifiable data.

(d) The applicant agrees to operate the CT scanner(s) at the proposed site in accordance with all applicable project delivery requirements set forth in Section 20 of these standards.

(e) For volume purposes, the new site shall remain associated with the existing CT service for a minimum of three years.

~~**Section 8. Requirements for approval for applicants proposing to replace an existing dental CT scanner**~~

~~Sec. 8. An applicant proposing to replace an existing dental CT scanner or service shall demonstrate the following, as applicable:~~

~~(1) An applicant proposing to replace an existing fixed or mobile dental CT scanner shall demonstrate all of the following:~~

~~(a) The replacement dental CT scanner will be located at the same site as the dental CT scanner to be replaced.~~

~~(b) the existing dental CT scanner(s) proposed to be replaced is fully depreciated according to generally accepted accounting principles, or, that the existing equipment clearly poses a threat to the safety of the public, or that the proposed replacement dental CT scanner offers technological improvements which enhance quality of care, increase efficiency, and/or reduce operating costs and patient charges.~~

~~(2) An applicant proposing to replace an existing fixed dental CT scanner service to a different site shall demonstrate that the proposed project meets all of the following:~~

~~(a) The existing fixed dental CT scanner service to be replaced has been in operation for at least 36 month as of the date an application is submitted to the Department.~~

~~(b) The proposed new site is within a 10-mile radius of a site at which an existing fixed dental CT scanner service is located if an existing fixed dental CT scanner service is located in a metropolitan statistical area county, or a 20-mile radius if an existing fixed dental CT scanner service is located in a rural or micropolitan statistical area county.~~

~~(c) The dental CT scanner service to be replaced performed at least an average of 200 dental CT examinations per fixed dental CT scanner in the most recent 12-month period for which the Department has verifiable data.~~

~~(d) The applicant agrees to operate the dental CT scanner service in accordance with all applicable project delivery requirements set forth in Section 20 of these standards.~~

~~(3) An applicant proposing to replace a fixed dental CT scanner(s) of an existing dental CT scanner service to a different site shall demonstrate that the proposed project meets all of the following:~~

~~(a) The existing dental CT scanner service from which the dental CT scanner(s) is to be replaced has been in operation for at least 36 months as of the date an application is submitted to the Department.~~

~~(b) For volume purposes, the new site shall remain associated with the existing CT service for a minimum of three years.~~

~~(c) The proposed new site is within a 10-mile radius of a site at which an existing fixed dental CT scanner service is located if an existing fixed dental CT scanner service is located in a metropolitan statistical area county, or a 20-mile radius if an existing fixed dental CT scanner service is located in a rural or micropolitan statistical area county.~~

~~(d) Each existing dental CT scanner at the service from which a scanner is to be replaced performed at least an average of 200 dental CT examinations per fixed dental CT scanner in the most recent 12-month period for which the Department has verifiable data.~~

~~(e) The applicant agrees to operate the dental CT scanner(s) at the proposed site in accordance with all applicable project delivery requirements set forth in Section 20 of these standards.~~

Section 9. Requirements for approval for applicants proposing to acquire an existing CT scanner service or an existing CT scanner(s)

Sec. 9. An applicant proposing to acquire an existing fixed or mobile CT scanner service, other than a ~~dental CT scanner service or a~~ hospital-based portable CT scanner service, shall demonstrate the following, as applicable:

(1) ~~An~~ THE applicant ~~proposing to acquire an existing fixed or mobile CT scanner service,~~ shall not be required to be in compliance with the volume requirement applicable to the seller/lessor on the date the acquisition occurs ~~demonstrate that a~~ IF THE proposed project meets ~~all~~ ONE of the following:

(a) ~~For an application for the proposed~~IT IS THE first acquisition of ~~an~~ THE existing fixed or mobile CT scanner service~~,~~ for which a final decision has not been issued after June 4, 2004~~, an existing CT scanner service to be acquired shall not be required to be in compliance with the volume requirement applicable to the seller/lessor on the date the acquisition occurs~~. ~~The CT scanner service shall be operating at the applicable volume requirements set forth in Section 20 of these standards in the second 12 months after the date the service is acquired, and annually thereafter.~~

(b) THE EXISTING FIXED OR MOBILE CT SCANNER SERVICE IS OWNED BY, IS UNDER COMMON CONTROL OF, OR HAS A COMMON PARENT AS THE APPLICANT, AND THE CT SCANNER SERVICE SHALL REMAIN AT THE SAME SITE.

(~~b~~2) For any application for proposed acquisition of an existing fixed or mobile CT scanner service, an applicant shall be required to demonstrate the following, as applicable:

(i) The fixed CT scanner service to be acquired performed at least 7,500 CT equivalents per fixed CT scanner in the most recent 12-month period for which the Department has verifiable data, unless an applicant meets all of the requirements of Section 3(1) OR MEETS THE REQUIREMENTS OF SECTION 9(1)(b).

(ii) The mobile CT scanner service to be acquired performed at least 3,500 CT equivalents per mobile CT scanner in the most recent 12-month period for which the Department has verifiable data, UNLESS AN APPLICANT MEETS THE REQUIREMENTS OF SECTION 9(1)(b).

(~~2~~3) An applicant proposing to acquire an existing fixed or mobile CT scanner(s) of an existing fixed or mobile CT scanner service shall demonstrate that the proposed project meets the following:

(a) For any application for proposed acquisition of an existing fixed or mobile CT scanner(s) of an existing fixed or mobile CT scanner service, an applicant shall be required to demonstrate the following, as applicable:

(i) The fixed CT scanner(s) to be acquired performed at least 7,500 CT equivalents per fixed CT scanner in the most recent 12-month period for which the department has verifiable data.

(ii) The mobile CT scanner(s) to be acquired performed at least 3,500 CT equivalents per mobile CT scanner in the most recent 12-month period for which the Department has verifiable data.

(4) The CT scanner service shall be operating at the applicable volume requirements set forth in Section 20 of these standards in the second 12 months after the date the service is acquired, and annually thereafter.

~~**Section 10. Requirements for approval for applicants proposing to acquire an existing dental CT scanner service or an existing dental CT scanner(s)**~~

~~Sec. 10. (1) An applicant proposing to acquire an existing fixed or mobile dental CT scanner service shall demonstrate that a proposed project meets all of the following:~~

~~(a) For an application for the proposed first acquisition of an existing fixed or mobile dental CT scanner service, for which a final decision has not been issued after the effective date of these standards, an existing dental CT scanner service to be acquired shall not be required to be in compliance with the volume requirement applicable to the seller/lessor on the date the acquisition occurs. The dental CT scanner service shall be operating at the applicable volume requirements set forth in Section 20 of these standards in the second 12 months after the date the service is acquired, and annually thereafter.~~

~~(b) For any application for proposed acquisition of an existing fixed or mobile dental CT scanner service, an applicant shall be required to demonstrate that the CT scanner service to be acquired performed at least 200 dental CT examinations per dental CT scanner in the most recent 12-month period, for which the Department has verifiable data.~~

~~(2) An applicant proposing to acquire an existing fixed dental CT scanner(s) of an existing fixed or mobile dental CT scanner service shall demonstrate that the proposed project meets the following:~~

~~(a) For any application for proposed acquisition of an existing fixed or mobile dental CT scanner(s) of an existing fixed or mobile dental CT scanner service, an applicant shall be required to demonstrate that the fixed or mobile dental CT scanner(s) to be acquired performed at least 200 dental CT examinations per dental CT scanner in the most recent 12-month period for which the Department has verifiable data.~~

Section 11. Requirements for a dedicated research fixed CT scanner

Sec. 11. An applicant proposing to add a fixed CT scanner to an existing CT scanner service for exclusive research use shall demonstrate the following:

(1) The applicant agrees that the dedicated research CT scanner will be used primarily (70% or more of the scans) for research purposes.

(2) The dedicated research CT scanner shall operate under a protocol approved by the applicant's Institutional Review Board, as defined by Public Law 93-348 and regulated by Title 45 CFR 46.

(3) The proposed site can have no more than three dedicated research fixed CT scanners approved under this section.

(4) The dedicated research scanner approved under this section may not utilize CT procedures performed on the dedicated CT scanner to demonstrate need or to satisfy CT CON review standards requirements.

~~**Section 12. Requirements for approval of an applicant proposing a CT scanner used for the sole purpose of performing dental CT examinations exclusively for research**~~

~~Sec. 12. (1) An applicant proposing a CT scanner used for the sole purpose of performing dental CT examinations exclusively for research shall demonstrate each of the following:~~

~~(a) The applicant operates a dental radiology program in a certified dental school.~~

~~(b) The research dental CT scanner shall operate under a protocol approved by the applicant's institutional review board.~~

~~(c) The applicant agrees to operate the research dental CT scanner in accordance with the terms of approval in Section 20(6).~~

~~(2) An applicant meeting the requirements of subsection (1) shall also demonstrate compliance with the requirements of sections 4(2), 4(4) and 4(5).~~

Section 13. Requirements for approval of a hospital-based portable CT scanner for initiation, expansion, replacement, and acquisition

Sec. 13. An applicant proposing to initiate, expand, replace, or acquire a hospital-based portable CT scanner shall demonstrate that it meets all of the following:

(1) An applicant is limited to the initiation, expansion, replacement, or acquisition of no more than two hospital-based portable CT scanners.

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

(3) The hospital has been certified as a level I or level II trauma facility by the American College of Surgeons, or has performed >100 craniotomies in the most recent 12- month period verifiable by the Department.

(4) The applicant agrees to operate the hospital-based portable CT scanner in accordance with all applicable project delivery requirements set forth in Section 20 of these standards.

(5) The approved hospital-based portable CT scanner will not be subject to CT volume requirements.

(6) The applicant may not utilize CT procedures performed on a hospital-based portable CT scanner to demonstrate need or to satisfy CT CON review standards requirements.

Section 14. Requirements for approval of a PET/CT hybrid for initiation, expansion, replacement, and acquisition

Sec. 14. An applicant proposing to initiate, expand, replace, or acquire a PET/CT hybrid shall demonstrate that it meets all of the following:

(1) There is an approved PET CON for the PET/CT hybrid, and the PET/CT 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 PET/CT hybrid in accordance with all applicable project delivery requirements set forth in Section 20 of these standards.

(3) The approved PET/CT hybrid will not be subject to CT volume requirements.

(4) A PET/CT scanner hybrid approved under the CON Review Standards for PET Scanner Services and the Review Standards for CT Scanner Services may not utilize CT procedures performed on a hybrid scanner to demonstrate need or to satisfy CT CON review standards requirements.

Section 15. Requirements for approval of a CT-angio hybrid unit for initiation, replacement, and acquisition

Sec. 15. An applicant proposing to initiate, replace, or acquire a hospital-based CT-angio hybrid unit 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 CT scanner service that has been operational for the previous 36 consecutive months and is meeting its minimum volume requirements.

(3) The proposed site offers the following services:
(a) diagnostic cardiac catheterization; or
(b) interventional radiology; or

(c) surgical services

(4) The proposed CT-angio hybrid unit must be located in one of the following rooms:
(a) cardiac catheterization lab; or
(b) interventional radiology suite; or
(c) licensed operating room

(5) Diagnostic CT studies shall not be performed on a CT-angio hybrid unit approved under this section unless the patient is currently undergoing a CT-angio hybrid interventional procedure and is in need of a secondary diagnostic CT study.

(6) The approved CT-angio hybrid shall not be subject to CT volume requirements.

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

Section 16. Additional requirements for approval of a mobile CT scanner service

Sec. 16. (1) An applicant proposing to initiate a mobile CT scanner service in Michigan shall demonstrate that it meets all of the following additional requirements:
(a) A separate CON application shall be submitted by the central service coordinator and each Michigan host facility.
(b) The normal route schedule, the procedures for handling emergency situations, and copies of all potential contracts related to the mobile CT scanner service shall be included in the CON application submitted by the central service coordinator.

(2) An applicant proposing to become a host facility on an existing mobile CT scanner network shall demonstrate that it meets all of the following additional requirements:
(a) Approval of the application will not result in an increase in the number of operating mobile CT scanners for the mobile CT scanner network unless the requirements of Section 5 have been met.
(b) A separate CON application has been filed for each host facility.

~~**Section 17. Additional requirements for approval of a mobile dental CT scanner service**~~

~~Sec. 17. (1) An applicant proposing to initiate a mobile dental CT scanner service in Michigan shall demonstrate that it meets all of the following additional requirements:~~
~~(a) A separate CON application shall be submitted by the central service coordinator and each Michigan host facility.~~
~~(b) The normal route schedule, the procedures for handling emergency situations, and copies of all potential contracts related to the mobile dental CT scanner service shall be included in the CON application submitted by the central service coordinator.~~

~~(2) An applicant proposing to become a host facility on an existing mobile dental CT scanner network shall demonstrate that it meets all of the following additional requirements:~~
~~(a) Approval of the application will not result in an increase in the number of operating mobile dental CT scanners for the mobile dental CT scanner network unless the requirements of Section 6 have been met.~~
~~(b) A separate CON application has been filed for each host facility.~~

Section 18. Requirements for approval of an applicant proposing to establish dedicated pediatric CT Scanner

Sec. 18. (1) An applicant proposing to establish dedicated pediatric CT shall demonstrate all of the following:

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

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

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

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

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

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

(2) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the requirements of Section 3 of these standards.

Section 19. Requirements for Medicaid participation

Sec. 19. 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 20. Project delivery requirements and terms of approval for all applicants

Sec. 20. An applicant shall agree that, if approved, the CT scanner(s) services shall be delivered in compliance with the following terms of approval.

(1) Compliance with these standards.

(2) Compliance with the following quality assurance standards:

(a) The applicant shall establish a mechanism to assure that the CT scanner facility is staffed so that:

(i) The screening of requests for CT procedures and interpretation of CT procedures will be performed by physicians with training and experience in the appropriate diagnostic use and interpretation of cross-sectional images of the anatomical region(s) to be examined, and

(ii) The CT scanner is operated by physicians and/or is operated by radiological technologists qualified by training and experience to operate the CT scanner safely and effectively.

For purposes of evaluating (a)(i), the Department shall consider it prima facie evidence of a satisfactory assurance mechanism as to screening and interpretation if the applicant requires the screening of

requests for and interpretations of CT procedures to be performed by physicians who are board certified or eligible in radiology or are neurologists or other specialists trained in cross-sectional imaging of a specific organ system. For purposes of evaluating (a)(i) the Department shall consider it prima facie evidence of a satisfactory assurance mechanism as to the operation of a CT scanner if the applicant requires the CT scanner to be operated by a physician or by a technologist registered by the American Registry of Radiological Technologists (ARRT) or the American Registry of Clinical Radiography Technologists (ARCRT). However, the applicant may submit and the Department may accept other evidence that the applicant has established a mechanism to assure that the CT scanner facility is appropriately and adequately staffed as to screening, interpretation, and/or operation of a CT scanner.

(b) The applicant shall employ or contract with a radiation physicist to review the quality and safety of the operation of the CT scanner.

(c) The applicant shall assure that at least one of the physicians responsible for the screening and interpretation as defined in subsection (a)(i) will be in the CT facility or available ~~on a 24-hour basis~~ (either on-site or through telecommunication capabilities) to make the final interpretation.

(d) In the case of an urgent or emergency CT scan, the applicant shall assure that a physician so authorized by the applicant to interpret initial scans will be on-site or available through telecommunication capabilities within 1 hour following completion of the scanning procedure to render an initial interpretation of the scan. A final interpretation shall be rendered by a physician so authorized under subsection (a)(i) within 24 hours.

(e) The applicant shall have, within the CT scanner facility, equipment and supplies to handle clinical emergencies that might occur within the CT unit, with CT facility staff trained in CPR and other appropriate emergency interventions, and a physician on site in or immediately available to the CT scanner at all times when patients are undergoing scans.

(f) Fixed CT scanner services ~~at each facility~~ shall be made available 24 hours a day for emergency patients if the facility operates an emergency room that provides 24-hour emergency care services as authorized by the local medical control authority to receive ambulance runs.

(g) The applicant shall accept referrals for CT scanner services from all appropriately licensed practitioners.

(h) The applicant shall establish and maintain: (a) a standing medical staff and governing body (or its equivalent) requirement that provides for the medical and administrative control of the ordering and utilization of CT patient procedures, and (b) a formal program of utilization review and quality assurance. These responsibilities may be assigned to an existing body of the applicant, as appropriate.

(i) An applicant approved under Section 18 must be able to prove that all radiologists, technologists and nursing staff working with CT patients have continuing education or in-service training on pediatric low-dose CT. The site must also be able to provide evidence of defined low-dose pediatric CT protocols.

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

(a) The applicant, to assure that the CT scanner will be utilized by all segments of the Michigan population, shall:

(i) not deny any CT scanner services to any individual based on ability to pay or source of payment;

(ii) provide all CT scanning services to any individual based on the clinical indications of need for the service; and

(iii) maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually.

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

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

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 approved CT scanners shall be operating at an average of 7,500 CT equivalents scanner per fixed scanner and 3,500 CT equivalents per mobile scanner per year for the second 12-month period after beginning operation of the CT scanner, and annually thereafter, except for those scanners exempt under applicable sections.

(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, annual budget and cost information, operating schedules, through-put schedules, demographic and diagnostic information, the volume of care provided to patients from all payor sources, and other data requested by the Department, and approved by the Commission. The applicant shall provide the required data on a separate basis for each separate and distinct site as required by the Department; in a format established by the Department; and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(c) Equipment to be replaced shall be removed from service.

(d) The applicant shall provide the Department with timely notice of the proposed project implementation consistent with applicable statute and promulgated rules.

(e) An applicant approved under Section 4 shall not be required to be in compliance with subsection (2).

~~(5) Compliance with the following dental CT scanner (fixed or mobile) requirements, if applicable:~~

~~(a) The CT scanner will be used for the sole purpose of dental CT examinations.~~

~~(b) The applicant shall demonstrate to the satisfaction of the Department that the person(s) (e.g., technician, dentist) operating the dental CT scanner has been appropriately trained and/or certified by one of the following groups, as recognized by the Department: a dental radiology program in a certified dental school, an appropriate professional society, or a dental continuing education program accredited by the American Dental Association.~~

~~(c) The applicant shall demonstrate to the satisfaction of the Department that the dental CT examinations generated by the dental CT scanner will be interpreted by a licensed dentist(s) trained and/or certified by one of the following groups, as recognized by the Department: a dental radiology program in a certified dental school, an appropriate professional society, or a dental continuing education program accredited by the American Dental Association.~~

~~(d) The applicant shall demonstrate to the satisfaction of the Department that the dentists using the dental CT examinations for performing dental procedures has had the appropriate training and/or experience certified by one of the following groups, as recognized by the Department: a dental radiology program in a certified dental school, an appropriate professional society, or a dental continuing education program accredited by the American Dental Association.~~

~~(e) The applicant, to assure that the dental CT scanner will be utilized by all segments of the Michigan population, shall:~~

~~(i) not deny dental CT scanner services to any individual based on ability to pay or source of payment;~~

~~(ii) provide dental CT scanning services to any individual based on the clinical indications of need for the service; 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.~~

~~(f) The CT scanner shall be operating at least 200 CT equivalents per year for the second 12-month period after beginning operation of the dental CT scanner and annually thereafter.~~

~~(g) The applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to, annual budget and cost information, operating schedules, through-put schedules, demographic and diagnostic information, the volume of care provided to patients from all payor sources, and other data requested by the Department, and approved by the Commission. The applicant shall provide the required data on a separate basis for each separate and distinct site as required by the Department; in a format established by the Department;~~

~~and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.~~

~~(h) Equipment to be replaced shall be removed from service.~~

~~(i) The applicant shall provide the Department with timely notice of the proposed project implementation consistent with applicable statute and promulgated rules.~~

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

~~(6) An applicant for a CT scanner used for dental research under Section 12(1) shall agree that the services provided by the CT scanner approved pursuant to Section 12(1) shall be delivered in compliance with the following terms of CON approval:~~

~~(a) The capital and operating costs relating to the CT scanner used for dental research pursuant to Section 12(1) shall be charged only to a specific research account(s) and not to any patient or third-party payor.~~

~~(b) The CT scanner used for dental research approved pursuant to Section 12(1) shall not be used for any purposes other than as approved by the institutional review board unless the applicant has obtained CON approval for the CT scanner pursuant to part 222 and these standards, other than Section 12.~~

(7) An applicant approved under Section 13 shall be in compliance with the following:

(a) Portable CT scanner can only be used by a qualifying program for the following purposes:

(i) Brain scanning of patients being treated in an adult or pediatric Intensive Care Unit (ICU).

(ii) Non-diagnostic, intraoperative guidance in an operating room.

(b) The approved applicant must provide annual reports to the Department by January 31st of each year for the preceding calendar year. This requirement applies to all applicants approved under Section 13.

(c) The following data must be reported to the Department:

(i) Number of adult studies (age>=18)

(ii) Number of pediatric studies (age<18)

(iii) Number of studies performed using a portable CT on the same patient while that patient is in an ICU

(8) An applicant approved under Section 15 shall be in compliance with the following:

(a) The proposed site offers the following services:

(i) diagnostic cardiac catheterization; or

(ii) interventional radiology; or

(iii) surgical services

(b) The proposed CT-Angio hybrid unit must be located in one of the following rooms:

(i) cardiac catheterization lab; or

(ii) interventional radiology suite; or

(iii) licensed operating room

(9) 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 21. Project delivery requirements and additional terms of approval for applicants involving mobile CT scanners

Sec. 21. (1) In addition to the provisions of Section 20, an applicant for a mobile CT scanner shall agree that the services provided by the mobile CT scanner(s) shall be delivered in compliance with the following terms of CON approval:

(a) A host facility shall submit only one CON application for a CT scanner for review at any given time.

(b) A mobile CT scanner with an approved CON shall notify the ~~Michigan~~ Department ~~of Community Health~~ prior to ending service with an existing host facility.

(c) A CON shall be required to add a host facility.

(d) A CON shall be required to change the central service coordinator.

(e) Each host facility must have at least one board certified or board eligible radiologist on its medical staff. The radiologist(s) shall be responsible for: (i) establishing patient examination and infusion protocol, and (ii) providing for the interpretation of scans performed by the mobile CT scanner.

(f) Each mobile CT scanner service must have an Operations Committee with members representing each host facility, the central service coordinator, and the central service medical director. This committee shall oversee the effective and efficient use of the CT scanner, establish the normal route schedule, identify the process by which changes are to be made to the schedule, develop procedures for handling emergency situations, and review the ongoing operations of the mobile CT scanner on at least a quarterly basis.

(g) The central service coordinator shall arrange for emergency repair services to be available 24 hours each day for the mobile CT scanner as well as the vehicle transporting the equipment. In addition, to preserve image quality and minimize CT scanner downtime, calibration checks shall be performed on the CT scanner at least once each work day and routine maintenance services shall be provided on a regularly scheduled basis, at least once a week during hours not normally used for patient procedures.

(h) Each host facility must provide a properly prepared parking pad for the mobile CT scanner of sufficient load-bearing capacity to support the vehicle, a waiting area for patients, and a means for patients to enter the vehicle without going outside (such as a canopy or enclosed corridor). Each host facility must also provide the capability for processing the film and maintaining the confidentiality of patient records. A communication system must be provided between the mobile vehicle and each host facility to provide for immediate notification of emergency medical situations.

(i) A mobile CT scanner service shall operate under a contractual agreement that includes the provision of CT scanner services at each host facility on a regularly scheduled basis.

(j) The volume of utilization at each host facility shall be reported to the Department by the central service coordinator under the terms of Section 20(2)(i).

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

Section 22. Determination of CT Equivalents

Sec. 22. CT equivalents shall be calculated as follows:

(a) Each billable procedure for the time period specified in the applicable section(s) of these standards shall be assigned to a category set forth in Table 1.

(b) The number of billable procedures for each category in the time period specified in the applicable section(s) of these standards shall be multiplied by the corresponding conversion factor in Table 1 to determine the number of CT equivalents for that category for that time period.

(c) The number of CT equivalents for each category shall be summed to determine the total CT equivalents for the time period specified in the applicable section(s) of these standards.

(d) The conversion factor for pediatric/special needs patients does not apply to procedures performed on a dedicated pediatric CT scanner.

Table 1 Category	Number of Billable CT Procedures		Conversion Factor		CT Equivalents
Adult Patient					
Head Scans w/o Contrast ~~(includes dental CT examinations)~~	_____	X	1.00	=	_____
Head Scans with Contrast	_____	X	1.25	=	_____

Head Scans w/o & w Contrast	_____	X	1.75	=	_____
Body Scans w/o Contrast	_____	X	1.50	=	_____
Body Scans with Contrast	_____	X	1.75	=	_____
Body Scans w/o & w Contrast	_____	X	2.75	=	_____
Bundled body Scan	_____	X	3.50	=	_____
Pediatric/Special Needs Patient					
Head scans w/o Contrast	_____	x	1.25	=	_____
~~(includes dental CT examinations)~~					
Head Scans with Contrast	_____	x	1.50	=	_____
Head Scans w/o & with Contrast	_____	x	2.00	=	_____
Body Scans w/o Contrast	_____	x	1.75	=	_____
Body Scans with Contrast	_____	x	2.00	=	_____
Body Scans w/o & with Contrast	_____	x	3.00	=	_____
Bundled body Scan	_____	X	4.00	=	_____
Total CT Equivalents					_____

Section 23. Documentation of projections

Sec. 23. An applicant required to project volumes under sections 3 and 4 shall demonstrate the following, as applicable:

(1) An applicant required to project under Section 3 shall demonstrate that the projection is based on historical physician referrals that resulted in an actual scan for the most recent 12-month period immediately preceding the date of the application. Historical physician referrals will be verified with the data maintained by the Department through its "Annual Hospital statistical survey" and/or "Annual Freestanding Statistical Survey."

~~(2) An applicant required to project under Section 4 shall demonstrate that the projection is based on a combination of the following for the most recent 12-month period immediately preceding the date of the application:~~

~~(a) the number of dental procedures performed by the applicant, and~~

~~(b) the number of committed dental procedures performed by referring licensed dentists. Further, the applicant and the referring licensed dentists shall substantiate the numbers through the submission of HIPAA compliant billing records.~~

(3) An applicant shall demonstrate that the projected number of referrals to be performed at the proposed site under subsection (1) are from an existing CT scanner service that is in compliance with the volume requirements applicable to that service, and will continue to be in compliance with the volume requirements applicable to that service subsequent to the initiation of the proposed CT scanner service by an applicant. ~~This does not include dental CT scanners.~~ Only excess CT equivalents equal to or greater than what is being committed pursuant to this subsection may be used to document projections under subsection (1). In demonstrating compliance with this subsection, an applicant shall provide each of the following:

(a) A written commitment from each referring physician that he or she will refer at least the volume of CT scans to be transferred to the proposed CT scanner service for no less than 3 years subsequent to the initiation of the CT scanner service proposed by an applicant.

(b) The number of referrals committed must have resulted in an actual CT scan of the patient at the existing CT scanner service from which referral will be transferred. The committing physician must make available HIPAA compliant audit material if needed upon Department request to verify referral sources and outcomes. Commitments must be verified by the most recent data set maintained by the Department through its "Annual Hospital Statistical Survey" and/or "Annual Freestanding Statistical Survey."

(c) The projected referrals are from an existing CT scanner service within a 75-mile radius for rural and micropolitan statistical area counties or 20-mile radius for metropolitan statistical area counties.

Section 24. Effect on prior CON review standards; comparative reviews

Sec. 24. (1) These CON review standards supersede and replace the CON Review Standards for Computed Tomography Scanner Services approved by the CON Commission on ~~March 18~~SEPTEMBER 25, 2014 and effective on ~~June 2~~DECEMBER 22, 2014.

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

APPENDIX A

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

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

APPENDIX B

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 AND HUMAN SERVICES

CERTIFICATE OF NEED REVIEW (CON) STANDARDS FOR NEONATAL INTENSIVE CARE SERVICES/BEDS AND SPECIAL NEWBORN NURSING SERVICES

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

Section 1. Applicability

Sec. 1. (1) These standards are requirements for the approval of the initiation, replacement, relocation, expansion, or acquisition of neonatal intensive care services/beds and the delivery of neonatal intensive care services/beds under Part 222 of the Code. Further, these standards are requirements for the approval of the initiation or acquisition of special care nursery (SCN) services. Pursuant to Part 222 of the Code, neonatal intensive care services/beds and special newborn nursing services are covered clinical services. 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) As used in these standards:

(a) "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.

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

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

(d) "Department" means the Michigan Department of ~~Community~~ Health AND HUMAN SERVICES (~~MDCH~~MDHHS).

(e) "Department inventory of beds" means the current list for each planning area maintained on a continuous basis by the Department of licensed hospital beds designated for NICU services and NICU beds with valid CON approval but not yet licensed or designated.

(f) "Existing NICU beds" means the total number of all of the following:

(i) licensed hospital beds designated for NICU services;

(ii) NICU beds with valid CON approval but not yet licensed or designated;

(ii) NICU beds under appeal from a final decision of the Department; and

(iii) proposed NICU beds that are part of an application for which a proposed decision has been issued, but is pending final Department decision.

(g) "Hospital" means a health facility licensed under Part 215 of the Code.

(h) "Infant" means an individual up to 1 year of age.

(i) "Licensed site" means in the case of a single site hospital, the location of the facility authorized by license and listed on that licensee's certificate of licensure; or in the case of a hospital with multiple sites, the location of each separate and distinct inpatient unit of the health facility as authorized by license and listed on that licensee's certificate of licensure.

(j) "Live birth" means a birth for which a birth certificate for a live birth has been prepared and filed pursuant to Section 333.2821(2) of the Michigan Compiled Laws.

(k) "Maternal referral service" means having a consultative and patient referral service staffed by a physician(s), on the active medical staff, that is board certified, or eligible to be board certified, in maternal/fetal medicine.

(l) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396 to 1396w-5.

(m) "Neonatal intensive care services" or "NICU services" means the provision of any of the following services:

(i) constant nursing care and continuous cardiopulmonary and other support services for severely ill infants;

(ii) care for neonates weighing less than 1,500 grams at birth, and/or less than 32 weeks gestation;

(iii) ventilatory support beyond that needed for immediate ventilatory stabilization;

(iv) surgery and post-operative care during the neonatal period;

(v) pharmacologic stabilization of heart rate and blood pressure; or

(vi) total parenteral nutrition.

(n) "Neonatal intensive care unit" or "NICU" means a specially designed, equipped, and staffed unit of a hospital which is both capable of providing neonatal intensive care services and is composed of licensed hospital beds designated as NICU. This term does not include unlicensed SCN beds.

(o) "Neonatal transport system" means a specialized transfer program for neonates by means of an ambulance licensed pursuant to Part 209 of the Code, being Section 333.20901 et seq.

(p) "Neonate" means an individual up to 28 days of age.

(q) "Perinatal care network," means the providers and facilities within a planning area that provide basic, specialty, and sub-specialty obstetric, pediatric and neonatal intensive care services.

(r) "Planning area" means the groups of counties shown in Appendix B.

(s) "Planning year" means the most recent continuous 12 month period for which birth data is available from the Vital Records and Health Data Development Section.

(t) "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.

(u) "Relocation of the designation of beds for NICU services" means a change within the same planning area in the licensed site at which existing licensed hospital beds are designated for NICU services.

(v) "Special care nursery services" or “SCN services” means provisions of ~~the~~ services ~~identified in subsections (i) through (v)~~ for infants with problems that are expected to resolve rapidly and who would not be anticipated to need subspecialty services on an urgent basis. THESE SERVICES INCLUDE:

(i) Care for ~~low birth weight~~ infants BORN greater than or equal to 32 weeks gestation AND/OR weighing GREATER THAN OR EQUAL TO 1,500grams ~~or more and/or greater than or equal to 32 weeks gestation~~;

(ii) enteral tube feedings;

(iii) cardio-respiratory monitoring to document maturity of respiratory control or treatment of apnea;

(iv) extended care following an admission to a neonatal intensive care unit for an infant not requiring ventilatory support; or

(v) provide mechanical ventilation or continuous positive airway pressure or both for a brief duration (not to exceed 24 hours combined).

Referral to a higher level of care should occur for all infants who need pediatric surgical or medical subspecialty intervention. Infants receiving transitional care or being treated for developmental maturation may have formerly been treated in a neonatal intensive care unit in the same hospital or another hospital. For purposes of these standards, SCN services are special newborn nursing services.

~~(i) Care for low birth weight infants weighing 1,500grams or more and/or greater than or equal to 32 weeks gestation;~~

~~(ii) enteral tube feedings;~~

~~(iii) cardio-respiratory monitoring to document maturity of respiratory control or treatment of apnea;~~

~~(iv) extended care following an admission to a neonatal intensive care unit for an infant not requiring ventilatory support; or~~

~~(v) provide mechanical ventilation or continuous positive airway pressure or both for a brief duration (not to exceed 24 hours combined).~~

(w) "WELL NEWBORN NURSERY SERVICES" MEANS PROVIDING THE FOLLOWING SERVICES AND DOES NOT REQUIRE A CERTIFICATE OF NEED:

(i) THE CAPABILITY TO PERFORM NEONATAL RESUSCITATION AT EVERY DELIVERY;

(ii) EVALUATE AND PROVIDE POSTNATAL CARE FOR STABLE TERM NEWBORN INFANTS;

(iii) STABILIZE AND PROVIDE CARE FOR INFANTS BORN AT 35 TO 37 WEEKS' GESTATION WHO REMAIN PHYSIOLOGICALLY STABLE; AND

(iv) STABILIZE NEWBORN INFANTS WHO ARE ILL AND THOSE BORN LESS THAN 35 WEEKS OF GESTATION UNTIL THEY CAN BE TRANSFERRED TO A HIGHER LEVEL OF CARE FACILITY.

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

Section 3. Bed need methodology

Sec. 3. (1) The number of NICU beds needed in a planning area shall be determined by the following formula:

(a) Determine, using data obtained from the Vital Records and Health Data Development Section, the total number of live births which occurred in the planning year at all hospitals geographically located within the planning area.

(b) Determine, using data obtained from the Vital Records and Health Data Development Section, the percent of live births in each planning area and the state that were less than 1,500 grams. The result is the very low birth weight rate for each planning area and the state, respectively.

(c) Divide the very low birth weight rate for each planning area by the statewide very low birth weight rate. The result is the very low birth weight rate adjustment factor for each planning area.

(d) Multiply the very low birth weight rate adjustment factor for each planning area by 0.0045. The result is the bed need formula for each planning area adjusted for the very low birth weight rate.

(e) Multiply the total number of live births determined in subsection (1)(a) by the bed need formula for the applicable planning area adjusted for the very low birth weight adjustment factor as determined in subsection (1)(d).

(2) The result of subsection (1) is the number of NICU beds needed in the planning area for the planning year.

Section 4. Requirements to initiate NICU services

Sec. 4. Initiation of NICU services means the establishment of a NICU at a licensed site that has not had in the previous 12 months a licensed and designated NICU or does not have a valid CON to initiate a NICU. The relocation of the designation of beds for NICU services meeting the applicable requirements of Section 6 shall not be considered as the initiation of NICU services/beds.

(1) An applicant proposing to initiate NICU services by designating hospital beds as NICU beds shall demonstrate each of the following:

(a)There is an unmet bed need of at least 15 NICU beds based on the difference between the number of existing NICU beds in the planning area and the number of beds needed for the planning year as a result of application of the methodology set forth in Section 3.

(b) Approval of the proposed NICU will not result in a surplus of NICU beds in the planning area based on the difference between the number of existing NICU beds in the planning area and the number of beds needed for the planning year resulting from application of the methodology set forth in Section 3.

(c) A unit of at least 15 beds will be developed and operated.

(d) For each of the 3 most recent years for which birth data are available from the Vital Records and Health Data Development Section, the licensed site at which the NICU is proposed had either: (i) 2,000 or more live births, if the licensed site is located in a metropolitan statistical area county; or (ii) 600 or more live births, if the licensed site is located in a rural or micropolitan statistical area county and is located more than 100 miles (surface travel) from the nearest licensed site that operates or has valid CON approval to operate NICU services.

Section 5. Requirements to replace NICU services

Sec. 5. Replacement of NICU beds means new physical plant space being developed through new construction or newly acquired space (purchase, lease or donation), to house existing licensed and designated NICU beds.

(1) An applicant proposing replacement beds shall not be required to be in compliance with the needed NICU bed supply determined pursuant to Section 3 if an applicant demonstrates all of the following:

(a) the project proposes to replace an equal or lesser number of beds designated by an applicant for NICU services at the licensed site operated by the same applicant at which the proposed replacement beds are currently located; and

(b) the proposed licensed site is in the same planning area as the existing licensed site and in the area set forth in Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, in which replacement beds in a hospital are not subject to comparative review.

Section 6. Requirements for approval to relocate NICU beds

Sec. 6. An applicant proposing to relocate the designation for NICU services shall demonstrate compliance with all of the following:

(1) The applicant is the licensed site to which the relocation of the designation of beds for NICU services is proposed.

(2) The applicant shall provide a signed written agreement that provides for the proposed increase, and concomitant decrease, in the number of beds designated for NICU services at the 2 licensed sites involved in the proposed relocation. A copy of the agreement shall be provided in the application.

(3) The existing licensed site from which the designation of beds for NICU services proposed to be relocated is currently licensed and designated for NICU services.

(4) The proposed project does not result in an increase in the number of beds designated for NICU services in the planning area unless the applicable requirements of Section 4 or 5 have also been met.

(5) The proposed project does not result in an increase in the number of licensed hospital beds at the applicant licensed site unless the applicable requirements of the CON Review Standards for Hospital Beds have also been met.

(6) The proposed project does not result in the operation of a NICU of less than 15 beds at the existing licensed site from which the designation of beds for NICU services are proposed to be relocated.

(7) If the applicant licensed site does not currently provide NICU services, an applicant shall demonstrate both of the following:

(a) the proposed project involves the establishment of a NICU of at least 15 beds; and

(b) for each of the 3 most recent years for which birth data are available from the Vital Records and Health Data Development Section, the applicant licensed site had either: (i) 2,000 or more live births, if the licensed site is located in a metropolitan statistical area county; or (ii) 600 or more live births, if the licensed site is located in a rural or micropolitan statistical area county and is located more than 100 miles from the nearest licensed site that operates or has valid CON approval to operate NICU services/beds. If the applicant licensed site has not been in operation for at least 3 years and the obstetrical unit at the applicant licensed site was established as the result of the consolidation and closure of 2 or more obstetrical units, the combined number of live births from the obstetrical units that were closed and

relocated to the applicant licensed site may be used to evaluate compliance with this requirement for those years when the applicant licensed site was not in operation.

(8) If the applicant licensed site does not currently provide NICU services or obstetrical services, an applicant shall demonstrate both of the following:

(a) the proposed project involves the establishment of a NICU of at least 15 beds; and

(b) the applicant has a valid CON to establish an obstetrical unit at the licensed site at which the NICU is proposed. The obstetrical unit to be established shall be the result of the relocation of an existing obstetrical unit that for each of the 3 most recent years for which birth data are available from the Vital Records and Health Data Development Section, the obstetrical unit to be relocated had either: (i) 2,000 or more live births, if the obstetrical unit to be relocated is located in a metropolitan statistical area county; or (ii) 600 or more live births, if the obstetrical unit to be relocated is located in a rural or micropolitan statistical area county and is located more than 100 miles from the nearest licensed site that operates or has valid CON approval to operate NICU services.

(9) The project results in a decrease in the number of licensed hospital beds that are designated for NICU services at the licensed site at which beds are currently designated for NICU services. The decrease in the number of beds designated for NICU services shall be equal to or greater than the number of beds designated for NICU services proposed to be increased at the applicant's licensed site pursuant to the agreement required by this subsection. This subsection requires a decrease in the number of licensed hospital beds that are designated for NICU services, but does not require a decrease in the number of licensed hospital beds.

(10) Beds approved pursuant to Section 7(2) shall not be relocated pursuant to this section, unless the proposed project involves the relocation of all beds designated for NICU services at the applicant's licensed site.

Section 7. Requirements for approval to expand NICU services

Sec. 7. (1) An applicant proposing to expand NICU services at a licensed site by designating additional hospital beds as NICU beds in a planning area shall demonstrate that the proposed increase will not result in a surplus of NICU beds based on the difference between the number of existing NICU beds in the planning area and the number of beds needed for the planning year resulting from application of the methodology set forth in Section 3.

(2) An applicant may apply and be approved for NICU beds in excess of the number determined as needed for the planning year in accordance with Section 3 if an applicant can demonstrate that it provides NICU services to patients transferred from another licensed and designated NICU. The maximum number of NICU beds that may be approved pursuant to this subsection shall be determined in accordance with the following:

(a) An applicant shall document the average annual number of patient days provided to neonates or infants transferred from another licensed and designated NICU, for the 2 most recent years for which verifiable data are available to the Department.

(b) The average annual number of patient days determined in accordance with subsection (a) shall be divided by 365 (or 366 for a leap year). The result is the average daily census (ADC) for NICU services provided to patients transferred from another licensed and designated NICU.

(c) Apply the ADC determined in accordance with subsection (b) in the following formula: ADC + 2.06 $\sqrt{ADC}$. The result is the maximum number of beds that may be approved pursuant to this subsection ~~up to 5 beds at each licensed site~~.

Section 8. Requirements for approval to acquire a NICU service

Sec. 8. Acquisition of a NICU means obtaining possession and control of existing licensed hospital beds designated for NICU services by contract, ownership, lease or other comparable arrangement.

(1) An applicant proposing to acquire a NICU shall not be required to be in compliance with the needed NICU bed supply determined pursuant to Section 3 for the planning area in which the NICU subject to the proposed acquisition is located, if the applicant demonstrates that all of the following are met:

(a) the acquisition will not result in an increase in the number of hospital beds, or hospital beds designated for NICU services, at the licensed site to be acquired;

(b) the licensed site does not change as a result of the acquisition, unless the applicant meets Section 6; and,

(c) the project does not involve the initiation, expansion or replacement of a covered clinical service, a covered capital expenditure for other than the proposed acquisition or a change in bed capacity at the applicant facility, unless the applicant meets other applicable sections.

Section 9. Requirements to initiate, acquire, or replace SCN services

Sec. 9. An applicant proposing SCN services shall demonstrate each of the following, as applicable, by verifiable documentation:

(1) All applicants shall demonstrate the following:
(a) A board certified neonatologist serving as the program director.
(b) The hospital has the following capabilities and personnel continuously available and on-site:
(i) the ability to provide mechanical ventilation and/or continuous positive airway pressure for up to 24 hours;
(ii) portable x-ray equipment and blood gas analyzer;
(iii) pediatric physicians and/or neonatal nurse practitioners; and
(iv) respiratory therapists, radiology technicians, laboratory technicians and specialized nurses with experience caring for premature infants.

(2) Initiation of SCN services means the establishment of an SCN at a licensed site that has not had in the previous 12 months a designated SCN or does not have a valid CON to initiate an SCN.
(a) In addition to the requirements of Section 9(1), an applicant proposing to initiate an SCN service shall have a written consulting agreement with a hospital which has an existing, operational NICU. The agreement must specify that the existing service shall, for the first two years of operation of the new service, provide the following services to the applicant hospital:
(i) receive and make recommendations on the proposed design of SCN and support areas that may be required;
(ii) provide staff training recommendations for all personnel associated with the new proposed service;
(iii) assist in developing appropriate protocols for the care and transfer, if necessary, of premature infants;
(iv) provide recommendations on staffing needs for the proposed service; and
(v) work with the medical staff and governing body to design and implement a process that will annually measure, evaluate, and report to the medical staff and governing body the clinical outcomes of the new service, including:
(A) mortality rates;
(B) morbidity rates including intraventricular hemorrhage (grade 3 and 4), retinopathy of prematurity (stage 3 and 4), chronic lung disease (oxygen dependency at 36 weeks gestation), necrotizing enterocolitis, pneumothorax, neonatal depression (apgar score of less than 5 at five minutes); and
(C) infection rates.
(b) SCN services shall be provided in unlicensed SCN beds located within the hospital obstetrical department or NICU service. Unlicensed SCN beds are not included in the NICU bed need.

(3) Replacement of SCN services means new physical plant space being developed through new construction or newly acquired space (purchase, lease or donation), to house an existing SCN service.
(a) In addition to the requirements of Section 9(1), an applicant proposing a replacement SCN service shall demonstrate all of the following:
(i) The proposed project is part of an application to replace the entire hospital.
(ii) The applicant currently operates the SCN service at the current licensed site.
(iii) The proposed licensed site is in the same planning area as the existing licensed site.

(4) Acquisition of an SCN service means obtaining possession and control of an existing SCN service by contract, ownership, lease or other comparable arrangement.
(a) In addition to the requirements of Section 9(1), an applicant proposing to acquire an SCN service shall demonstrate all of the following:
(i) The proposed project is part of an application to acquire the entire hospital.

(ii) The licensed site does not change as a result of the acquisition, unless the applicant meets subsection 3.

Section 10. Additional requirements for applications included in comparative reviews.

Sec. 10. (1) Any application subject to comparative review under Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, or under these standards, shall be grouped and reviewed comparatively with other applications in accordance with the CON rules.

(2) Each application in a comparative review 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(1) of the Michigan Compiled Laws, and all other applicable requirements for approval in the Code and these standards. If the Department determines that one or more of the competing applications satisfies all of the requirements for approval, these projects shall be considered qualifying projects. The Department shall approve those qualifying projects which, taken together, do not exceed the need, as defined in Section 22225(1), and which have the highest number of points when the results of subsection (2) are totaled. If 2 or more qualifying projects are determined to have an identical number of points, the Department shall approve those qualifying projects which, taken together, do not exceed the need, as defined in Section 22225(1), which are proposed by an applicant that operates a NICU at the time an application is submitted to the Department. If 2 or more qualifying projects are determined to have an identical number of points and each operates a NICU at the time an application is submitted to the Department, the Department shall approve those qualifying projects which, taken together, do not exceed the need, as defined in Section 22225(1), in the order in which the applications were received by the Department, based on the submission date and time, as determined by the Department when submitted.

(a) A qualifying project will have points awarded based on the geographic proximity to NICU services, both operating and CON approved but not yet operational, in accordance with the following schedule:

Proximity	Points Awarded
Less than 50 Miles to NICU service	0
Between 50-99 miles to NICU service	1
100+ Miles to NICU service	2

(b) A qualifying project will have points awarded based on the number of very low birth weight infants delivered at the applicant hospital or the number of very low birth weight infants admitted or refused admission due to the lack of an available bed to an applicant's NICU, and the number of very low birth weight infants delivered at another hospital subsequent to the transfer of an expectant mother from an applicant hospital to a hospital with a NICU. The total number of points to be awarded shall be the number of qualifying projects. The number of points to be awarded to each qualifying project shall be calculated as follows:

(i) Each qualifying project shall document, for the 2 most recent years for which verifiable data are available, the number of very low birth weight infants delivered at an applicant hospital, or admitted to an applicant's NICU, if an applicant operates a NICU, the number of very low birth weight infants delivered to expectant mothers transferred from an applicant's hospital to a hospital with a NICU, and the number of very low birth weight infants referred to an applicant's NICU who were refused admission due to the lack of an available NICU bed and were subsequently admitted to another NICU.

(ii) Total the number of very low birth weight births and admissions documented in subdivision (i) for all qualifying projects.

(iii) Calculate the fraction (rounded to 3 decimal points) of very low birth weight births and admissions that each qualifying project's volume represents of the total calculated in subdivision (ii).

(iv) For each qualifying project, multiply the applicable fraction determined in subdivision (iii) by the total possible number of points.

(v) Each qualifying project shall be awarded the applicable number of points calculated in subdivision (iv).

(c) An applicant shall have 1 point awarded if it can be demonstrated that on the date an application is submitted to the Department, the licensed site at which NICU services/beds are proposed has on its active medical staff a physician(s) board certified, or eligible to be certified, in maternal/fetal medicine.

(d) 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%	0.2
6 - <11%	0.4
11 - <16%	0.6
16 - <21%	0.8
21 - <26%	1.0
26 - <31%	1.2
31 - <36%	1.4
36 - <41%	1.6
41 - <46%	1.8
46% +	2.0

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 Hospital and Health Plan Reimbursement Division pursuant to Section 7 of the Medical Provider 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.

(3) Submission of conflicting information in this section may result in a lower point reward. 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 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 11. Requirements for Medicaid participation

Sec. 11. An applicant for NICU services and SCN services shall provide verification of Medicaid participation. An applicant that is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services if a CON is approved.

Section 12. Project delivery requirements and terms of approval

Sec. 12. An applicant shall agree that, if approved, the NICU and SCN services shall be delivered in compliance with the following terms of approval:

(1) Compliance with these standards.

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

(a) An applicant shall coordinate its services with other providers of obstetrical, perinatal, neonatal and pediatric care in its planning area, and other planning areas in the case of highly specialized services.

(b) An applicant shall develop and maintain a follow-up program for NICU graduates and other infants with complex problems. An applicant shall also develop linkages to a range of pediatric care for high-risk infants to ensure comprehensive and early intervention services.

(c) If an applicant operates a NICU that admits infants that are born at a hospital other than the applicant hospital, an applicant shall develop and maintain an outreach program that includes both case-finding and social support which is integrated into perinatal care networks, as appropriate.

(d) If an applicant operates a NICU that admits infants that are born at a hospital other than the applicant hospital, an applicant shall develop and maintain a neonatal transport system.

(e) An applicant shall coordinate and participate in professional education for perinatal and pediatric providers in the planning area.

(f) An applicant shall develop and implement a system for discharge planning.

(g) A board certified neonatologist shall serve as the director of neonatal services.

(h) An applicant shall make provisions for on-site physician consultation services in at least the following neonatal/pediatric specialties: cardiology, ophthalmology, surgery and neurosurgery.

(i) An applicant shall develop and maintain plans for the provision of highly specialized neonatal/pediatric services, such as cardiac surgery, cardiovascular surgery, neurology, hematology, orthopedics, urology, otolaryngology and genetics.

(j) An applicant shall develop and maintain plans for the provision of transferring infants discharged from its NICU to another hospital, as necessary for the care of an infant no longer requiring NICU services but unable to be discharged home.

(3) Compliance with the following applicable quality assurance standards for SCN services:

(a) An applicant shall coordinate its services with other providers of obstetrical, perinatal, neonatal and pediatric care in its planning area, and other planning areas in the case of highly specialized services.

(b) An applicant shall develop and implement a system for discharge planning.

(c) A board certified neonatologist shall serve as the SCN program director.

(d) The hospital continues to have the following capabilities and personnel continuously available and on-site:

(i) The ability to provide mechanical ventilation and/or continuous positive airway pressure for up to 24 hours;

(ii) portable x-ray equipment and blood gas analyzer;

(iii) pediatric physicians and/or neonatal nurse practitioners; and

(iv) respiratory therapists, radiology technicians, laboratory technicians and specialized nurses with experience caring for premature infants.

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

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

(b) The NICU and SCN services shall not deny NICU and SCN services to any individual based on ability to pay or source of payment.

(c) The NICU and SCN services shall provide NICU and SCN services to any individual based on clinical indications of need for the services.

(d) The NICU and SCN services shall maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually.

(e) Compliance with selective contracting requirements shall not be construed as a violation of this term.

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

(a) The NICU and SCN services shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to, annual budget and cost information, operating schedules, through-put schedules, 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.

(i) The SCN services shall provide data for the percentage of transfers to a higher level of care, hours of life at the time of transfer to a higher level of care, admissions to the SCN at less than 32 weeks gestation, number of admissions requiring respiratory support greater than 24 hours in duration, number of admissions to SCN, and rates of morbidity including: intraventricular hemorrhage (grade 3 and 4), retinopathy of prematurity (stage 3 and 4), chronic lung disease (oxygen dependency at 36 weeks gestation), necrotizing enterocolitis, and pneumothorax.

(b) The NICU and SCN services shall provide the Department with timely notice of the proposed project implementation consistent with applicable statute and promulgated rules.

(6) 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 13. Department inventory of beds

Sec. 13. The Department shall maintain a listing of the Department inventory of beds for each planning area.

Section 14. Effect on prior CON review standards; comparative reviews

Sec. 14. (1) These CON review standards supercede and replace the CON Review Standards for Neonatal Intensive Care Services/Beds approved by the Commission on ~~December 12, 2013~~SEPTEMBER 25, 2014 and effective on ~~March 3, 2014~~DECEMBER 22, 2014.

(2) Projects reviewed under these standards shall be subject to comparative review except for:

(a) Replacement beds meeting the requirements of Section 22229(3) of the Code, being Section 333.22229(3) of the Michigan Compiled Laws;

(b) The designation of beds for NICU services being relocated pursuant to Section 6 of these standards; or

(c) Beds requested under Section 7(2).

(d) SCN services requested under Section 9.

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

APPENDIX B

The planning areas for neonatal intensive care services/beds are the geographic boundaries of the group 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

2015 Bone Marrow Transplantation (BMT) Services Standard Advisory Committee

Members of the Committee:

SAC Chair, Dr. Bruce Carl, Purchaser, UAW Retiree Benefits Trust
Dr. Muneer Abidi, Expert, Spectrum Health Hospitals
Dr. Adil Akhtar, Expert, Beaumont Health System
Ms. Jennifer Barish, Consumer, BMT Link Network
Dr. Roland Chu, Expert, Children's Hospital of Michigan
Dr. Joan Herbert, Provider, MidMichigan Health
Dr. Feroze Momin, Expert, Oakwood Hospital, Dearborn
Dr. Edward Peres, Expert, Henry Ford Health System
Dr. Joseph P. Uberti, Expert, Karmanos Cancer Institute/McLaren Health
Dr. Michael Wiemann, Expert St.Johns Providence
Dr. Felicia Williams, Payer, BCBSM/BCN
Dr. Gregory Yanik, Expert, University of Michigan Health

The Committee met on the following dates: 11/18/2015, 12/16/2015, 1/14/2016, 2/11/2016, 3/10/2016, and 5/12/2016.

STANDARD ADVISORY COMMITTEE (SAC) CHARGES

The BMT SAC is charged to review and recommend any necessary changes to the BMT Services CON Standards regarding the following:

1. Consider and recommend if autologous BMT services should continue to be regulated by Michigan CON.
2. Consider and recommend if allogeneic BMT services should continue to be regulated by Michigan CON.
3. If the BMT SAC recommends that autologous and/or allogeneic BMT services should continue to be regulated by CON, then the SAC should recommend a methodology for determining the appropriate number of BMT services in Michigan.
4. In its deliberations of on these charges, the SAC shall consider the following: 1. National trends in CON regulation of BMT services and 2. Consistency of CON regulatory approach between BMT services and other covered clinical services.
5. Consider and report on how each recommendation address healthcare cost, quality and/or access in Michigan.
6. Consider any technical or other changes from the Department, e.g., updates or modifications consistent with other CON review standards and the Michigan Public Health Code.

At the introductory meeting of the BMT SAC, background information on the CON process and the SAC involvement was discussed. The committee over the next few meetings delved into the current reality of BM transplantation. Data was reviewed showing that Michigan BM transplants were basically stable at about 600 cases per year. The five institutions that are performing BM transplants report that they are under capacity, have adequate time frames for consultation and bone marrow typing and do not have any access issues from any area of the state. Many, but not all, members believed BM transplants may decrease in the future as better drugs and more focused therapies may obviate the need for BM transplants. A report prepared by Dr. Delamater showed adequate geographic access in that 84% of Michigan residents had 90 minute drive times to current BMT providers. (Appendix 1). There was continued discussion through many of the meetings as to whether there was an “un-met” need throughout the state or locally that is not being addressed by the current cap on new BM facilities. It was thought by many that underlying socioeconomic issues may result in certain populations not availing themselves of life-saving BM transplantation services but having more of these facilities would not change this outcome. Almost everyone agreed that there was a need for better education on when to refer these patients but that was a problem for the health system to solve and not the CON process.

The SAC reviewed national information on BMT regulation by other states. Only six states continue to regulate BM transplants by CON. Of these states, there is no methodology other than a cap to regulate facility proliferation. On the other hand, the committee did feel that there was inconsistency in how BM transplants were regulated as compared with other covered services by CON in Michigan

The SAC then turned its attention to formally evaluate continued regulation of CON in terms of cost, quality, and access. (Appendix 2) Although there were two separate charges to evaluate - Autologous vs Allogeneic - a majority of the committee felt that most factors applied to both. The members of the committee all voiced their opinion on various cost, quality and access effecting the decision to continue to regulate BM transplants by CON. In terms of cost, continued regulation of BMT services by CON allows lower costs due to economies of scale and more patient volumes to defray large fixed costs. Also physician, allied staff, and facilities costs can be kept lower if there is less competition for these highly skilled workers between the existing centers and new entrants. Innovative therapies, drugs, and clinical trials may lead to the establishment of alternative treatments which may replace BM transplants leading to lower volumes of transplants. Discontinuing CON regulation could lead to new BMT centers arising with increasing personnel and facility costs to support. In terms of quality, peer-reviewed data shows that existing Michigan BMT centers exceed national averages and that high patient volumes leads to more expertise and better outcomes. Transplant care is optimized if provided 24/7/365 by experienced providers. Discontinuing CON regulation would probably lead to decreased volumes at existing centers with concomitant loss of specialized personnel and under-utilization possibly leading to poorer outcomes. As to access, there was general agreement that it is determined by issues other than geographic considerations. Socioeconomic disparities, finding suitable donors, lack of caregivers, timely referral and evaluation of BMT eligibility, and appropriate HLA typing were thought as important as geographic location or driving distance in the transplantation process. Adding programs will not improve these access barriers. Their solution is outside the scope of the SAC. Charges 1 and 2 received a 10-2 vote that both Autologous and Allogeneic BM transplants should continue to be regulated by Michigan CON.

The most difficult but probably the most important work the SAC accomplished was in developing and debating alternative methodologies for CON regulation of Bone Marrow Services. As mentioned, a majority of the committee did not feel that these services should be regulated by a cap and that another methodology should be presented to the CON that was rational. It was obvious that geographic and driving distance considerations would preclude new entrant facilities, and it was also felt that existing providers should be held accountable. Outstanding work was done by two physicians – Drs. Akhtar and Yanik- to develop objective alternatives from the differing perspectives of a potential new provider and one based on the needs of the state. Dr. Akthar called his method: "BMT Need Methodology." and should be viewed as coming from a new provider perspective. (See Appendix 3 for detail and examples) There are 5 steps in the analysis:

1. Review State Tumor Registry Cases
2. Calculate Percentage likely to need Transplant
3. Applicant Institution would then multiply its Tumor Registry cases by the Percentage derived above. (Applicant would also be able to use volume "committed" to their institution.)
4. If the volume is greater than 30 cases per year, the applicant could then be designated as a BMT center.

Dr. Akthar noted that this methodology is more consistent with other CON regulated services in that it moves from a cap to Institution specific cases.

State needs perspective were presented by Dr. Gregory Yanik who proposed a "Needs Based Methodology" which required a three tier evaluation (Appendix 4 A and B):

1. Assess Performance of existing transplant centers versus national standards. (Compare MI percentages to US percentage of transplant cases) If state average is 5% lower than the national average **then**:
2. Assess Availability of transplant services at existing BMT centers using two criteria.
    a. Time to referral to consult
    b. Time to referral to receipt of sample for HLA typing

    If existing centers are unable to meet both metrics **then:**
3. Applicant Institution would need to show that using a 3 year average of its cases that it could support > 50 BMT cases per year.

Dr. Yanik believes this methodology forces existing BMT programs to continue to show superior to national performance in both volumes and availability as well as giving applicant institutions an objective way to show that they can support transplants for the various disorders requiring them. It was pointed out that the state does not require Tier 2 measures, and the existing institutions do not keep this data but that they could going forward. It was also agreed that the state should use a 3 year average time period for these tiering assessments.

A subcommittee examined both proposals in more detail and reviewed data showing that when Spectrum Butterworth Hospital opened a BMT center in 2013 that "volume" increased on the west side of the state without a decrease in volume in the

east side of the state (Appendix 5). This was part of an argument for “unmet” need being fulfilled when a new BMT center arises. However, this view is confounded by the fact that another existing BMT center in the east side of the state was losing volume to both east as well as west BMT centers with the total east volume staying the same or increasing slightly. The subcommittee did feel that a new center should have to prove a committed volume of 50 cases per year and it was noted that there was similarity between Step 4 of Dr. Akthar’s and Tier 3 of Dr. Yanik’s proposal.

Many of the same observations concerning cost, quality, and access are similar to the ones already stated in the review of charges 1 and 2. Most believed that irrespective of whether an institution or state needs approach were adopted that cost would not go down as there would be new fixed facility overhead and upkeep to pay for, more trained personnel would be required to be hired and supported, and that new accreditation costs would be added to the system, which are considerable. A minority felt that competition would ensue, but this is not likely and historically is unsupported from the hospital reimbursement perspective. Similarly, quality would be adversely affected as lower volumes at the newer institution would require time and a learning curve for the facility and staff. It was mentioned that a new institution could be required to have a mentor from an existing institution to catalyze rapid quality improvement. Access would be improved slightly, but only for patients at the new facility. Even for patients transferred from sister or system hospitals, there would still be the socioeconomic factors as well as the real issue of patient and family adapting to new caregivers in a new environment.

The motion to approve the needs based methodology by Dr. Akhtar was defeated by an 8-3 vote, the motion to approve the needs based methodology by Dr. Yanik was approved in a 9-2 vote.

Respectfully Submitted

Bruce E. Carl M.D.

June 6, 2016

Bone Marrow Transplantation: Review of Need Methodology

March 8, 2016

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General Observations

Bone Marrow Transplantation (BMT) is an extremely specialized service. According to the CON Annual Survey, only 633 adult (Age 21+) BMTs were performed in Michigan in 2014 on an adult population of more than 7 million. As a result, applying the need methodologies from other CON-regulated services (especially those for equipment, e.g., PET) may not be appropriate for BMT. Further, many of the other CON-regulated services' need methodologies contain either implicit or explicit assumptions regarding the regional or local "geography" of service utilization and/or need. Given the small total number of statewide BMTs each year, assessing regional variation may present difficulties due to small numbers and unstable rates.

- We note that the other transplantation services regulated by CON, Heart/Lung and Liver (HLL) Transplantation, also contain a provision to cap the number of services in Michigan. The HLL Standards cap the number of services at 3 for the entire state.
  - Implementing a hard cap as a means to regulate the supply of services is not an especially appealing approach. It is certainly not data-driven. However, the caps that are currently in place for both regulated transplantation services (BMT and HLL) may be a result of the complexity of the services themselves, signaling limited confidence in the ability to accurately predict unmet need for these highly-specialized services.

Given our past experience with CON, we believe population-based need methodologies are generally preferable over facility-based or facility-specific methodologies. Population-based need methodologies (those calculated for the entire state) provide all stakeholders (as well as the CON Commission and MDHHS CON Program) with an opportunity to assess the potential regional or local variations in utilization and/or unmet need across the state.

- However, population-based need methodologies can be much more difficult and time-consuming to develop (and implement), as they often require multiple data sources and broad-scale modeling assumptions about trends in service utilization or changes in the underlying population. When developing a population-based need methodology, finding an agreement on the model "assumptions" can be the most difficult part of this process, as it requires service-specific experts (representing all stakeholders) to work in tandem to develop an acceptable data-driven approach.

- Besse et al. (2015) provide an example of a population-based methodology to predict unmet need for BMT services. Although their approach is a generalized method applied to large service areas across the US, the authors do offer a basic blueprint for what this type of approach may potentially look like (with the important caveat that any methodology would have to be modified and specialized for BMT services in Michigan).
  - If georeferenced tumor registry data and cancer incidence data were made available for small areal units for the entire state (e.g., counties or zip codes), we believe that this information could be integrated with BMT MIDB utilization data and population (sociodemographic, e.g., age, gender, race/ethnicity, health insurance) data to develop a statewide predictive model of BMT need. The predicted BMT need data could be compared to the BMT utilization data and would represent an "expected vs. actual" approach to identifying unmet need.
  - An alternate approach would be to identify a proxy variable that signals a missed opportunity for BMT and can thus be used to estimate unmet need for this service. The proxy must be a non-BMT treatment mode (or a specific service use) that functions as an alternative to BMT, when BMT is the most appropriate treatment for the patient, but not utilized due to a lack of accessibility or availability. In this approach, the non-BMT treatment essentially functions as the proxy variable for unmet BMT need. This is the fundamental approach in the UESWL (lithotripsy) Standards, where an inpatient hospitalization for a kidney stone signals a missed opportunity for lithotripsy.

Geographic access to BMT does not appear to be lacking in Michigan when the state is compared to other states in the US (see the 2013 BMT report and Delamater and Uberti, 2016). However, for BMT, limited geographic access to services is likely trumped in importance by limited availability (population demand vs. facility supply) of services. However, one issue with BMT that causes difficulties in understanding availability is the lack of an easily quantifiable measure of the "supply" available. For other regulated services, such as acute care hospitals, the number of beds available at a particular location provides a relatively straightforward measure of the facility supply, thus occupancy rates (utilization/beds) can be used to understand if population demand is stressing the available supply of services (and thus potentially signaling potential unmet need). We are unaware of any such measure that can be used to evaluate BMT services.

From our understanding of the recent scientific literature, unmet need for BMT services is not (and will not be in the future) driven simply by a lack of facilities providing BMT, but by a lack the appropriate human resources and infrastructure necessary to provide BMT services (see Mahail et al., 2012). Hence, BMT service provision may be considered a zero-sum game, such that an increase in capacity in one place can only be gained via a decrease in capacity in another place.

Proposed Methodology (Dr. Akhtar)

We have reviewed the methodology provided by Dr. Akhtar (Powerpoint file) and the transcript from the BMT SAC meeting on February 11, 2016. We believe that the proposed methodology would not demonstrate need for BMT services as presented. Our most serious concern is that the methodology appears to only offer a mechanism to "transfer" BMT demand from existing BMT programs to proposed, new programs.

We present an example below to illustrate our concern. Although the example is extremely simplified, we believe that it accurately captures the fundamental approach underlying the proposed methodology. In the example, we consider BMT demand in a hypothetical state for one year. We consider a single type of cancer tumor and two hospitals in our state. In the example, only one hospital provides BMT services.

- Hospital 1 provides BMT services and Hospital 2 does not provide BMT services
  - Hospital 1 performed 10 BMTs for cancer tumors (all statewide BMTs were performed here)
- The total number of new tumor cases in the statewide registry was 50
  - 25 tumor registry cases were reported by each hospital
- To calculate the BMT factor, the proposed methodology would divide the 10 statewide BMTs by the 50 statewide tumor registry cases, reporting that 20% of all tumor cases resulted in a BMT
  - Hospital 2 could then multiply their 25 tumor registry cases by 0.2 (for 20%) and report that their new BMT service could generate 5 BMTs
  - However, the overall statewide demand would remain at 10 BMTs and the 5 BMTs at Hospital 2 would not represent a new or unmet demand for BMT services, but simply existing demand transferred from Hospital 1 to Hospital 2

We also express concerns over the lack of any "geography" in the proposed methodology. Importantly, the methodology does not consider whether BMT services are already available in the region of a proposed new facility, thus does not consider the existing supply of BMT services or the potential for duplication of services. A geographic component could potentially be added to the proposed methodology, possibly constraining the region(s) from which the cancer tumor registry cases could be drawn when applying for a new BMT service. However, even if a geographic constraint were to be added, this approach would not rectify the underlying "transfer" mechanism in the methodology.

A final concern in the proposed methodology is the use of tumor registry cases without incorporating the complex set of patient factors that are considered when determining whether BMT is an appropriate treatment option. For example, the age of the BMT patients are not considered in either the factor calculation

or the need methodology. At this time, we do not have a specific recommendation to alleviate this concern, but the straightforward use of the cancer tumor registry data appears to oversimplify the potential need for BMT services.

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CON REGULATION OF BMT SERVICES:

COST:

These were the top factors that the SAC felt CON regulation of allogeneic and autologous BMT regulated cost:

1) Regulating the number of programs, allows lower costs due to economy of scale of more patient volumes allowing facilities to bundle hospital and drug charges.
    a. Opposing point of view states that there is no data to support that economy of scale lowers cost.
2) CON regulation of BMT services minimizes cost by limiting the expense of a BMT allogeneic program by preventing too many hospitals from starting BMT programs. These include:
    a. BMT trained staff (physicians, nurses, stem cell lab personnel)
    b. Facilities: renovation to meet BMT standards, HLA laboratory, Apheresis center, Stem cell processing lab. This includes the cost of implementing and maintaining these services.
    c. Personnel to maintain quality standards: Clinical Nurse Specialist to maintain policies for FACT accreditation, data managers, BMT coordinators, social worker.
3) There are publications showing that CON regulated services have lower costs than states with no CON regulated services.
    a. Opposing point of view states that there is no specific cost comparison data specific to BMT.
4) The complexity of BMT treatment is complex and high risk, higher mortality than standard chemotherapy. By regulating BMT services, cost is minimized due to having experienced staff (e.g. nurses, BMT dedicated physicians, subspecialists comfortable with BMT related complications) who can navigate the BMT issues and thus minimize waste due to inexperience.
    a. Opposing point of view states that this argument can be made for all complex healthcare services, not just for BMT.
5) Deregulation will increase cost to the state and systems due to the cost of new programs and not having economy of scale to help with recouping cost.
    a. Opposing point of view argues that de-regulation should increase competition which could lower costs.
        i. This has worked on a business level, but has not always worked that way in healthcare.

These were the top factors that the SAC felt discontinuing CON regulation of allogeneic and autologous BMT servies would NEGATIVELY impact cost:

1) The number of active clinical trials may reduce the need of BMT related services. These include the promising field of immune-based therapies for acute leukemias and multiple myeloma.
    a. If the number of programs is not regulated, new BMT facilities (nursing, physicians, ancillary staff, lab and stem cell processing facilities) could be created

with a potential for decreasing BMT needs, thereby wasting healthcare dollars that could be used for other needed services.

   b. Opposing point of view states that it is too early to know if these newer therapies will alter the need for BMT.
   c. Opposing point of view argues that there is no data to support that states that do not regulate BMT have higher costs compared to CON states.
      i. University of Michigan has data to show that BMT costs are lower than national average. Since majority of states are NOT CON regulated states, University of Michigan and Karmanos Cancer Center argue that CON regulation in MI has contributed to lower costs.

2) The cost of maintaining FACT (Foundation for Accreditation of Cellular Therapeutics) accreditation, cost of renovating and building infrastructure for BMT services, and personnel with BMT experience is not trivial. Without, the volume of BMT patients, this could be significant expenditure of health care dollars that can impact taking away health care dollars that can be spent on much needed services for the community.
3) Compared to other BMT regulated services, the cost of BMT is low. BMT chemotherapy is no more costly (and sometimes less) than non-CON regulated cancer drugs.
4) As the indications for BMT are small, there is less concern for potential for excessive utilization and thus cost can be managed without CON regulation.

Quality:

These were the top factors that the SAC felt CON regulation of allogeneic and autologous BMT improved quality:

1. Data from the existing BMT centers show that state of MI provides high quality care. Outcomes exceed national averages.
   a. It is felt that CON regulation has helped with maintaining high volumes and that is why state of MI outcomes exceed national averages.
   b. There are publications that show that outcomes are directly proportional to volume of BMT patients.
   c. Opposing point of view feels that non-regulated BMT states can also demonstrate high quality of care.
2. CON regulation helps maintain the proper volume of patients:
   a. Volume of patients keeps all staff experienced with recognizing BMT complications. This is also important in not only the BMT staff, but all staff in the hospital who need to understand the complexity of BMT patients. This includes the other subspecialists who need to be experienced to care for BMT related complications. This improves the experience and familiarity of these treatments which translates to high quality of care.
      i. Dissenting point of view argues that FACT only requires 10 transplants in allogeneic HSCT and 10 autologous HSCT to apply for accreditation?. State of MI CON requires 30 transplants.

Commented [HB1]: CON regulation maintains the volume by continuing to limit access.

1. Disagreement that a minimum level of these transplants will ensure high quality, that only doing small numbers will not ensure that people are familiar with BMT.

3. Transplant care is optimized if provided 24/7/365 by transplant trained providers.
    a. There is a national shortage of transplant trained physicians.
        i. This is an extra year of training, lack of trainees entering these training programs.
            1. Another new program will potentially cannabalize from existing programs to staff new HSCT center thus putting the stress on the existing program and jeopardizing the high quality that currently exists in the state of MI.
        ii. Extending coverage with other hematology/oncology providers may not allow recognition of BMT complications in a timely manner.
        iii. Opposing point of view states that many specialties have shortages and that it should not be considered in CON consideration of a new program as long as other requirements are met.
4. Volume of patient is also important to keep physicians and facilities experience in providing long term follow up care as more patients are surviving BMT.

These were the top factors the SAC felt discontinuing CON regulation of allogeneic and autologous BMT services could NEGATIVELY impact quality.

1) By diluting patient volumes, this could impact the quality of current outcomes demonstrated by the BMT programs compared to national averages.
    a. Opposing point of view argues that opening 1-2 new programs will not put current programs on falling below 30 BMT patients (or whatever new minimum volume if set).
        i. Disagreement in that volume is needed to see all types of complications in BMT on a REGULAR frequency. With small volumes, high risk complications will not be seen as frequently, and physicians and staff will lose familiarity since more time will lapse between rare or serious complications.
2) As FACT accreditation ensures the program has a process to maintain quality, some SAC members felt this has been what will maintain the quality of the BMT programs in the state of MI.
    a. However, programs that have been through FACT has demonstrated that it does NOT take outcomes into account with maintaining accreditation
3) Discontinuing CON regulation and increase in the number of BMT programs will negative impact the experience and specialization of staff due to underutilization.
    a. Opposing point of view states that we currently do not collect data to support this concern
        i. Spectrum (Grand Rapids) opened a program and it did not adversely impact the numbers of the other Michigan BMT programs

ii. However, discussion was raised that Grand Rapids is a completely different geographic area. There are currently 3 BMT programs that service southeastern MI all at 50% capacity, averaged.

4) By allowing other BMT programs, continuity of care will improve patient's experience as they will be familiar with the facility and ancillary staff.

ACCESS:

These were the top factors that the SAC felt CON regulation of allogeneic and autologous BMT improved access:

1) Access is determined by issues other than geographic distance.
    a. Unable to identify a suitable HLA donor.
    b. Lack of caregivers to support the patient through BMT
    c. Economic pressures of unemployment due to medical leave.
    d. Timely referral and evaluation of BMT eligibility.
        i. Discussion if there really is an issue with timely referral as the BMT centers have stated that there is no wait for an initial consultation. This suggests that the delay may be on lack of education/awareness of referring physicians.
        ii. Discussion if determination of BMT eligibility (I.e. sending blood in for HLA typing) is also delaying or impairing access.
            1. Some of what is needed is driven by insurance to determine BMT approval process (repeating of tests)
2) Adding programs to existing programs will not improve these access barriers.
    a. Data was presented that when BMT program opened in western Michigan, more patients living in western MI received BMT, no decline in cases for SE Michigan, improving access.
        i. Total number of cases appeared to grow in state of MI suggesting that patients on that side of the state who may have gone to Indianapolis, or Chicago are able to receive BMT in MI.
        ii. Suggesting improved access
3) Comparing geographic access in Michigan compared to other states, distance to a BMT program in Michigan is comparable or better than most states in the US.
    a. The CON process helped with opening a program in Grand Rapids to improve access on the West side of Michigan which was underserved. Those patients were driving to Southeastern Michigan or other states to receive BMT.

These were the top factors the SAC felt CON regulation of allogeneic and autologous BMT services had NEGATIVELY affected access:

1) Minority and lower socioeconomic status patients may be negatively impacted by CON regulation as these patients are required to travel for BMT services.
2) Excess capacity does not equate to equal access.
3) Large systems with large volumes of patients should not have to displace their patients from their primary area of residence and primary care teams

4) Despite articles showing that MI has better geographic access, National Marrow and Donor Program has published there are still unmet BMT needs, including Michigan.
5) BMT volumes continue to increase, thus CON regulation may not be needed as more patients could be transplanted if access was improved by allowing the opening of other BMT programs.

Maintenance of a Cap on BMT services:

Cost:

These were the top factors that the SAC felt that maintaining a Cap on BMT services has maintained costs:

1) The Cap has allowed standardization of services therefore minimizing costs.
2) Cost of developing and maintaining a program is large
3) Healthcare costs per capita are highest in areas with duplicity of resources.
4) Regulation keeps cost low compared to non-CON regulated states.
    a. Opposing point of view states that this is not specific to BMT services.
5) Limiting programs allow bundling of costs (including drug charges)
6) More facilities in health care has not shown lower costs to purchasers of health care.

These were the factors the SAC felt that maintaining the Cap NEGATIVELY impacts cost:

1) The Cap does not force current programs to examine costs and resources.
    a. This is done locally at the system level as the hospital administration is what pays attention to the financial benefit of BMT services.
2) By removing the Cap, there is a concern that dilution of talent could lead to increase in personnel costs as programs compete to retain staff.
3) BMT costs in relation to total cancer care is LOW.
4) Free market forces should mean that more BMT facilities should increase competition a thus lower costs.

Quality:

These were the top factors that the SAC felt that maintaining a Cap on BMT services has maintained quality:

1) All BMT centers are performing at high quality with better outcomes than the national average.
    a. This is due to the CON Cap in the state of MI limiting BMT programs and thus having patients go to an experienced center.
        i. Risk adjusted.
        ii. Opposing point of view argues that there are non regulated states with just as good outcomes.
2) Experienced transplant physicians are limited, and thus increasing the number of BMT programs will dilute the number of experienced physicians.
3) Care is optimized by 24/7/365 coverage by transplant trained personnel at all levels.

These were the top factors the SAC felt that maintaining a Cap on BMT services has NEGATIVELY affected quality:

1) There is no reason to assume a new program would not also have high quality.
2) Removing the cap could entice more physicians to become transplant physicians
    a. Financial incentive as non-academic centers traditionally pay more, some prefer a non-academic environment, more competition may increase financial incentive.
3) Having more programs could increase current BMT workforce.

Access:

These were the top factors that the SAC felt that maintaining a Cap on BMT services has affected access:

1) With 3 centers in SE Michigan, and Grand Rapids, the patients currently have options and get a second opinion.
2) Oncologists outside SE Michigan (Mid- and Northern MI) do not perceive a lack of access for current BMT services.
3) Current CON has maintained access by increasing the cap when lack of access is identified.
    a. Opening a program in Grand Rapids to improve access in Western Michigan.
    b. Opposing point of view is that the Cap has failed to recognize lack of access.
        i. A Cap is not a methodology
    c. There is no current methodology to assess when a new BMT center is needed in the state of MI

These were the factors the SAC felt that maintaining the Cap on BMT Services has NEGATIVELY impacted access.

1) There is no established methodology that can reliably and objectively look at access and when a new program is needed.
2) Cap limits access by needing, as patients may have to travel.
3) More centers will improve access
4) More centers will give consumers additional options.

BMT Need Methodology

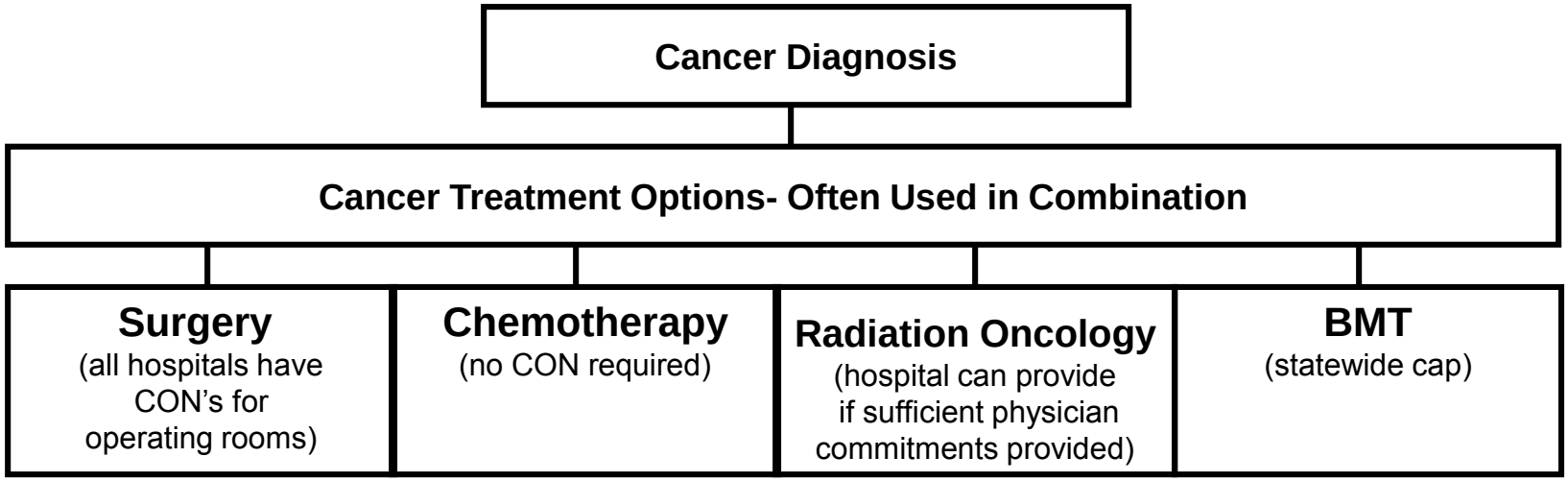
BMT SAC

February 11, 2016

Overview

- SAC has voted to continue CON regulation of BMT (Charges 1 & 2)
- SAC must now recommend a CON need methodology for BMT (Charge 3)
  - Recommended methodology must take into account “consistency of CON approach” between BMT and other CON covered services (Charge 4)
  - CON trend in Michigan has been toward institution-specific methodologies (vs. caps)

BMT is the Only Cancer Treatment Option with Program Limit



Consistency of CON Approach to Need

PET*	**based on**	**tumor registry cases**
ESWL*	**based on**	**urological discharges**
Open heart	**based on**	**cardiac discharges**
Radiation oncology	**based on**	**physician commitments**
BMT	**based on**	**cap**

*Cap removed in favor of institution specific need methodology

Attachment K

Proposed BMT Methodology

- Starts with Statewide Tumor Registry Cases for cancers for patients age 20+ most often requiring BMT (sources: Michigan Cancer Surveillance Program; Centers for Disease Control & Prevention)
- Each “cancer category” is multiplied by a “factor” (percentage) of cases likely to result in BMT. For the “base year” (2012- most recently available statewide tumor registry data), the factor is calculated by dividing the total Statewide BMT cases (from the Michigan Inpatient Data Base) by the Statewide Tumor Registry Cases.
  - This need methodology is very conservative because it does not take into account unmet need- the total “need” for the State is simply the total number of BMT’s performed.

BMT Need Methodology
Calculation of Factors (2012)

Attachment K

(A) Diagnosis	(B) 2012 State Registry Cases*	(C) Factor (Estimated % receiving BMT)***	(D) 2012 Statewide Volume**
Non-Hodgkins	2197	5.5%	121
Hodgkins	238	11.7%	28
Acute Leukemia (ALL/ AML)	515	21.6%	111
Chronic Leukemia (CML)	178	4.5%	8
Multiple Myeloma	702	27.1%	191
Myelodysplastic Syndrome	519	6.2%	32
Other	629	3.6%	23
Total	4978	10.3%	514

* Source: Michigan Cancer Surveillance Program; Centers for Disease Control
** Source: Michigan Inpatient Data Base (totals match closely with CON Annual Survey totals)
*** Calculated Field (D/B)

Proposed BMT Methodology (continued)

- Applicants for a new BMT program demonstrate need by applying their institutional tumor registry cases by cancer category to the corresponding factor, and summing the results. If the summed results meet the (TBD) "threshold", then the applicant would demonstrate need and could initiate a program.
  - Note: the FACT minimum volumes are 10*; the current BMT CON standard minimum volume is 30
- Applicants using their own tumor registry could combine their cases from other hospitals who agree to "commit" their cases to the applicant (consistent with other CON standards)
- Tumor registry cases at existing hospitals with a BMT program could not be used to support other applications
- Once tumor registry cases from a hospital are committed to an application, those tumor registry cases could not be used again as long as the new program is operational (consistent with other CON standards)
  - This provision limits the number of new programs that can be approved

*Source: Foundation for the Accreditation of Cellular Therapy, FACT-JACIE International Standards for Hematopoietic Cellular Therapy, 6th Edition.

BMT Need Methodology
Calculation of Factor, 2010-2012

Attachment K

(A) Diagnosis	2010 Factor (Estimated % receiving BMT)	2011 Factor (Estimated % receiving BMT)	2012 Factor (Estimated % receiving BMT)
Non-Hodgkins	4.9%	5.3%	5.5%
Hodgkins	14.5%	11.9%	11.7%
Acute Leukemia (ALL/ AML)	19.4%	21.6%	21.6%
Chronic Leukemia (CML)	2.7%	4.5%	4.5%
Multiple Myeloma	25.7%	26.3%	27.1%
Myelodysplastic Syndrome	2.9%	4.9%	6.2%
Other	6.9%	5.1%	3.6%
Total	9.8%	10.3%	10.3%

Conclusions

- Current cap approach is out of date and should be replaced with a rational, data based need methodology (Charges 3, 4)

- BMT methodology presented is consistent with need methodologies for other CON covered services

- Proposed next step is to request the Department to review, validate and make recommendations pertaining to this methodology

Need Based Methodology for BMT services in Michigan

G. Yanik MD

University of Michigan Medical Center

Needs Based Methodology

- **3-Tier Model. Basic Tenets:**
- The criteria should be a composite of national and statewide data. Not based upon an individual center's data.
- The need for BMT services is determined by more than geographic distance.
- The criteria should not be viewed as favorable to any one individual center.

Needs Based Methodology: 3 Tier Model

Metrics for evaluation:

Tier 1: Center Performance

Tier 2: Center Access

Tier 3: Center Volume
(For proposed centers)

Needs Based Methodology: Tier 1

Tier 1

- Assess Performance of Existing BMT Centers vs. National Standards.
- Determine the % of Transplants in MI for a Target Disorder, compared to National Average.
- Target Disorders: AML and Myeloma

Needs Based Methodology: Tier 1

Tier 1 Requires:

- **SEER data:** Total # cases in US (for that disorder).
- **CIBMTR data:** Total # BMT in US (for that disorder).
- **National BMT rate**: # BMT (CIBMTR) / SEER incidence.
- **Michigan BMT rate**: # BMT (MI) / Total # cases in MI.
- **Proposal for Tier 1:** If the state average is 5% less than national average, then proceed to Tier 2. (The metric must be met for both target disorders identified).

Needs Based Methodology: Tier 2

Tier 2

Access at existing BMT centers.

- **Two metrics**:

  Time from Referral to Consult. < 28 days

  Time from Referral to receipt HLA typing. < 14 days
- **Recommendation**:

  Metric should be a composite of statewide data.

  Existing BMT centers should meet both metrics.
- If this metric is not met, then proceed to Tier 3.

Needs Based Methodology: Tier 3

Tier 3 Justification.

Determine New Center's ability to support BMT.

- Examine a center's tumor registry. Determine the total number of cases by target disorder.
- Apply correction factor (% BMT) from Tier 1.
- Summate estimated number of BMT (for each target disorder)
- Metric: If estimate > 50 BMT/year total, a center would meet that metric.

Need Based Methodology

- **All 3 Tiers must be fulfilled for new center performance.**
- **Tier 1:** Holds existing BMT centers accountable for performance of certain level of BMT. Will account for changing trends in BMT, both overall and for particular target diseases.
- **Tier 2**: Holds existing BMT centers accountable for access / availability.
- **Tier 3**: Creates cost-efficiency. Eliminates a duplicity of resources, by preventing the opening of multiple small BMT programs within the state.

Needs Based Methodology

- Two different proposals have been presented:

Dr. Akhtar / Beaumont	Dr. Yanik / UM
Center Volume	Performance
	Access
	Center Volume

Needs Based Methodology: 2 views

Dr. Akhtar / Beaumont	Dr. Yanik / UM
"Unmet Need'	Existing BMT Services are Adequate
How will building a program at Beaumont fill this perceived need.	Access is Good
Are we focusing on the wrong need	High Quality (Outcome)
	Cost Efficient Care

BMT Transplant Volume: 2011 - 2015

	2011	2012	2013	2014	2015	2016
MICH	225	212	239	222	192	170*
DMC	275	276	260	277	274	TBD
HFH	48	53	69	78	89	TBD

	2011 - Present
University of Michigan	Volume has declined since 2013

BMT Transplant Volume: 2011 - 2015

	2011	2012	2013	2014	2015	2016
MICH	225	212	239	222	192	170*
DMC	275	276	260	277	274	TBD
HFH	48	53	69	78	89	TBD

	2011 - Present
University of Michigan	Volume has declined since 2013
Karmanos / DMC	BMT volume remained constant

BMT Transplant Volume: 2011 - 2015

	2011	2012	2013	2014	2015	2016
MICH	225	212	239	222	192	170*
DMC	275	276	260	277	274	TBD
HFH	48	53	69	78	89	TBD

	2011 - Present
University of Michigan	Volume has declined since 2013
Karmanos / DMC	BMT volume remained constant
Henry Ford Hospital	BMT volume increased by 40 cases /yr.

BMT Transplant Volume: 2011 - 2015

- UM lost transplant volume, the loss primarily from the west side of the state.

BMT Volume	2000 – 2011	2012 - 2016
West MI	31%	< 10%

- Karmanos performed the same number of transplants, on a fewer number of patients, with the patients older in age (60 years).

Second Transplants (Graft Rejection) at Karmanos				
2011	2012	2013	2014	2015
19	26	35	30	31

22 per year

32 per year

BMT Transplant Volume: 2011 - 2015

- Henry Ford increased their transplant volume. This growth led to an overall 12.3% growth in transplants in SE Michigan between 2011 - 2015.
- Does this mean there is an unmet need?

Not necessarily.
Are we focusing on the wrong need

"Building more transplant programs may not be the answer. Improving awareness of referring physicians may fill a greater need."

Improving Awareness for BMT services in the State of Michigan

Gregory Yanik

Jennifer Barish

Improving Awareness

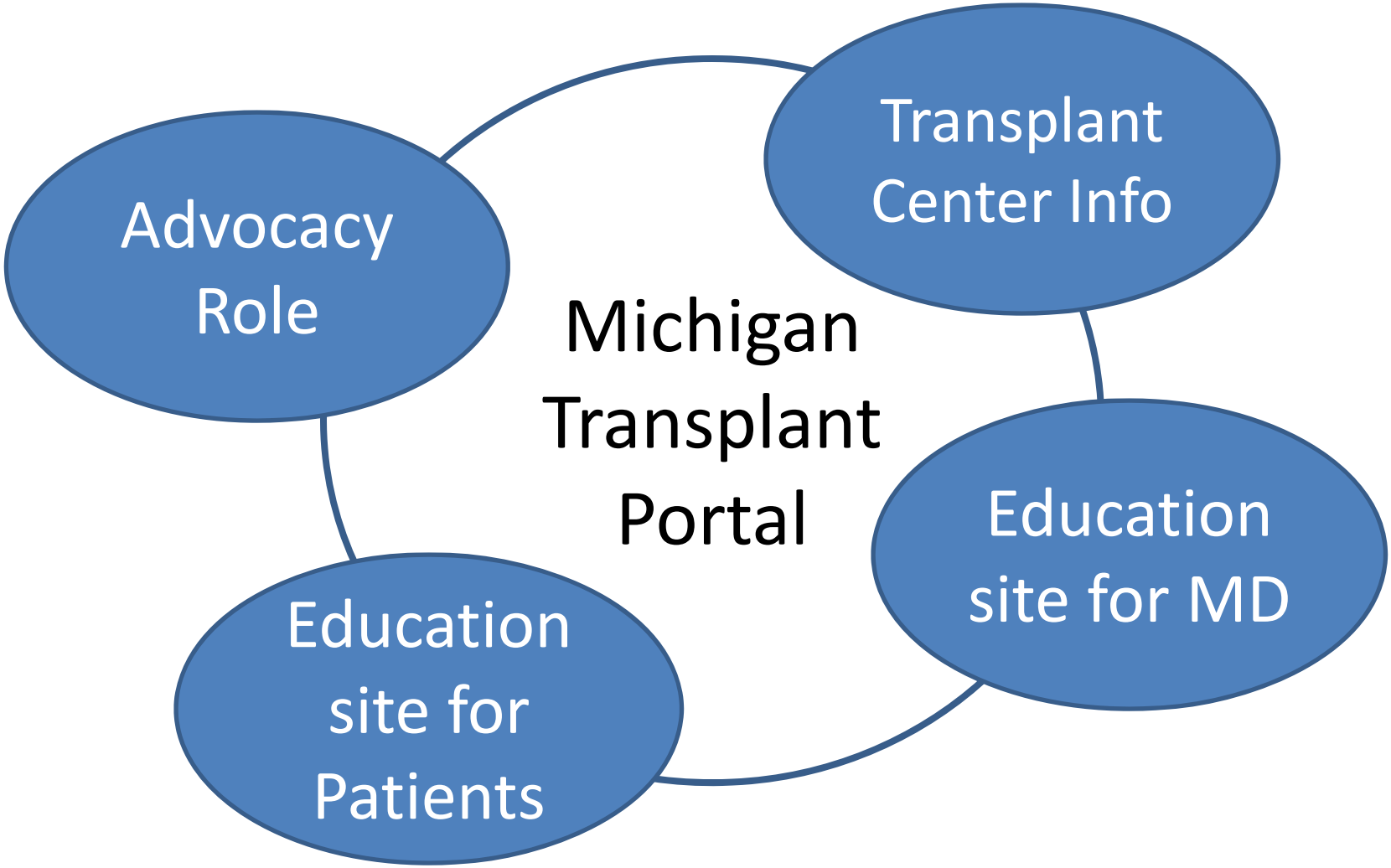
Improving Awareness:

- Of referring physicians.
- Of patients.
- Of transplant physicians.

Recommendation:

- **"Establish Michigan Transplant Portal"**
- Partnership of BMT centers, NBMT Link, non-BMT centers, Primary Insurers.

Web-based portal



Michigan Transplant Portal
Physician Information Site

- **Web-Based Portal:** Would contain BMT site specific information for referring MD's.

Physician Contact:
RN Coordinator:
Clinic:
Social Work:
Financial Counsel:
HLA Instructions:

Michigan Transplant Portal
Patient Site

- **Patient portal. Include Site Specific:**

"Welcome videos". Directions, Parking, Location of BMT center. Contact information for key BMT personnel / Clinic / ER at each site.

Michigan Transplant Portal
Education Site

Referring Physicians

Clinical care resources / guides.

- Indications for BMT.
- Transplant Eval (by disease).
- Post-BMT Vaccination.
- Long Term Follow-Up.
- Post-BMT disease monitoring.

For Patients

Use NBMT Link

Patient Resources / Public'ns

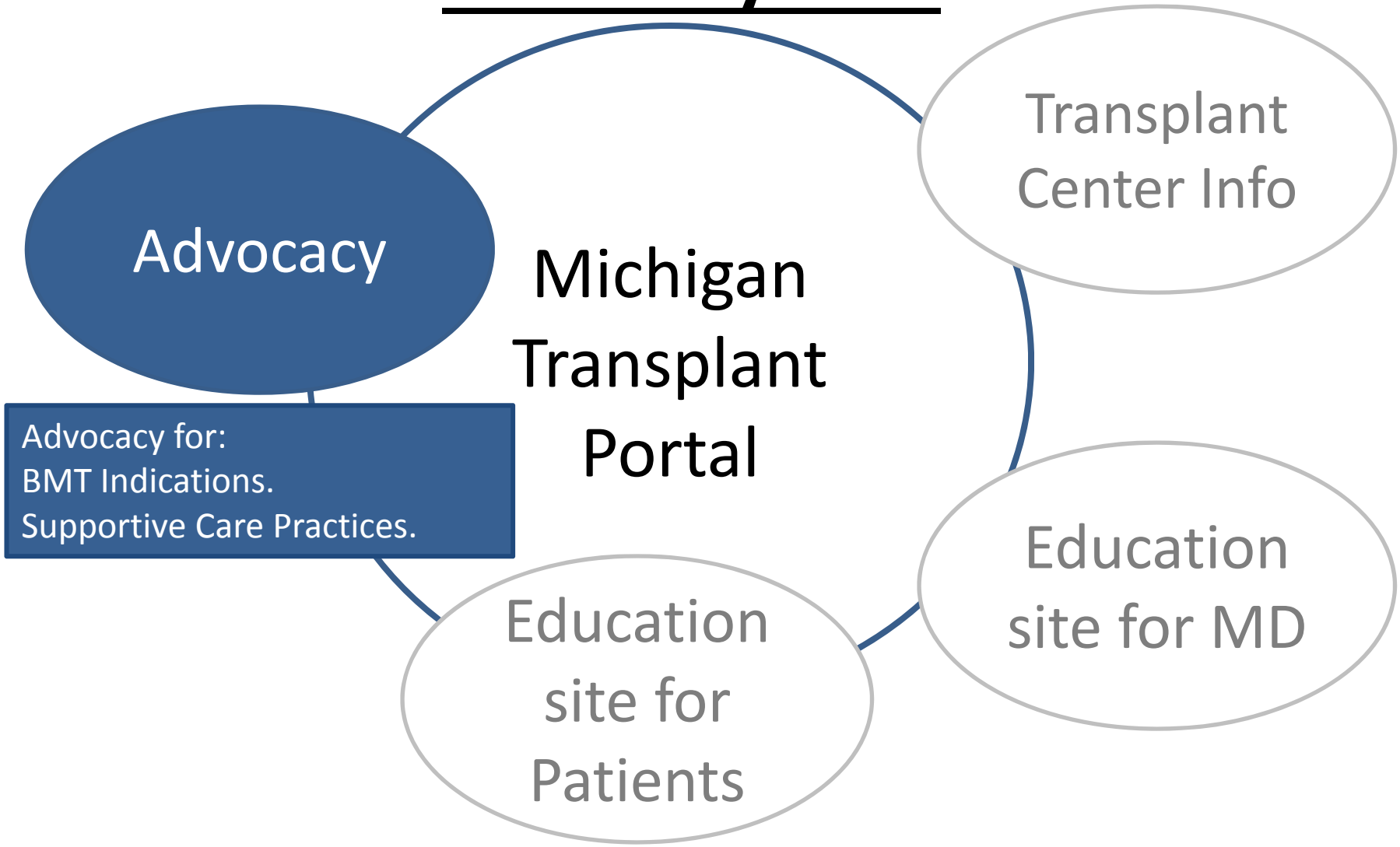
- Frequently asked BMT?
- GVHD Guide
- Caregiver's Guide
- Survivorship Guide

GVHD Phone Support Group.

Peer Support On-Call Programs.

Michigan Transplant Portal

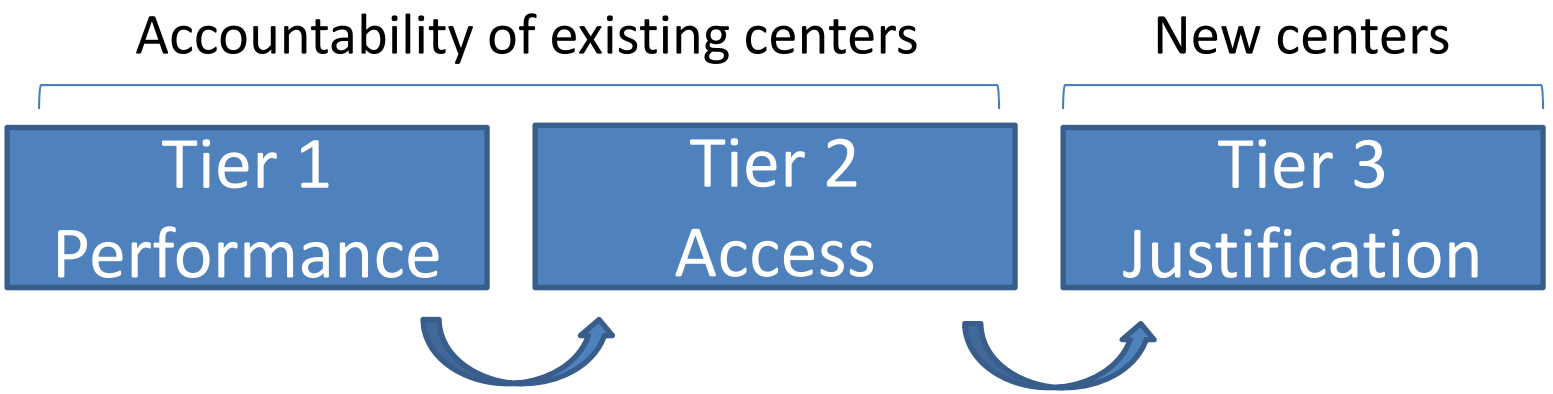
Advocacy Role



Michigan Transplant Portal: Conclusion

- **There is a need to better educate physicians and patients. Regarding:**
  - Indications for BMT. Timeliness of referrals.
  - How to refer patients into the system.
  - Resources for patients.
  - Resources for physician caregivers.

Proposed Need Based Methodology: Summary of Proposal



- **Three Tiers, in which:**
- **Current programs:** Must be held accountable.
- **New centers:** Must be able to justify their ability to support the service.

Conclusions

- There is no unmet need for BMT centers in the state of MI
- Existing transplant centers are providing high quality care in an economically responsible manner
- Timely transplant referrals are required to improve the access of patients to BMT not more transplant centers.
- A 3-Tier model should be considered.

Extra slides

Intensity of Stem Cell Transplantation Compared to Organ Transplantation

	1 Year Mortality
Heart Transplantation	10-15%
Kidney Transplantation	4-8%
Lung Transplantation	22%
Liver Transplantation	17%
Allogeneic and Unrelated Stem Cell Transplantation	40-50%

BMT Transplant Volume: 2011 - 2015

- Karmanos performed the same number of transplants, on a fewer number of patients, with the patients increasingly older in age (median 60 years).

Transplants for patients > 65 years in age at Karmanos				
2011	2012	2013	2014	2015
66	61	44	70	93

Second Transplants (Graft Rejection) at Karmanos				
2011	2012	2013	2014	2015
19	26	35	30	31

22 per year

32 per year

Needs Based Methodology:

We recommend that the SAC consider a Needs Based Methodology dependent upon a 3-tier criteria. The criteria should be based upon a composite of statewide transplant data, and not based upon an individual transplant program's data. The criteria cannot be viewed as favorable to one center.

Tier 1: Assess the PERFORMANCE of existing transplant centers versus national standards: Determine the composite number of transplants in our state for a target disorder, when compared to the national average for that same disorder. The target disorders would be adult AML and multiple myeloma, the two leading indications for transplant in the US. (The target disorders could be changed in future years by the CON, depending upon national trends in bone marrow transplantation,)
This metric requires analysis of:

a. SEER Data: Total number of cases for a target disease (AML, Multiple Myeloma) in US.
b. CIBMTR Data: Total number of transplants for a target disease (AML, Multiple Myeloma) in US.
c. National Average: # Transplants (AML or Myeloma) in US / Total number cases in US
d. State of Michigan Average: # Transplants (AML or Myeloma) / Total number cases in state.
e. If the state average is $\geq$ 5% less than the national average, **THEN:**

Tier 2: Assess AVAILABILITY of transplant at existing centers:
The availability of transplant services would be assessed by two factors: 1) Time from referral to consult. 2) Time from referral to receipt of sample for HLA typing. We recommend that the median time from referral to consult be ≤ 28 days. We recommend that the time from referral to receipt of HLA typing should be ≤ 14 days. The metric should reflect a composite of statewide transplant data, not based upon individual center performance. If existing transplant centers are unable to meet both metrics (time to referral, time to receive sample for HLA typing), **THEN:**

Tier 3: For an individual center to apply for transplant services, that center be able to adequately SUPPORT transplant for a target disorder. This metric requires examining a center's institutional tumor registry, to determine the total number of cases of AML and multiple myeloma /year within that institution (3-year average). Apply the correction factor from Tier 1 to that center's case load. If the estimated transplants for "AML + myeloma" exceeds 50, then the CON would give consideration to that center to develop a transplant program. Using a threshold of 50 transplants provides an element of cost-efficiency, as the fixed costs of establishing a program would be justified by patient volume. This also limits the duplicity of resources, limiting multiple smaller programs from opening transplant programs.

The proposed methodology focuses on the PERFORMANCE (Tier 1) and AVAILABILITY (Tier 2) of existing transplant centers, coupled with a new institution's ability to adequately SUPPORT transplant for that disorder (Tier 3). All 3 criteria must be fulfilled for a new center to open a transplant program within our state.

DIST 2 5-12-16 MTG
AKHTAR
Attachment K

IMPACT OF INCREASED BMT ACCESS IN MICHIGAN

BMT Discharge Trend by Planning Area (Source: Michigan Inpatient Data Base)

	2010 Adult BMT Discharges	2011 Adult BMT Discharges	2012 Adult BMT Discharges	2013 Adult BMT Discharges	2014 Adult BMT Discharges	2015 Adult BMT Discharges***
East Side Programs*						
Planning Area 1 Residents (East)	392	395	396	420	440	459
Planning Area 2 Residents (West)	130	123	122	112	107	64
Total East Programs	522	518	518	532	547	523
West Side Programs**						
Planning Area 1 Residents (East)	0	0	0	0	2	1
Planning Area 2 Residents (West)	2	1	2	35	61	95
Total West Programs	2	1	2	35	63	96
All MI Programs						
Planning Area 1 Residents (East)	392	395	396	420	442	460
Planning Area 2 Residents (West)	132	124	124	147	168	159
Total All MI Programs	524	519	520	567	610	619

*Henry Ford, Karmanos, U-M
**Spectrum
***Annualized based on Jan-Sept. 2015

BMT transplant volume (2011 – 2016): University of Michigan (UM) and Karmanos Cancer Center. Transplant volume at UM has declined by 24% over the past 5 years. Transplant volume at Karmanos has remained constant during this period.

Transplant volume (# of transplants/year)						
	2011	**2012**	**2013**	**2014**	**2015**	**2016**
UM	225	212	239	222	192	170*
Karmanos	275	276	260	277	274	TBD

At the University of Michigan, the lost volume reflects a shift in referrals from UM to the Spectrum (Grand Rapids) program. Between 2000 and 2011, West Michigan accounted for 31% of UM's transplant referrals. West Michigan now accounts for < 10% of UM's referrals. While Spectrum's transplant program has grown by 50 patients/year (2012 to present), UM's program has declined by 50 during this period.

Why has Karmanos' transplant volume remained constant? Karmanos was not dependent upon West Michigan for their referral pattern. Prior to 2012, the majority of patients in the Holland-Grand Rapids-Muskegon region were referred to UM for transplant, not Karmanos.

Is there an unmet need in SE Michigan for additional transplant centers: "Building more transplant programs is not the answer. Improving referring physician awareness may fill a greater need." (CIBMTR task force member). Will building another program in SE Michigan help fill a need, or will it lead to a shift in patients from one center to another (*P. Delamater review, March 2016*).

Will building another program in SE Michigan lead to duplicity in resources. Conversely, how cost efficient are current transplant centers?

Billable Charges	**National (Median $)**	**UM (Median $)**
Autologous BMT	212,000	185,000
Allogeneic BMT	479,000	249,000 (Related donor)
		373,000 (Unrelated donor)

- *Milliman Data Base, 2014*

What is the quality of care for transplant services in the state?

1-year Survival	**National (CIBMTR data)**	**UM (2012)**	**UM (2013)**
Related donor	73%	77%	69%
Unrelated donor	65%	70%	83%

How long are patients waiting to be seen? At UM, median time from referral to appointment: 12 days. The median time from referral to receipt of HLA blood test: 9 days.

Current centers in the state are providing high quality, cost efficient care, without delays.

CERTIFICATE OF NEED

2nd 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	2nd Quarter	Year-to-Date
Approved projects requiring 1-year follow up	58	130
Approved projects contacted on or before anniversary date	36	84
Approved projects completed on or before 1-year follow up	62%	
CON approvals expired	16	27
Total follow up correspondence sent	260	455
Total approved projects still ongoing	349	

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 all five 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 was closed after the facility was able to demonstrate compliance with the project delivery requirements through additional documentation.

- After a statewide review of Urinary Extracorporeal Shock Wave Lithotripsy Services data based on the 2013 Annual Survey, the Department opened 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. The investigations are still open.

- 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 Hospital Grosse Pointe – Referral from the Department's designee for PCI data registry for performing elective PCI cases at a primary PCI hospital without CON approval. The facility has entered into a settlement agreement after completing corrective actions plans and paid a civil fine of $1,565,000.

- Memorial Healthcare – During an application review, it was noted that the facility had entered into a lease renewal for an existing fixed MRI unit without CON approval. The facility had to add the lease renewal to the current CON application as corrective action and paid a civil fine of $5,500.

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

CERTIFICATE OF NEED

2nd 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	2nd Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Letters of Intent Received	120	N/A	224	N/A
Letters of Intent Processed within 15 days	120	100%	224	100%
Letters of Intent Processed Online	120	100%	224	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	2nd Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Applications Received	84	N/A	180	N/A
Applications Processed within 15 Days	84	100%	180	100%
Applications Incomplete/More Information Needed	60	71%	69	72%
Applications Filed Online*	79	100%	171	100%
Application Fees Received Online*	23	29%	41	24%

* 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	2nd Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Nonsubstantive Applications	33	100%	84	100%
Substantive Applications	35	100%	63	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	2nd Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Emergency Applications Received	0	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	2nd Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Amendments	14	100%	38	97%

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	2nd Quarter	Year-to-Date
Refunds Issued Pursuant to Section 22231	0	0

Other Measures

Activity	2nd Quarter		Year-to-Date	
	No.	Percent	No.	Percent
FOIA Requests Received	49	N/A	90	N/A
FOIA Requests Processed on Time	49	100%	90	100%
Number of Applications Viewed Onsite	0	N/A	1	N/A

FOIA – Freedom of Information Act.

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

DEPARTMENT OF

ATTORNEY GENERAL

MEMORANDUM

June 6, 2016

TO: Marc D. Keshishian, M.D.
CON Commission Chair

FROM: Joseph E. Potchen JEP
Division Chief
Corporate Oversight Division

RE: Legal Report for the June 15, 2016 Commission Meeting

I apologize that I am not able to attend the June 15, 2016 Commission meeting. I will be out of the state attending a national conference on opioid abuse.

The following is my legal report for the meeting:

We currently have one pending case in Oakland Circuit Court. In April, Regency at Independence Township filed a lawsuit against DHHS requesting a declaratory ruling to allow Regency to operate a new nursing home on a site different from the site stated in its application. Regency also appeals, as of right, DHHS's adverse decision regarding its request. The parties filed a stipulation to stay proceedings until August 15, 2016. The matter is set for status conference on August 25, 2016.

We also continue to work with DHHS staff to assist in developing standards and providing legal advice on various matters.

JEP/meg

Cc: Elizabeth Nagel

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 P

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	•	•	• R—	•P	•	•▲ F
Computed Tomography (CT) Scanner										PC	•	•	• R A	•	•	•	•	• R—	•	•P	•▲ F			
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—	•	•P	•▲ F			
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 approv
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 June 15, 2016

Updated June 8, 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	May 27, 2016	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.