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

Wednesday September 21, 2016

South Grand Building
333 S. Grand Ave,
1st Floor, Grand Conference Room
Lansing, MI 48933

**APPROVED MINUTES**

## I. Call to Order & Introductions

Chairperson Keshishian called the meeting to order at 9:31 a.m.

A. Members Present:

Denise Brooks-Williams
Gail J. Clarkson, RN
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:

None.

C. Department of Attorney General Staff:

Joseph Potchen

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

Tulika Bhattacharya
Beth Nagel
Tania Rodriguez
Brenda Rogers

## II. Review of Agenda

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

## III. Declaration of Conflicts of Interests

None.

## IV. Review of Minutes of June 15, 2016

Motion by Commissioner Falahee, seconded by Commissioner Tomatis, to approved the minutes as presented. Motion carried.

## V. Computed Tomography (CT) Scanner Services – July 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

Commissioner Falahee noted an edit on line 51 of the draft language: Change "…manufacturer, AND specifically…." to "manufacturer AND ARE specifically…."

C. Commission Final Action

Motion made by Commissioner Falahee, seconded by Commissioner Clarkston to take final action on the language (see Attachment B) as presented with the technical edit on line 51 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 11 - Yes, 0 - No, and 0 - Abstained.

## VI. Neonatal Intensive Care Services/Beds & Special Newborn Nursing Services – July 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

None.

B. Commission Discussion

None.

C. Commission Action

Motion by Commissioner Tomatis, seconded by Commissioner Mittlebrun to take final action on the language as presented (see Attachment D) and move the standards forward to the JLC and Governor for the 45-day review period. Motion carried in a vote of 11 - Yes, 0 - No, and 0 - Abstained.

## VII. Psychiatric Beds and Services – July 21, 2016 Public Hearing Summary & Report

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

Discussion followed.

A. Public Comment

1. Karen Amon, Bay Arenac Behavioral (see Attachment F)
2. Joe Sedlock, Mid-State Health Network (see Attachment G)

B. Commission Discussion

Discussion followed.

C. Commission Final Action

Motion by Commissioner Mukherji, seconded by Commissioner Mittlebrun to take final action on the language as presented including the technical amendment of changing 2% to 5% (and the updating the number of beds for each special population accordingly) in Section 3(1) of the Addendum (see Attachment H) and move the standards forward to the JLC and Governor for the 45-day review period. Motion carried in a vote of 11 - Yes, 0 - No, and 0 - Abstained.

## VIII. Nursing Home and Hospital Long-Term-Care Unit (NH-HLTCU) Beds – Workgroup Update (Written Only)

Chairperson Keshishian mentioned the NH-HLTCU Workgroup report (see Attachment I).

## IX. Hospital Beds – Re-calculation of Bed Need Numbers – Setting the Effective Date (Written Report from Paul Delamater)

Ms. Rogers gave an overview (see Attachment J).

Motion by Commissioner Falahee, seconded by Commissioner Brooks-Williams to set October 1, 2016 as the effective date for the updated bed need methodology. Motion carried in a vote of 11 - Yes, 0 - No, and 0 - Abstained.

## X. Review Draft of CON Commission Biennial Report to JLC

Chairperson Keshishian gave an overview (see Attachment K).

Discussion followed.

Motion by Commissioner Falahee, seconded by Commissioner Mittlebrun to have Chairperson Keshishian work with the Department and whomever else is appropriate, such as Commissioner Cowling, on drafting language for the report regarding psychiatric beds (the Commission highlighted telemedicine, a state registry, and loan forgiveness as important) for the December 7th CON Commission meeting. Motion carried in a vote of 11 - Yes, 0 - No, and 0 - Abstained.

## XI. Legislative Report

None.

## XII. Administrative Update

A. Planning and Access to Care Section Update

Ms. Nagel gave a verbal update of the section including the effective date of September 1st for the open heart surgery weights in amended Appendices A and B (see Attachment L), BMT status (see Attachment M), UESWL SAC status, and the Public Comment Period for the 2017 CON Review Standards.

Discussion on UESWL SAC followed.

Motion by Commissioner Falahee, seconded by Commissioner Hughes to have the Department draft language, as identified during the Public Comment Period, for the December 7th Commission meeting. Motion carried in a vote of 11 - Yes, 0 - No, and 0 - Abstained.

B. CON Evaluation Section Update

1. Compliance Report (see Attachment N)

2. Quarterly Performance Measures (see Attachment O)

## XIII. Legal Activity Report

Mr. Potchen gave an overview of the report (see Attachment P).

**XIV. Future Meeting Dates** – December 7, 2016, January 26, 2017, March 16, 2017, June 15, 2017, September 21, 2017, & December 7, 2017

**XV. Public Comment**

None.

**XVI. Review of Commission Work Plan**

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

A. Commission Discussion

None.

B. Commission Action

Motion by Commissioner Cowling, seconded by Commissioner Hughes to accept the work plan as presented including today's modifications. Motion Carried in a vote of 11 - Yes, 0 - No, and 0 - Abstained.

**XVII. Adjournment**

Motion by Commissioner Mukherji, seconded by Commissioner Mittlebrun to adjourn the meeting at 11:00 a.m. Motion Carried in a vote of 11 - Yes, 0 - No, and 0 - Abstained.

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

Date: August 2, 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 Computed Tomography (CT) Scanner 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 CT Scanner Services Standards at its June 15, 2016 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed CT Scanner Services Standards on July 14, 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 two organizations.

### Written Testimony:

1. *Heather Gietzen, DMD, MS, Council of Michigan Dental Specialties, Inc. (CMDS)*
    - Supports the draft language.

2. *William Sullivan, JD, Michigan Dental Association (MDA)*
    - Supports the draft language.

### Department Recommendation:

The Department supports the language as presented at the June 15, 2016 CON Commission meeting.

**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<br>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 Health and Human Services (MDHHS or Department)
**MEMORANDUM**
Lansing, MI

Date: August 2, 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 Neonatal Intensive Care Services /Beds (NICU) and Special Newborn Nursing 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 NICU and Special Newborn Nursing Services Standards at its June 15, 2016 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed NICU and Special Newborn Nursing Services Standards on July 14, 2016. Written testimony was accepted for an additional seven days after the hearing via an electronic link on the Commission's website. Testimony was received from one organization.

### Written Testimony:

1. *Ginger Williams, MD, Oaklawn Hospital*
    - Suggested the following language for more clarity *(The Department does not support this proposal as it deviates from the national guidelines where this definition was derived.)*:

Section 2. Definitions
(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~~ ***~~LESS THAN OR EQUAL TO~~*** ~~35 TO 37 WEEKS' GESTATION~~ WHO REMAIN PHYSIOLOGICALLY STABLE; ~~AND~~
***(IV) EVALUATE AND PROVIDE CARE FOR INFANTS ~~LESS THAN OR EQUAL TO 35 WEEKS GESTATION~~ WITH TYPICALLY SELF-LIMITED CONDITIONS (E.G., TRANSIENT TACHYPNEA OF THE NEWBORN); AND***
(~~iv~~ *V*) STABILIZE NEWBORN INFANTS WHO ARE ILL AND THOSE BORN LESS THAN ~~35~~ 34 WEEKS OF GESTATION UNTIL THEY CAN BE TRANSFERRED TO A HIGHER LEVEL OF CARE FACILITY.

**Department Recommendation:**

The Department supports the language as presented at the June 15, 2016 CON Commission meeting.

**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 |

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

Date: August 2, 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 June 15, 2016 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed Psychiatric Beds and Services Standards on July 14, 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 July 14, 2016 CON Public Hearing.

BAY ARENAC
BEHAVIORAL HEALTH



September 19, 2016

Marc D. Keshishian, M.D., Chairperson
Michigan Certificate of Need Commission
Department of Health and Human Services
5th Floor South Grand Building, 333 S. Grand Ave.
Lansing, MI 48933

**RE: PROPOSED UPDATES TO THE CON REVIEW STANDARDS FOR PSYCHIATRIC BEDS AND SERVICES**

Dear Dr. Keshishian and Honorable Commission Members:

Bay-Arenac Behavioral Health (BABH) is a Community Mental Health Services Program serving citizens in Bay and Arenac counties with intellectual/developmental disabilities, mental Illnesses and/or co-occurring substance use disorders. Access to in-patient care for individuals experiencing acute psychiatric illnesses is an essential service for individuals in our community.

BABH supports the addendum to the Michigan Certificate of Need Commission (CON) Review Standards establishing a statewide pool of psychiatric beds for special populations groups including persons with intellectual/developmental disabilities, persons with geriatric needs and persons with co-morbid medical needs.

In addition, BABHA would strongly encourage the CON Commission to consider these additional changes:

- Increase the occupancy threshold for all inpatient psychiatric units to at least 70% for adult beds and 50% for child/adolescent beds
- Increase the compliance sanctions for hospitals that do not meet the public patient obligations.

We wish to acknowledge the attention that the CON Commission has given to this important matter and express our gratitude for the continued dialogue and effort to improve the community safety net for our most vulnerable citizens.

Sincerely,

Christopher Pinter
Chief Executive Officer

cc: Lynda Zeller, MDHHS

MSHN
Mid-State Health Network



September 10, 2016

Marc D. Keshishian, M.D., Chairperson
Michigan Certificate of Need Commission (CON)
Department of Health and Human Services
Certificate of Need Policy Section
5th Floor South Grand Building, 333 S. Grand Ave.
Lansing, MI 48933

RE: PROPOSED UPDATES TO THE CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR PSYCHIATRIC BEDS AND SERVICES

Dear Dr. Keshishian and Honorable Commission Members:

Mid-State Health Network (MSHN) is a Prepaid Inpatient Health Plan (PIHP) providing services in partnership with twelve Community Mental Health Services Programs (CMHSPs) and nearly 70 Substance Abuse Prevention and Treatment providers. At any given time, there are more than 45,000 citizens in the care of our system, and through Medicaid and the Healthy Michigan Plan, we provide a safety net for more than 400,000 eligible individuals in our 21-county catchment area.

MSHN is pleased to be a partner with the Michigan Department of Health and Human Services in a pilot project to collect information relating to denials of access to inpatient care. Together with CON Commission staff, a great deal has been learned of the challenging experiences faced by almost 1,000 (to date) of our system's most vulnerable citizens; precisely at the point they need our system most. There is broad agreement among the pilot participants that we can do a lot better to ensure access to inpatient care for our most psychiatrically-needy family members, neighbors and others.

The proposed updates to the CON review standards for Psychiatric Beds and Services, specifically the addendum establishing Statewide Special Population Groups and psychiatric inpatient bed pool for those groups, are welcomed and applauded public policy change.

Individuals experiencing acute psychiatric illness that are in the three special population groups established within the proposed standards will greatly benefit from expanded access to inpatient care. Individuals in these groups have experienced the greatest barriers to access for no reason other than their comorbidities.

MSHN strongly encourages the CON Commission to adopt the proposed standards.

MSHN strongly encourages the CON Commission to recommend investments in the systems, staff and other mechanisms to strengthen its compliance/enforcement activity, including related rule promulgation that hold all accountable to the same standards.

There is more work to do! MSHN and our partner colleagues around the state will continue our work to improve access to psychiatric inpatient care for our publicly-supported citizens. This work will include development of statewide or centralized psychiatric inpatient bed inventory/availability systems and other important activities informed by the data gathered during the pilot phase of our inpatient denial study. We look forward to working with the CON Commission to achieve important improvements to this critically important system of care.

We truly appreciate the work of the CON Commission, especially your work to expand access to psychiatric inpatient care for people with intellectual/developmental disabilities, individuals with co-occurring serious medical conditions, and our geriatric population.

Sincerely,

Joseph P. Sedlock, MSA
Chief Executive Officer
Mid-State Health Network

C: Lynda Zeller
Elizabeth Hertel
Cynthia Kelly
MSHN CMHSP Participants

**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) IF THE SPECIALIZED PROGRAM IS BEING ADDED TO AN EXISTING ADULT OR CHILD/ADOLESCENT PSYCHIATRIC SERVICE ~~AS APPLICABLE~~, THEN THE EXISTING ~~SHALL BE ATTACHED OR GEOGRAPHICALLY ADJACENT TO A~~ LICENSED ADULT OR CHILD/ADOLESCENT PSYCHIATRIC SERVICE, AS APPLICABLE, ~~THAT IS MEETING~~SHALL MAINTAIN THE 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) IF THE SPECIALIZED PROGRAM ~~SHALL BE ATTACHED OR GEOGRAPHICALLY ADJACENT~~ IS BEING ADDED TO AN EXISTING ADULT LICENSED PSYCHIATRIC SERVICE, THEN THE EXISTING LICENSED PSYCHIATRIC SERVICE ~~THAT IS MEETING~~SHALL MAINTAIN THE 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) IF THE SPECIALIZED PROGRAM ~~SHALL BE ATTACHED OR GEOGRAPHICALLY ADJACENT~~IS BEING ADDED TO AN EXISTING LICENSED ADULT OR CHILD/ADOLESCENT PSYCHIATRIC SERVICE, THEN THE EXISTING ADULT OR CHILD/ADOLESCENT PSYCHIATRIC SERVICE, AS APPLICABLE, ~~THAT IS MEETING~~SHALL MAINTAIN THE 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.

# STATUS REPORT FROM THE NURSING HOME AND HOSPITAL LONG-TERM CARE UNIT WORKGROUP

**To: CON Commission**

**From: Marianne Conner, CPA**
**CON Workgroup Chair**
**Date: September 21, 2016 CON Commission meeting**

**RE: CON Workgroup status update**

The CON Workgroup has met twice so far: July 21, 2016 and August 17, 2016.

The Workgroup was given eight charges to consider. All eight were reviewed at the first meeting and a sub-group was formed to work on Charges 3 and 4 dealing with Special Populations and High Occupancy. Charge 5 to review the bed need methodology was tabled for a later meeting of the Workgroup when Paul Delamater would be available for some analysis.

At the second meeting, Tulika Bhattacharya provided further information on Charge 2 related to lease renewals. The Workgroup assigned members to work on language to present at the next meeting in October to address financial concerns of provider while maintaining the quality requirements.

The subgroup working on Charges 3 and 4 did not have time to meet but will present recommendations on needed Special Populations and Occupancy levels at the next meeting.

Finally, the Workgroup reviewed Charge 6 on quality metrics. The Department clarified that they were looking for guidance under Section 9 (1) (f) requiring an applicant to participate in a quality improvement program. The Workgroup determined there are currently limited options so they felt this should be discretionary by the Department. The Workgroup recommended that no changes be made to this Section to reflect a particular quality improvement program.

The agenda for our October meeting will include Charge 1 – the review of criteria for NH-HLTCU replacements and relocations including the Attorney General's interpretation; Charge 2 – the review of the lease renewal with proposed changes to relieve the financial burden on providers; Charges 3 and 4 – the initial findings of the subgroup on Special Populations and High Occupancy; and Charge 5 – the review of the bed need methodology with some findings provided by Paul Delamater.

The remaining Charge 7 on the revision of acquisition requirements and Charge 8 for technical changes are still to be addressed in following meetings.

# Acute Care Hospital Bed Need and Limited Access Areas
## 2016 Update

Paul L. Delamater

September 14, 2016

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## Summary

This report provides updated results for the Acute Care Hospital Bed Need and Limited Access Areas (LAAs). The tables and figures contained within are also provided as stand-alone files.

## Determination of Needed Hospital Bed Supply

The planning year used for the updated bed need is 2019, five years from the most recently available MIDB data (2014). The output of the methodology is found in Table 1. In this analysis, the most recent inventory of hospital beds (Dept Inv 2016) is compared to the predicted number of beds needed in 2019. For reference purposes, the difference between actual utilization in 2014 and predicted utilization in 2019 is also shown in Table 1. For a large majority of the Hospital Groups (28 of 33), the predicted bed need in 2019 was less than current utilization (2014), reflecting recent trends of declining inpatient hospitalizations and a shift toward alternate treatment options. For two Hospital Groups, the predicted bed need was the same as current utilization, and three Hospital Groups had a higher predicted utilization than current utilization.

The predicted statewide bed need for 2019 is 16,669 beds, which is roughly 700 beds less than the previous estimate (bed need for 2017, calculated in 2014). The underlying cause for the overall (and continued) decrease in Michigan's future bed need can be traced to the sustained decrease in acute care hospitalization. Figure 1 is a plot of statewide patient day utilization from 2000–2014 and clearly shows that patient days for Michigan have dropped substantially in the two years since the last bed need update (which used 2008–2012 data). This statewide trend was captured in the county-level patient day prediction phase of the Bed Need Methodology. Of the 84 county units (83 counties plus one "out of state" unit), a significant negative linear trend was detected in 41, resulting in predictions that were less than current utilization. A significant positive linear trend in patient days was detected in only 5 counties and no discernible trend was detected in 38 counties.

## Limited Access Areas

Figure 2 provides a map of the updated Limited Access Areas. The bed need for each LAA can be found in Table 2, while the zip codes associated with each LAA are listed in Table 3. Based on 2014 hospitalization data, the minimum number of predicted patient days for an underserved area to be considered an LAA

was 26,556. This value was calculated using the overall state rate of patient days per person (0.519) and a minimum population of 50,000, per the Review Standards.

Five LAAs were identified in the 2016 update, an increase from the 3 identified in the 2014 update. LAAs 1–3 are nearly identical to LAAs 1–3 from the 2014 update (Upper Peninsula, East/Central Northern Lower Peninsula, and Northwest Lower Peninsula). LAA 5 (East Southern Lower Peninsula) was previously identified as an LAA in 2012, but barely missed qualifying as one in the 2014 update (26,480 predicted patient days, which was only 76 less than the minimum requirement). LAA 4 has previously been recognized as an underserved area, but this region has never met the patient day threshold to be considered an LAA; notably, this region was also quite near the LAA threshold in the previous update, having 25,187 patient days (roughly 1,300 days under the LAA threshold in 2014).

The difference in the LAAs from the previous and current update are likely due to two sources, which are both non-health related changes. First, between 2014 and 2016, the MSU/GMU team switched to using the most recent roads data layer available from the Michigan CGI. Minor changes in the road network or the speed limits assigned to roads have the potential to influence the size of the underserved areas (those outside of a 30 minute drive to the nearest acute care hospital). Second, given that Zip Code boundaries change over time, an updated Zip Code layer was used in the current analysis. Because a Zip Code is counted as being a part of an underserved area if any populated portion of that Zip Code touches an underserved area, shifts in the boundary locations of the Zip Codes have the potential to affect the final results. The updates to the roads layer appears to have resulted in slight increases in the size of the underserved areas (only in some areas of the state). Thus, because the two "new" LAAs were very close to being classified as LAAs in the previous update, the results are not surprising given that updated data layers were used for the current analysis.

**Table 1. 2016 Bed Need Results.** Source data: 2010–2014 MIDB. Excess Bed Need is calculated as the difference between Bed Need 2019 and Dept Inv 2016.

| HG | ADC 2014 | Bed Need 2019 | Diff | Diff(%) | Bed Need 2019 | Beds 2016 | Dept Inv 2016 | Excess Bed Need |
|---|---|---|---|---|---|---|---|---|
| 1 | 2,888 | 2,559 | *-329* | *-11.39* | 2,559 | 4,084 | 4,045 | 1,486 |
| 2 | 2,595 | 2,419 | *-176* | *-6.78* | 2,419 | 3,489 | 3,507 | 1,088 |
| 3 | 1,518 | 1,362 | *-156* | *-10.28* | 1,362 | 2,233 | 2,173 | 811 |
| 4 | 1,370 | 1,202 | *-168* | *-12.26* | 1,202 | 2,001 | 2,001 | 799 |
| 5 | 1,547 | 1,447 | *-100* | *-6.46* | 1,447 | 1,788 | 1796 | 349 |
| 6 | 222 | 199 | *-23* | *-10.36* | 199 | 375 | 375 | 176 |
| 7 | 744 | 699 | *-45* | *-6.05* | 699 | 1,086 | 1,086 | 387 |
| 8 | 274 | 246 | *-28* | *-10.22* | 246 | 389 | 389 | 143 |
| 9 | 67 | 60 | *-7* | *-10.45* | 60 | 113 | 113 | 53 |
| 10 | 668 | 650 | *-18* | *-2.69* | 650 | 899 | 899 | 249 |
| 11 | 261 | 229 | *-32* | *-12.26* | 229 | 417 | 427 | 198 |
| 12 | 218 | 189 | *-29* | *-13.30* | 189 | 316 | 316 | 127 |
| 13 | 72 | 70 | *-2* | *-2.78* | 70 | 237 | 237 | 167 |
| 14 | 1,435 | 1,422 | *-13* | *-0.91* | 1,422 | 1,873 | 1,873 | 451 |
| 15 | 291 | 286 | *-5* | *-1.72* | 286 | 462 | 462 | 176 |
| 16 | 150 | 160 | 10 | 6.67 | 160 | 311 | 311 | 151 |
| 17 | 128 | 106 | *-22* | *-17.19* | 106 | 237 | 237 | 131 |
| 18 | 85 | 87 | 2 | 2.35 | 87 | 191 | 191 | 104 |
| 19 | 1,133 | 1,164 | 31 | 2.74 | 1,164 | 1,441 | 1,441 | 277 |
| 20 | 1,094 | 961 | *-133* | *-12.16* | 961 | 1,708 | 1,708 | 747 |
| 21 | 52 | 47 | *-5* | *-9.62* | 47 | 188 | 188 | 141 |
| 22 | 67 | 62 | *-5* | *-7.46* | 62 | 192 | 192 | 130 |
| 23 | 66 | 60 | *-6* | *-9.09* | 60 | 160 | 160 | 100 |
| 24 | 418 | 394 | *-24* | *-5.74* | 394 | 502 | 502 | 108 |
| 25 | 165 | 155 | *-10* | *-6.06* | 155 | 227 | 227 | 72 |
| 26 | 75 | 62 | *-13* | *-17.33* | 62 | 124 | 124 | 62 |
| 27 | 59 | 56 | *-3* | *-5.08* | 56 | 102 | 102 | 46 |
| 28 | 177 | 143 | *-34* | *-19.21* | 143 | 314 | 272 | 129 |
| 29 | 69 | 67 | *-2* | *-2.90* | 67 | 136 | 136 | 69 |
| 30 | 50 | 44 | *-6* | *-12.00* | 44 | 111 | 111 | 67 |
| 31 | 52 | 49 | *-3* | *-5.77* | 49 | 107 | 107 | 58 |
| 32 | 9 | 9 | 0 | 0.00 | 9 | 23 | 23 | 14 |
| 33 | 4 | 4 | 0 | 0.00 | 4 | 15 | 15 | 11 |
| **State** | **18,023** | **16,669** | **-1,354** | **-7.51** | **16,669** | **25,851** | **25,746** | **9,077** |

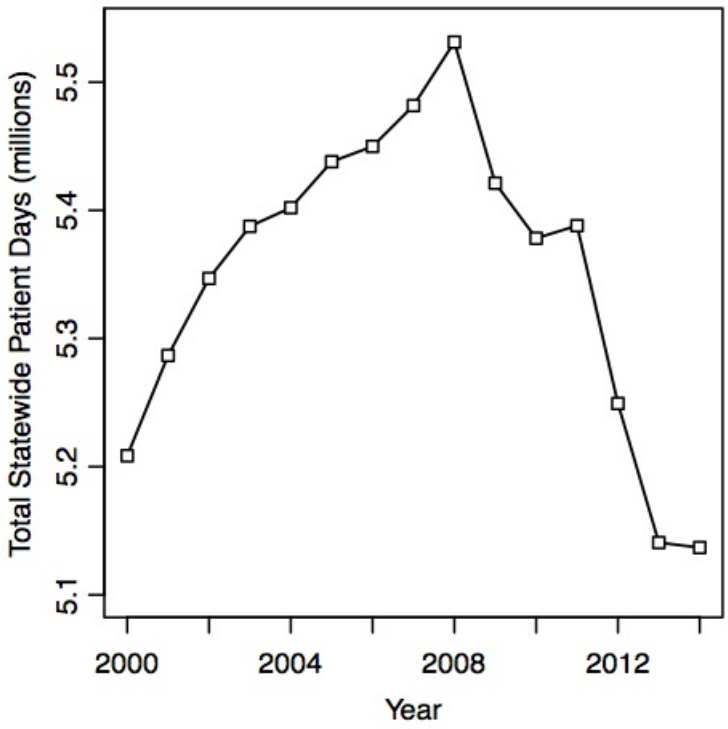
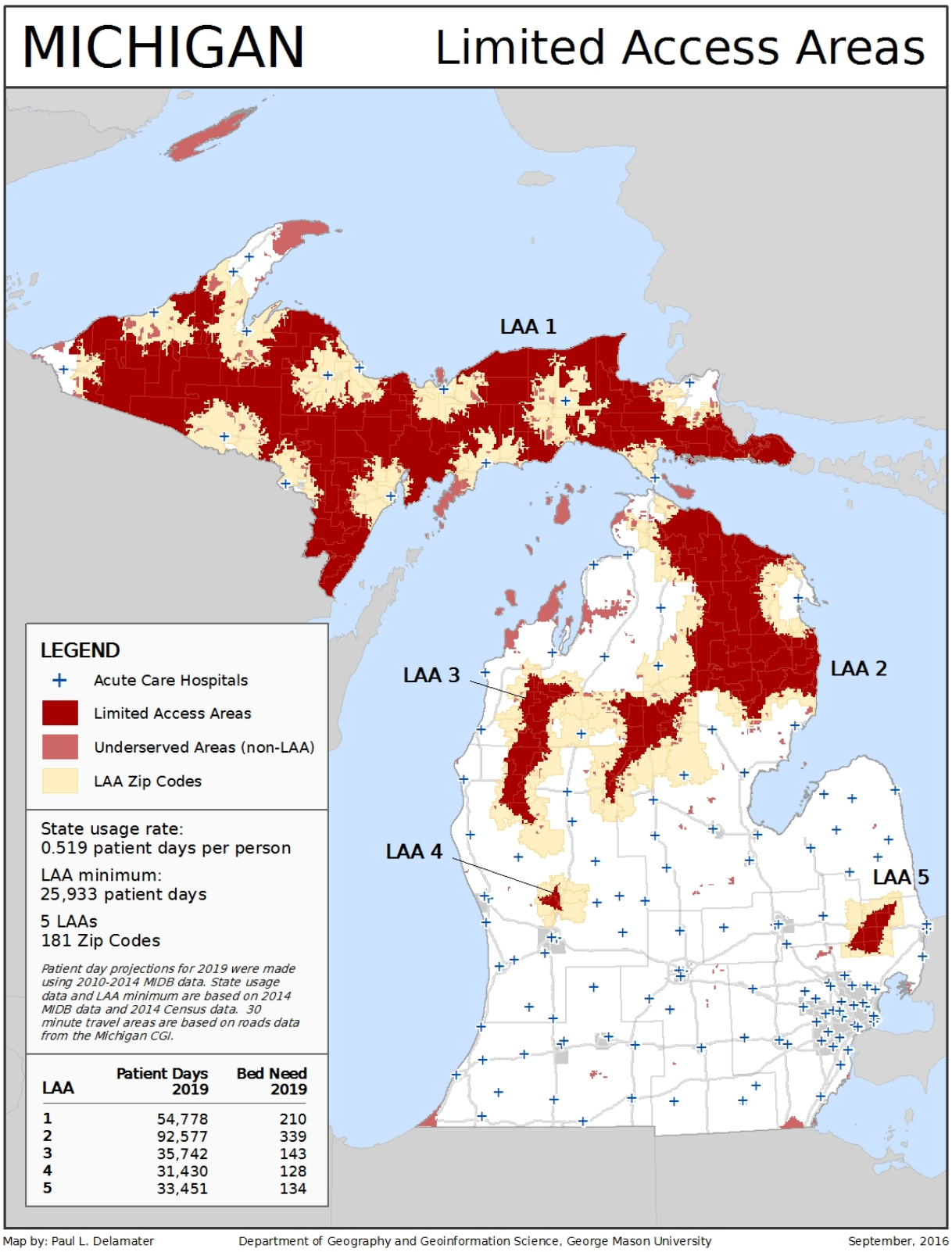



**Figure 1. Statewide Patient Days, 2000–2014**

**Table 2. Bed Need for Limited Access Areas**

| LAA | Predicted Patient Days | Bed Need 2019 |
|---|---|---|
| 1 | 54,778 | 210 |
| 2 | 92,577 | 339 |
| 3 | 35,742 | 143 |
| 4 | 31,430 | 128 |
| 5 | 33,451 | 134 |




| LAA | Patient Days 2019 | Bed Need 2019 |
|---|---|---|
| 1 | 54,778 | 210 |
| 2 | 92,577 | 339 |
| 3 | 35,742 | 143 |
| 4 | 31,430 | 128 |
| 5 | 33,451 | 134 |

**Figure 2. Limited Access Areas**

**Table 3. Limited Access Areas, Zip Codes**

| LAA 1 | | | LAA 2 | | LAA 3 | LAA 4 | LAA 5 |
|---|---|---|---|---|---|---|---|
| 49710 | 49829 | 49885 | 48619 | 49665 | 49304 | 49319 | 48002 |
| 49715 | 49831 | 49886 | 48621 | 49667 | 49309 | 49321 | 48003 |
| 49719 | 49833 | 49887 | 48624 | 49679 | 49349 | 49330 | 48005 |
| 49725 | 49834 | 49891 | 48625 | 49705 | 49402 | 49341 | 48006 |
| 49726 | 49835 | 49892 | 48629 | 49706 | 49459 | 49343 | 48014 |
| 49728 | 49836 | 49893 | 48632 | 49709 | 49601 | 49345 | 48022 |
| 49736 | 49837 | 49895 | 48635 | 49716 | 49619 | | 48041 |
| 49745 | 49838 | 49896 | 48636 | 49721 | 49620 | | 48062 |
| 49752 | 49839 | 49905 | 48647 | 49738 | 49625 | | 48065 |
| 49760 | 49840 | 49910 | 48651 | 49743 | 49638 | | 48097 |
| 49762 | 49841 | 49912 | 48653 | 49744 | 49643 | | 48367 |
| 49768 | 49847 | 49916 | 48654 | 49746 | 49644 | | 48444 |
| 49774 | 49848 | 49919 | 48656 | 49747 | 49645 | | |
| 49780 | 49849 | 49920 | 48705 | 49749 | 49649 | | |
| 49781 | 49853 | 49925 | 48721 | 49751 | 49656 | | |
| 49801 | 49854 | 49935 | 48728 | 49753 | 49663 | | |
| 49806 | 49855 | 49946 | 48737 | 49756 | 49668 | | |
| 49807 | 49858 | 49947 | 48738 | 49759 | 49683 | | |
| 49812 | 49861 | 49948 | 48739 | 49765 | 49689 | | |
| 49814 | 49862 | 49952 | 48740 | 49766 | | | |
| 49815 | 49866 | 49953 | 48742 | 49769 | | | |
| 49816 | 49868 | 49958 | 48743 | 49776 | | | |
| 49817 | 49873 | 49962 | 48745 | 49777 | | | |
| 49818 | 49874 | 49965 | 48750 | 49779 | | | |
| 49820 | 49878 | 49967 | 48761 | 49792 | | | |
| 49821 | 49879 | 49968 | 48762 | 49799 | | | |
| 49822 | 49880 | 49969 | 49305 | | | | |
| 49825 | 49881 | 49970 | 49631 | | | | |
| 49826 | 49883 | | 49632 | | | | |
| 49827 | 49884 | | 49651 | | | | |

Attachment K

WORKING DRAFT

**STATE OF MICHIGAN**

**RICK SNYDER,**
**Governor**

Michigan Certificate of Need Commission

SOUTH GRAND BUILDING
333 S. GRAND AVE
LANSING, MI 48933
Phone: (517) 335-6708



# MEMORANDUM

**Date:** September 21, 2016

**To:** Joint Legislative Committee (JLC)

**From:** Certificate of Need (CON) Commission

**RE:** Recommendations Pertaining to the CON Program

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MCL 333.22215(1)(f) requires the Commission, by January 1, 2005, and every 2 years after January 1, 2005, to "make recommendations to the joint committee regarding statutory changes to improve or eliminate the certificate of need program."

To start, we would like to remind the JLC that the CON Commission is composed of 11 volunteers and oversees 15 covered services. The CON Commissioners receive no compensation for their services, other than reimbursement for travel expenses. The Commission meets five times per year and all meetings are held in Lansing. Every CON Commission meeting is open to the public and subject to the Open Meetings Act. Each CON Commission meeting starts with a declaration of conflicts of interests.

The Commission respectfully submits the following:

Based on our continuous review of the program, the Commission believes and unanimously recommends that the program should be fully supported as it is serving a valuable need. In our bi-partisan judgment, we strongly believe the current CON process meets the statutory objectives for the program. Members of the Commission as well as staff continue to meet with members of the Legislature to answer questions regarding the CON process.

In addition to the responsibility of submitting the 2-year report to the JLC, MCL 333.22215(1)(e) of the CON law requires the Commission to "Annually assess the operations and effectiveness of the certificate of need program based on periodic reports from the department and other information available to the commission." Copies of FY2015 and FY2016 CON Program Annual Activity Reports are being provided with this Memo. Along with these annual reports, the Department provides quarterly program section performance reports to the Commission. These reports demonstrate the effectiveness of the CON program in processing letters of intent, applications,

emergency applications, and amendments, as well as issuing decisions within the specified time frames set forth in the Administrative Rules.

Pursuant to MCL 333.22215 (1)(m), the CON Commission is to "… review and, if necessary, revise each set of certificate of need review standards at least every 3 years." A Public Comment Period is held in October prior to the review year to determine what, if any, changes need to be made for each standard scheduled for review. The following review standards are up for review in 2017: Cardiac Catheterization Services, Hospital Beds, Megavoltage Radiation Therapy (MRT) Services/Units, Open Heart Surgery Services, Positron Emission Tomography (PET) Scanner Services, and Surgical Services. A Standard Advisory Committees (SAC) completed its review of the Bone Marrow Transplantation (BMT) Services, and the Commission is pursuing the recommendation to develop a needs based methodology. Currently, there is a workgroup reviewing CON Review Standards for Nursing Home and Hospital Long-Term Care Unit (NH-HLTCU) Beds and Addendum for Special Population Groups. Consideration for deregulation of Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services/Units is pending review. The Commission actively seeks input from the public and always includes opportunities for public comment/hearings prior to any Commission action.

We would like to provide the JLC a brief summary of our activities and accomplishments since the January, 2015 report. In the last two years, the Commission has updated 10 of the 15 Review Standards for covered services. In some instances, technical changes were made to modernize standards and/or remove unnecessary regulation, e.g., removed volume requirements for replacement of an MRI unit. In other instances, major changes were made to benefit the cost, quality and access of healthcare for Michigan citizens. Some examples include the addition of elective PCI services without on-site OHS services to Cardiac Catheterization Services Standards and updating the quality reporting criteria for primary and elective PCI for hospitals providing therapeutic cardiac catheterization services, primary PCI services without on-site OHS services, and elective PCI services without on-site OHS service; and the addition of Inpatient rehabilitation facility hospital (IRF) hospital to the Hospital Beds Standards to allow for the same considerations as Long-term (acute) care hospital (LTAC Hospital). All of these changes, both technical and policy, have been made with the multiple opportunities for public input and with the recommendations of subject matter experts. A summary of all of the approved changes to various CON Review Standards is attached.

During its review of the Psychiatric Beds and Services standards, which will be included in the FY2017 CON Program Annual Activity Report, the Commission is recommending the following which are outside the scope of the CON Program:

- Telepsychiatry
- Psych observation units
- EMS involvement
- Mobile crisis units
- State Health Registry- available bed dashboard
- Protocols for safe discharge
- Emergency Department Evaluation
- Enhanced Education-lessons learned case studies
- Change the state laws
- Universal transfer forms-medical clearance

*(Needs to be further developed by Commission.)*

The CON Commission appreciates the continuing support of the Governor and the Legislature for the CON program.

Respectfully yours,

Marc D. Keshishian, MD, Chairperson

Suresh K. Mukherji, MD, FACR, Vice-Chairperson

Denise Brooks-Williams

Gail J. Clarkson, RN

Kathleen Cowling, DO

James B. Falahee, Jr., JD

Debra Guido-Allen

Robert L. Hughes

Jessica A. Kochin

Tom Mittelbrun III

Luis A. Tomatis, MD

c: Nick Lyon, Director, MDHHS
Nancy Vriebel, Chief Deputy Director, MDHHS
Elizabeth Hertel, Senior Deputy Director of Policy, Planning and Legislative Services, MDHHS
Joseph Potchen, Division Chief, Corporate Oversight Division, Attorney General's Office
Beth Nagel, Planning Office Director, MDHHS
Tulika Bhattacharya, Manager, CON Evaluation Section, MDHHS
Brenda Rogers, Special Assistant to the CON Commission, Planning and Access to Care Section, MDHHS

# SUMMARY OF CON REVIEW STANDARDS REVISIONS (FY2015 – FY2016)

During FY2015, the CON Commission revised the review standards for Cardiac Catheterization Services, Computed Tomography (CT) Services, Hospital Beds, Magnetic Resonance Imaging (MRI) Services, Megavoltage Radiation Therapy (MRT) Services/Units, Neonatal Intensive Care Services/Beds (NICU) and Special Newborn Nursing Services, Nursing Home and Hospital Long-Term Care Unit (NH-HLTCU) Beds and Addendum for Special Population Groups, Positron Emission Tomography (PET) Scanner Services, Surgical Services, and Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services/Units.

The revisions to the CON Review Standards for Cardiac Catheterization Services include the following and have been implemented.

- Section 2: Definitions have been modified, and new definitions have been added as follows:
    - "Cardiac catheterization service" means the provision of one or more of the following types of procedures: adult diagnostic cardiac catheterizations; adult therapeutic cardiac catheterizations; and pediatric cardiac catheterizations. This definition was updated.
    - “Elective percutaneous coronary intervention (PCI)” means a PCI procedure performed on a non-emergent basis. Definition added to allow for elective PCI without on-site open heart surgery.
    - “Elective PCI services without on-site open heart surgery (OHS)” means performing PCI, percutaneous transluminal coronary angioplasty (PTCA), and coronary stent implantation on an organized, regular basis in a hospital having a diagnostic cardiac catheterization service and a primary PCI service but not having OHS on-site and adhering to patient selection as outlined in the SCAI/ACC/AHA Expert Consensus Document: 2014 Updated on PCI Without On-Site Surgical Backup and published in circulation 2014, 129:2610-2626 and its update or further guideline changes. Definition added to allow for elective PCI without on-site open heart surgery.
    - “Primary percutaneous coronary intervention (PCI)” means a PCI performed on an acute myocardial infarction (AMI) patient with confirmed ST elevation or new left bundle branch block on an emergent basis. This definition was updated.
    - “Primary PCI service without on-site OHS” means performing primary PCI on an emergent basis in a hospital having a diagnostic cardiac catheterization service. Definition added for clarity.
    - "Therapeutic cardiac catheterization service" means providing therapeutic cardiac catheterizations on an organized, regular basis in a laboratory to treat and resolve anatomical and/or physiological problems in the heart. Procedures include PCI, PTCA, atherectomy, stent, laser, cardiac valvuloplasty, balloon atrial septostomy, catheter ablation, cardiac permanent pacemaker, ICD device implantations, transcatheter valve, other structural heart disease procedures, PTCA with coronary stent implantation and left sided arrhythmia therapeutic procedures. The term does not include the intra coronary administration of drugs where that is the only therapeutic intervention. This definition was updated.
- Section 3(3): Revised consistent with current practice.

- Section 4: New section that provides the requirements to initiate primary PCI service without on-site OHS (previously included in Section 3) or elective PCI services without on-site OHS services (new to standards). To be considered for an elective PCI service without on-site OHS services, the applicant shall have operated a primary PCI service for one year prior to the date of application. If the applicant was not approved as a primary PCI service prior to the effective date of the new standards, then, in addition, the applicant shall demonstrate that there is no PCI or OHS service within 60 radius miles or 60 minutes travel time from the proposed site.
- Section 7: Modified the language consistent with other CON review standards to clarify that any acquisition of a cardiac catheterization service, after the first acquisition, on or after February 27, 2012, must be meeting volume requirements to be acquired.
- Section 10(2): Revised consistent with current practice and national guidelines. Included a requirement for applicant hospitals providing therapeutic cardiac catheterization services, primary PCI services without on-site OHS service, or elective PCI services without on-site OHS service to participate with a data registry administered by the Department or its designee (currently BMC2) that monitors quality and risk adjusted outcomes.
- Section 10(4): Revised language for consistency with other changes in the standards as well as consistency with other CON review standards.
- Section 10(5): Updated the quality reporting criteria for primary and elective PCI for hospitals providing therapeutic cardiac catheterization services, primary PCI services without on-site OHS services, or elective PCI services without on-site OHS service.
- Section 10(6) and (7): Added for administrative feasibility and consistent with other CON review standards.
- Section 12: Added requirements for documentation of projections for applicants proposing to initiate an elective PCI service without on-site OHS services.
- Appendix A: Updated the counties based on the 2010 Census data.
- Other technical edits.

The revisions to the CON Review Standards for CT Services include the following and have been implemented:

- Section 24: Technical edit.
- Appendix B: Updated the counties based on the 2010 Census data.

The revisions to the CON Review Standards for Hospital Beds include the following and have been implemented:

- Section 2: Definitions have been modified consistent with other CON review standards, and new definitions have been added as follows:
    - "Inpatient rehabilitation facility hospital" or "IRF hospital" means a hospital that has been approved to participate in the Title XVIII (Medicare) program as a prospective payment system (PPS) exempt inpatient rehabilitation hospital in accordance with 42 CFR Part 412 Subpart P. Definition added to allow for IRF Hospitals the same considerations as LTAC Hospitals.
    - "Replace beds" means a change in the location of the licensed hospital, the replacement of a portion of the licensed beds at the same licensed site, or the one-time replacement of less than 50% of the licensed beds to a new site within 250 yards of the building on the licensed site containing more than 50% of the licensed beds, which may include a new site across a highway(s) or street(s) as

defined in MCL 257.20 and excludes a new site across a limited access highway as defined in MCL 257.26. The hospital beds will be in new physical plant space being developed in new construction or in newly acquired space (purchase, lease, donation, etc.) within the replacement zone. Definition modified to allow for a one-time replacement of beds to property separated by a road(s).

- Section 5: Modified consistent with other CON review standards.
- Section 6(2): Modified to allow for IRF Hospitals the same considerations as LTAC Hospitals.
- Section 7(2): Modified to allow for the one-time replacement of beds to property separated by a road(s). This includes the same additional language as added in the definition of "replace beds."
- Removal of Previous Section 10: Technical edit consistent with other CON Review Standards.
- Appendix B: Updated the counties based on the 2010 Census data.
- Other technical edits.

The revisions to the CON Review Standards for MRI Services include the following and have been implemented:

- Previous Section 2(1)(hh), (ii) and (rr): Technical edit consistent with other CON Review Standards.
- Section 20: Technical edit.
- Appendix A: Updated the counties based on the 2010 Census data.

The revisions to the CON Review Standards for MRT Services/Units include the following and have been implemented:

- Section 2: Definitions have been modified, moved, and/or deleted if no longer needed, and new definitions have been added as follows:
    - "Dedicated stereotactic radiosurgery unit" means an MRT unit for which more than 90 percent of cases will be treated with radiosurgery. The term wasn't previously defined.
    - "Megavoltage radiation therapy" or "MRT" means a clinical modality in which patients with cancer, other neoplasms, cerebrovascular system abnormalities, or certain benign conditions are treated with radiation which is delivered by a MRT unit. This definition was updated.
    - "Simulation" means the precise mock-up of a patient treatment with an apparatus that uses a diagnostic x-ray tube, magnetic resonance imaging device, or computed tomography scanner, which is used in reproducing the two-dimensional or three-dimensional internal or external geometry of the patient, for use in treatment planning and delivery. This definition was updated.
    - "Special purpose MRT unit" or "special purpose unit" or "special unit" means any of the following types of MRT units: (i) dedicated stereotactic radiosurgery unit, (ii) dedicated total body irradiator (TBI), or (iii) an OR-based IORT unit. This definition was updated.
    - "Treatment visit" means one patient encounter during which MRT is administered and billed. One treatment visit may involve one or more treatment ports or fields. Each separate encounter by the same patient at different times of the same day shall be counted as a separate treatment visit. Definition updated for clarification.

- Section 4(1)(a) and (d): Updated language to allow for replacement of a special purpose unit with a non-special purpose unit . The site at which a special purpose unit is replaced shall continue to operate a non-special purpose unit.
- Section 5(2)(a): Updated language to reflect that if expanding an existing MRT service with a special purpose MRT unit, that the applicant shall demonstrate that the existing and approved special purpose MRT units are averaging 1,000 ETVs in the most recent 12-month period in addition to the non-special MRT units averaging 8,000 ETVs in the most recent 12-month period.
- Section 6: Modified the language consistent with other CON review standards to clarify that any acquisition of an MRT service, after the first acquisition, on or after November 21, 2011, must be meeting volume requirements to be acquired.
- Section 10 Table 1 Equivalent Treatments: Updated to better reflect current practice.
- Section 11(2)(e)(ii): Revised as the American College of Radiology (ACR) and the American Society for Radiation Oncology (ASTRO) are no longer one organization, but two separate organizations.
- Other technical edits.

The revisions to the CON Review Standards for NICU and Special Newborn Nursing Services include the following and have been implemented:

- Section 14: Technical edit.
- Appendix A: Updated the counties based on the 2010 Census data.

The revisions to the CON Review Standards for NH-HLTCU Beds and Addendum for Special Population Groups include the following and have been implemented:

- Section 1: Modified for consistency with other CON review standards.
- Section 2: Definitions have been modified, moved, and/or deleted if no longer needed, and a new definition has been added as follows:
    - "Applicant's cash" has been revised to include contributions designated for the project from the landlord to reflect the investment by the lease holder.
    - "Proposed licensed site" means the physical location and address (or legal description of property) of the proposed project or within 250 yards of the physical location and address (or legal description of property) and within the same planning area of the proposed project that will be authorized by license and will be listed on that licensee's certificate of licensure. This definition would allow for 250 yards of movement, if necessary, when a CON application has been approved, but the specific site cannot be used for new construction.
- Section 6(1)(a)(vi) and other applicable sections: Changed "outstanding" to "delinquent" to meet the intent and aid in administering this requirement.
- Section 6(1)(d)(ii) and 6(1)(d)(iii)(B): The Staffing/Bed Utilization Ratios Report is no longer available. The CON Annual Survey will now be used.
- Section 6(2)(c) and other applicable sections: Revised consistent with change under comparative review criteria in Section 10(7).
- Section 7(1)(b) and (c): Language revised consistent with the proposed new definition for "proposed licensed site."
- Section 7(3)(c)(i): Removed three mile radius language as it is no longer necessary. This was originally drafted for the pilot programs (new design model) in 2008, and all pilot programs are now CON approved.

- Section 8(1): Removed the restrictions of relocating no more than 50% of a nursing home's beds and the seven year restriction making it consistent with HLTCUs and added that relocation of beds shall not increase the number of rooms with three or more bed wards at the receiving facility
- Section 10(2): Updated to reduce redundancy and to simplify while maintaining the high consideration of Medicaid access.
- Old Section 10(3): Removed the points for Medicare participation within the most recent 12 months based on the modifications made to Section 10(2).
- New Section 10(3): Removed redundant special focus nursing home/HLTCU language.
- Section 10(4): Revised points. Qualifying projects that already participate or plan to participate in a culture change model will receive three points. They will receive an additional 5 points if the culture change model is a Department approved model.
- Old Section 10(6): Removed the requirement for sprinklers as this became Federal law in 2013.
- New Section 10(6): Revised to award points if there is climate control for the entire facility.
- Section 10(7): Revised language and points for facility design to create a more homelike environment for the resident while recognizing that there is still a need for semi-private rooms too.
- Old Section 10(11): Removed for redundancy as this is a requirement in the Administrative Rules.
- Section 10(10): Revised to award points if the entire facility will have no more than double occupancy rooms at completion of the project to help with improved quality of care.
- Section 10(11): Points revised to balance the points of comparative review based on the relevance of care to the resident.
- Section 10(12): Revised to reflect technology Innovations to better reflect on changes in healthcare, i.e. wireless nurse call/paging system for the proposed project; wireless internet with resident access to related equipment/device in entire facility; integrated electronic medical records system for the entire facility; a backup generator for the proposed project.
- Section 10(13): Added points if the proposed project includes bariatric rooms to ensure access for the bariatric resident.
- Section 11: Divided requirements into distinct groups consistent with other standards: quality assurance, access to care, and monitoring and reporting.
    - Under subsection (1), added clarifying language that an applicant approved pursuant to Section 10 will be held accountable for complying with the requirements agreed to in the awarding of beds for the approved project.
    - Under new subsection (3), added access to care requirements consistent with other CON review standards.
- Other technical edits.

The revisions to the CON Review Standards for PET Scanner Services include the following and have been implemented:

- Section 6(1) and (2): Updated acquisition language for clarity consistent with other CON review standard.
- Section 11(4)(a): Technical edit.
- Section 19: Technical edit.
- Appendix C: Updated the counties based on the 2010 Census data.

The revisions to the CON Review Standards for UESWL Services/Units include the following and have been implemented:

- Section 12: Technical edit.
- Appendix C: Updated the counties based on the 2010 Census data.

During FY2016, the CON Commission revised the review standards for Magnetic Resonance Imaging (MRI) Services.

The revisions to the CON Review Standards for MRI Services include the following and have been implemented:

- Section 2: Definition has been modified as follows:
    - "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. Definition updated to better reflect practice and improve quality.
- Section 4(2): Definition has been modified as follows:
    - "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. Definition updated for clarity.
- Section 4(3): Removed volume requirements for replacement of an MRI unit consistent with other CON review standards. Reduced regulation allows for facilities to more easily update equipment when it has surpassed its useful life.
- Section 4(4): Removed volume requirements for replacement of an existing mobile MRI host site to a new location. Reduced regulation allows for facilities to more easily replace an existing mobile MRI host site to a new location.
- Section 4(5): The 36-month in operation requirement is waived if one of the following has been met. Reduced regulation allows for facilities to more easily replace an existing fixed MRI service and its unit(s) to a new location in certain situations that are unforeseen to the applicant.
    - (i) The owner of the building where the site is located has incurred a filing for bankruptcy under Chapter Seven (7) within the last three years;
    - (ii) The ownership of the building where the site is located has changed within 24 months of the date of the service being operational;

  Removed volume requirements for replacement of an existing fixed MRI service and its unit(s) to a new site in certain situations that are unforeseen to the applicant:
    - (i) The owner of the building where the site is located has incurred a filing for bankruptcy under Chapter Seven (7) within the last three years;

    - (ii) The ownership of the building where the site is located has changed within 24 months of the date of the service being operational; or
    - (iii) The MRI service being replaced is part of the replacement of an entire hospital to a new geographic site and has only one (1) MRI unit.
- Section 6: Modified the language consistent with other CON review standards to clarify that any acquisition of an existing MRI unit from an existing MRI service must be meeting volume requirements to be acquired.
- Section 7: Modified the language consistent with other CON review standards to clarify that MRI adjusted procedures performed on a dedicated MRI unit cannot be used to demonstrate need or to satisfy MRI CON review standards requirements.
- Section 14(2)(d)(i)(D): Updated name of document.
- Section 18(4), (7), and (8): Revised for clarity.
- Other technical edits.

The following review standards were reviewed with an anticipated completion in FY2017:

Bone Marrow Transplantation (BMT) Services was reviewed by a standard advisory committee (SAC) and a recommendation was provided to the Commission at their June 2016 meeting. Development of a needs based methodology is in process.

Computed Tomography (CT) Services: Proposed action was taken by the Commission at its June 2016 meeting. The standards were submitted to the joint legislative committee (JLC) and a Public Hearing was held. The Commission took final action at its September 2016 Commission meeting and were submitted to the JLC and Governor for the required 45-day review period. Standards will become effective in FY2017.

MRI Services were reviewed a second time in FY2016 for recommendations regarding common ownership. Final action was taken by the Commission at its June 2016 meeting. The standards were submitted to the joint legislative committee (JLC) and the Governor for the required 45-day review period. Standards will become effective in FY2017.

Neonatal Intensive Care Services/Beds (NICU) and Special Newborn Nursing Services: Proposed action was taken by the Commission at its June 2016 meeting. The standards were submitted to the joint legislative committee (JLC) and a Public Hearing was held. The Commission took final action at its September 2016 Commission meeting and were submitted to the JLC and Governor for the required 45-day review period. Standards will become effective in FY2017.

Nursing Home and Hospital Long-Term Care Unit (NH-HLTCU) Beds and Addendum for Special Population Groups is being reviewed by an informal workgroup.

Psychiatric Beds and Services: Proposed action was taken by the Commission at its June 2016 meeting. The standards were submitted to the joint legislative committee (JLC) and a Public Hearing was held. The Commission took final action at its September 2016 Commission meeting and were submitted to the JLC and Governor for the required 45-day review period. Standards will become effective in FY2017.

Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services/Units: (*still pending review*).

# Open Heart Surgery Weights: Appendix Updates

August 10, 2016

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## Summary

The weight values found in Appendix A (adult principal and non-principal) and Appendix B (pediatric) of the Open Heart Surgery Standards were updated using 2014 MIDB data per the existing methodology outlined in the Standards. The new weights do contain slight variations from the weight values calculated in 2012 (using 2010 MIDB data); however, they appear to be congruent with previous updates and not a cause for alarm. I provide two minor recommendations for modifying the Standards, 1) aligning the Group labels in the two tables comprising Appendix A and 2) including the OHS procedure codes as an additional Appendix.

## Appendix A

The methodology used to update Appendix A is provided in Section 8.(1), which includes the steps for calculating the weight values for principal diagnoses in 8.(1)(a) and non-principal diagnoses in 8.(1)(b). MIDB inpatient data from 2014, with the associated primary and secondary diagnostic (DX) and procedure (PX) codes for each patient record, were used. The associated DX codes can be found in Appendix A. The associated PX codes were drawn from information provided by the MDHHS CON Section in 2012. The list of hospitals having operational open heart surgery programs was gathered from the 2014 CON Annual Survey results, which was unchanged from 2010.

Table 1 contains the updated weight values for the principal diagnoses in Appendix A (the first section). In the previous update, the 2010 weights were compared to the weights from 2005, so these are also included for reference.

**Table 1. Procedures (PX), diagnoses (DX), and weights (W) for principal diagnoses in Appendix A**

| | 2005 | | | 2010 | | | 2014 | | |
|---|---|---|---|---|---|---|---|---|---|
| **Group** | **PX** | **DX** | **W** | **PX** | **DX** | **W** | **PX** | **DX** | **W** |
| A | 2,395 | 3,170 | 0.755521 | 2,589 | 3,543 | 0.730737 | 2,980 | 4,790 | 0.622129 |
| B | 262 | 552 | 0.474638 | 458 | 714 | 0.641457 | 533 | 785 | 0.678981 |
| C | 175 | 574 | 0.304878 | 193 | 533 | 0.362101 | 180 | 385 | 0.467532 |
| D | 6,815 | 38,833 | 0.175495 | 5,019 | 22,390 | 0.224163 | 3,975 | 13,487 | 0.294728 |
| E | 2,219 | 18,613 | 0.119218 | 1,846 | 18,191 | 0.101479 | 1,636 | 18,259 | 0.089600 |
| F | 608 | 44,094 | 0.013789 | 588 | 43,992 | 0.013366 | 541 | 42,224 | 0.012813 |
| *State* | *12,474* | *105,836* | | *10,693* | *89,363* | | *9,845* | *79,930* | |

As Table 1 shows, the weights for Groups A, E, and F continued to fall slightly from 2005 to 2014. Groups B, C, and D have increased over this time period. The decrease in the total number of procedures (for the

state) agrees with the decrease observed in the Annual Survey data over these two years.

The updates for the non-principal diagnoses table in Appendix A (the second section) are found in Table 2. As the results show, the updated values are highly similar to the previous update.

**Table 2. Procedures (PX), diagnoses (DX), and weights (W) for non-principal diagnoses in Appendix A**

| | 2005 | 2010 | | | 2014 | | |
|---|---|---|---|---|---|---|---|
| **Group** | **W** | **PX** | **DX** | **W** | **PX** | **DX** | **W** |
| A | 0.021698 | 39 | 2,311 | 0.016876 | 54 | 3,125 | 0.017280 |
| B | 0.020900 | 30 | 996 | 0.030120 | 39 | 1,385 | 0.028159 |
| C | 0.014470 | 91 | 7,521 | 0.012099 | 93 | 7,627 | 0.012194 |
| D | 0.008064 | 167 | 21,837 | 0.007648 | 211 | 27,363 | 0.007711 |
| E | 0.001879 | 164 | 111,881 | 0.001466 | 170 | 104,099 | 0.001633 |
| F | 0.001190 | 88 | 72,970 | 0.001206 | 97 | 79,372 | 0.001222 |
| *State* | | *579* | *217,516* | | *664* | *222,971* | |

## Appendix B

The methodology used to update Appendix B is provided in Section 9.(1). Table 3 contains the updated weight values, along with the weight values from 2005 and 2010 for reference.

**Table 3. Procedures (PX), diagnoses (DX), and weights (W) for Appendix B**

| | 2005 | 2010 | | | 2014 | | |
|---|---|---|---|---|---|---|---|
| **Group** | **W** | **PX** | **DX** | **W** | **PX** | **DX** | **W** |
| Congenital | 0.174027 | 1,340 | 5,714 | 0.234512 | 1,712 | 9,528 | 0.179681 |
| Other | 0.018182 | 32 | 1,685 | 0.018991 | 27 | 2,073 | 0.013025 |
| *State* | | *1,372* | *7,399* | | *1,739* | *11,601* | |

The weight values for both categories fell in the recent update. The Congenital category weight dropped mainly to a larger increase in the number of diagnoses relative to the increase in procedures. The origin of this change is not clear; however, it does match with the increase in non-principal diagnoses also observed in this category (Group A) for the adult-only values found in Table 2.

## Recommended Modifications of the OHS Review Standards

The labels for the diagnosis groups found in Appendix A of the Standards change for the principal and non-principal tables, as shown in Table 4. This appears to be a result of the specific "order" in which to tabulate the diagnoses, per Section 8.(1)(b)(i–iii). However, it is confusing. An alternative approach would be to keep the Group labels the same between tables in Appendix A, but provide the specific order of tabulation in the text of Section 8.(1)(b).

**Table 4. Diagnosis Group labels in Appendix A**

| Category | Principal Group | Non-principal Group |
|---|---|---|
| Valves | A | D |
| Aortic Aneurysm | B | B |
| Congenital Anomalies | C | A |
| Other Chronic Ischemic | D | E |
| Acute Myocardial Infarction | E | C |
| All Other Heart Conditions | F | F |

Another potential modification of the Standards is to explicitly include the OHS procedure codes (used in Sections 8 and 9) in an additional appendix (see document included with this report), as follows:

**ICD-9-CM Codes Appropriate of Open Heart Surgery**

**35, Operations on valves and septa of heart:**
35.10–14, 35.20–28, 35.31–35, 35.39, 35.41–42, 35.50–54, 35.60–63, 35.70–73, 35.81–84, 35.91–95

**36, Operations on vessels of heart:**
36.03, 36.10–17, 36.19, 36.2, 36.31–32, 36.39, 36.91, 36.99

**37, Other operations on heart and pericardium:**
37.10–11, 37.31–33, 37.35, 37.41, 37.49, 37.62–67, 37.74

**38, Incision, excision, and occlusion of vessels:**
38.05, 38.15, 38.35, 38.45, 38.65, 38.85

**39, Other operations on vessels:**
39.00, 39.21–23, 39.54, 39.61–62, 39.73

# SURVEY

*Study Title: Development of a Bone Marrow Transplantation Need Methodology*

Thank you for participating in this survey and for taking the time to answer these questions about Bone Marrow Transplant (BMT). The information gathered from this survey will be employed in an effort to develop an evidence-based and objective BMT Need Methodology that will be used by Michigan's Certificate of Need (CON) Program for regulation and planning purposes.

Before you complete the survey, please review and digitally sign the Informed Consent Form accompanying this document (BMT_Survey_Consent.docx).

The purpose of the survey is to collect your expert opinion and any other information you are willing to provide regarding BMT access, utilization, and need. The questions contained in this survey cover an extremely broad set of topics, and in some cases, request extremely specialized information as it pertains to BMT. Hence, please feel free to respond to only those questions you believe that you are qualified to answer. Further, some questions are purposefully open-ended, so please feel free to elaborate as you see fit. Given your expertise, any additional context or information you may be able to provide will likely be extremely useful in the development of a need methodology.

Please feel free to prepare your responses in any file format (e.g., .doc, .docx, .rtf).

When complete, please forward your digitally-signed Informed Consent Form and Survey response document (via email) to Dr. Paul Delamater (pdelamat@gmu.edu).

Again, we thank you for your time and assistance,

Paul Delamater and Ashton Shortridge

A population-based need methodology, in general, attempts to assess whether the *supply* of health care services is sufficient to meet the population's *need* for those services. An extremely important facet of any need methodology is the ability to accurately and quantitatively measure the *potential supply* of services that is available to the population. When quantitative measures of supply exist, they can be compared to *observed or estimated population need* in an effort to identify whether the two are in agreement. For example, the number of acute care hospital beds provides a quantitative measure of potential supply for acute care hospital services, which can then be compared to estimates of the population's need for those services.

Further, measures of potential supply can be used to distinguish facilities from one another, which is important when the population need varies from place to place within some larger region. Continuing from the example above, the number of hospital beds required to meet the population's need in a high population region (e.g., a large city) will be different than the number needed for a low population region (e.g., a rural area).

## **Question 1.**

Are there objective, quantitative measures of the *potential supply* provided by BMT facilities? Are there characteristics of BMT facilities that would allow facilities to be distinguished from one another, based on their *potential transplant volume* (e.g., transplants per year)? If yes, please identify and describe these measures and indicate, to the best of your knowledge, whether this information/data is readily or publicly available.

Note 1: this question addresses *potential transplant volume*, which may be different than measuring *actual transplant volume*, which can be accomplished via currently available facility utilization data.

Note 2: this question purposefully does not address *quality* of care, only *supply/volume* of care.

In a population-based need methodology, it is also extremely important to accurately and quantitatively capture *observed or estimated population need*. This can be quite difficult in practice or in applied settings. One approach is to use *population utilization* data for this purpose. While population utilization does provide some information regarding population need, these two measures cannot always be assumed to be equivalent to one another– as previous research has shown that an oversupply of services can lead to *overutilization* of services (utilization is greater than actual need) and an undersupply of services can lead to *unmet need* for services (utilization is less than actual need).

Barriers to access (e.g., financial, service availability, geographic location) are often what lead to an *unmet need* for services in the population. By definition, unmet need is not directly measurable. As a result, unmet need for a particular treatment or service is often indirectly measured or estimated via a proxy variable. For health care services, two commonly-employed proxy variable types are:

- an adverse outcome (or set of outcomes) that is preventable, given access to and utilization of the particular treatment or service, or
- an alternative treatment (or set of treatments) that is generally considered inferior, which signals a missed opportunity for the particular treatment or service.

An example of the "adverse outcome" proxy variable is to use the rate of very-low weight births in a population as an indicator for an unmet need for prenatal health care services. An example of the "inferior treatment" variable is to use inpatient hospitalizations for kidney stone removal as a proxy for an unmet need for outpatient lithotripsy services.

**Question 2.**

Are there *health outcomes* that could possibly signal an *unmet need* for BMT? If yes, please identify and describe these measures and indicate, to the best of your knowledge, whether this information/data is readily or publicly available.

Note 1: this question only addresses *unmet* need, which may be different than overall need.

**Question 3.**

Are there *procedures* or *treatments* that are currently used as a potential alternative to BMT (again, to possibly signal a missed BMT opportunity) that could signal an *unmet need* for BMT? If yes, please identify and describe these measures and indicate, to the best of your knowledge, whether this information/data is readily or publicly available.

Note 1: this question only addresses *unmet* need, which may be different than overall need.

In the previous question, *barriers to access* (e.g., financial, service availability, geographic location) were invoked. Barriers to access (in health care) function as impediments that restrict people from receiving a health care treatment or service and can be broken into various types. Potential barriers can be categorized into three broad types, based on previous research in health services. These are:

- *Accessibility* can be considered as the geographic component. In this, the barrier to access in based on the distance or travel time required to access the service or treatment. An example is the use of Limited Access Areas for acute care hospital beds, which identify regions of the state that are located more than 30 minutes (by vehicle) from the nearest facility.
- *Availability* can be considered as the supply component. In this, the barrier to access is based on an inadequate supply of services. A simple example is when there are not enough primary care physicians to meet the needs of a population.
- *Affordability* can be considered the financial component. In the US, we often consider this as a lack of health insurance; however, this barrier can also be extended to consider scenarios when a person has insurance, but the particular treatment or service is not fully covered, leading to out-of-pocket costs that are unaffordable by that person.

The relative importance of different types of barriers will shift depending on the particular health care service under examination. Because BMT is an extremely specialized service, we expect that the barriers to access are likely to be much different than those for a broadly available health care service such as acute care hospital beds. Further, in reviewing the current literature, we have uncovered other potential BMT-specific barriers to access including: the age of the patient needing BMT; donor availability; and awareness/knowledge of BMT as a treatment option for both providers and patients.

**Question 4.**

In your opinion, what are the most important barriers to access BMT services that should be (or could be) considered in the development of a population-based need methodology? Please feel free to expand on the role(s) that these barriers play, as they relate to generating an unmet need for BMT services.

One common question that is asked when evaluating state-level *utilization of* and *access to* health care services is, "how does our state compare to others?". In some cases, state-to-state comparisons can offer important information, but they may not be appropriate for all health care services.

**Question 5.**

For BMT services, are comparisons of Michigan with other states valid, given that appropriate steps are taken to adjust for variations in the populations among states? In your opinion, do these types of comparisons have the potential to provide useful information on whether the population in Michigan is being adequately served?

Suppose that a state has an unmet need for BMT services and there is no potential to expand the supply of service that the current BMT facilities offer. Specifically, in this scenario, a new facility is required to meet the unmet need.

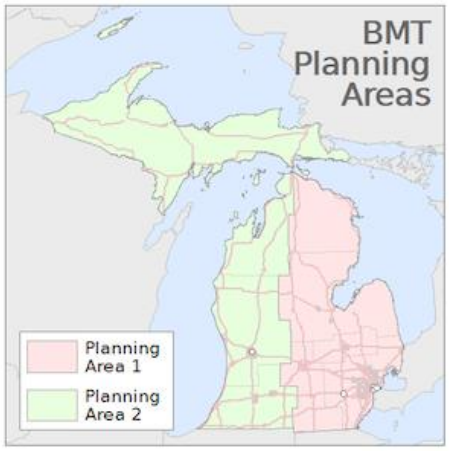
**Question 6.**

Is there a minimum transplant volume threshold (e.g., 20 transplants/year) that should be or can be used to assist in determining the need for a new facility? If possible, please identify any information sources that you consulted in determining this threshold.

**Question 7.**

If a new BMT facility opens, are there quality metrics or thresholds that can be used to ensure that the new facility is providing high-quality care? If possible, please identify any information sources that you consulted in determining this threshold.

In an effort to promote a regional approach to health care planning and regulation (in lieu of a facility-based approach), facilities or geographic regions are often "grouped" together to form planning units. For example, individual acute care hospitals are grouped into Hospital Groups (based on facilities that serve similar geographic regions), forming the planning units in the hospital bed need methodology. In another example, Michigan has eight HSAs (groups of counties) that are used as the planning units for other health care services. The "scale" of the planning units is generally reflective of the specialization level (or volume) of the service, e.g., there are more planning units for hospital beds (33) than there are for NICU services (8). Currently, there are two BMT planning areas defined in the Michigan BMT Review Standards (see graphic).




**Question 8.**

Given the specialized nature of BMT and the small number of yearly transplants (relative to other services), should a potential need methodology implement a regional approach, or should potential need simply be assessed at a state-level? If a regionalization approach were to be considered, please identify any important factors that you believe should be considered in defining regions or groups of facilities (e.g., a minimum population threshold in a region; minimum geographic area served by a region; travel time among facilities).

**Question 9.**

Suppose that an unmet need for BMT services is identified in a large, highly rural region of Michigan that does not have a BMT facility (e.g., in the Upper Peninsula). What considerations that should or could be taken into account when siting a new facility such that the facility is located in a geographic location that will sufficiently address this need?

In Estimating Demand and Unmet Need for Allogeneic Hematopoietic Cell Transplantation in the United States Using Geographic Information Systems by Besse et al. (2015), the authors provide a data-driven, population-based need methodology. The basic approach can be summarized as follows:

- Calculate the *yearly rate of incidence* for malignant and nonmalignant diseases treatable by allogeneic HCT, categorized by age group for the global population. The rates are gathered from SEER data and scientific literature. In this case, the global population refers to the entire population under study (i.e., the US population).
- For each malignant and nonmalignant disease (and age category), calculate the *proportion of cases eligible for allogeneic HCT* based on treatment guidelines, scientific literature, and expert opinion.
- For each geographic region, multiply the age-specific population of that region by the *yearly rate of incidence* and the *proportion of cases eligible for allogeneic HCT* for each malignant and nonmalignant disease. The output is the disease-specific yearly number of allogeneic HCTs for each age category in each region.
- Sum the disease-specific number of allogeneic HCTs for each disease and age category to calculate the total estimated yearly HCT demand for that geographic region.
- Compare the total estimated yearly HCT demand to the actual number of HCTs performed by facilities in the geographic region (to determine whether an unmet need exists and its magnitude).

The approach by Besse et al. (2015) appears to rely on the large numbers in the global estimations (in both the numerator and denominator) to produce *stable* incidence rates for the various disease/age categories (10 disease categories, 4 age categories, see Appendix A).

**Question 10.**

Generally, are the links among BMT-related disease incidence rates, proportion of disease cases receiving BMT, and population characteristics robust enough to be used for BMT planning and regulation purposes? Why or why not?

**Question 11.**

Given the (relatively) small number of yearly BMTs performed in Michigan, any population-based need methodology may be subject to unstable rates caused by the small numbers problem. Are there "more aggregated" groupings of diseases or population age groups than those offered in Besse et al. (2015) that would be more appropriate for a state-level methodology and potentially lessen the impact of the small numbers problem?

A population-based need methodology will likely have a heavy data requirement. The yearly number of BMTs can be gathered from the MIDB and the CON Annual Survey. Detailed population characteristics are readily available from the US Census.

**Question 12.**

If an approach similar to Besse et al. (2015) were to be implemented, please indicate, to the best of your knowledge, any potential sources that provide cancer/disease data for Michigan and whether this information/data is readily or publicly available.

Note 1: we are especially interested in data that is or may be available for small areal units (e.g. counties) or at a facility level.

**Appendix A**

Disease and age groups from Estimating Demand and Unmet Need for Allogeneic Hematopoietic Cell Transplantation in the United States Using Geographic Information Systems by Besse et al. (2015).

**Diseases**

Chronic myelogenous leukemia; Acute lymphoblastic leukemia; Acute myeloid leukemia; Chronic lymphocytic leukemia; Non-Hodgkin lymphoma; Multiple myeloma; Hodgkin disease; Myelodysplastic syndromes; Nonmalignant immune deficiency disorders; Hemoglobinopathies

**Age groups**

0–19; 20–54; 55–64; 65–74

CERTIFICATE OF NEED

**3rd 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 | 3rd Quarter | Year-to-Date |
|---|---|---|
| Approved projects requiring 1-year follow up | 116 | 246 |
| Approved projects contacted on or before anniversary date | 85 | 169 |
| Approved projects completed on or before 1-year follow up | 73% | |
| CON approvals expired | 11 | 38 |
| Total follow up correspondence sent | 261 | 716 |
| Total approved projects still ongoing | 354 | |

*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 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.

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

CERTIFICATE OF NEED

**3rd 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 | 3rd Quarter | | Year-to-Date | |
|---|---|---|---|---|
| | No. | Percent | No. | Percent |
| Letters of Intent Received | 93 | N/A | 317 | N/A |
| Letters of Intent Processed within 15 days | 93 | 100% | 317 | 100% |
| Letters of Intent Processed Online | 93 | 100% | 317 | 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 | 3rd Quarter | | Year-to-Date | |
|---|---|---|---|---|
| | No. | Percent | No. | Percent |
| Applications Received | 75 | N/A | 255 | N/A |
| Applications Processed within 15 Days | 75 | 100% | 255 | 100% |
| Applications Incomplete/More Information Needed | 64 | 85% | 193 | 86% |
| Applications Filed Online* | 69 | 100% | 240 | 100% |
| Application Fees Received Online* | 21 | 30% | 62 | 26% |

* 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 | 3rd Quarter | | Year-to-Date | |
|---|---|---|---|---|
| | Issued on Time | Percent | Issued on Time | Percent |
| Nonsubstantive Applications | 47 | 100% | 131 | 100% |
| Substantive Applications | 35 | 100% | 98 | 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 | 3rd 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 | 3rd Quarter | | Year-to-Date | |
|---|---|---|---|---|
| | Issued on Time | Percent | Issued on Time | Percent |
| Amendments | 16 | 94% | 54 | 96% |

Section 22231(10) of the Public Health Code requires the Department to issue a refund of the application fee, upon written request, if the Director exceeds the time set forth in this section for a final decision for other than good cause as determined by the Commission.

| Activity | 3rd Quarter | Year-to-Date |
|---|---|---|
| Refunds Issued Pursuant to Section 22231 | 0 | 0 |

**Other Measures**

| Activity | 3rd Quarter | | Year-to-Date | |
|---|---|---|---|---|
| | No. | Percent | No. | Percent |
| FOIA Requests Received | 44 | N/A | 134 | N/A |
| FOIA Requests Processed on Time | 44 | 100% | 134 | 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

September 14, 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 September 21, 2016 Commission Meeting

We currently have one pending case in Oakland Circuit Court. In April, 2016 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.

In August, 2016, the Circuit Court ordered a stay of all proceedings until March 16, 2017. The matter is set for status conference on March 16, 2017.

In addition to this case, we 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.**

## 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— |
| **Cardiac Catheterization Services** | | | | | | | | | | | | | | | | | | | | | | PC | | |
| **Computed Tomography (CT) Scanner** | | | | | | | | | | PC | • | • | • R A | • | • | • | • | • R— | •P | • | •▲ F | | | |
| **Hospital Beds** | | | | | | | | | | | | | | | | | | | | | | PC | | |
| **Magnetic Resonance Imaging (MRI) Services** | • R A | • | • | • | • | • | • | • | • | • | • | • R— | • | •P | •▲ F R— | • | •P | •▲ F | | | | | | |
| **Megavoltage Radiation Therapy (MRT) Services/Units** | | | | | | | | | | | | | | | | | | | | | | PC | | |
| **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 | • | • | • | • | • | • | • | • | • |
| **Open Heart Surgery (OHS) Services** | | | | | | | | | | | | | | | | | | | | | | PC | | |
| **Positron Emission Tomography (PET) Scanner Services** | | | | | | | | | | | | | | | | | | | | | | PC | | |
| **Psychiatric Beds and Services** | • R A | • | • | • | • | • | • | • | • | • | • | • R | • | • | • R— | • P | • | •▲ | • P | • | •▲ F | | | |
| **Surgical Services** | | | | | | | | | | | | | | | | | | | | | | PC | | |
| **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 |
| **2-year Report to Joint Legislative Committee (JLC) – 1/1/15** | | | | | | | | | | | | | | | | | | | D | | | | | R |

KEY

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

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

**For Approval September 21, 2016**

Updated August 3, 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.