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

Wednesday December 7, 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 9:41 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

B. Members Absent:

Luis Tomatis, MD

C. Department of Attorney General Staff:

Joseph Potchen

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

Tulika Bhattacharya
Amber Meyers
Beth Nagel
Tania Rodriguez
Brenda Rogers

## II. Review of Agenda

Motion by Commissioner Brooks-Williams, seconded by Commissioner Cowling, to approve the agenda as presented. Motion carried.

## III. Declaration of Conflicts of Interests

None.

## IV. Review of Minutes of September 21, 2016

Motion by Commissioner Mittlebrun, seconded by Commissioner Clarkson, to approved the minutes as presented. Motion carried.

## V. Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services – Draft Language

Chairperson Keshishian provided an overview of the process. Ms. Rogers gave an overview of the draft language (see Attachment A).

A. Public Comment

Melissa Cupp, RWC Advocacy
Carrie Linderoth, Kelley Cawthorne
Robert Meeker, Greater Michigan Lithotripsy

B. Commission Discussion

Commissioner Falahee noted an edit on lines 92 and 100 of the draft language: Change "…THAT HAS…." to ",…."

C. Commission Proposed Action

Motion made by Commissioner Falahee, seconded by Commissioner Hughes to take proposed action on the language (see Attachment A) as presented with the technical edit on lines 92 and 100 and move to Public Hearing and forward to the Joint Legislative Committee (JLC). Motion carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

## VI. Bone Marrow Transplantation (BMT) Services – Report

Mr. Delamater provided a report (see Attachment B).

A. Public Comment

Patrick O'Donovan, Beaumont

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Guido-Allen, seconded by Commissioner Cowling based on the Department's recommendations, based on the report received and the data reviewed, recommends deregulation of BMT and move to Public Hearing and forward to the JLC. Motion failed in a vote of 5 - Yes, 5 - No, and 0 - Abstained.

Motion by Commissioner Falahee, seconded by Commissioner Mukherji to preferably at the March meeting, to present language along the lines that Commissioner Mukherji discussed: what can we find from other states or what can you find anywhere that would put some parameters around BMT so that it's not just tied to a number that's 30 years old, whether it's minimum number, whether it's academic medical center, whatever, to request the Department to come back with language that does not include an arbitrary number. Motion carried in a vote of 9 - Yes, 0 - No, and 1 - Abstained.

## VII. 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 C).

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

Motion by Commissioner Falahee, seconded by Commissioner Cowling to approve the report (see Attachment D) and move forward to the JLC. Motion carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

## IX. Legislative Report

Ms. Nagel provided a verbal update.

## X. Administrative Update

A. Planning and Access to Care Section Update

Ms. Nagel announced that Matt Lori is the interim replacement for Elizabeth Hertel.

B. CON Evaluation Section Update

Ms. Bhattacharya announced the Sallie Flanders is retiring at the end of December. She presented the following:

1. Compliance Report (see Attachment E)

2. Quarterly Performance Measures (see Attachment F)

3. FY2016 CON Annual Report (see Attachment G)

## XI. Legal Activity Report

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

**XII. Future Meeting Dates** – January 26, 2017 – Special Commission Meeting, March 16, 2017, June 15, 2017, September 21, 2017, & December 7, 2017

## XIII. Public Comment

None.

## XIV. Review of Commission Work Plan

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

A. Commission Discussion

None.

B. Commission Action

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

## XV. Adjournment

Motion by Commissioner Brooks-Williams, seconded by Commissioner Guido-Allen to adjourn the meeting at 11:17 a.m. Motion Carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

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

**CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR URINARY EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY (UESWL) 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 approval to initiate, replace, expand, or acquire an UESWL service/unit under Part 222 of the Code. Urinary extracorporeal shock wave lithotripsy is a covered clinical service for purposes of Part 222 of the Code. 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) "Central service coordinator" OR "CSC" means the organizational unit that has operational responsibility for a mobile UESWL service and its unit(s) and that is a legal entity authorized to do business in the state of Michigan.

(b) "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.

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

(d) "Complicated stone disease treatment capability" means the expertise necessary to manage all patients during the treatment of kidney stone disease. This includes, but is not limited to:

(i) A urology service that provides skilled and experienced ureteroscopic stone removal procedures and

(ii) Experienced interventional radiologic support.

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

(f) "Existing mobile UESWL unit" means a CON-approved and operational UESWL unit and transporting equipment operated by a central service coordinator that provides UESWL services to two or more host sites.

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

(h) "Existing UESWL unit" means the utilization of a CON-approved and operational UESWL unit.

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

(j) "Host site" means the site at which a mobile UESWL unit is authorized to provide UESWL services.

(k) "Licensed site" means either of the following:

(i) In the case of a single site health facility, the location of the facility authorized by license and listed on that licensee's Certificate of Licensure.

(ii) In the case of a health facility with multiple sites, the location of each separate and distinct health facility as authorized by license and listed on that licensee's Certificate of Licensure.

(l) "Michigan Inpatient Database" or "MIDB" means the database that is compiled by the Michigan Health and Hospital Association or successor organization. The database consists of inpatient discharge records from all Michigan hospitals and Michigan residents discharged from hospitals in border states for a specific calendar year.

(m) "Mobile UESWL unit" means a UESWL unit and transporting equipment operated by a central service coordinator that provides UESWL services to two or more host sites.

(n) "Planning area" means the state of Michigan.
(o) “Region” means the geographic areas set forth in Appendix B.
(p) “Renewal of a lease” means extending the effective period of a lease for an existing UESWL unit that does not involve either the replacement/upgrade of a UESWL unit, as defined in Section 4, or a change in the parties to the lease.
(q) “Retreatment” means a UESWL procedure performed on the same side of the same patient within 6 months of a previous UESWL procedure performed at the same UESWL service. In the case of a mobile service, the term includes a retreatment performed at a different host site if the initial treatment was performed by the same service.
(r) "Ureteroscopic stone removal procedure" means a stone removal procedure conducted in the ureter by means of an endoscope that may or may not include laser technology.
(s) "Urinary extracorporeal shock wave lithotripsy" or "UESWL" means a procedure for the removal of kidney stones that involves focusing shock waves on kidney stones so that the stones are pulverized into sand-like particles, which then may be passed through the urinary tract.
(t) “UESWL service” means either the CON-approved utilization of a UESWL unit(s) at one site in the case of a fixed UESWL service or at each host site in the case of a mobile UESWL service.
(u) "UESWL unit" means the medical equipment that produces the shock waves for the UESWL procedure.

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

**Section 3. Requirements to initiate a urinary extracorporeal shock wave lithotripsy service**

Sec. 3. Initiate a UESWL service means to begin operation of a UESWL unit, whether fixed or mobile, at a site that does not offer (or has not offered within the last consecutive 12-month period) approved UESWL services. The term does not include the acquisition or replacment of an existing UESWL service or the renewal of a lease.

(1) An applicant proposing to initiate a UESWL service shall demonstrate each of the following:
(a) The capability to provide complicated stone disease treatment on-site.
(b) At least 1,000 procedures are projected pursuant to the methodology set forth in Section 10(1).
(c) The proposed UESWL service shall be provided at a site that provides, or will provide, each of the following:
(i) On-call availability of an anesthesiologist and a surgeon.
(ii) On-site Advanced Cardiac Life Support (ACLS)-certified personnel and nursing personnel.
(iii) EITHER ~~On~~on-site OR THROUGH A CONTRACTUAL AGREEMENT WITH ANOTHER HEALTH FACILITY THAT HAS IV supplies and materials for infusions and medications, blood and blood products, and pharmaceuticals, including vasopressor medications, antibiotics, and fluids and solutions.
(iv) On-site general anesthesia, EKG, cardiac monitoring, blood pressure, pulse oximeter, ventilator, general radiography and fluoroscopy, cystoscopy, and laboratory services.
(v) On-site crash cart.
(vi) On-site cardiac intensive care unit or a written transfer agreement with a hospital that has a cardiac intensive care unit.
(vii) EITHER ~~O~~on-site OR THROUGH A CONTRACTUAL AGREEMENT WITH ANOTHER HEALTH FACILITY THAT HAS A 23-hour holding unit.

**Section 4. Requirements to replace an existing UESWL unit(s)**

Sec. 4. Replace an existing UESWL unit means an equipment change of an existing UESWL unit, other than an upgrade, proposed by an applicant that results in that applicant operating the same number of UESWL units before and after the project completion. The term does not include an upgrade of an existing UESWL unit, changing a mobile UESWL unit to a fixed UESWL unit, or changing a fixed UESWL unit to a mobile UESWL unit. Replacement also means a change in the location of a fixed UESWL unit(s) from the existing site to a different site, OR a change in the geographic location of an existing fixed UESWL service and its unit(s) from an existing site to a different site.

(1) "Upgrade an existing UESWL unit" means any equipment change, other than a replacement, that involves a capital expenditure of $125,000 or less in any consecutive 24-month period.

(2) An applicant proposing to replace an existing UESWL unit(s) shall demonstrate the following:
(a) Each existing UESWL unit of the service proposing to replace a UESWL unit has averaged at least 1,000 UESWL procedures per unit during the most recent continuous 12-month period for which the Department has verifiable data.
(b) Each UESWL unit of the service proposing to replace a UESWL unit is projected to perform at least 1,000 UESWL procedures per unit per year pursuant to the methodology set forth in Section 10.

(3) An applicant proposing to replace a UESWL unit shall demonstrate one or more of the following:
(a) The existing equipment clearly poses a threat to the safety of the public.
(b) The proposed replacement UESWL unit offers technological improvements that enhance quality of care, increase efficiency, or reduce operating costs and patient charges.
(c) The existing equipment is fully depreciated according to generally accepted accounting principles.

(4) An applicant that demonstrates that it meets the requirements in this subsection shall not be required to demonstrate compliance with Section 4(2):
(a) The proposed project involves replacing 1 existing fixed UESWL unit with 1 mobile UESWL unit.
(b) The proposed mobile unit will serve at least 1 host site that is located in a region other than the region in which the fixed UESWL unit proposed to be replaced is located currently.
(c) At least 100 UESWL procedures are projected in each region in which the proposed mobile UESWL unit is proposed to operate when the results of the methodology in Section 10 are combined for the following, as applicable:
(i) All licensed hospital sites committing MIDB data pursuant to Section 11, as applicable, that are located in the region identified in subsection (c).
(ii) All sites that receive UESWL services from an existing UESWL service and propose to receive UESWL services from the proposed mobile unit and that are located in the region identified in subsection (c).
(d) A separate application from each host site is filed at the same time the application to replace a fixed unit is submitted to the Department.
(e) The proposed mobile UESWL unit is projected to perform at least 1,000 procedures annually pursuant to the methodology set forth in Section 10.

(5) An applicant proposing to ~~relocate~~ REPLACE ~~its~~ AN existing FIXED UESWL service and its unit(s) TO A NEW SITE shall demonstrate that the proposed project meets all of the following:
(a) ~~The UESWL service and its unit(s) to be relocated is a fixed UESWL unit(s).~~
~~(b)~~ The UESWL service to be ~~relocated~~ 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 (d)(i) OR (ii).
(~~c~~b) The site to which the UESWL service will be ~~relocated~~ REPLACED meets the requirements of Section 3(1)(c).
(~~d~~c) The proposed new site is in the state of Michigan and within a 25-mile radius of the existing site of the UESWL service to be ~~relocated~~REPLACED.
(~~e~~d) The UESWL service and its unit(s) to be ~~relocated~~ REPLACED performed an average of at least 1,000 procedures per unit in the most recent 12-month period for which the Department has verifiable data UNLESS ONE OF THE FOLLOWING REQUIRMENTS ARE MET:~~.~~
(i) THE OWNER OF THE BUILDING WHERE THE SITE IS LOCATED HAS INCURRED A FILING FOR BANKRUPTCY UNDER CHAPTER SEVEN (7) WITHIN THE LAST THREE YEARS;
(ii) THE OWNERSHIP OF THE BUILDING WHERE THE SITE IS LOCATED HAS CHANGED WITHIN 24 MONTHS OF THE DATE OF THE SERVICE BEING OPERATIONAL; OR
(iii) THE UESWL SERVICE BEING REPLACED IS PART OF THE REPLACEMENT OF AN ENTIRE HOSPITAL TO A NEW GEOGRAPHIC SITE AND HAS ONLY ONE (1) UESWL UNIT.

(~~f~~e) The applicant agrees to operate the UESWL service and its unit(s) in accordance with all applicable project delivery requirements set forth in Section 9 of these standards.

(6) An applicant proposing to ~~relocate~~ REPLACE a fixed UESWL unit(s) of an existing UESWL service shall demonstrate that the proposed project meets all of the following:

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

(b) The site to which the UESWL unit(s) will be ~~relocated~~ REPLACED meets the requirements of Section 3(1)(c).

(c) The proposed new site is in the state of Michigan and within a 25-mile radius of the existing site of the fixed UESWL unit to be ~~relocated~~REPLACED.

(d) Each existing UESWL unit(s) at the service from which a unit is to be ~~relocated~~ REPLACED performed at least an average of 1,000 procedures per fixed unit in the most recent 12-month period for which the Department has verifiable data.

(e) The applicant agrees to operate the UESWL unit(s) in accordance with all applicable project delivery requirements set forth in Section 9 of these Standards.

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

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

**Section 5. Requirements for approval to expand an existing UESWL service**

Sec. 5. Expand an existing UESWL service means the addition of one UESWL unit at an existing UESWL service. An applicant proposing to expand an existing UESWL service, whether fixed or mobile, unless otherwise specified, shall demonstrate the following:

(1) All of the applicant's existing UESWL units, both fixed and mobile, at the same geographic location as the proposed additional UESWL unit, have performed an average of at least 1,800 procedures per UESWL unit during the most recent 12-month period for which the Department has verifiable data. In computing this average, the Department will divide the total number of UESWL procedures performed by the applicant's total number of UESWL units, including both operational and approved but not operational fixed and mobile UESWL units.

(2) The applicant shall project an average of at least 1,000 procedures for each existing and proposed fixed and mobile UESWL unit(s) as a result from the application of the methodology in Section 10 of these standards for the second 12-month period after initiation of operation of each additional UESWL unit whether fixed or mobile.

(3) An applicant proposing to expand an existing mobile UESWL service must provide a copy of the existing or revised contracts between the central service coordinator and each host site(s) that includes the same stipulations as specified in Section 7(1)(c).

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

Sec. 6. Acquisition of an existing UESWL service or existing UESWL unit(s)" means obtaining possession or control of an existing fixed or mobile UESWL service or existing UESWL unit(s) by purchase, lease, donation, or other comparable arrangement.

(1) ~~An~~ THE applicant ~~proposing to acquire an existing fixed or mobile UESWL service and its unit(s)~~ 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 UESWL service~~,~~ for which a final decision has not been issued after May 2, 1998~~, an existing UESWL 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 UESWL service and its unit(s) shall be operating at the applicable volume requirements set forth in Section 9 of these standards in the second 12 months after the date the service and its unit(s) is acquired, and annually thereafter.~~

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

(2) For any application for proposed acquisition of an existing fixed or mobile UESWL service, except ~~the first~~ AN application approved pursuant to subsection (~~a~~1), ~~for which a final decision has not been issued after May 2, 1998~~, an applicant shall be required to demonstrate that the UESWL service and its unit(s) to be acquired performed an average of at least 1,000 procedures per unit in the most recent 12-month period for which the Department has verifiable data.

(~~2~~3) An applicant proposing to acquire an existing fixed or mobile UESWL unit(S) of an existing UESWL service shall demonstrate that the proposed project meets all of the following:

(a) For any application for proposed acquisition of an existing fixed or mobile UESWL unit(s), an applicant shall be required to demonstrate that the UESWL unit(s) to be acquired performed an average of at least 1,000 procedures per unit in the most recent 12-month period for which the Department has verifiable data.

(b) The requirements of Section 3(1)(c) have been met.

(4) The UESWL service and its unit(s) shall be operating at the applicable volume requirements set forth in Section 9 of these standards in the second 12 months after the date the service and its unit(s) is acquired, and annually thereafter.

**Section 7. Additional requirements for approval for mobile UESWL services**

Sec. 7. (1) An applicant proposing to begin operation of a mobile UESWL service in Michigan shall demonstrate that it meets all of the following:

(a) At least 100 UESWL procedures are projected in each region in which the proposed mobile UESWL unit is proposing to operate when the results of the methodology in Section 10 are combined for the following, as applicable:

(i) All licensed hospital sites committing MIDB data pursuant to Section 11, as applicable, that are located in the region identified in subsection (b).

(ii) All sites that receive UESWL services from an existing UESWL unit and propose to receive UESWL services from the proposed mobile unit are located in the region(s) identified in subsection (b).

(b) The normal route schedule, the procedures for handling emergency situations, and copies of all potential contracts related to the mobile UESWL service and its unit(s) shall be included in the CON application submitted by the central service coordinator.

(2) The requirements of sections 3, 4, and subsection (1)(a) shall not apply to an applicant that proposes to add a Michigan site as a host site if the applicant demonstrates that the mobile UESWL service and its unit(s) operates predominantly outside of Michigan and all of the following requirements are met:

(a) The proposed host site is located in a rural or micropolitan statistical area county.

(b) All existing and approved Michigan UESWL service and its unit(s) locations (whether fixed or mobile) are in excess of 50 miles from the proposed host site and within a region currently served by a UESWL mobile service operating predominantly outside of Michigan.

(c) A separate CON application has been submitted by the CSC and each proposed host site.

(3) A central service coordinator proposing to add, or an applicant proposing to become, a host site on either an existing or a proposed mobile UESWL service shall demonstrate that it meets the requirements of Section 3(1)(C).

(4) A central service coordinator proposing to add, or an applicant proposing to become, a host site on an existing mobile UESWL service in a region not currently served by that service shall demonstrate that at least 100 UESWL procedures are projected in each region in which the existing mobile UESWL service is proposing to add a host site when the results of the methodology in Section 10 are combined for the following, as applicable:

(a) All licensed hospital sites committing MIDB data pursuant to Section 11, as applicable, are located in that region(s).

(b) All sites that receive UESWL services from an existing UESWL service and its unit(s) and propose to receive UESWL services from the proposed mobile service and its unit(s) are located in that region(s).

**Section 8. Requirements for Medicaid participation**

Sec. 8. 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 service if a CON is approved.

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

Sec 9. An applicant shall agree that, if approved, UESWL services, including all existing and approved UESWL units, shall be delivered in compliance with the following:

(1) Compliance with these standards.

(2) Compliance with the following quality assurance standards:

(a) The medical staff and governing body shall receive and review at least annual reports describing activities of the UESWL service, including complication rates, morbidity data, and retreatment rates.

(b) An applicant shall accept referrals for UESWL services from all appropriately licensed health care practitioners.

(c) An applicant shall develop and utilize a standing medical staff and governing body rule that provides for the medical and administrative control of the ordering and utilization of UESWL services.

(d) An applicant shall require that each urologist serving as a UESWL surgeon shall have completed an approved training program in the use of the lithotripter at an established facility with UESWL services.

(e) An applicant shall establish a process for credentialing urologists who are authorized to perform UESWL procedures at the applicant facility. This shall not be construed as a requirement to establish specific credentialing requirements for any particular hospital or UESWL site.

(f) A urologist who is not an active medical staff member of an applicant facility shall be eligible to apply for limited staff privileges to perform UESWL procedures. Upon request by the Department, an applicant shall provide documentation of its process that will allow a urologist who is not an active medical staff member to apply for medical staff privileges for the sole and limited purpose of performing UESWL procedures. In order to be granted staff privileges limited to UESWL procedures, a urologist shall demonstrate that he or she meets the same requirements, established pursuant to the provisions of subsection (e), that a urologist on an applicant facility's active medical staff must meet in order to perform UESWL procedures.

(g) An applicant shall provide UESWL program access to approved physician residency programs for teaching purposes.

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

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

(i) Not deny any UESWL services to any individual based on inability to pay or source of payment,

(ii) Provide all UESWL 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.

(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 UESWL service 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) Each UESWL unit, whether fixed or mobile, shall perform at least an average of 1,000 procedures per unit per year in the second 12 months of operation and annually thereafter. The central service coordinator shall demonstrate that a mobile UESWL unit approved pursuant to these standards performed at least 100 procedures in each region that is served by the mobile unit. For purposes of this requirement, the number of UESWL procedures performed at all host sites in the same region shall be combined.

(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; and demographic, diagnostic, morbidity and mortality information; primary diagnosis code; whether the procedure was a first or retreatment UESWL procedure; what other treatment already has occurred; outpatient or inpatient status; complications; and whether follow-up procedures (e.g., percutaneous nephrotomy) were required, as well as the volume of care provided to patients from all payor sources. An applicant shall provide the required data on a separate basis for each host site or 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.

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

(5) Compliance with the following mobile UESWL requirements, if applicable:

(a) The volume of UESWL procedures performed at each host site shall be reported to the Department by the central service coordinator.

(b) An applicant with an approved CON for a mobile UESWL service shall notify the Department and the local CON review agency, if any, at least 30 days prior to dropping an existing host site.

(c) Each mobile UESWL service shall establish and maintain an Operations Committee consisting of the central service coordinator's medical director and members representing each host site and the central service coordinator. This committee shall oversee the effective and efficient use of the UESWL unit, 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 UESWL service and its unit(s) on at least a quarterly basis.

(d) The central service coordinator shall arrange for emergency repair services to be available 24 hours each day for the mobile UESWL unit equipment and the vehicle transporting the equipment.

(e) If the host site will not be performing the lithotripsy procedures inside the facility, it must provide a properly prepared parking pad for the mobile UESWL unit 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 site also must provide the capability for maintaining the confidentiality of patient records. A communication system must be provided between the mobile vehicle and each host site to provide for immediate notification of emergency medical situations.

(f) A mobile UESWL service shall operate under a contractual agreement that includes the provision of UESWL services at each host site on a regularly scheduled basis.

(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 10. Methodology for projecting UESWL procedures**

Sec. 10. (1) The methodology set forth in this subsection shall be used for projecting the number of UESWL procedures at a site or sites that do not provide UESWL services as of the date an application is submitted to the Department. In applying the methodology, actual inpatient discharge data, as specified in the most recent Michigan Inpatient Database available to the Department on the date an application is deemed complete shall be used for each licensed hospital site for which a signed data commitment form has been provided to the Department in accordance with the provisions of Section 11. In applying inpatient discharge data in the methodology, each inpatient record shall be used only once and the following steps shall be taken in sequence:

(a) The number of inpatient records with a diagnosis, either principal or nonprincipal, of ICD-9-CM codes 592.0, 592.1, or 592.9 (see Appendix D for ICD-10-CM Codes) shall be counted.

(b) The result of subsection (a) shall be multiplied by the factor specified in Appendix A for each licensed hospital site that is committing its inpatient discharge data to a CON application. If more than one licensed hospital site is committing inpatient discharge data in support of a CON application, the products from the application of the methodology for each licensed hospital site shall be summed.

(c) The result of subsection (b) is the total number of projected UESWL procedures for an application that is proposing to provide fixed or mobile UESWL services at a site, or sites in the case of a mobile service, that does not provide UESWL service, either fixed or mobile, as of the date an application is submitted to the Department.

(2) For a site or sites that provide UESWL services as of the date an application is submitted to the Department, the actual number of UESWL procedures performed at each site, during the most recent continuous 12-month period for which the Department has verifiable data, shall be the number used to project the number of UESWL procedures that will be performed at that site or sites.

(3) For a proposed UESWL unit, except for initiation, the results of subsections (1) and (2), as applicable, shall be summed and the result is the projected number of UESWL procedures for the proposed UESWL unit for purposes of the applicable sections of these standards.

(4) An applicant that is projecting UESWL procedures pursuant to subsection (1) shall provide access to verifiable hospital-specific data and documentation using a format prescribed by the Department.

**Section 11. Requirements for MIDB data commitments**

Sec. 11. (1) In order to use MIDB data in support of an application for UESWL services, an applicant shall demonstrate or agree to, as applicable, all of the following.

(a) A licensed hospital site whose MIDB data is used in support of a CON application for a UESWL service shall not use any of its MIDB data in support of any other application for a UESWL service for 5 years following the date the UESWL service to which the MIDB data are committed begins to operate. The licensed hospital site shall be required to commit 100% of its inpatient discharge data to a CON application.

(b) The licensed hospital site, or sites, committing MIDB data to a CON application has completed the departmental form(s) that agrees to or authorizes each of the following:

(i) The Michigan Health and Hospital Association may verify the MIDB data for the Department.

(ii) An applicant shall pay all charges associated with verifying the MIDB data.

(iii) The commitment of the MIDB data remains in effect for the period of time specified in subsection (1)(a).

(c) A licensed hospital site that is proposing to commit MIDB data to an application is admitting patients regularly as of the date the director makes the final decision on that application under Section 22231(9) of the Code, being Section 333.22231(9) of the Michigan Compiled Laws.

(2) The Department shall consider an MIDB data commitment in support of an application for a UESWL service from a licensed hospital site that meets all of the following:

(a) The licensed hospital site proposing to commit MIDB data to an application does not provide, or does not have a valid CON to provide, UESWL services, either fixed or mobile, as of the date an application is submitted to the Department.

(b) The licensed hospital site proposing to commit MIDB data is located in a region in which a proposed fixed UESWL service is proposed to be located or, in the case of a mobile unit, has at least one host site proposed in that region.

(c) The licensed hospital site meets the requirements of subsection (1), as applicable.

**Section 12. Effect on prior planning policies; comparative reviews**

Sec. 12. (1) These CON review standards supersede and replace the CON review standards for urinary extracorporeal shock wave lithotripsy (UESWL) services approved by the CON Commission on ~~March 18~~SEPTEMBER 25, 2014 and effective on ~~June~~ DECEMBER 22, 2014.

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

**APPENDIX A**

**Factor For Calculating Projected UESWL Procedures**

(1) Until changed by the Department, the factor to be used in Section 10(1)(b) used for calculating the projected number of UESWL procedures shall be 1.~~09~~104.

(2) The Department may amend Appendix A by revising the factor in subsection (1) in accordance with the following steps:

(a) Steps for determining statewide UESWL adjustment factor:

(i) Determine the total statewide number of inpatient records with a diagnosis, either principal or nonprincipal, of ICD-9-CM codes 592.0, 592.1, or 592.9 (see Appendix D for ICD-10-CM Codes) for the most recent year for which Michigan Inpatient Database information is available to the Department.

(ii) Determine the total number of UESWL procedures performed in the state using the Department's Annual Hospital Questionnaire for the same year as the MIDB being used in subsection (i) above.

(iii) Divide the number of UESWL procedures determined in subsection (ii) above by the number of inpatient records determined in subsection (i) above.

(b) Steps for determining "urban/rural" adjustment factor:

(i) For each hospital, assign urban/rural status based on the ~~2000 census~~COUNTY CLASSIFICATIONS FOUND IN APPENDIX C. "Metropolitan statistical area counties" will be assigned "urban" status, and "micropolitan statistical area" and "rural" counties will be assigned "rural" status.

(ii) Aggregate the records from step (a)(i) by zip code "urban/rural" status.

(iii) Identify the zip codes in which all records are either "urban" status or "rural" status. Aggregate the number of records and zip code populations separately by "urban/rural" status.

(iv) For zip codes having records in both "urban" and "rural" status, Calculate the proportion of records in "urban" and "rural" by dividing the respective number of records by the total number of records for that zip code. Multiply the population of each zip code by its respective "urban" and "rural" proportions.

(v) Aggregate the records and populations from step (b)(iv) separately by "urban/rural" status.

(vi) The sub-totals from step (v) will then be added to the sub-totals from step (iii) to produce totals for "urban" & "rural" separately. Calculate the "urban" and "rural" discharge rates per 10,000 (DRU and DRR, respectively) by dividing the total number of records by the total population for each status, then multiplying by 10,000.

(vii) Divide the urban discharge rate by the rural discharge rate (DRU/DRR) to calculate the "urban/rural" adjustment factor. Multiply the statewide adjustment factor identified in step (a)(iii) by the "urban/rural" adjustment factor. The result is the revised factor for calculating UESWL procedures.

(3) The Department shall notify the Commission when this revision is made and the effective date of the revision.

**APPENDIX B**

Counties assigned to each region are as follows:

| Region | Counties | | | |
|---|---|---|---|---|
| 1 | Livingston | Monroe | Macomb | 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 | Mecosta | Montcalm | Muskegon |
| | Newaygo | Oceana | Osceola | Ottawa |
| 5 | Genesee | Lapeer | Shiawassee | |
| 6 | Arenac | Bay | Clare | Gladwin |
| | Gratiot | Huron | Iosco | Isabella |
| | Midland | Ogemaw | Roscommon | Saginaw |
| | Sanilac | Tuscola | | |
| 7 | Alcona | Alpena | Antrim | Benzie |
| | Crawford | Charlevoix | Cheboygan | Emmet |
| | Gd. Traverse | Kalkaska | Leelanau | Manistee |
| | Missaukee | Montmorency | Oscoda | Otsego |
| | Presque Isle | Wexford | | |
| 8 | Alger | Baraga | Chippewa | Delta |
| | Dickinson | Gogebic | Houghton | Iron |
| | Keweenaw | Luce | Mackinac | Marquette |
| | Menominee | Ontonagon | Schoolcraft | |

**APPENDIX C**

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 | Marquett | |

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 D**

**ICD-9-CM TO ICD-10-CM CODE TRANSLATION**

| ICD-9 CODE | DESCRIPTION | ICD-10 CODE | DESCRIPTION |
|---|---|---|---|
| 592.0 | Calculus of Kidney | N20.0 | Calculus of Kidney |
| | | N20.2 | Calculus of Kidney with Calculus of Ureter |
| 592.1 | Calculus of Ureter | N20.1 | Calculus of Ureter |
| | | N20.2 | Calculus Of Kidney with Calculus of Ureter |
| 592.9 | Urinary Calculus | N20.9 | Urinary Calculus, Unspecified |
| | | N22 | Calculus of Urinary Tract in Diseases Classified Elsewhere |

"ICD-9-CM Code" means the disease codes and nomenclature found in the International Classification of Diseases - 9th Revision - Clinical Modification, prepared by the Commission on Professional and Hospital Activities for the U.S. National Center for Health Statistics.

"ICD-10-CM Code" means the disease codes and nomenclature found in the International Classification Of Diseases - 10th Revision - Clinical Modification, National Center for Health Statistics.

# Bone Marrow Transplant
## Need Methodology Update

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George Mason University
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December 7th, 2016 | Michigan CON Commission

# Overview

- BMT in Michigan
- Survey / Results
- Moving Forward

# Data Sources

- CON Annual Survey
- MIDB (ICD-9-CM)
  - 41.00 – 41.09
- US Census

# BMT in Michigan



| | Michigan Residents | | | OOS Residents |
|---|---|---|---|---|
| **Year** | **MI Hospitals** | **OOS Hospitals** | **Total** | **MI Hospitals** |
| 2009 | 542 | 35 | 577 | 19 |
| 2010 | 582 | 25 | 607 | 28 |
| 2011 | 594 | 50 | 644 | 17 |
| 2012 | 600 | 37 | 637 | 19 |
| 2013 | 624 | 33 | 657 | 31 |
| 2014 | 682 | 42 | 724 | 23 |
| *2009-14* | *3,624* | *222* | *3,846* | *137* |

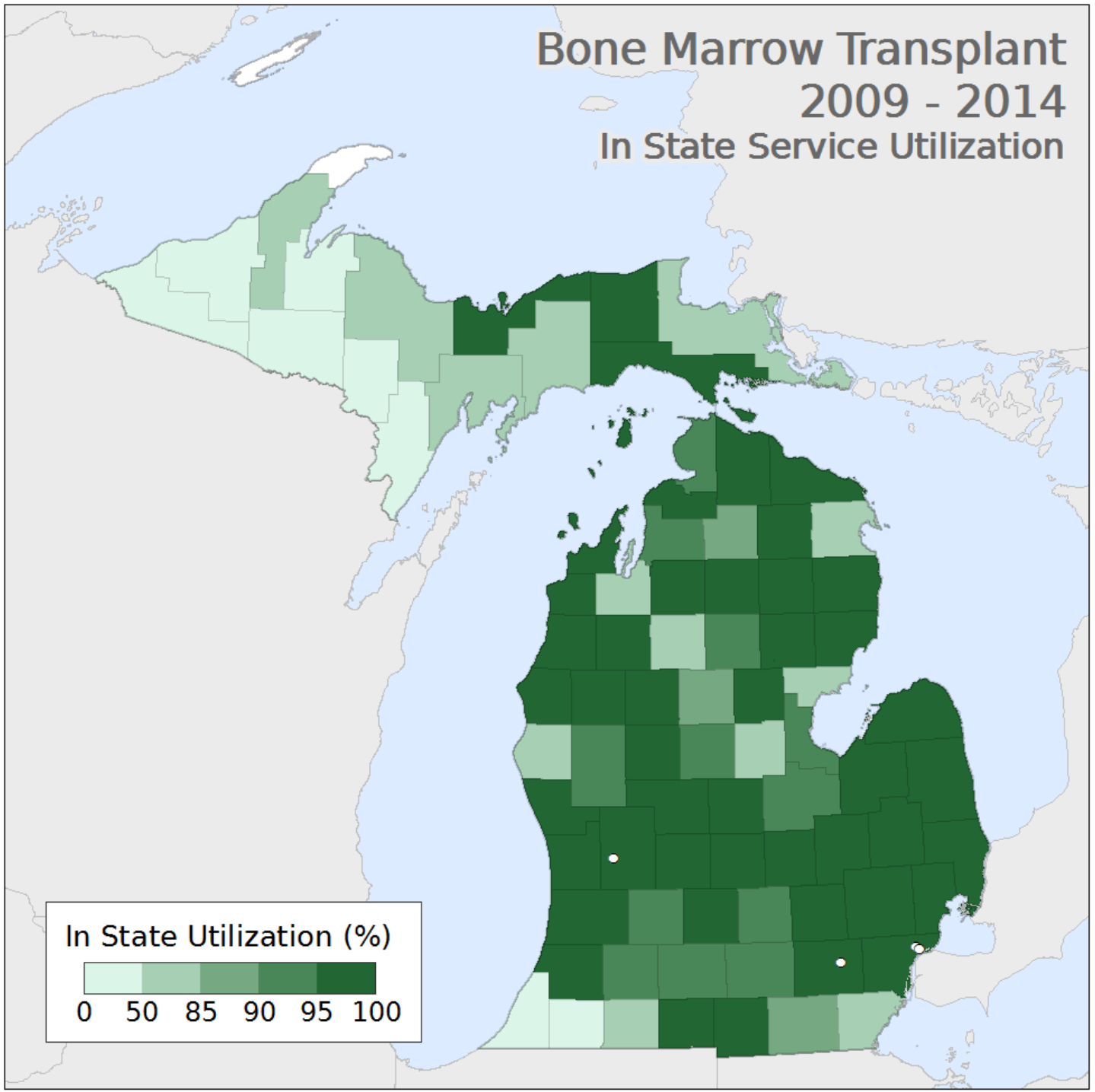
*Counts from MIDB*

# BMT in Michigan



| | Michigan Residents | | Michigan Hospitals | |
|---|---|---|---|---|
| **Year** | **In State** | **Out of State** | **In State** | **Out of State** |
| 2009 | 93.93 | 6.07 | 96.61 | 3.39 |
| 2010 | 95.88 | 4.12 | 95.41 | 4.59 |
| 2011 | 92.24 | 7.76 | 97.22 | 2.78 |
| 2012 | 94.19 | 5.81 | 96.93 | 3.07 |
| 2013 | 94.98 | 5.02 | 95.27 | 4.73 |
| 2014 | 94.20 | 5.80 | 96.74 | 3.26 |
| *2009-14* | *94.23* | *5.77* | *96.36* | *3.64* |

*Values are percents*
*Data from MIDB*


Bone Marrow Transplant
2009 - 2014
In State Service Utilization
In State Utilization (%)
0 50 85 90 95 100

# BMT in Michigan



| | Count | | Percent | | Per 100,000 | | |
|---|---|---|---|---|---|---|---|
| **Year** | **Male** | **Female** | **Male** | **Female** | **Male** | **Female** | **Total** |
| 2009 | 347 | 230 | 60.14 | 39.86 | 7.14 | 4.56 | 5.83 |
| 2010 | 357 | 250 | 58.81 | 41.19 | 7.36 | 4.96 | 6.14 |
| 2011 | 364 | 280 | 56.52 | 43.48 | 7.51 | 5.57 | 6.52 |
| 2012 | 391 | 246 | 61.38 | 38.62 | 8.06 | 4.89 | 6.44 |
| 2013 | 384 | 273 | 58.45 | 41.55 | 7.90 | 5.42 | 6.64 |
| 2014 | 438 | 286 | 60.50 | 39.50 | 8.99 | 5.67 | 7.30 |
| *2009-14* | *2,281* | *1,565* | *59.31* | *40.69* | *7.83* | *5.18* | *6.48* |

*Data from MIDB and Census Bureau*
*Michigan Residents*

# BMT in Michigan



| | Age Group | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Year** | **0-9** | **10-19** | **20-29** | **30-39** | **40-49** | **50-59** | **60-69** | **70-79** |
| 2009 | 6.76 | 2.77 | 7.63 | 8.49 | 15.94 | 27.56 | 28.08 | 2.77 |
| 2010 | 6.92 | 3.29 | 6.59 | 5.60 | 14.66 | 29.16 | 30.15 | 3.62 |
| 2011 | 7.76 | 4.04 | 5.75 | 6.83 | 15.37 | 26.86 | 27.17 | 6.21 |
| 2012 | 8.79 | 4.55 | 6.12 | 4.71 | 9.89 | 25.43 | 34.85 | 5.65 |
| 2013 | 4.26 | 4.57 | 7.31 | 6.54 | 12.79 | 28.46 | 28.16 | 7.91 |
| 2014 | 7.18 | 3.31 | 4.01 | 4.42 | 11.05 | 28.73 | 32.46 | 8.84 |
| *2009-14* | *6.94* | *3.77* | *6.16* | *6.03* | *13.18* | *27.72* | *30.21* | *5.98* |

*Values are percents (of all BMTs)*
*Data from MIDB*
*Michigan Residents*

# BMT in Michigan



| | Age Group | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Year** | **0-9** | **10-19** | **20-29** | **30-39** | **40-49** | **50-59** | **60-69** | **70-79** |
| 2009 | 3.13 | 1.11 | 3.50 | 4.06 | 6.42 | 11.10 | 16.99 | 2.92 |
| 2010 | 3.40 | 1.41 | 3.18 | 2.86 | 6.31 | 12.22 | 18.53 | 4.00 |
| 2011 | 4.13 | 1.88 | 2.88 | 3.79 | 7.17 | 11.82 | 16.87 | 7.14 |
| 2012 | 4.68 | 2.13 | 2.99 | 2.60 | 4.66 | 11.02 | 20.67 | 6.24 |
| 2013 | 2.36 | 2.24 | 3.63 | 3.72 | 6.37 | 12.70 | 16.78 | 8.62 |
| 2014 | 4.41 | 1.82 | 2.16 | 2.76 | 6.24 | 14.15 | 20.62 | 10.26 |
| *2009-14* | *3.68* | *1.76* | *3.05* | *3.30* | *6.20* | *12.17* | *18.46* | *6.64* |

*Values are BMTs per 100,000 people*
*Data from MIDB and Census Bureau*
*Michigan Residents*

# BMT in Michigan



| | Male | | | | Female | | | |
|---|---|---|---|---|---|---|---|---|
| **Year** | **0-19** | **20-39** | **40-59** | **60-79** | **0-19** | **20-39** | **40-59** | **60-79** |
| 2009 | 30 | 54 | 149 | 114 | 25 | 39 | 102 | 64 |
| 2010 | 34 | 38 | 153 | 132 | 28 | 36 | 113 | 73 |
| 2011 | 35 | 45 | 149 | 135 | 41 | 36 | 123 | 80 |
| 2012 | 52 | 38 | 138 | 163 | 33 | 31 | 87 | 95 |
| 2013 | 33 | 51 | 153 | 147 | 25 | 40 | 118 | 90 |
| 2014 | 47 | 33 | 167 | 191 | 29 | 28 | 121 | 108 |
| *2009-14* | *231* | *259* | *909* | *882* | *181* | *210* | *664* | *510* |

*Counts from MIDB*
*Michigan Residents*

# BMT in Michigan



| | Male | | | | Female | | | |
|---|---|---|---|---|---|---|---|---|
| **Year** | **0-19** | **20-39** | **40-59** | **60-79** | **0-19** | **20-39** | **40-59** | **60-79** |
| 2009 | 2.18 | 4.38 | 10.56 | 16.26 | 1.91 | 3.16 | 7.01 | 8.00 |
| 2010 | 2.51 | 3.11 | 10.87 | 18.33 | 2.17 | 2.94 | 7.79 | 8.93 |
| 2011 | 2.63 | 3.68 | 10.64 | 17.99 | 3.24 | 2.95 | 8.52 | 9.45 |
| 2012 | 3.97 | 3.09 | 9.94 | 20.96 | 2.65 | 2.53 | 6.07 | 10.87 |
| 2013 | 2.55 | 4.10 | 11.14 | 18.28 | 2.03 | 3.24 | 8.33 | 9.98 |
| 2014 | 3.68 | 2.62 | 12.32 | 22.95 | 2.38 | 2.25 | 8.66 | 11.60 |
| *2009-14* | *2.91* | *3.50* | *10.90* | *19.23* | *2.39* | *2.84* | *7.72* | *9.86* |

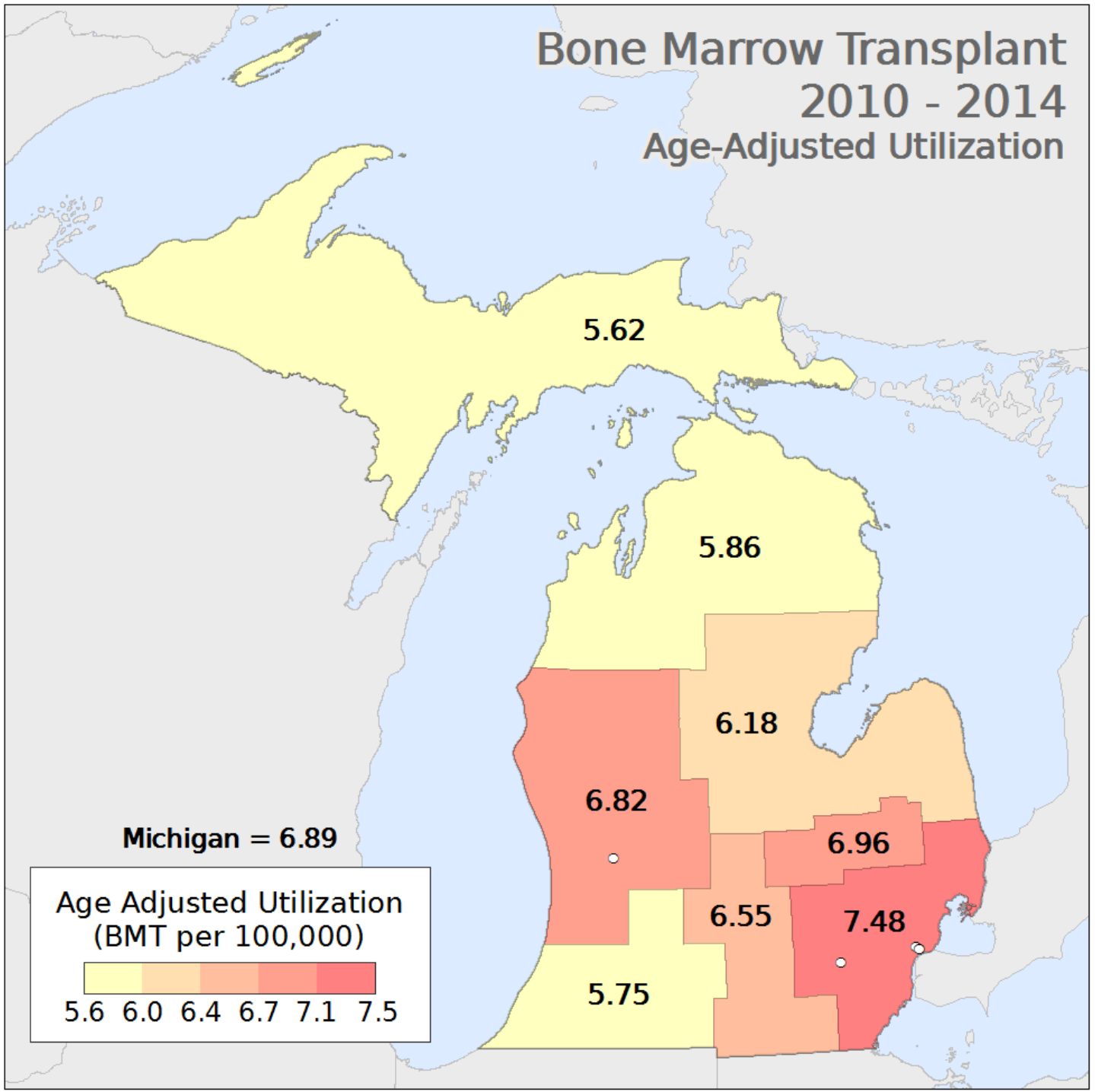
*Values are BMTs per 100,000 people*
*Data from MIDB and Census Bureau*
*Michigan Residents*

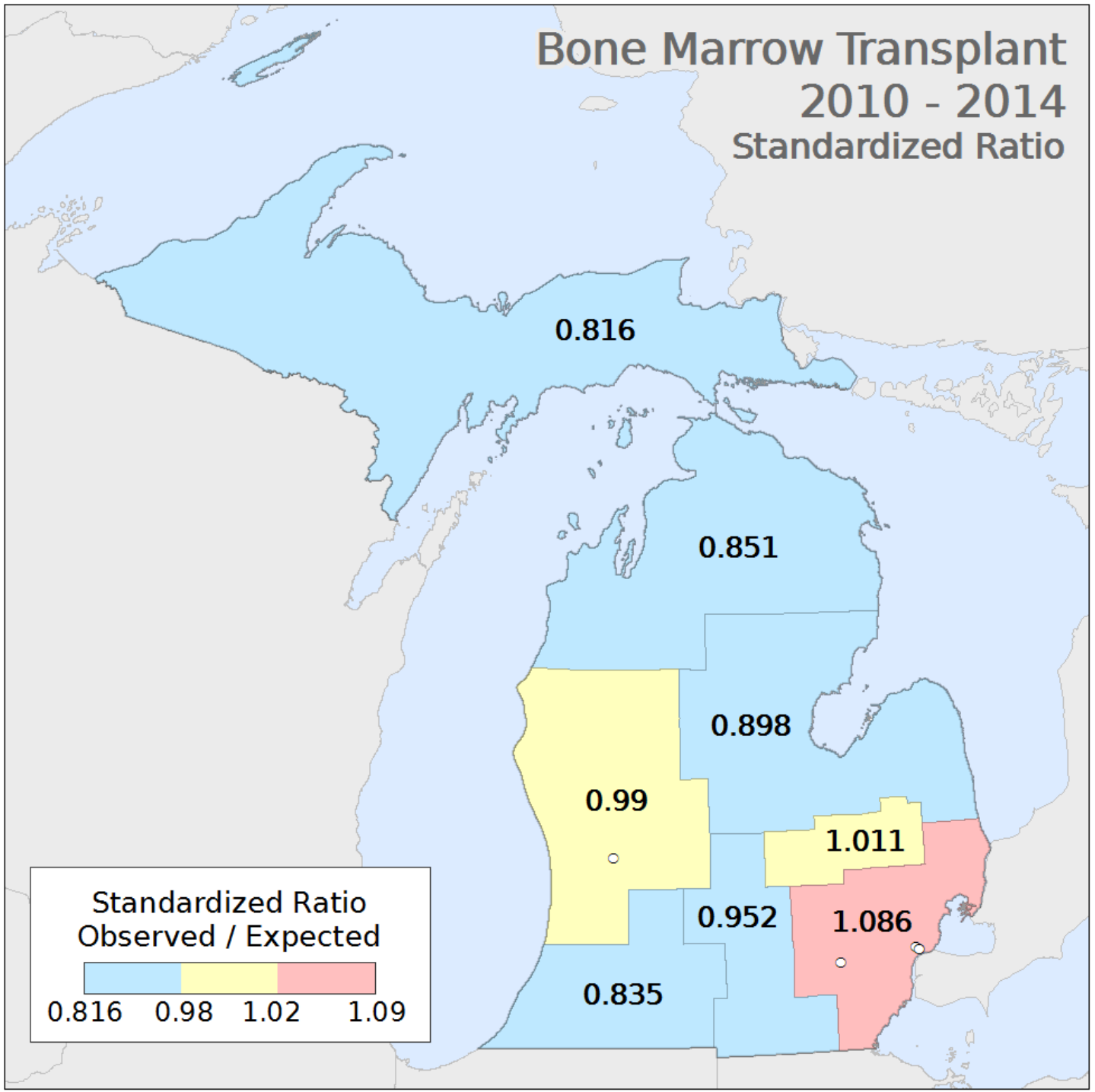
# BMT in Michigan

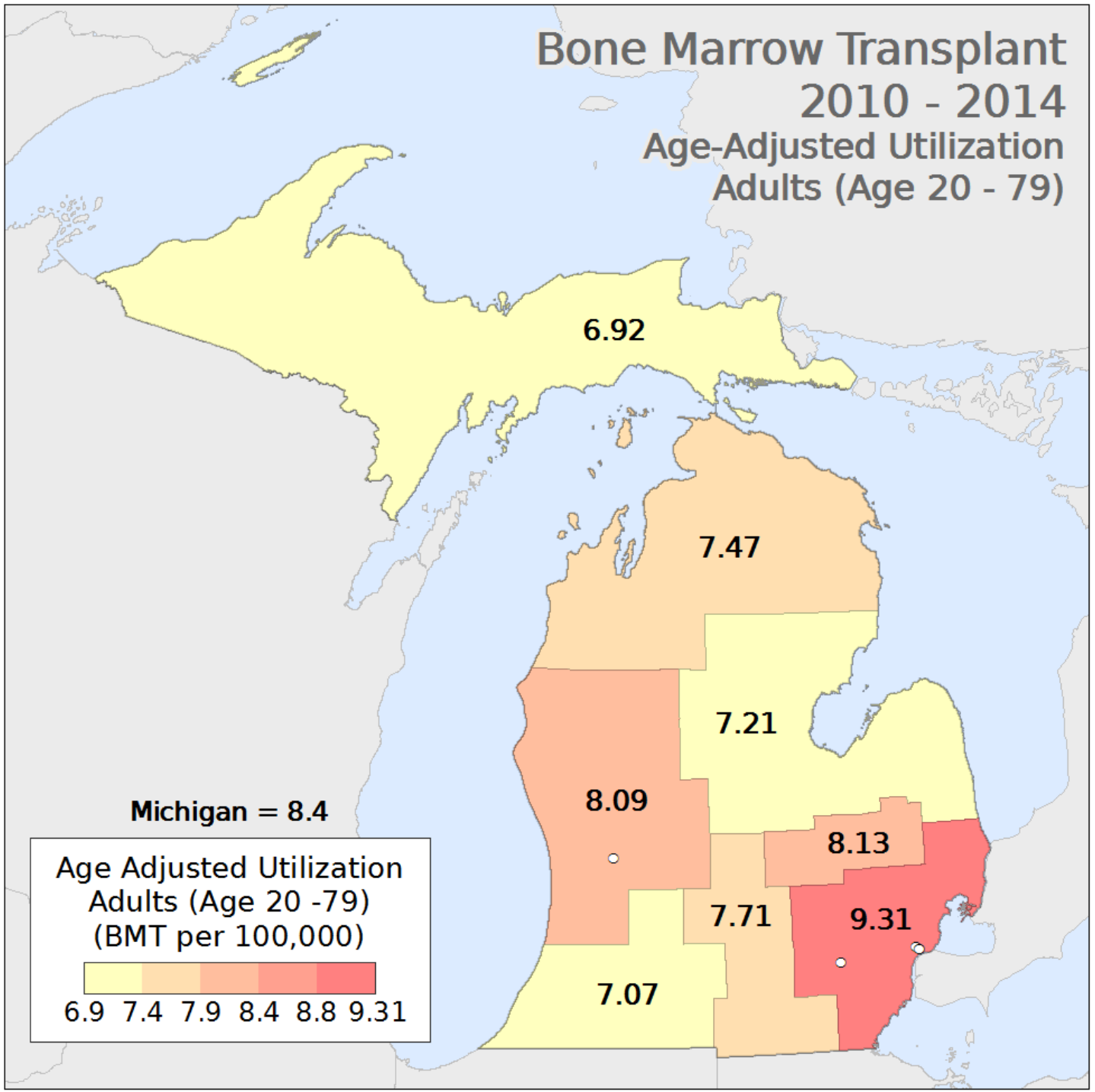


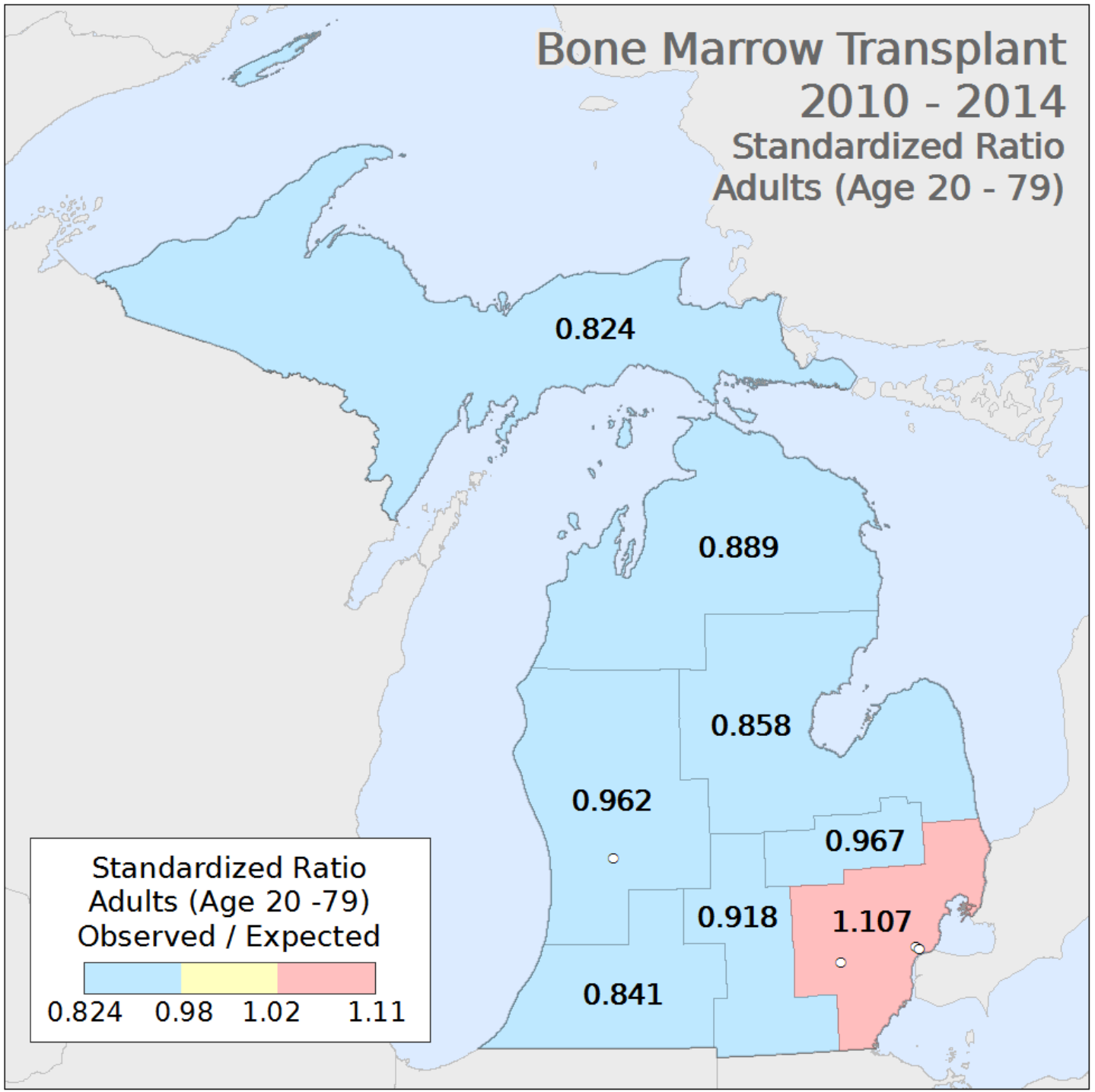
| | Race / Ethnicity | | | | | | |
|---|---|---|---|---|---|---|---|
| **Year** | **White** | **Black** | **Asian** | **AIAN** | **Hispanic** | **Other** | **Missing** |
| 2009 | 84.75 | 13.00 | 0.69 | 0.35 | 0.87 | 0.35 | 0.00 |
| 2010 | 68.86 | 11.70 | 0.16 | 0.16 | 0.49 | 11.04 | 7.58 |
| 2011 | 81.68 | 13.82 | 1.71 | 1.24 | 0.93 | 0.31 | 0.31 |
| 2012 | 64.05 | 11.30 | 0.78 | 0.47 | 0.00 | 10.52 | 12.87 |
| 2013 | 61.04 | 11.72 | 1.83 | 0.30 | 0.46 | 7.31 | 17.35 |
| 2014 | 62.57 | 13.95 | 0.69 | 0.28 | 0.83 | 5.66 | 16.02 |

*Values are percents (of all BMTs)*
*Data from MIDB*
*Michigan Residents*


Bone Marrow Transplant
2010 - 2014
Age-Adjusted Utilization
5.62
5.86
6.18
6.82
6.96
6.55
7.48
5.75
Michigan = 6.89
Age Adjusted Utilization
(BMT per 100,000)
5.6 6.0 6.4 6.7 7.1 7.5


Bone Marrow Transplant
2010 - 2014
Standardized Ratio
0.816
0.851
0.898
0.99
1.011
0.952
1.086
0.835
Standardized Ratio
Observed / Expected
0.816
0.98
1.02
1.09


Bone Marrow Transplant
2010 - 2014
Age-Adjusted Utilization
Adults (Age 20 - 79)
6.92
7.47
7.21
8.09
8.13
7.71
9.31
7.07
Michigan = 8.4
Age Adjusted Utilization
Adults (Age 20 -79)
(BMT per 100,000)
6.9 7.4 7.9 8.4 8.8 9.31


Bone Marrow Transplant
2010 - 2014
Standardized Ratio
Adults (Age 20 - 79)
0.824
0.889
0.858
0.962
0.967
0.918
1.107
0.841
Standardized Ratio
Adults (Age 20 -79)
Observed / Expected
0.824 0.98 1.02 1.11

# Need Methodology



- CON Aims
  - Cost, Quality, and
  - Access
    - Methodology to evaluate utilization of and access to BMT
      - Unmet need for BMT in Michigan?

# Need Methodology



- Fundamental question
  - Does the supply of the service meet the needs of the population?
    - Example for acute care hospital beds
    - Is projected utilization higher than the capacity of the current system?
      - Need/Utilization (patient days / 365)
      - Supply (beds)
      - If need is greater than supply, there will be "unmet" need

# BMT Survey Overview

Attachment B

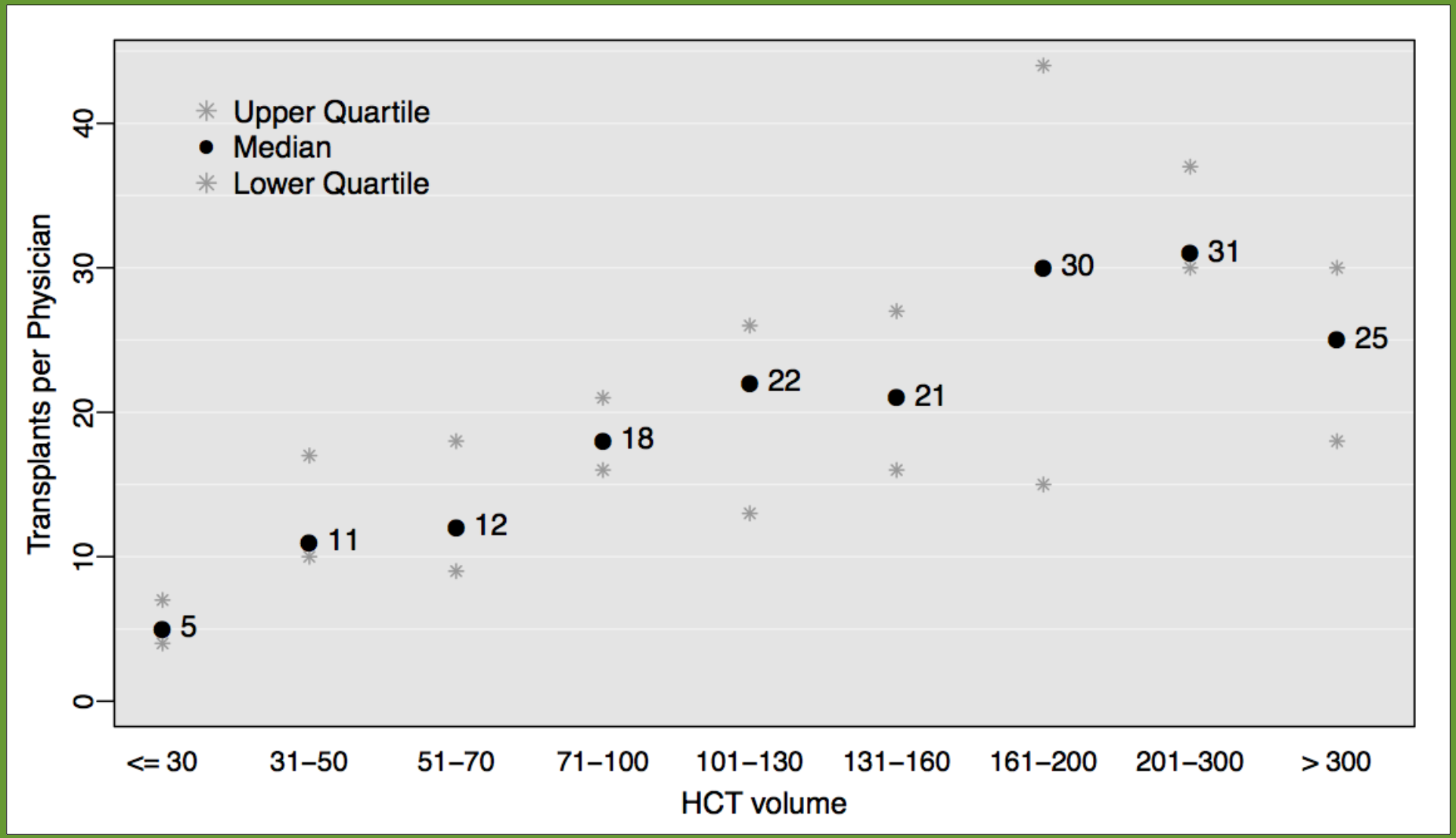
- Not a traditional survey, more similar to an information request
- Sent to 20
  - Recent BMT SAC members
  - BMT Experts (identified from literature)
- Received 3 responses
  - Poorly designed/worded survey?

# BMT Survey #1

- Measuring potential "supply"
  - Beds
    - *No BMT-specific limit on hospital beds*
  - Physicians
    - *Potential?*
  - Support staff

# BMT Survey #1






Redrafted from Majhail, N. S., et al.. (2015). National Survey of Hematopoietic Cell Transplantation Center Personnel, Infrastructure, and Models of Care Delivery. Biology of Blood and Marrow Transplantation, 21(7), 1308–1314.

# BMT Survey #2-3

- Measuring "unmet need" for BMT services
  - Health outcomes that signal unmet need?
    - *No*
  - Proxy procedures/treatments that signal unmet need?
    - *No*
    - *New advancements in cancer treatment*

# BMT Survey #4

- Barriers to BMT
  - *Financial costs*
  - *Social costs*
    - *Caregiving and support network*
  - *New / unfamiliar care team*
  - *Physician knowledge / referrals*
  - *Geography*
  - *Age / co-morbidities*
  - *Donor availability*
  - *Physician availability*

# BMT Survey #5

- Comparisons to other states
  - *Yes, but with caution*
  - Utilization
    - Maryland and North Carolina
  - Regulation
    - Alabama, Florida, Maryland, and North Carolina

# State Comparison

| Michigan | 2010 | 2011 | 2012 | 2013 | 2014 |
|---|---|---|---|---|---|
| BMT | 610 | 611 | 619 | 655 | 705 |
| Population | 9,877,369 | 9,876,589 | 9,886,879 | 9,900,506 | 9,916,306 |
| BMT (per 100,000) | 6.18 | 6.19 | 6.26 | 6.62 | 7.11 |

*Data from MIDB and Census Bureau*

| North Carolina | 2010 | 2011 | 2012 | 2013 | 2014 |
|---|---|---|---|---|---|
| BMT | 582 | 625 | 649 | 693 | 757 |
| Population | 9,558,979 | 9,651,025 | 9,747,021 | 9,845,432 | 9,940,387 |
| BMT (per 100,000) | 6.09 | 6.48 | 6.66 | 7.04 | 7.62 |

*Data from https://www2.ncdhhs.gov/dhsr/ncsmfp/index.html and Census Bureau*

| Maryland | 2010 | 2011 | 2012 | 2013 |
|---|---|---|---|---|
| BMT | 297 | 319 | 288 | 320 |
| Population | 5,788,409 | 5,844,171 | 5,890,740 | 5,936,040 |
| BMT (per 100,000) | 5.13 | 5.46 | 4.89 | 5.39 |

*Data from CON Regulation of Organ Transplant Services in Maryland and Census Bureau*

# Alabama CON

- Transplantation Services
- Applicant must demonstrate
  - Other facilities are operating at ≥80% capacity or unwilling to take new patients
  - Qualified personnel available instate and existing programs will not be detrimentally affected

*Alabama Administrative Code, Chapter 410-2-3, Specialty Services*
*http://www.alabamaadministrativecode.state.al.us/docs/hp/410-2-3.pdf*

# Florida CON

- Transplantation Services
  - Pediatric / Adult Allogeneic
    - 10 transplants, limited to teaching and research hospitals
  - Adult Autologous
    - 10 transplants, limited to teaching and research hospitals; or community hospitals having a research program, or who are affiliated with a research program

*Florida Administrative Code, Rule: 59C-1.044, Organ Transplantation*
*https://www.flrules.org/gateway/ruleNo.asp?id=59C-1.044*

# Maryland CON

- Transplantation Services
  - Past utilization to predict future utilization (+3 years)
    - Time series analysis (3 years past data)
    - Incorporates utilization patterns
      - Similar to MI Acute Care Hospital Beds

*Maryland State Health Plan, 10.24.15: Organ Transplant Services*
*http://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_shp/hcfs_shp.aspx*

# Maryland CON (cont.)

- Transplantation Services
  - Utilization thresholds to determine whether need exists
    - Autologous (10), Allogeneic (40)
  - All other programs operating above thresholds
  - Preference for less programs operating at higher volumes

*Maryland State Health Plan, 10.24.15: Organ Transplant Services*
*http://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_shp/hcfs_shp.aspx*

# North Carolina CON

- Transplantation Services
  - Need demonstrated when all existing services provide ≥20 transplants
  - Limited to facilities with solid organ transplant services
  - Limited to Academic Medical Center Teaching Hospitals

*North Carolina State Medical Facilities Plan, Chapter 7, Transplantation Services*
*https://www2.ncdhhs.gov/dhsr/ncsmfp/index.html*

# BMT Survey #6

- Minimum BMT volume
  - *Foundation for Accreditation of Cellular Therapy (FACT)*
    - 10 allogeneic
    - 5 autologous
  - Currently in the Review Standards
    - 30 (at least 10 allogeneic)

# BMT Survey #7

- Quality metrics
  - *Center for International Blood and Marrow Transplant Research (CIBMTR)*
  - *Foundation for the Accreditation of Cellular Therapy (FACT) Accreditation*
  - *Centers of Distinction*
  - *Performs clinical trials*

# BMT Survey #8



- Regional- or state-based methodology
  - *Regional, if data can support*
    - *Existing supply/capacity*
    - *Importance of 60 minute travel*
      - *Threshold for relocation*

# BMT Survey #9

- If unmet need identified in unserved location, how to locate facility?
  - Poor question (terrible example)
    - Was attempting to rectify idea of a "regional" population approach
      - Population is distributed throughout a geographic region
      - A facility is located at a point in space

# BMT Survey #10



- BMT planning and regulation
  - Besse et al. (2015) approach to estimate demand and unmet need
    - BMT-related disease incidence rates
    - Proportion of disease cases receiving BMT
    - Population characteristics
  - *Too simplistic*
    - *Complexity of pathway to BMT not addressed*
    - *Spatial scale*

# BMT Survey #11

- BMT planning and regulation
  - More aggregated disease and age groupings in Besse et al. (2015)?
    - 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
    - 0-19; 20-54; 55-64; 65-74
  - *No*
  - *Non-Hodgkins, Hodgkins, Acute Leukemia (ALL/AML), Chronic Leukemia (CML), Multiple Myeloma, Myelodysplastic Syndrome, Other*

# BMT Survey #12

- BMT planning and regulation
  - Potential data sources for data-driven need methodology?
    - *Michigan Cancer Surveillance Program*
    - Facility Tumor Registries?

# Moving Forward

- Methodology
  - Facility-based
    - Concerns over "transfer" of current utilization, rather than identifying unmet need
  - Regional time series analysis
    - Could be promising
  - How to measure supply/capacity of current BMT services?

# Questions or Comments?

## Bone Marrow Transplant
## Need Methodology Update

Paul L. Delamater
Dept of Geography and Geoinformation Science
George Mason University
pdelamat@gmu.edu
December 7th, 2016 | Michigan CON Commission

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

**To: CON Commission**

**From: Marianne Conner, CPA**
**CON Workgroup Chair**
**Date: December 7, 2016 CON Commission meeting**

**RE: CON Workgroup status update**

The CON Workgroup has met twice since the last CON Commission meeting: October 13, 2016 and November 10, 2016.

During these two meetings the Workgroup has had excellent participation by both provider organizations, professional groups, the Ombudsman's office, and the CON Department. Good dialogue has led to much thoughtful consideration of the charges given the group.

Charge 1 to Review the criteria for NH-HLTCU replacements and the relocation of beds. The group received the information from the Attorney General's Office confirming that replacement projects more than 2 miles but less than 3 miles can be exempted from comparative review. The group then worked on language to further clarify exemptions on new design models within the planning area which will be presented to the Commission once the wording is finalized.

Charge 2 to look at lease renewals had much discussion. While CON wishes to review all lease renewals without regard to the capital threshold, the group was interested in finding ways to relieve the financial burden of these CON lease renewals. While the workgroup agreed that all were willing to go through the review process to be sure they are meeting current standards, the financial cost was excessive especially for those doing straight lease renewals with related parties. The AG's interpretation of the standard does not provide the group with much room to try to address the financial concerns and other avenues may be used rather than through the Commission.

Charge 3 to update the language of the High Occupancy standard was reviewed at our November meeting. The group discussed what the new industry high occupancy percentage looks like. Also, if the group were to propose changing the percentage, what other requirements should be imposed on the facility in order to obtain the additional beds including dual certification of the new beds, eliminate any wards existing in the facility, and limits on relocation and transfer of the beds. Wording for these proposed changes will be brought back to the workgroup at the December meeting by the subcommittee.

Charge 4 to review the Special Populations Subcommittee presented to the workgroup in November a draft proposal to create a new special population for Bariatric Patients. The group discussed what the standards would be and agreed to use Section 10 of the Review Standards, subsection 13 which awarded points to projects for bariatric rooms as a baseline for the new special population. The subcommittee will bring back the proposed wording at the next workgroup in December.

Charge 5 on bed need methodology was discussed at both meetings. Dr. Delamater's methodology was reviewed and the issues related to incorrect and late data being provided by providers. The workgroup requested that a few questions of clarification be asked of Dr. Delamater to determine if any changes will be proposed by the workgroup.

Charge 7 had to be tabled for the December meeting. The workgroup anticipates possibly having an additional meeting in January in order to finalize all 8 charges.

Attachment D

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:** December 7, 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. 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 the Commission’s review of the Psychiatric Beds and Services standards, which will be included in the FY2017 CON Program Annual Activity Report, there were numerous letters and comments made regarding patients waiting in emergency rooms for admission. This was especially true for adolescents and geriatric patients.

Many suggestions were made to solve the problem that were outside the purview of the CON Commission. One of these suggestions that many providers feel would be most helpful, particularly with helping find placement for patients in need of inpatient care, is the development of a web-based psychiatric bed registry.

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: At its September 21, 2016 meeting, the Commission assigned the Department to draft language for the December 7, 2016 CON Commission meeting. Review of standards to be finalized in FY2017.

CERTIFICATE OF NEED

**4th 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 | 4th Quarter | Year-to-Date |
|---|---|---|
| Approved projects requiring 1-year follow up | 68 | 314 |
| Approved projects contacted on or before anniversary date | 29 | 198 |
| Approved projects completed on or before 1-year follow up | 74% | |
| CON approvals expired | 13 | 51 |
| Total follow up correspondence sent | 134 | 850 |
| Total approved projects still ongoing | 367 | |

*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.

- Integrated Mobile Imaging – MRI Network No. 88 – During an application review, it was noted that the central service coordinator (CSC) for Network 88 had replaced the mobile MRI unit without CON approval. The same CSC, however, had CON approval to acquire and replace another MRI Network No. 94 but they ended up replacing the unit on MRI Network No. 88 instead. The CSC had to add the cost of replacement to the current CON application as corrective action and paid a civil fine of $5,500.

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

CERTIFICATE OF NEED

**4th 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 | 4th Quarter | | Year-to-Date | |
|---|---|---|---|---|
| | No. | Percent | No. | Percent |
| Letters of Intent Received | 125 | N/A | 442 | N/A |
| Letters of Intent Processed within 15 days | 122 | 98% | 439 | 99% |
| Letters of Intent Processed Online | 125 | 100% | 442 | 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 | 4th Quarter | | Year-to-Date | |
|---|---|---|---|---|
| | No. | Percent | No. | Percent |
| Applications Received | 65 | N/A | 320 | N/A |
| Applications Processed within 15 Days | 64 | 98% | 319 | 99% |
| Applications Incomplete/More Information Needed | 49 | 75% | 242 | 76% |
| Applications Filed Online* | 65 | 100% | 305 | 100% |
| Application Fees Received Online* | 15 | 23% | 77 | 25% |

* 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 | 4th Quarter | | Year-to-Date | |
|---|---|---|---|---|
| | Issued on Time | Percent | Issued on Time | Percent |
| Nonsubstantive Applications | 38 | 100% | 169 | 100% |
| Substantive Applications | 40 | 100% | 138 | 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 | 4th 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 | 4th Quarter | | Year-to-Date | |
|---|---|---|---|---|
| | Issued on Time | Percent | Issued on Time | Percent |
| Amendments | 20 | 100% | 74 | 97% |

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

| Activity | 4th Quarter | Year-to-Date |
|---|---|---|
| Refunds Issued Pursuant to Section 22231 | 0 | 0 |

**Other Measures**

| Activity | 4th Quarter | | Year-to-Date | |
|---|---|---|---|---|
| | No. | Percent | No. | Percent |
| FOIA Requests Received | 44 | N/A | 178 | N/A |
| FOIA Requests Processed on Time | 44 | 100% | 178 | 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.

Attachment G

# *MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES*

# *CERTIFICATE OF NEED (CON) PROGRAM*

# *ANNUAL ACTIVITY REPORT*

***October 2015 through September 2016***
***(FY2016)***

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

**http://www.michigan.gov/con**

*MDHHS is an Equal Opportunity Employer, Services and Program Provider*

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## *EXECUTIVE SUMMARY*

One of the Michigan Department of Health and Human Services (MDHHS or Department) duties under Part 222 of the Public Health Code, MCL 333.22221(b), is to report to the Certificate of Need (CON) Commission annually on the Department's performance under this Part. This is the Department's 28th report to the Commission and covers the period beginning October 1, 2015, through September 30, 2016 (FY 2016). Data contained in this report may differ from prior reports due to updates subsequent to each report's publishing date.

### ***Administration***

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

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

During FY 2016, the Department has continued to make process improvements in both the Policy and Evaluation Sections. The Department made substantial progress in revising specific areas of the CON administrative rules, which is now in its final phase of the rule making process.

The Evaluation Section has initiated a compliance pilot program to monitor the denial of treatment for inpatient psychiatric patients and collect information from the Prepaid Inpatient Health Plans (PIHP). This pilot program is part of the department's evaluation of the mental health services and related issues in order to propose policy changes to enhance access to care. The Section completed enhancements to the CON Annual Survey tool for proper submission and validation of nursing home patient days of care data which resulted in more accurate bed need calculation for this service. The Section successfully completed review and approval of applications for elective percutaneous coronary intervention (PCI) services without on-site open heart surgery (OHS) services under the newly established review standards, forms, review processes and accreditation criteria, and worked with both departmental and external subject matter experts to ensure proper review of elective PCI services.

The Policy Section assisted the Commission to make the necessary modifications to the CON Review standards to better reflect practice, improve quality, reduce regulation to replace equipment, and to add clarity to the MRI services standards; added special population groups for developmentally disabled, geriatrics, and medical psychiatric to provide more access to psychiatric beds for these specific hard to place patients; removed dental CT scanners from CON regulation for dentists; and added clarifying language to NICU & Special Newborn Nursing Services. (Note: With the exception of MRI, these changes will become effective in FY2017.)

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

## ***CON Required***

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

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

## ***CON Application Process***

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

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

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

## ***FY 2016 in Review***

In FY 2016, there were 442 Letters of Intent received resulting in 320 applications filed for CON review and approval, including one (1) emergency application. In addition, the Department received 76 amendments to previously approved applications. In total, the Department approved 303 proposed projects resulting in approximately $1,314,654,311 of new capital expenditures into Michigan's healthcare system. The Department also surveyed 1,137 facilities and collected statistical data.

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

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

This report is filed by the Department in accordance with MCL 333.22221(f). The report presents information about the nature of these CON applications and decisions, as well as the Commission's actions during the reporting period. Several tables include benchmarks for timely processing of applications and issuing decisions as set forth in the CON Administrative Rules. Note that the data in the report represents some applications that were carried over from last fiscal year while others may be carried over into next fiscal year.

## *HISTORICAL OVERVIEW OF MICHIGAN'S CERTIFICATE OF NEED PROGRAM*

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

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

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

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

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

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

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

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

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

## *ADMINISTRATION OF THE CERTIFICATE OF NEED PROGRAM*

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

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

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

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

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

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

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

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

## *CERTIFICATE OF NEED PROCESS*

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

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

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

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

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

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

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

## LETTERS OF INTENT

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

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

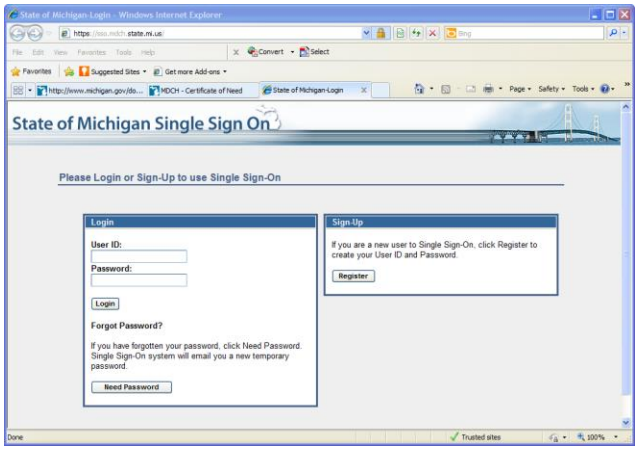
***TABLE 1***
*LETTERS OF INTENT RECEIVED AND PROCESSED WITHIN 15 DAYS*
*FY2012 - FY2016*

| | LOIs Received | Processed within 15 Days | Percent Processed within 15 Days | Waivers Processed* |
|---|---|---|---|---|
| ***FY2012*** | 422 | 422 | 100% | 43 |
| ***FY2013*** | 440 | 438 | 99% | 61 |
| ***FY2014*** | 333 | 332 | 99% | 39 |
| ***FY2015*** | 435 | 434 | 99% | 44 |
| ***FY2016*** | 442 | 439 | 99% | 71 |

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

In FY 2016, LOIs were processed in a timely manner as required by Administrative Rule and available for public viewing on the online application system. The online system allows for faster processing of LOIs and subsequent applications by the Evaluation Section, as well as modifying these applications by applicants when needed.

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




*http://www.mi.gov/con*

## TYPES OF CERTIFICATE OF NEED APPLICATION REVIEWS

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

### *Nonsubstantive*

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

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

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

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

***Substantive Individual***

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

***Comparative***

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

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

**Figure 1** delineates services/beds subject to comparative review.

| ***FIGURE 1***<br>*Services/Beds Subject to Comparative Review in FY2016* | |
|---|---|
| Neonatal Intensive Care Unit | Nursing Home/HLTCU Beds |
| Hospital Beds | Nursing Home Beds for Special Population Groups |
| Psychiatric Beds | |
| Transplantations | |

*Note: See individual CON review standards for more information.*

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

| ***TABLE 2***<br>*APPLICATIONS RECEIVED BY REVIEW TYPE*<br>*FY2012 - FY2016* | | | | | |
|---|---|---|---|---|---|
| | **FY2012** | **FY2013** | **FY2014** | **FY2015** | **FY2016** |
| ***Nonsubstantive**** | 160 | 161 | 117 | 194 | 171 |
| ***Substantive Individual*** | 135 | 152 | 114 | 129 | 148 |
| ***Comparative*** | 10 | 8 | 2 | 0 | 0 |
| ***TOTALS*** | 305 | 321 | 233 | 323 | 319 |

*Note: Does not include one (1) emergency CON application.*

* Includes swing bed applications.

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

***TABLE 3***
*APPLICATIONS RECEIVED AND PROCESSED WITHIN 15 DAYS*
*FY2012 - FY2016*

| | FY2012 | FY2013 | FY2014 | FY2015 | FY2016 |
|---|---|---|---|---|---|
| ***Applications Received*** | 305 | 326 | 235 | 326 | 320 |
| ***Processed within 15 Days*** | 290 | 326 | 235 | 324 | 318 |
| ***Percent Processed within 15 Days*** | 95% | 100% | 100% | 99% | 99% |

*Note: Includes emergency CON and swing bed applications.*

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

***TABLE 4***
*AVERAGE NUMBER OF DAYS IN REVIEW CYCLE BY REVIEW TYPE*
*FY2012- FY2016*

| | FY2012 | FY2013 | FY2014 | FY2015 | FY2016 |
|---|---|---|---|---|---|
| ***Nonsubstantive*** | 41 | 38 | 40 | 42 | 38 |
| ***Substantive Individual*** | 114 | 117 | 117 | 112 | 104 |
| ***Comparative*** | 117 | 119 | 116 | N/A | N/A |

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

## *EMERGENCY CERTIFICATES OF NEED*

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

***TABLE 5***
*EMERGENCY CON DECISIONS ISSUED*
*FY2012 - FY2016*

| | FY2012 | FY2013 | FY2014 | FY2015 | FY2016 |
|---|---|---|---|---|---|
| *Emergency CONs Issued* | 2 | 5 | 2 | 2* | 0* |
| *Percent Issued within 10 Working Days* | 100% | 100% | 100% | 100% | N/A |

*One emergency CON application was submitted but withdrawn before a decision was to be issued.

## *PROPOSED DECISIONS*

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

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

***TABLE 6***
*PROPOSED DECISIONS ISSUED*
*FY2012- FY2016*

| | Nonsubstantive | | Substantive Individual | | Comparative | |
|---|---|---|---|---|---|---|
| | Issued | Issued on Time | Issued | Issued on Time | Issued | Issued on Time |
| *FY2012* | 155 | 100% | 115 | 100% | 3 | 100% |
| *FY2013* | 147 | 100% | 145 | 100% | 9 | 100% |
| *FY2014* | 119 | 100% | 130 | 100% | 6 | 100% |
| *FY2015* | 195 | 100% | 118 | 100% | 0 | N/A |
| *FY2016* | 169 | 100% | 138 | 100% | 0 | N/A |

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

***TABLE 7***
*COMPARISON OF PROPOSED DECISIONS BY DECISION TYPE*
*FY2012- FY2016*

| | Approved | Approved w/ Conditions | Disapproved | Percent Disapproved | TOTAL |
|---|---|---|---|---|---|
| *FY2012* | 244 | 19 | 10 | 4% | 243 |
| *FY2013* | 261 | 35 | 10 | 3% | 306 |
| *FY2014* | 222 | 28 | 7 | 3% | 257 |
| *FY2015* | 261 | 53 | 1 | 0.3% | 315 |
| *FY2016* | 226 | 81 | 0 | 0% | 307 |

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

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

## *FINAL DECISIONS*

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

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

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

| ***TABLE 8*** *FINAL DECISIONS ISSUED FY2012- FY2016* | |
|---|---|
| *FY2012* | 283 |
| *FY2013* | 309 |
| *FY2014* | 256 |
| *FY2015* | 316 |
| *FY2016* | 303 |

***FIGURE 2***
***FY 2016 FINAL DECISIONS ISSUED BY HEALTH SERVICE AREAS***


*Note: Figure 2 does not include 3 out-state decision.*

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

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

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

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

***Covered Capital Expenditures***
This category includes capital expenditure project in a clinical area of a licensed health facility that is equal to or above the threshold set forth in Part 222. Typical examples of covered capital expenditure projects include construction, renovation, or the addition of space to accommodate increases in patient treatment or care areas not already covered. In 2015 the covered capital expenditure threshold was $3,197,500 and as of January 1, 2016, the covered capital expenditure threshold was decreased to $3,180,000. The threshold is updated in January of every year.

| ***TABLE 9***<br>*FINAL DECISIONS ACTIVITY CATEGORY*<br>*FY2012 - FY2016* | | | | | |
|---|---|---|---|---|---|
| ***Approved*** | **FY2012** | **FY2013** | **FY2014** | **FY2015** | **FY2016** |
| *Acquire, Begin, or Replace a Health Facility* | 25 | 38 | 47 | 68 | 26 |
| *Change in Bed Capacity* | 57 | 52 | 46 | 34 | 42 |
| *Covered Clinical Services* | 188 | 241 | 191 | 214 | 240 |
| *Covered Capital Expenditures* | 55 | 44 | 47 | 33 | 49 |
| ***Disapproved*** | | | | | |
| *Acquire, Begin, or Replace a Health Facility* | 9 | 2 | 4 | 0 | 0 |
| *Change in Bed Capacity* | 12 | 5 | 5 | 1 | 0 |
| *Covered Clinical Services* | 2 | 0 | 0 | 1 | 0 |
| *Covered Capital Expenditures* | 10 | 3 | 5 | 1 | 0 |

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

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

| ***TABLE 10***<br>*COMPARISON OF FINAL DECISIONS BY DECISION TYPE*<br>*FY2012 - FY2016* | | | | |
|---|---|---|---|---|
| | **Approved** | **Approved With Conditions** | **Disapproved** | **Totals** |
| ***Number of Final Decisions*** | | | | |
| ***FY2012*** | 245 | 24 | 14 | 283 |
| ***FY2013*** | 268 | 36 | 5 | 309 |
| ***FY2014*** | 223 | 28 | 5 | 256 |
| ***FY2015*** | 261 | 53 | 2 | 316 |
| ***FY2016*** | 224 | 79 | 0 | 303 |
| ***Total Project Costs*** | | | | |
| ***FY2012*** | $ 1,018,583,923 | $ 61,902,640 | $ 119,186,198 | $ 1,199,672,761 |
| ***FY2013*** | $ 724,546,360 | $ 239,908,373 | $ 321,167,591 | $ 1,285,622,324 |
| ***FY2014*** | $ 904,329,614 | $ 196,996,469 | $ 39,529,999 | $ 1,140,856,082 |
| ***FY2015*** | $ 2,077,265,073 | $ 239,911,843 | $ 5,554,114 | $ 2,322,741,030 |
| ***FY2016*** | $ 1,000,284,403 | $ 314,369,908 | $ 0 | $ 1,314,654,311 |

*Note: Final decisions include emergency CON applications.*

In FY2016, there were no CON applications that received a final decision of disapproval from the Department.

## CERTIFICATE OF NEED ACTIVITY SUMMARY COMPARISON

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

| TABLE 11<br>CON ACTIVITY COMPARISON<br>FY2012 - FY2016 | | | | |
|---|---|---|---|---|
| | **Number of Applications** | **Difference from Previous Year** | **Total Project Costs** | **Difference from Previous Year** |
| ***Letters of Intent Processed*** | | | | |
| *FY2012* | 422 | (4%) | $1,969,641,919 | (52%) |
| *FY2013* | 440 | 4% | $1,661,621,556 | (16%) |
| *FY2014* | 333 | (24%) | $1,282,834,192 | (23%) |
| *FY2015* | 435 | 31% | $2,894,486,078 | 126% |
| *FY2016* | 442 | 2% | $1,527,863,597 | (47%) |
| ***Applications Submitted*** | | | | |
| *FY2012* | 307 | (3%) | $1,351,924,859 | (65%) |
| *FY2013* | 326 | 6% | $1,539,877,626 | 14% |
| *FY2014* | 235 | (28%) | $ 904,601,983 | (41%) |
| *FY2015* | 326 | 39% | $2,526,962,926 | 179% |
| *FY2016* | 320 | (2%) | $1,235,892,460 | (51%) |
| ***Final Decisions Issued*** | | | | |
| *FY2012* | 283 | (13%) | $1,199,672,761 | (72%) |
| *FY2013* | 309 | 9% | $1,285,622,324 | 7% |
| *FY2014* | 256 | (17%) | $1,140,856,082 | (11%) |
| *FY2015* | 316 | 23% | $2,322,741,030 | 104% |
| *FY2016* | 303 | (4%) | $1,314,654,311 | (43%) |

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

## AMENDMENTS

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

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

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

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

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

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

***TABLE 12***
*AMENDMENTS RECEIVED AND DECISIONS ISSUED*
*FY2012 - FY2016*

| | FY2012 | FY2013 | FY2014 | FY2015 | FY2016 |
|---|---|---|---|---|---|
| *Amendments Received* | 68 | 73 | 63 | 84 | 76 |
| *Amendment Decisions Issued* | 66 | 84 | 60 | 88 | 76 |
| *Percent Issued within Required Time Frame* | 100% | 100% | 99% | 100% | 97% |

## *NEW CERTIFICATE OF NEED CAPACITY*

**Table 13** provides a comparison of existing covered services, equipment and facilities already operational to new capacity approved in FY 2016. One hundred and ten (110) of the 303 CON approvals in FY 2016 were for new or additional capacity. The remaining approvals were for replacement equipment, relocation of existing services, acquisitions, renovations and other capital expenditures.

***TABLE 13***
*COVERED CLINICAL SERVICES AND BEDS*
*FY2016*

| *Covered Clinical Services/Beds* | Existing Sites | Existing Units/Beds | New Sites | New Units/Beds |
|---|---|---|---|---|
| ***Air Ambulances*** | 15 | 20 | 1 | 1 |
| ***Cardiac Catheterization Services*** | 69 | 224 | 0 | 7 |
| ***Primary PCI*** | 15 | N/A | 0 | N/A |
| ***Elective PCI**** | 0 | N/A | 10 | N/A |
| ***Open Heart Surgical Services*** | 34 | N/A | 0 | N/A |
| ***Surgical Services*** | 270 | 1,446 | 5 | 26 |
| ***CT Scanners Services*** | 469 | 561 | 42 | 46 |
| ***MRI Services*** | 329 | 248 | 5 | 3 |
| ***PET Services*** | 90 | 28 | 3 | 0 |
| ***Lithotripsy Services*** | 101 | 17 | 3 | 0 |
| ***MRT Services*** | 67 | 134 | 1 | 3 |
| ***Transplant Services*** | 8 | N/A | 0 | N/A |
| ***Hospitals*** | 184 | 26,440 | 1 | 62 |
| ***NICU Services*** | 22 | 632 | 0 | 0 |
| ***SCN Services*** | 13 | N/A | 1 | N/A |
| ***Extended Care Services Program (Swing Beds)*** | 36 | 326 | 1 | 6 |
| ***Nursing Homes/HLTCU*** | 508 | 52,537 | 0 | 148 |
| ***Psychiatric Hospitals/Units*** | 63 | 2,545 | 0 | 58 |
| ***Psychiatric Flex Beds*** | 3 | 44 | 0 | 0 |

*Note: Table 13 does not account for facilities closed, services or equipment no longer operational, or beds delicensed and returned to the various bed pools. New sites include mobile host sites for CT, Lithotripsy, MRI and PET services.*
** New service category for elective PCI at a site that already offers primary PCI service.*

## COMPLIANCE ACTIONS

**Table 14** shows there were 303 projects requiring follow-up for FY 2016 based on the Department's Monthly Follow-up/Monitoring Report as shown below.

| TABLE 14<br>FOLLOW UP AND COMPLIANCE ACTIONS<br>FY2012 - FY2016 | | | | | |
|---|---|---|---|---|---|
| | **FY2012** | **FY2013** | **FY2014** | **FY2015** | **FY2016** |
| *Projects Requiring 1-yr Follow-up* | 386 | 340 | 350 | 251 | 303 |
| *Approved CONs Expired* | 69 | 127 | 97 | 95 | 51 |
| *Compliance Orders Issued* | 2 | 1 | 6 | 30 | 10 |

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

## ANALYSIS OF CERTIFICATE OF NEED PROGRAM FEES AND COSTS

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

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

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

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

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

| ***TABLE 15A*** *NUMBER OF CON APPLICATIONS BY FEE FY2012 - FY2014* | | | |
|---|---|---|---|
| *CON Fee* | **FY2012** | **FY2013** | **FY2014** |
| *$ 0** | 2 | 6 | 0 |
| *$1,500* | 147 | 139 | 5 |
| *$5,500* | 96 | 97 | 8 |
| *$8,500* | 62 | 84 | 7 |
| *TOTAL* | 307 | 326 | 20 |

| ***TABLE 15B*** *NUMBER OF CON APPLICATIONS BY FEE FY2014 – FY2016* | | | |
|---|---|---|---|
| *CON Fee* | **FY2014** | **FY 2015** | **FY2016** |
| *$ 0** | 3 | 6 | 1 |
| *$3,000* | 103 | 146 | 166 |
| *$8,000* | 70 | 91 | 96 |
| *$11,000* | 23 | 36 | 27 |
| *$15,000* | 16 | 47 | 30 |
| *TOTAL* | 215 | 326 | 320 |

*Note*: Table 15A and 15B may not match fee totals in Table 16, as Table 16 accounts for refunds, overpayments, MFA funding, etc.

** No fees are required for emergency CON and swing beds applications.*

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

| ***TABLE 15C*** *NUMBER OF ADDITIONAL CON APPLICATIONS FEES FY2014 – FY2016* | | | |
|---|---|---|---|
| *CON Fee Category* | **FY2014** | **FY 2015** | **FY2016** |
| *Complex Project* | 8 | 3 | 0 |
| *Expedited Review* | 27 | 38 | 42 |
| *LOI Waiver** | 37 | 34 | 69 |
| *Amendment** | 32 | 44 | 54 |
| *Annual Survey (Facilities)* | 1,191 | 1,107 | 1,099 |

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

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

| ***TABLE 16*** *CON PROGRAM COST AND REVENUE SOURCES FOR FY2012– FY2016* | | | | | |
|---|---|---|---|---|---|
| | **FY2012** | **FY2013** | **FY2014** | **FY2015** | **FY2016** |
| *Program Cost* | $1,802,307 | $1,785,688 | $1,967,395 | $2,115,182 | $2,051,035 |
| *Fees/Funding* | $1,298,504 | $1,508,118 | $1,823,772 | $2,620,083 | $2,350,168 |
| *Fees % of Costs* | 72% | 84% | 93% | 100%+ | 100%+ |

*Source: MDHHS Budget and Finance Administration.*

## *CERTIFICATE OF NEED COMMISSION ACTIVITY*

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 received final approval by the CON Commission on March 16, 2016 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective May 27, 2016. The final language changes include the following:

- 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 15, 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 15, 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 21, 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 15, 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 15, 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 21, 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 15, 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 21, 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: At its September 21, 2016 meeting, the Commission assigned the Department to draft language for the December 7, 2016 CON Commission meeting. Review of standards to be finalized in FY2017.

## *APPENDIX I - CERTIFICATE OF NEED COMMISSION*

Marc D. Keshishian, MD, CON Commission Chairperson
Suresh Mukherji, MD, CON Commission Vice-Chairperson
Denise Brooks-Williams
Gail J. Clarkson, RN, NHA
Kathleen Cowling, DO
James B. Falahee, Jr., JD
Debra Guido-Allen, RN
Robert L. Hughes
Jessica A. Kochin
Gay L. Landstrom, RN (Appointment expired and replaced by Debra Guido-Allen)
Thomas Mittlebrun, III (Replaced Charles M. Gayney)
Luis A. Tomatis, MD

For a list and contact information of the current CON Commissioners, please visit our web site at **http://www.michigan.gov/con**.

DEPARTMENT OF

ATTORNEY GENERAL

# MEMORANDUM

December 1, 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 December 7, 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
Brenda Rodgers
Tulika Bhattacharya

**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

| | 2016 | | | | | | | | | | | | 2017 | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 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 | • | • | • | • | • | • R— | | | | | | | | | | | | |
| **Cardiac Catheterization Services** | | | | | | | | | | PC | | | • R A | | | | | | | | | | | |
| **Computed Tomography (CT) Scanner** | • R A | • | • | • | • | • R— | •P | • | •▲ F | | | | | | | | | | | | | | | |
| **Hospital Beds** | | | | | | | | | | PC | | | • R A | | | | | | | | | | | |
| **Magnetic Resonance Imaging (MRI) Services** | • | •P | •▲ F R— | • | •P | •▲ F | | | | | | | | | | | | | | | | | | |
| **Megavoltage Radiation Therapy (MRT) Services/Units** | | | | | | | | | | PC | | | • R A | | | | | | | | | | | |
| **Neonatal Intensive Care Services/Beds and Special Newborn Nursing Services** | • R A | • | • | • | • | • R— | •P | • | •▲ F | | | | | | | | | | | | | | | |
| **Nursing Home and Hospital Long-Term-Care Unit (NH-HLTCU) Beds**** | • R A | • | • A | • | • | • | • | • | • | • | • | • | | | | | | | | | | | | |
| **Open Heart Surgery (OHS) Services** | | | | | | | | | | PC | | | • R A | | | | | | | | | | | |
| **Positron Emission Tomography (PET) Scanner Services** | | | | | | | | | | PC | | | • R A | | | | | | | | | | | |
| **Psychiatric Beds and Services** | • | • | • R— | • P | • | •▲ | • P | • | •▲ F | | | | | | | | | | | | | | | |
| **Surgical Services** | | | | | | | | | | PC | | | • R A | | | | | | | | | | | |
| **Urinary Extracorporeal Shock Wave Lithotripsy Services** | • R A | • | • | • | • | • | • | • | • | • | • | • R— | •P | • | •▲ F | | | | | | | | | |
| **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) – 1/1/17** | | | | | | | | • | D • | • | • | • R | | | | | | | | | | | | |
| **FY2016 CON Annual Report** | | | | | | | | • | • | • | • | • 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 December 7, 2016**

Updated November 2, 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.