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

Thursday, March 21, 2019

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

APPROVED MINUTES

I. Call to Order & Introductions

Chairperson Falahee called the meeting to order at 9:32 a.m.

A. Members Present:

James B. Falahee, Jr., JD, Chairperson
Thomas Mittelbrun, Vice-Chairperson
Denise Brooks-Williams (arrived at 10:02 a.m.)
Lindsey Dood
Tressa Gardner, DO
Debra Guido-Allen, RN
Robert Hughes
Melanie LaLonde
Amy McKenzie, MD
Melisa Oca, MD

B. Members Absent:

Stewart Wang, MD

C. Department of Attorney General Staff:

Carl Hammaker

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

Tulika Bhattacharya
Amber Myers
Beth Nagel
Tania Rodriguez

II. Review of Agenda

Motion by Commissioner Mittelbrun, seconded by Commissioner Hughes to approve the agenda as presented. Motion carried.

III. Declaration of Conflicts of Interests

None.

IV. Review of Minutes of December 6, 2018

Motion by Commissioner Lalonde, seconded by Commissioner Mittelbrun to approve the minutes as presented. Motion carried.

V. Megavoltage Radiation Therapy Services/Units Standard Advisory Committee (MRTSAC) Final Report and Draft Language

MRTSAC Chairperson Brian Kastner, MD provided the report and presentation (Attachment A).

A. Public Comment

Tracy Dietz, Henry Ford Health System
David Walker, Spectrum Health

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Mittelbrun, seconded by Commissioner Gardner to take proposed action on the language (Attachment B) as presented and move forward to Public Hearing and to the Joint Legislative Committee (JLC). Motion carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

VI. Psychiatric Beds and Services – Public Hearing Summary

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

A. Public Comment

None.

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Mittelbrun seconded by Commissioner Guido-Allen to take final action on the language (Attachment D) as presented and move forward to the JLC and Governor for the 45-day review period. Motion carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

VII. Air Ambulance Services – October 5 – 19, 2018 Public Comment Period Summary & Report

Ms. Nagel gave an overview of the public comment period summary (Attachment E) and the Department's recommendations.

A. Public Comment

None.

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Brooks-Williams, seconded by Commissioner Hughes to accept the Department's recommendation as presented to continue regulation until the Department's Emergency Medical Services (EMS) Licensing can update its rules to include Air Ambulance specific requirements. Motion carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

VIII. Computed Tomography (CT) Scanner Services – October 5 – 19, 2018 Public Comment Period Summary & Report

Ms. Nagel gave an overview of the public comment period summary (Attachment F) and the Department's recommendations.

A. Public Comment

David Bloom, MD, Michigan Medicine

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Brooks-Williams, seconded by Commissioner Lalonde to accept the Department's recommendation as presented to continue regulation and to form a workgroup to make a recommendation regarding the maintenance volume, dedicated pediatric CT scanners definition, extending the exemption under Section 3(1) to 24-hour freestanding emergency departments. Motion carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

IX. Neonatal Intensive Care Services/Beds and Special Newborn Nursing Services (NICU and SNN) – October 5 – 19, 2018 Public Comment Period Summary & Report

Ms. Nagel gave an overview of the public comment period summary (Attachment G) and the Department's recommendations.

A. Public Comment

Sudhakar Ezhuthachan, MD, Henry Ford Health System
Marlena Hendershot, Sparrow Health System
Padma Karna, MD, Sparrow Health System

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Mittelbrun, seconded by Commissioner Oca to accept the Departments recommendation to create a Standard Advisory Committee (SAC) to review the issues identified; delegate to the chairperson to draft the charge and seat the SAC. Motion carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

X. Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups (NH-HLTCU) – October 5 – 19, 2018 Public Comment Period Summary & Report

Ms. Nagel gave an overview of the public comment period summary (Attachment H) and the Department's recommendations.

A. Public Comment

Walt Wheeler, Wheeler Associates
Pat Anderson, Health Care Association of Michigan (HCAM)

B. Commission Discussion

Discussion follows.

C. Commission Action

Motion by Commissioner Dood, seconded by Commissioner Mittelbrun to accept the Departments recommendation to create a SAC to review the issues identified by the Department in the summary report except the review of definitions for nursing home beds and other parts of the Standards to make it clearer that existing nursing home beds include nursing homes and nursing home beds that are non-operational or unavailable for occupancy when they are licensed under a building program agreement approved by the Michigan Department of Licensing and Regulatory Affairs (LARA) pursuant to section 20144 of the Public Health Code; delegate to the chairperson to draft the charge and seat the SAC. Motion carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

XI. Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services/Units Services – October 5 – 19, 2018 Public Comment Period Summary & Report

Ms. Nagel gave an overview of the public comment period summary (Attachment I) and the Department's recommendations.

A. Public Comment

Marlena Hendershot, Sparrow Health System

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Brooks-Williams, seconded by Commissioner McKenzie to accept the Departments recommendation and have the Department draft language to review at a future meeting for the issues identified. Motion carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

XII. Psychiatric Beds and Services Workgroup Interim Report (Written Only)

Chairperson Falahee mentioned the written report (Attachment J) from Laura Hirshbein, MD, PhD, Psychiatric Beds and Services Workgroup Chairperson.

XIII. Bone Marrow Transplantation Services Standard Advisory Committee (BMTSAC) Interim Report (Verbal)

Chairperson Falahee provided a verbal report on behalf of BMTSAC Co-Chairpersons Philip J. Stella, MD and Joseph Uberti, MD.

XIV. Administrative Update

A. Planning & Access to Care Section Update

Ms. Nagel provided an update.

B. CON Evaluation Section Update

Ms. Bhattacharya provided an update on the following items:

1. Compliance Report (Attachment K)
2. Quarterly Performance Measures (Attachment L)
3. FY 2018 Annual Activity Report (Attachment M)

XV. Legal Activity Report

Mr. Hammaker provided an update on the CON legal activity (Attachment N).

XVI. Future Meeting Dates: June 13, 2019, September 19, 2019, and December 5, 2019

XVII. Public Comment

None.

XVIII. Review of Commission Work Plan

Ms. Nagel provided an overview of the changes to the Work Plan including actions taken at today's meeting (Attachment O).

A. Commission Discussion

None.

B. Commission Action

Motion by Commissioner Guido-Allen, seconded by Commissioner Brooks-Williams to accept the Work Plan as presented with updates from today's meeting. Motion carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

XIX. Election of Officers

Motion by Commissioner Guido-Allen, seconded by Commission Gardner, to nominate and elect Commissioner Falahee as the Chairperson and Commissioner Mittelbrun as Vice-Chairperson of the Commission. Motion Carried in a vote of 10 - Yes, 0 - No and 0 - Abstained.

XX. Adjournment

Motion by Commissioner Mittelbrun, seconded by Commissioner Lalonde to adjourn the meeting at 11:44 a.m. Motion Carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

FINAL REPORT FROM THE MRT SAC

To: CON Commission
From: Brian Kastner, MD
MRT SAC Chair
Date: March 21, 2019 CON Commission meeting
RE: MRT SAC Report

The CON Commission gave two charges to the SAC: treatment weightings and volume requirements. The SAC approached the question of treatment weightings by first agreeing that **weightings should reflect MRT utilization time**. The SAC agreed to **maintain a 15-minute base unit** for the equivalent treatment visit (ETV) to both preserve consistency with previous standards and to simplify evaluation of the impact of any subsequently proposed volume standards. Secondly, we **conducted a survey** to determine the standard or average time required to deliver treatments of varying complexity. Thereafter, the SAC **revised the weightings** to reflect the results of this survey. The SAC provided clarification to definitions regarding MR-guided radiotherapy and patient-specific quality assurance for stereotactic procedures.

In discussion of volume requirements, the SAC discussed the changing practice patterns trending toward hypo-fractionated and accelerated treatment courses. This trend **has lowered the logistical and financial burden on patients and payers** while at the same time **preserving, and even improving, quality**. Stated differently, the **adoption of hypo-fractionation is improving the metrics of cost, quality and access**. However, adoption of hypo-fractionation has also **contributed to lower utilization of MRT units to the point that many centers were failing to meet minimum volume requirements**. In consideration of the Minimum volume, we observed that the current 8000 ETV minimum assumed 8-hour-per-day of continuous treatment. While one may argue 8000 to be a reasonable initiation volume, we felt this to be unreasonably high for a minimum volume. After thorough discussion of cost, quality and access, we agreed that any unit delivering at least **4000 ETV** per year should be considered as meeting **minimum volume**. The SAC subsequently produced a consensus statement in this regard (see attached).

We also considered volume requirements for MRT replacement, initiation and expansion. The discussion regarding these volumes included express consideration of cost, quality and access. The SAC concluded that further consideration of changes to replacement, initiation and expansion volumes should await potential impact from implementation of our proposed changes to the weighting and minimum volume standards.

Attachment to MRT SAC Final Report 3-21-19

STATEMENT

Given the complexities of the charge we face with updating the weights and volumes, I believe it is advisable to provide a statement to the CON Commission that clearly articulates why we are recommending a 4,000 ETV Minimum or Maintenance volume. In my opinion, this is best done by voting on a statement, a "Sense of the SAC", that puts on record the rationale behind the recommendation. To that end, I would like to make the following motion:

MOTION

I move that the members of the SAC adopt the following statement to be incorporated into the Chairman's final report to the CON Commission:

We, the members of the 2018 MRT Standard Advisory Committee, wish to convey the rationale behind the SAC's recommendation to decrease the maintenance volume for a non-special MRT unit to 4,000 ETVs. We view the maintenance volume as the minimum level of operations at which a MRT service justifies its continued existence. Radiation Oncology departments operate in the outpatient setting, caring for fragile patients, and therefore typically operate 8 hours per day with the potential to generate as much as 8,000 ETVs per year per unit within the confines of this typical clinic schedule. The current Maintenance Volume requirement (8,000 ETV requirement) requires a unit to operate at 100% utilization just to maintain compliance with CON regulations. This requirement fails to acknowledge the fact that patients and machines are unpredictable, and that any operation that includes human involvement simply cannot sustain 100% utilization, even outside of the healthcare setting. Understanding that 4,000 ETVs equates to approximately 4 hours per day of treatment time, and that 4 hours per day of treatment time equates to approximately 5 to 6 hours of operational time, we believe 4,000 ETVs per unit per year is a more appropriate Maintenance volume for the following reasons:

Cost: Once a CON for a MRT unit has been approved and implemented, a majority of the costs have already been incurred by the system – constructing the space, purchasing the unit, etc. Closing a unit that has already been paid for and is operating at a volume at or above 4,000 ETVs per year only serves to decrease access not save costs. Fining a unit that is operating at a reasonable volume (between 4000 – 8000 ETVs) also adds to the cost of providing the service. However, operating a unit with very low utilization could increase the cost per treatment, and therefore we believe 4,000 to be an appropriate Maintenance Volume requirement.

Quality: Although no specific studies have shown a specific level of utilization needed to ensure quality, the SAC agreed that delivering as low as 4,000 ETVs per unit should not compromise quality. In fact, the average utilization of MRT units nationally, according to the American Society for Radiation Oncology (ASTRO), is between 40% and 60%, demonstrating that the proposed 50% utilization Maintenance Volume should not put Michigan's patients at risk.

Access: New patients are diagnosed with cancer every day and it important that they have access to timely treatment. Requiring all MRT services to operate at 100% utilization (the current requirement) leaves little room to accommodate new patients. In addition, closing, sanctioning or fining all programs

operating below 100% utilization could create a massive access problem across the State. Setting an appropriate maintenance volume will help to ensure continued access.

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

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR MEGAVOLTAGE RADIATION THERAPY (MRT) SERVICES/UNITS

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

Section 1. Applicability

Sec. 1. These standards are requirements for approval to initiate, replace, expand, or acquire an MRT service under Part 222 of the Code. MRT services and units are a covered clinical service pursuant to Part 222 of the Code. The Department shall use these 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) "Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

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

(c) "Dedicated stereotactic radiosurgery/STEROTACTIC BODY RADIATION THERAPY (SRS/SBRT) unit" means an MRT unit for which more than 90 percent of cases will be treated with radiosurgery AND/OR SBRT.

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

(e) "Equivalent treatment visit" or "ETV" means a unit of measure, based on the type of treatment visit that reflects the relative average length of time one patient spends in one treatment visit in an MRT unit.

(f) “Excess ETVs” means the number of ETVs performed by an existing MRT service in excess of 10,000 per MRT unit. The number of MRT units used to compute excess ETVs shall include both existing and approved but not yet operational MRT units. In the case of an MRT service that operates or has a valid CON to operate that has more than one MRT unit at the same site; the term means number of ETVs in excess of 10,000 multiplied by the number of MRT units at the same site. For example, if an MRT service operates, or has a valid CON to operate, two MRT units at the same site, the excess ETVs is the number that is in excess of 20,000 (10,000 x 2) ETVs.

(g) "Existing MRT service" means a CON approved and operational facility and equipment used to provide MRT services including but not limited to the simulator(s), block fabrication materials, and all existing MRT units at a geographic location(s).

(h) "Existing MRT unit" means a CON approved and operational equipment used to provide MRT services.

(i) "Heavy particle accelerator" means a machine such as a cyclotron which produces beams of high energy particles such as protons, neutrons, pions, carbon ions, or other heavy ions with masses greater than that of an electron.

(j) "High MRT unit" or "HMRT unit" means a heavy particle accelerator or any other MRT unit operating at an energy level equal to or greater than 30.0 million electron volts (megavolts or MEV).

(k) "Intensity modulated radiation therapy" or "IMRT" means a visit utilizing only the computer controlled multi-leaf collimator part of the CMS definition for IMRT.

(l) "Intraoperative MRT unit" or "IORT unit" means an MRT unit that is designed to emit only electrons, located in an operating room in the surgical department of a licensed hospital and available for the treatment of a patient undergoing a surgical procedure with megavoltage radiation.

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

(n) "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.

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

(p) "MRT unit" or "unit" means a CON approved linear accelerator; cobalt unit; or other piece of medical equipment operating at an energy level equal to or greater than 1.0 million electron volts (megavolts or MEV) for the purpose of delivering doses of radiation to patients with cancer, other neoplasms, or cerebrovascular system abnormalities.

(q) "Michigan Cancer Surveillance Program" means the program for the collection and analysis of information on cancer in Michigan operated by the Department mandated by Act 82 of 1984, being Section 333.2619 of the Michigan Compiled Laws.

(r) "Non-special MRT unit" or "non-special unit" means an MRT unit other than an MRT unit meeting the definition of a special purpose MRT unit or an HMRT unit.

(s) "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.

(t) "Special purpose MRT unit" or "special purpose unit" or "special unit" means any of the following types of MRT units: (i) dedicated ~~stereotactic radiosurgery~~SRS/SBRT unit, (ii) dedicated total body irradiator (TBI), or (iii) an OR-based IORT unit.

(u) "Total body irradiator" or "TBI" means a specially modified dedicated cobalt unit certified as a total body irradiator by the Nuclear Regulatory Commission (NRC) or a permanently modified dedicated linear accelerator that uses a very wide beam of gamma rays or x-rays to irradiate the entire body simultaneously.

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

(w) "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.

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

Section 3. Requirements to initiate an MRT service

Sec. 3. Initiate means the establishment of an MRT service where an MRT service is not currently provided. The term does not include replacement of an existing MRT service. An applicant proposing to initiate an MRT service shall demonstrate the following, as applicable to the proposed project.

(1) An applicant proposing to initiate an MRT service shall demonstrate the following:
(a) The applicant projects 8,000 equivalent treatment visits for each proposed unit.
(b) The proposed MRT unit is not a special purpose MRT unit.

(2) An applicant that demonstrates all of the following shall not be required to be in compliance with the requirement in subsection (1):
(a) The site of the proposed MRT service is located in a rural or micropolitan statistical area county.
(b) The site of the proposed MRT service is 60 driving miles or more, verifiable by the Department, from the nearest MRT service.
(c) The applicant projects 5,500 equivalent treatment visits for each proposed unit.
(d) The proposed MRT unit is not a special purpose MRT unit.

(3) An applicant that demonstrates all of the following shall not be required to be in compliance with the requirement in subsection (1):
(a) The applicant is a hospital licensed under part 215 of the Code.

(b) The site of the proposed MRT service is a hospital licensed under part 215 of the Code and located in planning area 8.

(c) The site of the proposed MRT service is 90 driving miles or more, verifiable by the department, from the nearest MRT service.

(d) The applicant provides comprehensive imaging services including at least the following:

(i) Fixed magnetic resonance imaging (MRI) services,

(ii) Fixed computed tomography (CT) services, and

(iii) Mobile positron emission tomography (PET) services.

(e) The proposed MRT unit is not a special purpose MRT unit.

(4) An applicant proposing to initiate an MRT service with an HMRT unit shall demonstrate the following:

(a) The applicant is a single legal entity authorized to do business in the State of Michigan.

(b) The applicant is a collaborative that consists of at least 40% of all Michigan-based hospital MRT services with more than 30,000 equivalent treatment visits based on the most current data available to the Department. Hospital MRT service means an MRT service owned by a hospital or owned by a corporation that is itself wholly owned by hospital(s).

(c) The applicant shall include hospital MRT services from more than one planning area from one or both of the following:

(i) Hospital MRT services qualified under subsection (b).

(ii) Hospital MRT services with the highest number of equivalent treatment visits in a planning area.

(d) Equivalent treatment visits for this subsection shall be those from the most recent CON Annual Survey.

(e) An application shall not be approved if it includes an MRT service described in subsection (i) or (ii) except as provided in subsections (iii) or (iv).

(i) An MRT service that was part of another application under this subsection.

(ii) An MRT service owned by, under common control of, or has a common parent, as an MRT service under subsection (i).

(iii) The prior application, or the approved CON, were subsequently disapproved or withdrawn.

(iv) The application includes a commitment from the MRT service described in subsection (i) to surrender the CON, or application, described in subsection (i) and that commitment is fulfilled at the time the application under this section is approved.

(f) An application shall not be approved if it includes any of the following:

(i) An MRT service that is approved but not operational, or that has a pending application, for a heavy particle accelerator.

(ii) An MRT service that is owned by, under common control of, or has a common parent, as an MRT service described by subsection (i), unless the application under this subsection includes a commitment from the MRT service described in subsection (i) to surrender the CON, or application, described in subsection (i) and that commitment is fulfilled at the time the application under this section is approved.

(g) An application shall not be approved if it includes any of the following:

(i) An MRT service that is approved for a heavy particle accelerator that is operational.

(ii) An MRT service that is owned by, under common control of, or has a common parent, as an MRT service described by subsection (i), unless the application under this section includes a commitment from the MRT service described in subsection (i) to surrender the CON described in subsection (i), and that commitment is fulfilled at the time the HMRT unit is approved and operational under this subsection.

(h) The applicant shall provide documentation of its process, policies and procedures, acceptable to the Department that allows any other interested entities to participate in the collaborative utilization of the HMRT unit.

(i) The applicant shall provide an implementation plan, acceptable to the Department, for financing and operating the MRT service utilizing an HMRT that includes how physician staff privileges, patient review, patient selection, and patient care management shall be determined.

(j) The applicant shall indicate that its proposed HMRT unit will be available to both adult and pediatric patients.

(k) The applicant shall demonstrate simulation capabilities available for use in treatment planning.

(5) Applicants under this section shall demonstrate the following staff will be provided:
(a) One (1) FTE board-certified or board-qualified physician trained in radiation oncology.
(b) One (1) board-certified or board-qualified radiation physicist certified in therapeutic radiologic physics.
(c) One (1) dosimetrist, a person who is familiar with the physical and geometric characteristics of the radiation equipment and radioactive sources commonly employed and who has the training and expertise necessary to measure and generate radiation dose distributions and calculations under the direction of a medical physicist and/or a radiation oncologist.
(d) Two (2) FTE radiation therapists registered or eligible by the American Registry of Radiological Technologists (ARRT).
(e) One (1) program director who is a board-certified physician trained in radiation oncology who may also be the physician required under subsection (5)(a).

Section 4. Requirements to replace an existing MRT unit or service

Sec. 4. Replacement of an existing MRT unit means an equipment change that results in a new serial number or requiring the issuance of a new radiation safety certificate from the State of Michigan Radiation Safety Section. Replacement also means the relocation of an MRT service or unit to a new site. Replacement does not include an upgrade to an existing MRT unit with the addition or modification of equipment or software; the replacement components; or change for the purpose of maintaining or improving its efficiency, effectiveness, and/or functionality. An applicant requesting to replace an existing MRT unit(s) or MRT service shall demonstrate the following, as applicable to the proposed project.

(1) An applicant proposing to replace an existing MRT unit(s) shall demonstrate the following:
(a) The replacement unit(s) is a non-special unit and is replacing a non-special unit, or is a special purpose unit and is replacing a non-special purpose unit or a special purpose unit.
(b) The MRT unit(s) to be replaced is fully depreciated according to generally accepted accounting principles or either of the following:
(i) The existing MRT unit(s) poses a threat to the safety of the patients.
(ii) The replacement MRT unit(s) offers technological improvements that enhance quality of care, increased efficiency, and a reduction in operating costs and patient charges.
(c) The applicant agrees that the unit(s) to be replaced will be removed from service on or before beginning operation of the replacement unit(s).
(d) The site at which a special purpose unit is replaced shall continue to operate a non-special purpose unit.

(2) An applicant proposing to replace an existing MRT service to a new site shall demonstrate the following:
(a) The proposed site is within the same planning area as the existing MRT service site.
(b) The existing MRT unit(s) shall be operating at the following volumes, as applicable to the proposed project:
(i) Non-special MRT unit(s) at 8,000 equivalent treatment visits per unit or 5,500 for a unit approved under Section 3(2) or 3(3).
(ii) HMRT unit(s) AT 8,000 equivalent treatment visits per unit.
(iii) Special purpose unit(s) at 1,000 equivalent treatment visits per unit.

(3) An applicant proposing to replace an MRT unit(s) of an existing MRT service to a new site shall demonstrate the following:
(a) The applicant is the same legal entity as the existing MRT service.
(b) For volume purposes, the new site shall remain associated with the existing MRT service for a minimum of three years.
(c) The MRT unit(s) to be relocated is a non-special MRT unit(s).
(d) The existing non-special MRT unit(s) of the MRT services from where the unit is being relocated from shall be operating at a minimum average volume of 8,000 equivalent treatment visits per unit.
(e) The proposed site meets the requirements of Section 3(5).

(f) The proposed site is within the same planning area as the existing MRT service site.
(g) The existing MRT service has been in operation for at least 36 months as of the date the application was submitted to the Department.

Section 5. Requirements to expand an existing MRT service

Sec. 5. An applicant proposing to expand an existing MRT service by adding an MRT unit(s) shall demonstrate the following, as applicable to the proposed project.

(1) An applicant proposing to add a non-special MRT unit(s) shall demonstrate an average of 10,000 equivalent treatment visits was performed in the most recent 12-month period on each of the applicant's existing and approved non-special MRT units.

(2) An applicant proposing to expand an existing MRT service with a special purpose MRT unit shall demonstrate the following, as applicable to the proposed project:
(a) An average of 8,000 equivalent treatment visits was performed in the most recent 12-month period on each of the applicant's existing and approved non-special MRT units and an average of 1,000 equivalent treatment visits was performed in the most recent 12-month period on each of the applicant's existing and approved special purpose MRT units.
(b) An applicant proposing to add a dedicated total body irradiator shall operate a bone marrow transplantation program or have a written agreement to provide total body irradiation services to a hospital that operates a bone marrow transplantation program.
(c) An applicant proposing to add an intraoperative MRT unit in an existing or proposed hospital operating room shall demonstrate that the unit is a linear accelerator with only electron beam capabilities.

Section 6. Requirements to acquire an existing MRT service

Sec. 6. Acquiring an existing MRT service means obtaining possession and control by contract, ownership, lease, or another comparable arrangement and renewal of lease for an existing MRT unit(s). An applicant proposing to acquire an MRT service shall demonstrate the following, as applicable to the proposed project.

(1) An application for the first acquisition of an existing MRT service, other than the renewal of a lease, on or after November 21, 2011, shall not be required to be in compliance with the applicable volume requirements set forth in Section 11. The MRT service shall be operating at the applicable volumes set forth in the project delivery requirements in the second 12 months of operation of the service by the applicant and annually thereafter.

(2) For any application proposing to acquire an existing MRT service, except the first application approved pursuant to subsection (1), an applicant shall be required to document that the MRT service to be acquired is operating in compliance with the volume requirements set forth in Section 11 of these standards applicable to an existing MRT service on the date the application is submitted to the Department.

(3) An applicant proposing to renew a lease for an existing MRT unit shall demonstrate the renewal of the lease is more cost effective than replacing the equipment.

Section 7. Requirements for a dedicated research MRT unit(s)

Sec. 7. An applicant proposing to add a dedicated research MRT unit shall demonstrate the following:

(1) The applicant is an existing MRT service.

(2) The applicant agrees that the dedicated research MRT unit(s) will be used primarily (70% or more of treatments) for research purposes.

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

(4) The applicant operates a therapeutic radiation residency program approved by the American Medical Association, the American Osteopathic Association, or an equivalent organization.

(5) The proposed site can have no more than two dedicated research MRT units.

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 services, if a CON is approved.

Section 9. Methodology for projecting equivalent treatment visits

Sec. 9. An applicant being reviewed under Section 3 shall apply the methodology set forth in this section in computing the projected number of equivalent treatment visits.

(1) An applicant shall demonstrate that the projection is based on the commitments of the treatments provided by the treating physician(s) for the most recent 12-month period immediately preceding the date of the application. The commitments of the treating physician(s) will be verified with the data maintained by the Department through its “CON Annual Survey.”
(a) For the purposes of this section, treating physician means the staff physician of the MRT service directing and providing the MRT treatment, not the referring physician.

(2) An applicant shall demonstrate that the projected number of commitments to be performed at the proposed site under subsection (1) are from an existing MRT service that is in compliance with the volume requirements applicable to that service and will continue to be in compliance with the volume requirements applicable to that service subsequent to the initiation of the proposed MRT service by an applicant. Only excess ETVs equal to or greater than what is being committed pursuant to this subsection may be used to document projections under subsection (1). In demonstrating compliance with this subsection, an applicant shall provide each of the following:
(a) A written commitment from each treating physician that he or she will treat at least the volume of MRT treatments to be transferred to the proposed MRT service for no less than 3 years subsequent to the initiation of the MRT service proposed by an applicant.
(b) The number of treatments committed must have resulted in an actual treatment of the patient at the existing MRT service from which the treatment will be transferred. The committing physician must make available HIPAA compliant audit material if needed upon Department request to verify referral sources and outcomes. Commitments must be verified by the most recent data set maintained by the Department through its “CON Annual Survey.”
(c) The projected commitments are from an existing MRT service within the same planning area as the proposed MRT service.

Section 10. Equivalent treatment visits

Sec. 10. Equivalent treatment visits shall be calculated as follows:

(1) For the time period specified in the applicable sections, assign each actual treatment visit provided to one applicable treatment visit category set forth in Table 1.

(2) The number of treatment visits for each category in the time period specified in the applicable section(s) of these standards shall be multiplied by the corresponding equivalent treatment visits weight in Table 1 to determine the number of equivalent treatment visits for that category for that time period.

(3) The number of equivalent treatment visits for each category determined pursuant to subsection (2) shall be summed to determine the total equivalent treatment visits for the time period specified in the applicable sections of these standards.

(4) THE WEIGHTING IN TABLE 1 IS BASED ON TYPICAL TREATMENT TIMES AND ASSUMES AN ETV EQUALS APPROXIMATELY 15 MINUTES OF TIME ON THE MRT UNIT.

TABLE 1
Equivalent Treatments

Treatment Visit Category	Non-Special Visit Weight	Special Visit Weight
Simple	~~1.00~~.66	
Intermediate	1.~~1~~000	
Complex	~~1.25~~2.00	
IMRT	~~2.00~~1.66	
Total Body Irradiation	~~8~~5.00	~~8~~5.00
HMRT Therapy		~~5.00~~3.33
Stereotactic radio-surgery/radio-therapy*	~~8~~4.00	~~8~~4.00
IORT		20.00

All patients under 5 years of age receive a 2.00 additive factor.

Gating receives a 1.00 additive factor. Gating is the capturing and monitoring of the target's or fiducial's motion during radiation treatment and the modulation of the radiation beam in order to more precisely deliver radiation to the target and/or decrease the radiation dose to the surrounding normal tissue.

MR-GUIDED REAL TIME TRACKING RADIATION W/O ADAPTIVE RECEIVES A 2.00 ADDITIVE FACTOR. MR-GUIDED REAL TIME TRACKING RADIATION W/O ADAPTIVE MEANS A VISIT INVOLVING AN INTEGRATED MRI/MRT UNIT PROVIDING MR IMAGES IN THE TREATMENT ROOM BEFORE AND DURING AN MRT TREATMENT OF ANY COMPLEXITY.

MR-GUIDED REAL TIME TRACKING RADIATION WITH ADAPTIVE RECEIVES A 3.00 ADDITIVE FACTOR. MR-GUIDED REAL TIME TRACKING RADIATION WITH ADAPTIVE MEANS A VISIT INVOLVING AN INTEGRATED MRI/MRT UNIT PROVIDING MR IMAGES IN THE TREATMENT ROOM BEFORE AND DURING AN MRT TREATMENT OF ANY COMPLEXITY; ALONG WITH CREATION, EVALUATION AND DELIVERY OF A NEW RADIATION THERAPY PLAN WHILE THE PATIENT REMAINS IN THE TREATMENT ROOM.

PATIENT SPECIFIC QA FOR IMRT RECEIVES A 2.0 ADDITIVE FACTOR, NOT TO EXCEED TWICE PER COURSE OF TREATMENT. PATIENT SPECIFIC QA FOR IMRT MEANS VERIFICATION OF RADIATION DELIVERED DOSE AND/OR FLUENCE THROUGH PHYSICAL MEASUREMENT WITH A DOSIMETRY PHANTOM AND/OR DETECTOR ARRAY IN THE TREATMENT ROOM. PRIOR TO THE START OF TREATMENT AND USING ALL OF THE PARAMETERS OF THE PATIENT'S TREATMENT PLAN, ONE OR MORE POINTS IN THE DELIVERED DISTRIBUTION SHOULD BE COMPARED AGAINST THE PLANNED DISTRIBUTION.

PATIENT SPECIFIC QA FOR SRS/SBRT RECEIVES A 3.0 ADDITIVE FACTOR, NOT TO EXCEED TWICE PER COURSE OF TREATMENT. PATIENT SPECIFIC QA FOR SRS/SBRT MEANS VERIFICATION OF RADIATION DELIVERED DOSE AND/OR FLUENCE THROUGH PHYSICAL MEASUREMENT WITH A DOSIMETRY PHANTOM AND/OR DETECTOR ARRAY IN THE

TREATMENT ROOM. PRIOR TO THE START OF TREATMENT AND USING ALL OF THE PARAMETERS OF THE PATIENT'S TREATMENT PLAN, ONE OR MORE POINTS IN THE DELIVERED DISTRIBUTION SHOULD BE COMPARED AGAINST THE PLANNED DISTRIBUTION.

* After the first isocenter, each additional isocenter receives ~~6~~ 1.33 equivalent treatment visits. There is a maximum of five visits per course of therapy.

(4) "Simple treatment visit" means a treatment visit involving a single treatment site, single treatment field, or parallel opposed fields with the use of no more than simple blocks.

(5) "Intermediate treatment visit" means a treatment visit involving two separate treatment sites, three or more fields to a single treatment site, or the use of special blocking.

(6) "Complex treatment visit" means a treatment visit involving three or more treatment sites, tangential fields with wedges, rotational or arc techniques or other special arrangements, or custom blocking.

(7) "IMRT treatment visit" means a visit utilizing only the computer controlled multi-leaf collimator part of the CMS definition for IMRT.

(8) "Stereotactic treatment visit" means a visit involving the use of a stereotactic guiding device with radiotherapy for the ablation of a precisely defined intracranial and/or extracranial tumor or lesion.

(9) "Intraoperative treatment visit" means a treatment visit where a dose of megavoltage radiation is delivered to a surgically exposed neoplasm or cancerous organ/site using a dedicated unit.

(10) "Isocenter" means the virtual point in space about which the MRT unit operates and is placed at the center of the tumor for the delivery of the radiation treatment.

(11)"Course of treatment" means the planned series of visits that compose a plan for treatment of one or more cancer sites for a single patient.

Section 11. Project delivery requirements terms of approval for all applicants

Sec. 11. An applicant shall agree that, if approved, the MRT service, including all existing and approved MRT units, shall be delivered in compliance with the following:

(1) Compliance with these standards.

(2) Compliance with the following quality assurance standards:

(a) An applicant shall assure that the MRT service is staffed and operated by physicians and/or radiation therapists qualified by training and experience to operate the unit safely and effectively. The Department shall consider it prima facie evidence if the applicant requires the equipment to be operated by a physician who is board certified or board qualified in either radiation oncology or therapeutic radiology, and/or a radiation therapist certified by the American Registry of Radiological Technologists (ARRT) or the American Registry of Clinical Radiography Technologists (ARCRT). The applicant may also submit, and the Department may accept, other evidence.

(b) An applicant shall have the following staff:

(i) One (1) full-time equivalent (FTE) board-certified or board- qualified physician trained in radiation oncology for each 250 patients treated with MRT annually.

(ii) One (1) FTE board-certified or board-qualified radiation physicist, certified in therapeutic radiologic physics, immediately available during hours of operation.

(iii) One (1) dosimetrist for every 300 patients treated with MRT annually.

(iv) Two (2) radiation therapists registered or eligible by the American Registry of Radiological Technologists (ARRT), for every MRT unit per shift of operation (not including supervisory time).

(v) One (1) FTE program director who is a board-certified physician trained in radiation oncology who may also be the physician required under subsection (i). The Department shall consider it prima facie evidence as to the training of the physician(s) if the physician is board certified or board qualified in radiation oncology and/or therapeutic radiology.

(c) All MRT treatments shall be performed pursuant to a radiation oncologist and at least one radiation oncologist will be immediately available during the operation of the unit(s).

(d) An applicant shall have equipment and supplies to handle clinical emergencies that might occur. Staff will be trained in CPR and other appropriate emergency interventions and shall be on-site in the MRT unit at all times when patients are treated. A physician shall be on-site or immediately available to the MRT unit at all times when patients are treated.

(e) An applicant shall operate a cancer treatment program. The Department shall consider it prima facie evidence if the applicant submits evidence of a cancer treatment program approved by the American College of Surgeons Commission on Cancer. A cancer treatment program is a coordinated, multi-disciplinary approach to the treatment of patients with cancer or other neoplasms, which must provide on-site simulation capability, and, either on-site or through written agreements with other providers, all of the following services: access to consultative services from all major disciplines needed to develop a comprehensive treatment plan, a computer-based treatment planning system, medical radiation physicist involvement, MRT capability including electron beam capability, treatment aid fabrication capability, brachytherapy, a multi-disciplinary cancer committee, a tumor registry, patient care evaluation studies, and cancer prevention and education programs. The applicant may also submit, and the Department may accept, other evidence. Patient care evaluation studies means a system of patient care evaluation, conducted at least twice annually, that documents the methods used to identify problems and the opportunities to improve patient care. Tumor registry means a manual or computerized data base containing information about all malignancies and only those that are diagnosed and/or treated at the applicant's facility. The malignancies must be reportable to the Michigan Cancer Surveillance Program as required pursuant to Public Act 82 of 1984, as amended.

(i) An applicant shall submit evidence of accreditation by the American College of Surgeons Commission on cancer, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), or the Healthcare Facilities Accreditation Program (HFAP) within the first three years of operation and continue to participate annually thereafter.

(ii) An applicant shall submit evidence of accreditation by the American College of Radiology (ACR), American Society for Radiation Oncology (ASTRO) or the American College of Radiation Oncology (ACRO) within the first three years of operation and continue to participate annually thereafter.

(f) The MRT service will have simulation capability at the same location.

(g) An applicant shall participate in the Michigan Cancer Surveillance Program.

(h) The applicant agrees to operate a special purpose MRT unit(s) only for the specific use for which it was approved.

(i) An applicant approved to operate a dedicated total body irradiator that uses cobalt as the source of radiation shall obtain and maintain Nuclear Regulatory Commission certification. An applicant approved to operate a dedicated total body irradiator that is a permanently modified linear accelerator, or an HMRT unit, shall meet any requirements specified by the State of Michigan Radiation Safety Section.

(j) All patients treated on an HMRT unit shall be evaluated for potential enrollment in research studies focusing on the applicability and efficacy of utilizing an HMRT unit for treatment of specific cancer conditions. The number of patients treated, number enrolled in research studies, and the types of cancer conditions involved shall be provided to the Department as part of the CON Annual Survey.

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

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

(a) The applicant shall accept referrals for MRT services from all appropriately licensed health care practitioners.

(b) To assure that the MRT service and its unit(s) will be utilized by all segments of the Michigan population, the applicant shall:

(i) not deny MRT services to any individual based on ability to pay or source of payment,

(ii) provide MRT services to an individual based on the clinical indications of need for the service, and

(iii) maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually. Compliance with selective contracting requirements shall not be construed as a violation of this term.

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

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

(a) Non-special MRT units ~~and HMRT units~~ shall be operating at a minimum average volume of ~~8~~4,000 Equivalent Treatment Visits per unit annually by the end of the third full year of operation, and annually thereafter. HMRT units shall be operating at a minimum average volume of 8,000 Equivalent Treatment Visits per unit annually by the end of the third full year of operation, and annually thereafter. All special purpose MRT units shall be operating at a minimum average volume of 1,000 equivalent treatment visits per special purpose unit by the end of the third full year of operation, and annually thereafter. An applicant shall not include any treatments conducted on a dedicated research MRT unit.

(b) ~~Non-special MRT units and~~ HMRT units approved pursuant to Section 3(2) or 3(3) of these standards shall be operating at a minimum average volume of 5,500 equivalent treatment visits per unit by the end of the third full year of operation, and annually thereafter. An applicant shall not include any treatments conducted on a dedicated research MRT unit.

(c) An applicant is not required to be in compliance with subsections (4)(a) or (b) if the applicant is replacing an MRT unit under ~~section~~ Section 4(1).

(d) An applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to, annual budget and cost information, operating schedules, through-put schedules, demographic and diagnostic information, and the volume of care provided to patients from all payor sources and other data requested by the Department. Data shall be provided by each type of MRT unit in a format established by the Department and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(e) Services provided on a dedicated research MRT unit shall be delivered in compliance with the following terms:

(i) Capital and operating costs for research treatment visits shall be charged only to a specific research account(s) and not to any patient or third-party payor.

(ii) The dedicated research MRT unit shall not be used for any purposes other than as approved by the IRB.

(iii) The treatments on a dedicated research MRT unit shall not be used for any volume purposes.

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

Section 12. Effect on prior CON review standards; comparative reviews

Sec. 12. Proposed projects reviewed under these standards shall not be subject to comparative review. These standards supersede and replace the CON Review Standards for MRT Services/Units approved by the CON Commission on ~~March 28, 2013~~JUNE 11, 2015 and effective ~~May 24, 2013~~SEPTEMBER 14, 2015.

APPENDIX A

PLANNING AREAS BY COUNTY

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

APPENDIX B

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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

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

Date: March 4, 2018

TO: The Certificate of Need (CON) Commission

FROM: Brenda Rogers, Special Assistant to the CON Commission, Office of Planning, CON Policy, MDHHS

RE: Summary of Public Hearing Comments on Psychiatric Beds and Services Standards

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Public Hearing Testimony

Pursuant to MCL 333.22215 (3), the Certificate of Need (CON) Commission "...shall conduct a public hearing on its proposed action." The Commission took proposed action on the Psychiatric Beds and Services Standards at its December 6, 2018 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed Psychiatric Beds and Services Standards on February 6, 2019. Written testimony was accepted for an additional seven days after the hearing. Testimony was received from 17 organizations.

Written Testimony:

1.) Mona Makki LLP, Director, ACCESS Community Health and Research Center

- Supports the proposed language.

2.) Karen Amon, LMSW, CADC, Director of Integrated Health, Bay Arenac Behavioral Health

- Supports increasing accessibility for inpatient psychiatric services for children and adolescents which she believes is the intent of the proposed changes. However, "If there is capacity for adult beds to be relocated, I propose that the occupancy for public adult patients be increased higher than the current 50%. Consider the need for children and adolescents by increasing the number of beds without the relocation of adult beds." Urges the Commission to continue work on expanding access to inpatient psychiatric services for children, adolescents and adults who are deemed public patients.

3.) Christopher Pinter, Chief Executive Officer, Bay Arenac Behavioral Health

- Supports increasing the occupancy threshold for all inpatient psychiatric units to at least 70% for adult beds and 50% for child/adolescent beds and

increasing the compliance sanctions for hospitals that do not meet the public patient obligations.

4.) Monique Stanton, President & CEO, CARE of Southeastern Michigan

- Supports the proposed language.

5.) Carolyn Wilson, MGBA, RN, EVP & Chief Operating Officer, Beaumont Health

- Supports the proposed language.

6.) Brent L. Wirth, President/CEO, Easterseals Michigan

- Supports the proposed language.

7.) Jessie Martori, Chief Executive Officer, Cedar Creek Hospital of Michigan

- Supports the proposed language.

8.) Judge Linda Davis, Executive President, Families Against Narcotics (FAN)

- Supports the proposed language.

9.) Andrew M. Hotaling, Chief Executive Officer, Forest View Psychiatric Hospital

- Supports the proposed language.

10.) Julie Szyska, Chief Executive Officer, Havenwyck Hospital

- Supports the proposed language.

11.) Cathrine Frank, Chair- Psychiatry Behavioral Health Services, Henry Ford Health System (HFHS)

- HFHS has the following concerns:
  - It's only a temporary solution to a larger issue of demand.
  - "…the concept of moving pediatric beds from one part of the Planning area to a different part of the Planning area may lead to a gap in bed availability for local communities."
  - "Section 9(11)(b)- While referenced in the proposed language, it should be stated that the applicant shall demonstrate through the most recent 12 months of available data, that the facility is not just promising to provide care to specific subsets of the population but should have to show that they provided the care referenced in the draft language. More specifically, the receiving facility should have to provide documentation that they actually provided at least 50% of their beds to care for public patients."
  - "Section 9(11)(d)- Further clarification is needed for 'collaborative agreement'. Additionally, the agreement's impact on access to the community at large should be considered."
  - "HFHS requests that any further action by the Commission be paused until the Psych Bed Workgroup recommendations on this charge are complete…."

12.) Leon Judd, President, NAMI Metro

- Supports the proposed language.

13.) Rhonda M. Powell, Director, Macomb County, Department of Health & Community Services

- Supports the proposed language.

14.) Matthew Owens, MA, LPC, LLP, Chief Network Officer, Oakland Community Health Network

- Supports the proposed language.

15.) Jaimie Clayton, President/CEO, Oakland Family Services

- Supports the proposed language.

16.) Joseph M. Tassee, FACHE, President and CEO (Interim), Southwest Solutions

- Supports the proposed language.

17.) Kari D. Walker, President and CEO, The Guidance Center

- Supports the proposed language.

18.) Edward D'Angelo, President & CEO, The Information Center

- Supports the proposed language.

Department Recommendation:

The Department supports the language as presented at the December 6, 2018 CON Commission meeting.

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR PSYCHIATRIC BEDS AND SERVICES

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

Section 1. Applicability

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

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

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

Section 2. Definitions

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

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

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

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

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

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

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

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

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

(i) "Department" means the Michigan Department of Health and Human Services (MDHHS).

(j) "Department inventory of beds" means the current list maintained for each planning area on a continuing basis by the Department which includes:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 3. Determination of needed inpatient psychiatric bed supply

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

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

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

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

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

(d) Divide the ADC by 0.75.

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

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

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

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

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

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

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

Section 4. Bed need for inpatient psychiatric beds

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

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

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

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

(5) Modifications made by the Commission pursuant to this Section shall not require Standard Advisory Committee action, a public hearing, or submittal of the standard to the Legislature and the Governor in order to become effective.

Section 5. Modification of the child/adolescent use rate by changing the base year

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

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

(3) Modifications made by the Commission pursuant to subsection (1) shall not require Standard Advisory Committee action, a public hearing, or submittal of the standard to the Legislature and the Governor in order to become effective.

Section 6. Requirements for approval to initiate service

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

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

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

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

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

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

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

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

Section 7. Requirements for approval to replace beds

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

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

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

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

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

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

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

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

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

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

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

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

(6) The relocation of beds under this section shall not result in initiation of a new adult or child/adolescent service EXCEPT FOR AN EXISTING ADULT INPATIENT PSYCHIATRIC SERVICE REQUESTING TO INITIATE A CHILD/ADOLESCENT INPATIENT PSYCHIATRIC SERVICE IN AN OVERBEDDED CHILD/ADOLESCENT PLANNING AREA PURSUANT TO SECTION 9(11).

Section 9. Requirements for approval to increase beds

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

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

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

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

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

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

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

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

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

(9) An applicant shall not be required to be in compliance with subsection (1) if the applicant demonstrates that the application meets both of the following:
(a) The Director of the Department determines that an exception to subsection (1) should be made and certifies in writing that the proposed project is a direct response to a Department plan for reducing the use of public institutions for acute mental health care through the closure of a state-owned psychiatric hospital; and
(b) The proposed beds will be located in the area currently served by the public institution that will be closed as determined by the Department.

(10) An applicant proposing to add new adult and/or child/adolescent psychiatric beds, as the receiving licensed inpatient psychiatric hospital or unit under Section 8, shall demonstrate that it meets all of the requirements of this subsection and shall not be required to be in compliance with the bed need if the application meets all other applicable CON review standards and agrees and assures to comply with all applicable project delivery requirements.
(a) The approval of the proposed new inpatient psychiatric beds shall not result in an increase in the number of licensed inpatient psychiatric beds in the planning area.
(b) The applicant meets the requirements of subsections (4), (5), (6), and (7) above.
(c) The proposed project to add new adult and/or child adolescent psychiatric beds, under this subsection, shall constitute a change in bed capacity under Section 1(2) of these standards.
(d) Applicants proposing to add new adult and/or child/adolescent psychiatric beds under this subsection shall not be subject to comparative review.

(11) AN APPLICANT PROPOSING TO INITIATE A NEW CHILD/ADOLESCENT PSYCHIATRIC SERVICE, AS THE RECEIVING LICENSED INPATIENT PSYCHIATRIC HOSPITAL OR UNIT UNDER SECTION 8(6), SHALL DEMONSTRATE THAT IT MEETS ALL OF THE REQUIREMENTS OF THIS SUBSECTION AND SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH THE BED NEED IF THE APPLICATION MEETS ALL OTHER APPLICABLE CON REVIEW STANDARDS AND AGREES AND ASSURES TO COMPLY WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS.
(a) THE APPROVAL OF THE PROPOSED NEW INPATIENT PSYCHIATRIC BEDS SHALL NOT RESULT IN AN INCREASE IN THE NUMBER OF LICENSED INPATIENT PSYCHIATRIC BEDS IN THE PLANNING AREA.
(b) THE APPLICANT MEETS THE REQUIREMENTS OF SUBSECTIONS (4), (5), AND (6) ABOVE.
(c) THE APPLICANT IS REQUESTING A MINIMUM OF 10 CHILD/ADOLSCENT PSYCHIATRIC BEDS TO A MAXIMUM OF 20 BEDS.
(d) THE APPLICANT:
(i) IS RELATED THROUGH COMMON OWNERSHIP, IN WHOLE OR IN PART, OR THROUGH COMMON CONTROL, WITH AN ACUTE-CARE HOSPITAL THAT HAS AN EMERGENCY DEPARTMENT THAT PROVIDES 24-HOUR EMERGENCY CARE SERVICES AND WHERE

CHILD/ADOLESCENT PATIENTS WITH A PSYCHIATRIC AND/OR DEVELOPMENTAL DISABILITY DIAGNOSIS PRESENT AT AN AVERAGE OF AT LEAST 100 VISITS PER YEAR FOR EACH OF THE THREE MOST RECENT YEARS IN WHICH THERE IS DATA VERIFIABLE BY THE DEPARTMENT; AND

(ii) HAS AN AGREEMENT WITH THE ACUTE-CARE HOSPITAL TO GIVE PRIMARY CONSIDERATION FOR ADMISSION OF CHILD/ADOLESCENT PATIENTS FROM THE ACUTE-CARE HOSPITAL'S EMERGENCY DEPARTMENT IN NEED OF AN INPATIENT PSYCHIATRIC HOSPITAL ADMISSION.

(iii) HAS A COLLABORATIVE AGREEMENT WITH AN EXISTING CHILD/ADOLESCENT PSYCHIATRIC HOSPITAL OR UNIT FOR CONSULTATION AND SUPPORTIVE SERVICES WITH A PROPOSED TERM OF NOT LESS THAN TWELVE MONTHS AFTER IMPLEMENTATION.

(e) THE PROPOSED SITE FOR THE NEW CHILD/ADOLESCENT BEDS HAS NOT PREVIOUSLY BEEN APPROVED FOR BEDS UNDER THIS SUB-SECTION.

(f) THE PROPOSED PROJECT TO ADD NEW CHILD ADOLESCENT PSYCHIATRIC BEDS, UNDER THIS SUBSECTION, SHALL CONSTITUTE A CHANGE IN BED CAPACITY UNDER SECTION 1(2) OF THESE STANDARDS.

(g) APPLICANTS PROPOSING TO ADD NEW CHILD/ADOLESCENT PSYCHIATRIC BEDS UNDER THIS SUBSECTION SHALL NOT BE SUBJECT TO COMPARATIVE REVIEW.

Section 10. Requirements for approval for flex beds

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

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

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

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

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

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

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

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

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

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

Section 12. Additional requirements for applications included in comparative review

Sec. 12. (1) Any application subject to comparative review under Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, or under these standards, shall be grouped and reviewed comparatively with other applications in accordance with the CON rules.

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

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

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

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

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

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

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

(g) A qualifying project will have 4 points deducted if the Department has issued, within three years prior to the date on which the CON application was deemed submitted, a temporary permit or provisional license due to a pattern of licensure deficiencies at any psychiatric hospital or unit owned or operated by the applicant in this state.

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

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

41 - <46%	9
46% +	10

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

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

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

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

Section 13. Requirements for approval -- all applicants

Sec. 13. (1) An applicant shall provide verification of Medicaid participation. An applicant that is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services if a CON is approved.

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

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

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

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

(1) Compliance with these standards.

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

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

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

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

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

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

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

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

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

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

(iii) maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually. Compliance with selective contracting requirements shall not be construed as a violation of this term.

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

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

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

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

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

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

(b) Flex beds approved under section 10 shall be counted as existing adult inpatient psychiatric beds.

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

(d) The applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to: annual budget and cost information, operating schedules, and demographic, diagnostic, morbidity and mortality information, as well as the volume of care provided to patients from all payor sources. The applicant shall provide the required data on a separate basis for each licensed site; in a format established by the Department; and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

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

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

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

(6) Nothing in this section prohibits the Department from taking compliance action under MCL 333.22247.

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

Section 15. Project delivery requirements - additional terms of approval for child/adolescent service

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

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

(i) a child/adolescent psychiatrist;

(ii) a child psychologist;

(iii) a psychiatric nurse;

(iv) a psychiatric social worker;

(v) an occupational therapist or recreational therapist; and

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

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

(d) There shall be the following minimum staff employed either on a full time basis or access to on a consulting basis as needed:

(i) a pediatrician;

(ii) a child neurologist;

(iii) a neuropsychologist;

(iv) a speech and language therapist;

(v) an audiologist; and

(vi) a dietician.

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

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

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

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

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

Section 16. Department inventory of beds

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

Section 17. Planning areas

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

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

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

Sec. 18. (1) These CON review standards supercede and replace the CON Review Standards for Psychiatric Beds and Services, approved by the CON Commission on ~~December 13, 2012~~SEPTEMBER 21, 2016 and effective on ~~March 22, 2013~~DECEMBER 9, 2016.

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

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

APPENDIX A

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

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

PLANNING AREA	ADULT BEDS PER 10,000 ADULT POPULATION
1	3.09143
2	2.40602
3	2.44460
4	2.39174
5	3.07912
6	1.75052
7	0.83839
8	2.26654
STATE	2.64279

APPENDIX B

CON REVIEW STANDARDS FOR CHILD/ADOLESCENT INPATIENT PSYCHIATRIC BEDS

The use rate per 1000 population age 0-17, for purposes of these standards, effective April 1, 2015, and until otherwise changed by the Commission, is 25.664.

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

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

Section 1. Applicability; definitions

Sec. 1. (1) This addendum supplements the CON review standards for psychiatric beds and services and shall be used for determining the need for projects established to better meet the needs of special population groups within the mental health populations.

(2) Except as provided in sections 2, 3, 4, 5, 6, and 7 of this addendum, these standards supplement, and do not supersede, the requirements and terms of approval required by the CON Review Standards for Psychiatric Beds and Services.

(3) The definitions which apply to the CON Review Standards for Psychiatric Beds and Services shall apply to these standards.

(4) For purposes of this addendum, the following terms are defined:
(a) "Developmental disability unit" means a unit designed for psychiatric patients (adult or child/adolescent as applicable) who have been diagnosed with a severe, chronic disability as outlined in Section 102, 42 USC 15002, of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (DD Act) and its update or future guideline changes.
(b) "Geriatric psychiatric unit" means a unit designed for psychiatric patients aged 65 and over.
(c) "Medical psychiatric unit" means a unit designed for psychiatric patients (adult or child/adolescent as applicable) who have also been diagnosed with a medical illness requiring hospitalization, e.g., patients who may be on dialysis, require wound care or need intravenous or tube feeding.

Section 2. Requirements for approval -- applicants proposing to increase psychiatric beds -- special use exceptions

Sec. 2. A project to increase psychiatric beds in a planning area which, if approved, would otherwise cause the total number of psychiatric beds in that planning area to exceed the needed psychiatric bed supply or cause an increase in an existing excess as determined under the applicable CON review standards for psychiatric beds and services, may nevertheless be approved pursuant to this addendum.

Section 3. Statewide pool for the needs of special population groups within the mental health populations

Sec. 3. (1) A statewide pool of additional psychiatric beds consists of 370 beds needed in the state is established to better meet the needs of special population groups within the mental health populations. The number of beds in the pool is based on five percent of the statewide bed need for psychiatric inpatient beds rounded up to the next ten. Beds in the pool shall be distributed as follows and shall be reduced in accordance with subsection (2):
(a) Developmental disability beds will be allocated 110 adult beds and 20 child/adolescent beds.
(b) Geriatric psychiatric beds will be allocated 110 adult beds.
(c) Medical psychiatric beds will be allocated 110 adult beds and 20 child/adolescent beds.

(2) By setting aside these beds from the total statewide pool, the Commission's action applies only to applicants seeking approval of psychiatric beds pursuant to sections 4, 5, and 6. It does not preclude the

care of these patients in units of hospitals, psychiatric hospitals, or other health care settings in compliance with applicable statutory or certification requirements.

(3) Increases in psychiatric beds approved under this addendum for special population groups shall not cause planning areas currently showing an unmet bed need to have that need reduced or planning areas showing a current surplus of beds to have that surplus increased.

(4) The Commission may adjust the number of beds available in the statewide pool for the needs of special population groups within the mental health populations concurrent with the biennial recalculation of the statewide psychiatric inpatient bed need. Modifying the number of beds available in the statewide pool for the needs of special population groups within the mental health populations pursuant to this section shall not require a public hearing or submittal of the standard to the Legislature and the Governor in order to become effective.

Section 4. Requirements for approval for beds from the statewide pool for special population groups allocated to developmental disability patients

Sec. 4. The CON commission determines there is a need for beds for applications designed to determine the efficiency and effectiveness of specialized programs for the care and treatment of developmental disability patients as compared to serving these needs in general psychiatric unit(s).

(1) An applicant proposing to begin operation of a new adult or child/adolescent psychiatric service or add beds to an existing adult or child/adolescent psychiatric service under this section shall demonstrate with credible documentation to the satisfaction of the Department each of the following:

(a) The applicant shall submit evidence of accreditation as follows:

(i) Documentation of its existing developmental disability program by the National Association for the Dually Diagnosed (NADD) or another nationally-recognized accreditation organization for developmental disability care and services; or

(ii) within 24-months of accepting its first patient, the applicant shall obtain NADD or another nationally-recognized accreditation organization for the developmental disability beds proposed under this subsection.

(b) The applicant proposes programs to promote a culture within the facility that is appropriate for developmental disability patients.

(c) Staff will be specially trained in treatment of developmental disability patients.

(d) The proposed beds will serve only developmental disability patients.

(2) All beds approved pursuant to this subsection shall be certified for Medicaid.

Section 5. Requirements for approval for beds from the statewide pool for special population groups allocated to geriatric psychiatric patients

Sec. 5. The CON commission determines there is a need for beds for applications designed to determine the efficiency and effectiveness of specialized programs for the care and treatment of geriatric psychiatric patients as compared to serving these needs in general psychiatric unit(s).

(1) An applicant proposing to begin operation of a new adult psychiatric service or add beds to an existing adult psychiatric service under this section shall demonstrate with credible documentation to the satisfaction of the Department each of the following:

(a) The applicant shall submit evidence of accreditation as follows:

(i) Documentation of its existing geriatric psychiatric program by the Commission on Accreditation of Rehabilitation Facilities (CARF) or another nationally-recognized accreditation organization for geriatric psychiatric care and services; or

(ii) within 24-months of accepting its first patient, the applicant shall obtain CARF or another nationally-recognized accreditation organization for the geriatric psychiatric beds proposed under this subsection.

(b) The applicant proposes programs to promote a culture within the facility that is appropriate for geriatric psychiatric patients.

(c) Staff will be specially trained in treatment of geriatric psychiatric patients.

(d) The proposed beds will serve only geriatric psychiatric patients.

(2) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.

Section 6. Requirements for approval for beds from the statewide pool for special population groups allocated to medical psychiatric patients

Sec. 6. The CON commission determines there is a need for beds for applications designed to determine the efficiency and effectiveness of specialized programs for the care and treatment of medical psychiatric patients as compared to serving these needs in general psychiatric unit(s).

(1) An applicant proposing to begin operation of a new adult or child/adolescent psychiatric service or add beds to an existing adult or child/adolescent psychiatric service under this section shall demonstrate with credible documentation to the satisfaction of the Department each of the following:

(a) The beds will be operated as part of a specialized program exclusively for adult or child/adolescent medical psychiatric patients, as applicable, within a licensed hospital licensed under part 215 of the code.

(b) The applicant shall submit evidence of accreditation as follows:

(i) Documentation of its existing medical psychiatric program by CARF or another nationally-recognized accreditation organization for medical psychiatric care and services; or

(ii) within 24-months of accepting its first patient, the applicant shall obtain CARF or another nationally-recognized accreditation organization for the medical psychiatric beds proposed under this subsection.

(c) The applicant proposes programs to promote a culture within the facility that is appropriate for medical psychiatric patients.

(d) Staff will be specially trained in treatment of medical psychiatric patients.

(e) The proposed beds will serve only medical psychiatric patients.

(2) All beds approved pursuant to this subsection shall be certified for Medicaid.

Section 7. Acquisition of psychiatric beds approved pursuant to this addendum

Sec. 7. (1) An applicant proposing to acquire psychiatric beds from the statewide pool for special population groups allocated to developmental disability shall meet the following:

(a) The applicant shall submit evidence of accreditation of the existing developmental disability program by the National Association for the Dually Diagnosed (NADD) or another nationally-recognized accreditation organization for developmental disability care and services.

(b) Within 24-months of accepting its first patient, the applicant shall obtain NADD or another nationally-recognized accreditation organization for the developmental disability beds proposed under this subsection.

(c) The applicant proposes programs to promote a culture within the facility that is appropriate for developmental disability patients.

(d) Staff will be specially trained in treatment of developmental disability patients.

(e) The proposed beds will serve only developmental disability patients.

(f) All beds approved pursuant to this subsection shall be certified for Medicaid.

(2) An applicant proposing to acquire psychiatric beds from the statewide pool for special population groups allocated to geriatric psychiatric shall meet the following:

(a) The applicant shall submit evidence of accreditation of the existing geriatric psychiatric program by CARF or another nationally-recognized accreditation organization for geriatric psychiatric care and services.

(b) Within 24-months of accepting its first patient, the applicant shall obtain CARF or another nationally-recognized accreditation organization for the geriatric psychiatric beds proposed under this subsection.

(c) The applicant proposes programs to promote a culture within the facility that is appropriate for geriatric psychiatric patients.

(d) Staff will be specially trained in treatment of geriatric psychiatric patients.

(e) The proposed beds will serve only geriatric psychiatric patients.

(f) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.

(3) An applicant proposing to acquire psychiatric beds from the statewide pool for special population groups allocated to medical psychiatric shall meet the following:

(a) The applicant shall submit evidence of accreditation of the existing medical psychiatric program by CARF or another nationally-recognized accreditation organization for medical psychiatric care and services.

(b) Within 24-months of accepting its first patient, the applicant shall obtain CARF or another nationally-recognized accreditation organization for the medical psychiatric beds proposed under this subsection.

(c) The applicant proposes programs to promote a culture within the facility that is appropriate for medical psychiatric patients.

(d) Staff will be specially trained in treatment of medical psychiatric patients.

(e) The proposed beds will serve only medical psychiatric patients.

(f) All beds approved pursuant to this subsection shall be certified for Medicaid.

Section 8. Project delivery requirements -- terms of approval for all applicants seeking approval under section 3(1) of this addendum

Sec. 8. (1) An applicant shall agree that if approved, the services shall be delivered in compliance with the terms of approval required by the CON Review Standards for Psychiatric Beds and Services.

(2) An applicant for beds from the statewide pool for special population groups allocated to developmental disability patients shall agree that, if approved, all beds approved pursuant to that subsection shall be operated in accordance with the following terms of CON approval:

(a) The applicant shall document, at the end of the third year following initiation of beds approved an annual average occupancy rate of 80 percent or more. If this occupancy rate has not been met, the applicant shall reduce beds to a number of beds necessary to result in a 80 percent average annual occupancy for the third full year of operation and annually thereafter. The number of beds reduced shall revert to the total statewide pool established for developmental disability beds.

(b) An applicant shall staff the proposed unit for developmental disability patients with employees that have been trained in the care and treatment of such individuals.

(c) An applicant shall maintain NADD certification or another nationally-recognized accreditation organization for developmental disability care and services.

(d) An applicant shall establish and maintain written policies and procedures for each of the following:

(i) Patient admission criteria that describe minimum and maximum characteristics for patients appropriate for admission to the developmental disability unit.

(ii) The transfer of patients requiring care at other health care facilities.

(iii) Upon admission and periodically thereafter, a comprehensive needs assessment, a treatment plan, and a discharge plan that at a minimum addresses the care needs of a patient following discharge.

(e) If the specialized program is being added to an existing adult or child/adolescent psychiatric service, then the existing licensed adult or child/adolescent psychiatric service, as applicable, shall

maintain the volume requirements outlined in Section 14 of the CON Review Standards for Psychiatric Beds and Services.

(f) The developmental disability unit shall have a day/dining area within, or immediately adjacent to, the unit(s), which is solely for the use of developmental disability patients.

(g) The developmental disability unit shall have direct access to a secure outdoor or indoor area at the facility appropriate for supervised activity.

(h) The applicant shall maintain programs to promote a culture within the facility that is appropriate for developmental disability patients.

(3) An applicant for beds from the statewide pool for special population groups allocated to geriatric psychiatric patients shall agree that if approved, all beds approved pursuant to that subsection shall be operated in accordance with the following terms of CON approval:

(a) The applicant shall document, at the end of the third year following initiation of beds approved an annual average occupancy rate of 80 percent or more. If this occupancy rate has not been met, the applicant shall reduce beds to a number of beds necessary to result in a 80 percent average annual occupancy for the third full year of operation and annually thereafter. The number of beds reduced shall revert to the total statewide pool established for geriatric psychiatric beds.

(b) An applicant shall staff the proposed unit for geriatric psychiatric patients with employees that have been trained in the care and treatment of such individuals.

(c) An applicant shall maintain CARF certification or another nationally-recognized accreditation organization for geriatric psychiatric care and services.

(d) An applicant shall establish and maintain written policies and procedures for each of the following:

(i) Patient admission criteria that describe minimum and maximum characteristics for patients appropriate for admission to the geriatric psychiatric unit.

(ii) The transfer of patients requiring care at other health care facilities.

(iii) Upon admission and periodically thereafter, a comprehensive needs assessment, a treatment plan, and a discharge plan that at a minimum addresses the care needs of a patient following discharge.

(e) If the specialized program is being added to an existing adult licensed psychiatric service, then the existing licensed psychiatric service shall maintain the volume requirements outlined in Section 14 of the CON Review Standards for Psychiatric Beds and Services.

(f) The geriatric psychiatric unit shall have a day/dining area within, or immediately adjacent to, the unit(s), which is solely for the use of geriatric psychiatric patients.

(g) The geriatric psychiatric unit shall have direct access to a secure outdoor or indoor area at the facility appropriate for supervised activity.

(h) The applicant shall maintain programs to promote a culture within the facility that is appropriate for geriatric psychiatric patients.

(4) An applicant for beds from the statewide pool for special population groups allocated to medical psychiatric patients shall agree that, if approved, all beds approved pursuant to that subsection shall be operated in accordance with the following CON terms of approval.

(a) The applicant shall document, at the end of the third year following initiation of beds approved an annual average occupancy rate of 80 percent or more. If this occupancy rate has not been met, the applicant shall reduce beds to a number of beds necessary to result in a 80 percent average annual occupancy for the third full year of operation and annually thereafter. The number of beds reduced shall revert to the total statewide pool established for medical psychiatric beds.

(b) An applicant shall staff the proposed unit for medical psychiatric patients with employees that have been trained in the care and treatment of such individuals.

(c) An applicant shall maintain CARF certification or another nationally-recognized accreditation organization for medical psychiatric care and services.

(d) An applicant shall establish and maintain written policies and procedures for each of the following:

(i) Patient admission criteria that describe minimum and maximum characteristics for patients appropriate for admission to the medical psychiatric unit.

(ii) The transfer of patients requiring care at other health care facilities.

(iii) Upon admission and periodically thereafter, a comprehensive needs assessment, a treatment plan, and a discharge plan that at a minimum addresses the care needs of a patient following discharge.

(e) If the specialized program is being added to an existing licensed adult or child/adolescent psychiatric service, then the existing adult or child/adolescent psychiatric service, as applicable, shall maintain the volume requirements outlined in Section 14 of the CON Review Standards for Psychiatric Beds and Services.

(f) The medical psychiatric unit shall have a day/dining area within, or immediately adjacent to, the unit(s), which is solely for the use of medical psychiatric patients.

(g) The medical psychiatric unit shall have direct access to a secure outdoor or indoor area at the facility appropriate for supervised activity.

(h) The applicant shall maintain programs to promote a culture within the facility that is appropriate for medical psychiatric patients.

Section 9. Comparative reviews, effect on prior CON review standards

Sec. 9. (1) Projects proposed under Section 4 shall be considered a distinct category and shall be subject to comparative review on a statewide basis.

(2) Projects proposed under Section 5 shall be considered a distinct category and shall be subject to comparative review on a statewide basis.

(3) Projects proposed under Section 6 shall be considered a distinct category and shall be subject to comparative review on a statewide basis.

MDHHS Recommendations for CON Standards Scheduled for 2019 Review

Air Ambulance Services Standards			
Department Recommendations: Air Ambulance (AA) services should continue to be regulated until the Department's Emergency Medical Services (EMS) Licensing can update its rules to include Air Ambulance specific requirements.			
Identified Issues	**Issue Recommended for Substantive Review?**	**Recommended Course of Action to Review Issues**	**Other/Comments**
AA Standards are preempted by the Federal Aviation Administration (FAA).	Not at this time.	Continue regulation and review the AA Licensure rules once they are available. At that time, the Commission should consider deregulation of AA Services.	

Pursuant to MCL 333.22215 (1) (m), the Certificate of Need (CON) Commission is to "…review, and if necessary, revise each set of CON standards at least every 3 years." In accordance with the established review schedule on the Commission Work Plan, the AA Services Standards are scheduled for review in calendar year 2019.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 5 - 19, 2018. Testimony was received from five organizations and is summarized as follows:

1. *Mark Cook, Blue Cross Blue Shield of Michigan (BCBSM)*
    - Supports continued regulation.
    - Supports strengthening standards with additional transparency requirements for air ambulance providers.

2. *Patrick O'Donovan, Beaumont Health*
    - Supports continued regulation with no changes.

3. *Tiffany Obetts, RN, BSN, AeroMed/Spectrum Health*
    - Supports continued regulation under the current standards and project delivery requirements until the EMS Section develops rules pertaining to improving the quality of air ambulance services.

4. *Sean Gehle, Ascension Michigan*
    - No recommended changes.

5. *Bret Jackson, Economic Alliance for Michigan (EAM)*
    - Supports continued regulation.

Background:

The Federal Aviation Administration Authorization (FAA) Act of 1994 preempts need determination requirements of state programs for AA services (additional information below). As such, the Michigan CON program may not include language that restricts AA service in Michigan based on need for the service. The Department has historically recommended CON deregulation of AA service due to this federal restriction of regulating need. However, many individuals and organizations involved in AA services in Michigan have advocated to continue CON regulation of this service to preserve the quality-related requirements that are not federally restricted.

In 2013, the CON Commission held an AA workgroup that focused on updating the Michigan CON AA Services Standard to be aligned with the federal law. At its March 18, 2014 meeting, the Commission took final action on standards that removed all language regarding need. At this meeting, the Commission stated that AA Service would remain regulated by CON until the EMS licensing in the Department of Health and Human Services could update the licensure process to include AA specific criteria that are currently found in the CON standards. In 2016, this was reaffirmed by the Commission as administrative rules had not been finalized.

Currently, the Michigan administrative rules for EMS are in the process of a complete overhaul and adding air ambulance regulation is just one part of this larger update. There is no anticipated timeframe for completion. The Department will keep the Commission updated on the progress.

Summary of FAA Exemption:

The US Department of Transportation (US DOT), in attempting to clarify the limits of federal regulation, has indicated that the while the FAA regulates air safety, states are free to regulate medical safety.

The areas where federal preemption has been asserted are as follows: requirement for 24/7 service, requirement for a CON, regulation of rates, response times, bases of operation, bonding requirements, and accounting and reporting systems, matters concerning aviation safety including equipment, operation, and pilot qualifications, requirements for certain avionics/navigation equipment, requirements for general liability coverage, and safety aspects of medical equipment installation, storage on aircraft and safety training of medical personnel. Court decisions have found in favor of the Helicopter Emergency Medical Service (HEMS) programs when states have required a CON.

Further, the Federal district court in Med-Trans found a State Certificate of Need program requiring an air ambulance provider to obtain a "valid EMS Provider License" and have an "EMS Peer Review Committee" in place to operate as a Specialty Care Transport Program preempted under Federal law. 581 F. Supp. 2d at 737. Under the facts of that case, the court found that the challenged regulations could be used to affect entry into the air ambulance market for reasons other than medical ones.

The court stated: The collective effect of the challenged regulations is to provide local government officials a mechanism whereby they may prevent an air carrier from operating at all within the state.... The court therefore finds that the [regulations] are preempted to the extent that they require approval of county government officials which, if denied, would preclude plaintiff from operating within the state. 583 F. Supp. 2d at 738.

AA Survey Data for 2017:

Annual survey data for 2017 is the latest available and can be found here:

Service Providers
https://www.michigan.gov/documents/mdhhs/150_-_Air_Ambulence_Utilization_626608_7.pdf

Additional Services
https://www.michigan.gov/documents/mdhhs/152_-_Air_Ambulance_Additional_Services_626609_7.pdf

MDHHS Recommendations for CON Standards Scheduled for 2019 Review

Computed Tomography (CT) Scanner Services Standards			
Department Recommendations: CT Scanner services should continue to be regulated. The Commission should form a workgroup to make a recommendation regarding the maintenance volume.			
Identified Issues	**Issue Recommended for Substantive Review?**	**Recommended Course of Action to Review Issues**	**Other/Comments**
Review the possibility of extending the exemption under Section 3(1) to 24-hour freestanding emergency departments. The exemption currently allows a hospital that provides 24-hour emergency care services to be exempt from the volume requirements for its first CT scanner.	No.		There is no indication that this is a widespread problem. A free-standing Emergency Room can obtain a CT scanner through the current CON standards for initiation and is expected to meet the project delivery requirements at the time of approval.
Review the possibility of exempting the use of temporary mobile CT scanners when used for less than 90 days from having to file a CON.	No.		There is no indication that this is a widespread problem. Allowing a provision as described would contradict the CON statute and have impact on other standards. Further, there are emergency CON provisions that allow for urgent, temporary situations to be addressed.
Make a definitional revision to more accurately classify pediatric patients. The proposal is to increase the age limit for pediatric CT studies through 21 years of age (<22 years of age).	No.		There is no indication that this is a widespread problem. Changing the definition of child/adolescent would have implications for other CON standards. Current CON standards do not prohibit patients aged 18-21 from receiving treatment on a

			dedicated pediatric CT unit as long as 70 percent of the procedures on the dedicated unit are done on patients less than 18 years of age.
Review maintenance volume requirements.	Yes.	Form a workgroup to advise on the maintenance volume.	The maintenance volume should be reviewed as it has not been reviewed by recent workgroups.

Pursuant to MCL 333.22215 (1) (m), the Certificate of Need (CON) Commission is to "…review, and if necessary, revise each set of CON standards at least every 3 years." In accordance with the established review schedule on the Commission Work Plan, the CT Scanner Services Standards are scheduled for review in calendar year 2019.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 5 - 19, 2018. Testimony was received from seven organizations and is summarized as follows:

1. *Patrick O'Donovan, Beaumont Health*
    - Supports continued regulation.
    - Supports extending the exemption under Section 3(1) to 24-hour freestanding emergency departments. The exemption currently allows a hospital that provides 24-hour emergency care services to be exempt from the volume requirements for its first CT scanner.

2. *Barbara Bressack, Henry Ford Health System (HFHS)*
    - Supports continued regulation with no changes.

3. *David Walker, Spectrum Health*
    - Supports continued regulation.
    - Recommends exempting the use of temporary mobile CT scanners when used for less than 90 days from having to file a CON. Currently, the standards require a non-substantive application to be filed which can take 45 – 75 days. They state that "This adds an undue administrative and financial burden to health systems and negatively affects patient care as the review time often extends beyond the time the unit would have been utilized."

4. *Robert Casalou, Mercy Health and Saint Joseph Mercy Health System*
    - No recommended changes.

5. *T. Anthony Denton, JD, MHA, Et al., University of Michigan Health System (UMHS)*
    - Supports continued regulation.
    - Supports a definitional revision to more accurately classify pediatric patients. They propose increasing the age limit for pediatric CT studies through 21 years of age (<22 years of age).

6. *Sean Gehle, Ascension Michigan*
    - Recommends reviewing the maintenance volume requirement for existing units.

7. *Bret Jackson, Economic Alliance for Michigan (EAM)*
    - Supports continued regulation.
    - Supports the Commission to research the numerous underperforming free-standing facilities.

Background:

The CT standards were reviewed with a workgroup in 2016. The current effective date of the CT standards is December 9, 2016.

CT Survey Data for 2017:

Annual survey data for 2017 is the latest available and can be found here:

Hospital and Freestanding CT
https://www.michigan.gov/documents/mdhhs/101_-_CT_Services_Hospital_and_Freestanding_626600_7.pdf

Portable and Ded Ped CT
https://www.michigan.gov/documents/mdhhs/102_-_CT_Services_Portable_and_Ded_Ped_626602_7.pdf

CT CSC
https://www.michigan.gov/documents/mdhhs/104_-_CT_Services_-CSC_626603_7.pdf

Mobile Routes CT
https://www.michigan.gov/documents/mdhhs/106_-_CT_Services_Mobile_Routes_626604_7.pdf

MDHHS Recommendations for CON Standards Scheduled for 2019 Review

Neonatal Intensive Care Services/Beds and Special Newborn Nursing Services (NICU and SNN) Standards			
Department Recommendations: This service should continue to be regulated. The Commission should form a standard advisory committee (SAC) to make a recommendation regarding the issues noted as needing substantive review below.			
Identified Issues	**Issue Recommended for Substantive Review?**	**Recommended Course of Action to Review Issues**	**Other/Comments**
Review Section 2(1)(v) for the following: Should Special Care Nurseries (SCN) only be required to meet the mechanical ventilation requirements in at least 75% of the babies vs 100%?	No.		The Department completed a comprehensive compliance review of SCN in 2018, and this was not found to be an issue. The requirements noted are consistent with national guidelines, and the Department would not support any regulation that does not minimally meet national guidelines for special care nurseries.
Should High Flow Nasal Cannula (HFNC) treatment and/or Neonatal Abstinence Syndrome (NAS) be included as accepted services for SCNs.	Yes.	Form a SAC and place this issue on the charge.	
Should CPAP continue to be limited to 24 hours in SCNs?	No.		The Department completed a comprehensive compliance review of SCN in 2018, and this was not found to be an issue. The requirements noted are consistent with national guidelines, and the Department would not support any regulation that does not minimally meet national

			guidelines for special care nurseries.
Review whether or not to allow Special Care Nurseries to offer total parenteral nutrition (TPN). Currently, only NICUs are able to provide TPN.	No.		The requirement noted is consistent with national guidelines, and the Department would not support any regulation that does not minimally meet national guidelines for special care nurseries.
Review Section 12(2)(h) and if telemedicine should be a component of Level III NICU or, minimally, clarify that on-site physician consultation services may also be accomplished through telemedicine physician consultation services.	Yes.	Form a SAC and place this issue on the charge.	
Review the current NICU bed occupancy rates across the state to see if changes are necessary to ensure adequate access.	Yes.	Form a SAC and place this issue on the charge.	The Department supports reviewing access to SCN and NICU services. However, these standards already have a high occupancy provision that facilities are utilizing when their occupancy needs to increase.
Minimum size of a NICU unit is 15 beds now. Should there be an exception for hospitals in Rural/Micro counties?	Yes.	Form a SAC and place this issue on the charge.	This issue was identified by the CON Evaluation Section.
Review the definition of NICU services in Section 2(1)(m).	Yes.	Form a SAC and place this issue on the charge.	This issue was identified by the CON Evaluation Section.

Pursuant to MCL 333.22215 (1) (m), the Certificate of Need (CON) Commission is to "…review, and if necessary, revise each set of CON standards at least every 3 years." In accordance with the established review schedule on the Commission Work Plan, the NICU Standards are scheduled for review in calendar year 2019.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 5 - 19, 2018. Testimony was received from six organizations and is summarized as follows:

1. *Patrick O'Donovan, Beaumont Health*
    - Supports continued regulation with no changes.

2. *Sudhakar Ezhuthachan, MD, Henry Ford Health System (HFHS)*
    - Supports continued regulation.
    - SCNs should only be required to meet the mechanical ventilation requirements in at least 75% of the babies vs 100% given the "multitude of factors that can result in the baby needing to stay at the SCN beyond the 24 hours in order to ensure safe transport of the baby to a NICU."
    - Allow SCNs to offer total parenteral nutrition (TPN). Currently, only level 3 NICUs are able to provide TPN. It is stated that "This change in standards will:
        - reduce transfers;
        - reduce the burden of level 3 NICUs to accept more babies (perhaps only to transfer them back as soon as feeds are adequate;
        - provide better opportunity to keep mom and baby together; and
        - allow for TPN to be administered appropriately for more efficient nutrition for the baby."

3. *Edgar Beaumont, MD, Spectrum Health*
    - Supports continued regulation.
    - Recommends modifying the definition of SCN in Section 2(v)(v) to include High Flow Nasal Cannula (HFNC) treatment as an accepted service. "This will provide clarity on the appropriate use and time of use for respiratory support before a transfer to a higher level of care is necessary."
    - Recommends adding Neonatal Abstinence Syndrome (NAS) as a service adequate for special care nursery services (SCN) in Section 2(v). "Treatment in an SCN will allow newborns to receive the treatment they need without having to be transferred to a NICU, where it is possible the closest service is many miles away."

4. *Robert Casalou, Mercy Health and Saint Joseph Mercy Health System*
    - Supports continued regulation.
    - Modify the definition of SCN services in Section 2(1)(v) so that mechanical ventilation, not CPAP, should be limited to 24 hours as the AAP Policy Statement separates them.
    - "The CON standards for NICUs (Section 12(2)(h)) should recognize telemedicine as a part of the Level III NICU toolbox or, minimally, clarify that 'on-site physician consultation services' may also be accomplished through telemedicine physician consultation."

5. *Sean Gehle, Ascension Michigan*

- "Recommends modifying the language in the definition of Special Care Nursery and in section (9) requiring that the provision of mechanical ventilation or continuous positive airway pressure be no more than 24 hours to language that would provide that this requirement would only have to be met 75% of time." A baby that is on CPAP may not be that unstable and may only need a couple hours past the 24-hour mark before coming off CPAP or vent.

6. *Bret Jackson, Economic Alliance for Michigan (EAM)*
    - Recommends review of "the current NICU bed occupancy rates across the state to see if changes are necessary to ensure adequate access. Currently, numerous facilities are reporting over 80% occupancy with a few hospitals reporting over 90% occupancy."

Background:

The NICU and SNN Services standards were reviewed with the Department drafting language for some technical edits for the Commission to review. The current effective date of the NICU and SNN Services standards is December 9, 2016.

NICU Survey Data for 2017:

Annual survey data for 2017 is the latest available and can be found here:

https://www.michigan.gov/documents/mdhhs/030_NICU_Beds_by_HSA_626572_7.pdf

MDHHS Recommendations for CON Standards Scheduled for 2019 Review

Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups (NH-HLTCU) Standards			
Department Recommendations: The Commission should form a standard advisory committee (SAC) to make recommendations regarding the issues noted as needing substantive review below.			
Identified Issues	**Issue Recommended for Substantive Review?**	**Recommended Course of Action to Review Issues**	**Other/Comments**
Recommend to the Legislature the amendment of the fees for non-substantive CON applications.	No.		Application fees are set in state statute and cannot be addressed in the CON standards.
Review the bed methodology.	Yes.	Form a SAC and place this issue on the charge.	At the March 27, 2018 CON Commission meeting, the Commission postponed indefinitely the setting of the effective date of the new bed need numbers and to establish a SAC in 2019 to review the methodology with Dr. Delamater.
Review requirements and application fees for renewal of leases.	No.		By statute, lease renewals over capital expenditure threshold are subject to CON review. The standards cannot conflict with the statute. Also, application fees are set in state statute and cannot be amended in the CON standards.
Review the definitions for nursing home beds and other parts of the Standards to make it clearer that existing nursing home beds include nursing homes and nursing home beds that are non-operational or unavailable for occupancy when	Yes.	Form a SAC and place this issue on the charge.	The definitions in this standard and the concept of non-operational beds may be explored. However, building agreements are solely under the authority of the Michigan Department of

they are licensed under a building program agreement approved by the Michigan Department of Licensing and Regulatory Affairs (LARA) pursuant to section 20144 of the Public Health Code.			Licensing and Regulatory Affairs and cannot be used for decision making in the CON process.
Review whether or not adequate access exists for Medicaid patients and the potential need to expand specialty population beds.	Yes.	Form a SAC and place this issue on the charge.	
Review relocation of nursing home beds under Section 8 and the possibility of requiring only one application instead of two needing to be filed.	No.		Relocation is both a change in capacity and a change in ownership of beds. By statute, this requires a CON application from the provider that owns the beds currently and an application from the provider that will receive the beds. This is consistent with other CON licensed bed standards.
Add project delivery requirement for patient transfer language to sections 7(1) and 7(2) – "*the current patients of the facility/beds being replaced shall be admitted to the replacement beds when the replacement beds are licensed, to the extent that those patients desire to transfer to the replacement facility/beds*."	Yes.	The Department can draft this language for review and input from a SAC.	This issue was identified by the CON Evaluation Section. This is technical edit that reiterates a project delivery requirement found in 11(2)(c).
Similar to other bed standards, add a minimum occupancy requirement in Section 6 (add new beds) and Section 8 (add beds thru relocation), before an existing home can add new NH beds or relocate beds from another facility.	Yes.	The Department can draft this language for review and input from a SAC.	This issue was identified by the CON Evaluation Section.

Pursuant to MCL 333.22215 (1) (m), the Certificate of Need (CON) Commission is to "…review, and if necessary, revise each set of CON standards at least every 3 years." In accordance with the established review schedule on the Commission Work Plan, the NH-HLTCU Standards are scheduled for review in calendar year 2019.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 5 - 19, 2018. Testimony was received from four organizations and is summarized as follows:

1. *David G. Stobb, Ciena Healthcare*
    - Supports continued regulation.
    - CON application fees for lease renewals should be reduced. Request the Legislature to amend the fees for non-substantive CON applications. They state that the fees place a burden on the facilities and that they add cost to the healthcare system.
    - Support a thorough review of the bed need methodology.

2. *Melissa Samuel, Health Care Association of Michigan (HCAM)*
    - Supports continued regulation.
    - Support a thorough review of the bed need methodology.
    - "Recommend requiring only a waiver be filed when a lease renewal at the existing site which does not involve changes to access or quality." They state, "The need to review the renewal of an existing lease seems redundant as the original lease has already been reviewed and approved."
    - HCAM "recommends the application fee be based on the annual value of the leased facility and not the total value of a multi-year lease."
    - Need clarification on acquisitions and operating facility in Section 7 (3)(c)(iii) which "sets up the example of an existing facility continuing operation while the replacement is being built and how to handle residents." If LARA provides the facility with a building program agreement to close and then reopen, they state "it is not practicable to track the residents who were displaced."
    - Review definitions for conformance with any proposed changes.
    - Review relocation of nursing home beds under Section 8. Instead of two CONs needing to be filed, require only the receiving facility to file the CON with an addendum that includes information regarding the donor facility since the donor facility is actually reducing bed capacity, and bed reductions are not typically reviewed by CON.

3. *Lorenzo Cavaliere, Oakland Senior Living Operations LLC*
    - "Amend the definitions for nursing home beds and other parts of the Standards to make it clearer that existing nursing home beds include nursing homes and nursing home beds that are non-operational or unavailable for occupancy when they are licensed under a building program

agreement approved by the Michigan Department of Licensing and Regulatory Affairs (LARA) pursuant to section 20144 of the Public Health Code." (Possible amendment language is included in the Public Comment Period material.)

4. *Sean Gehle, Ascension Michigan*
    - "Recommends reviewing whether or not adequate access exists for Medicaid patients and the potential need to expand specialty population beds as the population continues to age."

Background:

The NH-HLTCU Standards regulate a licensed health facility, not a covered clinical service. Therefore, deregulation is not an option.

Nursing Homes were last reviewed by a workgroup in 2016. The effective date of the current standards is September 21, 2017.

NH-HLTCU Survey Data for 2017:

Annual survey data for 2017 is the latest available and can be found here:

https://www.michigan.gov/mdhhs/0,5885,7-339-71551_2945_5106-312854--,00.html

MDHHS Recommendations for CON Standards Scheduled for 2019 Review

Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services/Units Standards			
Department Recommendations: UESWL should continue to be regulated. The Commission should request the Department to draft language to review at a future meeting for the issues identified below.			
Identified Issues	**Issue Recommended for Substantive Review?**	**Recommended Course of Action to Review Issues**	**Other/Comments**
Review the removal of the 100 procedure volume per region requirement from the Project Delivery Requirements in Section 9(4)(a) and any other areas of the standards such as Section 4(3)(c) and Section 7(1)(a).	No.		Projecting 100 procedures per region demonstrates need for the service in that geographic area, which is the basis for the requirement.
Review adding to the acquisition section of the standards to allow for an existing mobile lithotripsy route to acquire another existing lithotripsy route and merge the two together which would result in a single route with approval to provide service to all host sites approved on both routes at the time of application.	No.		This can currently be accomplished under the acquisition and expansion standards. This is consistent with other mobile equipment CON standards.
Review possible modification of Section 9(5)(c) of the Project Delivery Requirements which requires each mobile lithotripsy service to establish and maintain an Operations Committee to oversee the effective and efficient use of the lithotripsy unit(s).	No.		This requirement is important to allow for local input into the service. Host sites can authorize others to represent them in the Operations Committee.
Review the requirements for fixed lithotripsy units be revised from 1,000 to 500 procedures per unit annually for the minimum required volume in the project delivery requirements as well as replacement and acquisition, to be consistent with	Yes.	The Department can draft this language for the workgroup or Commission to consider.	

the newly approved language for initiation.			
For clarity, add the following language as a subsection to Section 7(3): "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 applicant for a host site."	Yes.	The Department can draft this language for the workgroup or Commission to consider.	This issue was identified by the CON Evaluation Section. This is a technical edit.
For clarity, add the following language as a subsection to Section 7(1): "A separate CON application has been submitted by the CSC and each proposed host site."	Yes.	The Department can draft this language for the workgroup or Commission to consider.	This issue was identified by the CON Evaluation Section. This is a technical edit.

Pursuant to MCL 333.22215 (1) (m), the Certificate of Need (CON) Commission is to "…review, and if necessary, revise each set of CON standards at least every 3 years." In accordance with the established review schedule on the Commission Work Plan, the UESWL Standards are scheduled for review in calendar year 2019.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 5 - 19, 2018. Testimony was received from eight organizations and is summarized as follows:

1. *Scott Sasserson, United Medical Systems (UMS) for Great Lakes Lithotripsy (GLL) and Michigan CON, LLC*
    - Remove the 100 procedure volume per region requirement from the Project Delivery Requirements in Section 9(4)(a) and any other areas of the standards such as Section 4(3)(c) and Section 7(1)(a). This was previously removed from Section 7(4) of the standards to allow for expansion of geographic access.
    - Add to the acquisition section of the standards to allow for an existing mobile lithotripsy route to acquire another existing lithotripsy route and merge the two together which would result in a single route with approval to provide service to all host sites approved on both routes at the time of application. They state that this would improve access and reduce costs.
    - Recommends modification of Section 9(5)(c) of the Project Delivery Requirements which requires each mobile lithotripsy service to establish and maintain an Operations Committee to oversee the effective and

efficient use of the lithotripsy unit(s). They are requesting that there is "an adequate representation of host sites" and not requiring "every" host site to have membership.

2. *Barbara Bressack, Henry Ford Health System (HFHS)*
    - Supports continued regulation and no changes.

3. *Anne Mitchell, Citizen*
    - Supports continued regulation.

4. *David Walker, Spectrum Health*
    - Supports continued regulation and no changes.

5. *Robert Casalou, Mercy Health – Saint Joseph Mercy Health System*
    - Supports continued regulation and no changes.

6. *T. Anthony Denton, JD, MHA, University of Michigan Health System (UMHS)*
    - Supports continued regulation and no changes.

7. *Sean Gehle, Ascension Michigan*
    - No recommended changes.

8. *Brett Jackson, Economic Alliance for Michigan (EAM)*
    - No review is currently necessary.

Background:

UESWL was last reviewed by the Department in 2016/2017. The effective date of the current standards is May 29, 2018.

UESWL Survey Data for 2017:

Annual survey data for 2017 is the latest available and can be found here:

Host Site Report:
https://www.michigan.gov/documents/mdhhs/090_-_Litho_Services_Host_Site_Utilization_626597_7.pdf

Mobile Providers Report:
https://www.michigan.gov/documents/mdhhs/094_-_Litho_Mobile_Routes_626599_7.pdf

Central Service Coordinators and Host Sites by Mobile Route Report
https://www.michigan.gov/documents/mdhhs/092_-_Litho_Services_Mobile_CSC_626598_7.pdf

Interim Report
Psychiatric Beds and Services Workgroup Meeting
13 March 2019
Prepared by Laura Hirshbein, MD, PhD

Since the last interim report (on 11/28/18), the Psychiatric Beds and Services Workgroup has met three more times, on 13 December 2018, 10 January 2019, and 7 March 2019. In addition, there were three smaller subgroups that formed to address specific topics (outlined below). In total, we have had robust engagement with numerous stakeholders across the state.

In our last three meetings, we focused on three of the charges that have required more extensive exploration: bed need methodology, the special pool beds, and the comparative review criteria. Paul Delamater presented a couple of times and also led a subgroup that met via teleconference to explore possible alternatives to the current bed need methodology. Arlene Elliott led a subgroup to explore the comparative review criteria, and they had a great deal of discussion via email and teleconference on standards, language, and published literature. And I led a subgroup to look at the special pool beds, with a particular focus on the types of beds and numbers recommended.

At this point, we have completed a review of the charges of the workgroup. There is a summary document of the workgroup's recommendations that is in draft form and was discussed at the last meeting on 7 March. The summary document will be updated and circulated to the participants of the workgroup over the next few weeks to allow for final comments. We expect that our recommendations will be presented to the CON Commission before the next meeting in June.

CERTIFICATE OF NEED

1st Quarter Compliance Report to the CON Commission

October 1, 2018 through September 30, 2019 (FY 2019)

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

MCL 333.22247

(1) The department shall monitor compliance with all certificates of need issued under this part and shall investigate allegations of noncompliance with a certificate of need or this part.

(2) If the department determines that the recipient of a certificate of need under this part is not in compliance with the terms of the certificate of need or that a person is in violation of this part or the rules promulgated under this part, the department shall do 1 or more of the following:

(a) Revoke or suspend the certificate of need.

(b) Impose a civil fine of not more than the amount of the billings for the services provided in violation of this part.

(c) Take any action authorized under this article for a violation of this article or a rule promulgated under this article, including, but not limited to, issuance of a compliance order under section 20162(5), whether or not the person is licensed under this article.

(d) Request enforcement action under section 22253.

(e) Take any other enforcement action authorized by this code.

(f) Publicize or report the violation or enforcement action, or both, to any person.

(g) Take any other action as determined appropriate by the department.

(3) A person shall not charge to, or collect from, another person or otherwise recover costs for services provided or for equipment or facilities that are acquired in violation of this part. If a person has violated this subsection, in addition to the sanctions provided under subsection (2), the person shall, upon request of the person from whom the charges were collected, refund those charges, either directly or through a credit on a subsequent bill.

Activity Report

Follow Up: In accordance with Administrative Rules 325.9403 and 325.9417, the Department tracks approved Certificates of Need to determine if proposed projects have been implemented in accordance with Part 222. By rule, applicants are required to either implement a project within one year of approval or execute an enforceable contract to purchase the covered equipment or start construction, as applicable. In addition, an applicant must install the equipment or start construction within two years of approval.

Activity	1st Quarter	Year-to-Date
Approved projects requiring 1-year follow up	69	69
Approved projects contacted on or before anniversary date	45	45
Approved projects completed on or before 1-year follow up	65%	
CON approvals expired	11	11
Total follow up correspondence sent	201	201
Total approved projects still ongoing	310	

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.

- Guardian Flight, LLC - The facility completed a change of ownership transaction and offered Air Ambulance services without CON approval. The facility was required to establish a process to ensure that CON covered services needing approval prior to operation is properly approved and should involve management level education within the organization about the CON process and requirements. The facility was required to pay a civil fine of $48,549.

- Mercy Health - Muskegon – The facility notified the Department that they have not fully complied with the terms and conditions of an approved CON within the required deadline. The Department was further notified that the facility took prompt action(s) after discovery of the error to obtain the accreditation at Mercy Health - Muskegon. The facility was required to submit a written corrective action plan, establishing a process to ensure that all terms and conditions of all CON approved projects are appropriately met and should involve management level education within the organization about the CON processes and requirements. The facility submitted documentations of full accreditation within 90 days and was required to pay a civil fine of $4,000.

- Ciena Healthcare Management – The Department was notified that Regency at Waterford licensed additional Nursing Home beds than what was approved by CON which had approval for multiple bed relocation CONs and some of those were expired. The facility was required to submit all necessary applications for the change in bed capacity with required application fees and implement these CONs on an expedited basis.

- The Department has completed statewide compliance reviews for Neonatal Intensive Care Unit (NICU) beds, Special Care Nursery (SCN) services, and Urinary Shockwave Lithotripsy (UESWL) services. Please see attached report detailing findings of the statewide compliance reviews.

- The Department proposes conducting statewide compliance reviews for Magnetic Resonance Imaging (MRI) and Positron Emission Tomography (PET) scanner services utilizing the most recent CON Annual Survey and MRI Utilization List data. The Department is in the process of evaluating annual survey data, review standard requirements, and CON approved facilities for these selected services to identify the facilities for compliance investigations. The finding of the statewide compliance reviews will be reported to the CON Commission at a later date.

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

CERTIFICATE OF NEED

1st Quarter Program Activity Report to the CON Commission

October 1, 2018 through September 30, 2019 (FY 2019)

This quarterly report is designed to assist the CON Commission in monitoring and assessing the operations and effectiveness of the CON Program Section in accordance with Section 22215(1)(e) of the Public Health Code, 1978 PA 368.

Measures

Administrative Rule R325.9201 requires the Department to process a Letter of Intent within 15 days upon receipt of a Letter of Intent.

Activity	1st Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Letters of Intent Received	72	N/A	72	N/A
Letters of Intent Processed within 15 days	70	97%	70	97%
Letters of Intent Processed Online	72	100%	72	100%

Administrative Rule R325.9201 requires the Department to request additional information from an applicant within 15 days upon receipt of an application, if additional information is needed.

Activity	1st Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Applications Received	69	N/A	69	N/A
Applications Processed within 15 Days	69	100%	69	100%
Applications Incomplete/More Information Needed	30	43%	30	43%
Applications Filed Online*	61	100%	61	100%
Application Fees Received Online*	25	41%	25	41%

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

Administrative rules R325.9206 and R325.9207 require the Department to issue a proposed decision for completed applications within 45 days for nonsubstantive, 120 days for substantive, and 150 days for comparative reviews.

Activity	1st Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Nonsubstantive Applications	30	100%	30	100%
Substantive Applications	35	100%	35	100%
Comparative Applications	2	100%	2	100%

Note: Data in this table may not total/correlate with application received table because receive and processed dates may carry over into next month/next quarter.

Measures – continued

Administrative Rule R325.9227 requires the Department to determine if an emergency application will be reviewed pursuant to Section 22235 of the Public Health Code within 10 working days upon receipt of the emergency application request.

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

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

Activity	1st Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Amendments	24	100%	24	100%

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

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

Other Measures

Activity	1st Quarter		Year-to-Date	
	No.	Percent	No.	Percent
FOIA Requests Received	118	N/A	118	N/A
FOIA Requests Processed on Time *	118	100%	118	100%
Number of Applications Viewed Onsite	0	N/A	0	N/A

FOIA – Freedom of Information Act.

*Request processed within 5 days or an extension filed.

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

Attachment M

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

CERTIFICATE OF NEED (CON) PROGRAM

ANNUAL ACTIVITY REPORT

October 2017 through September 2018
(FY2018)

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

http://www.michigan.gov/con

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TABLE OF CONTENTS

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 30th report to the Commission and covers the period beginning October 1, 2017, through September 30, 2018 (FY 2018). 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, Planning and Legislative Services Administration provides support for the CON Commission (Commission) and its Standard Advisory Committees (SACs). 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 2018, the Department has continued to make process improvements in both the Policy and Evaluation Sections.

The Evaluation Section implemented a streamlined and centralized system for receipt of all application documents and inquiries for timely submission and response. The Section also implemented an electronic system to distribute CON decision letters to interested parties for on-time access. The Department completed a statewide compliance review of all facilities providing cardiac catheterization and MRT services. The Section also facilitated several webinars to provide up-to-date information on revised standards and project delivery requirements, and CON reporting requirements.

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 initiate surgical service when under common ownership, add clarity to the Lithotripsy standards about support services and provision to initiate fixed service; add provision to replace IRF beds to a new site in the hospital beds standards to allow better access to rehabilitation services; add provisions to replace cardiac catheterization and open heart surgery services.

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, Planning and Legislative Services 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 2018 in Review

In FY 2018, there were 371 Letters of Intent received resulting in 296 applications filed for CON review and approval. In addition, the Department received 80 amendments to previously approved applications. In total, the Department approved 275 proposed projects resulting in approximately $2,135,290,160 of new capital expenditures into Michigan's healthcare system. The Department also surveyed 1,098 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 FY2018, the CON Commission revised the review standards for Surgical Services and Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) 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 FY2018.

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 or 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

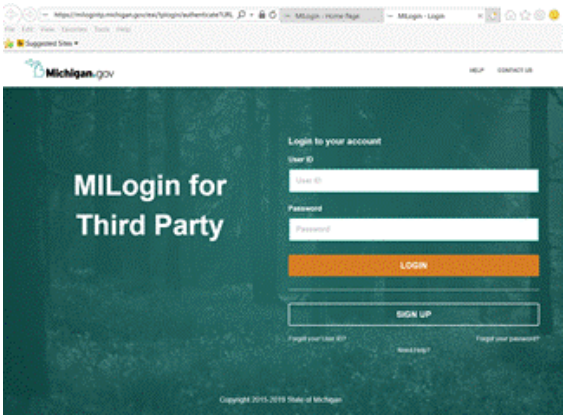
The CON Administrative Rules, specifically Rule 9201, provides that Letters of Intent (LOI) must be processed within 15 days of receipt. Processing an LOI includes entering data in the management information system, verifying historical facility information, and obtaining proof of authorization to do 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
FY2014 - FY2018

	LOIs Received	Processed within 15 Days	Percent Processed within 15 Days	Waivers Processed*
FY2014	333	332	99%	39
FY2015	435	434	99%	44
FY2016	442	439	99%	71
FY2017	341	340	99%	24
FY2018	371	370	99%	73

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



In FY 2018, 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.

TYPES OF CERTIFICATE OF NEED APPLICATION REVIEWS

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

Nonsubstantive

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

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

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

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

Substantive Individual

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

Comparative

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

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

Figure 1 delineates services/beds subject to comparative review.

FIGURE 1 *Services/Beds Subject to Comparative Review in FY2018*	
Neonatal Intensive Care Unit	Nursing Home/HLTCU Beds
Hospital Beds	Nursing Home Beds for Special Population Groups
Psychiatric Beds	Psychiatric Beds for Special Population Groups
Transplantations	

Note: See individual CON review standards for more information.

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

TABLE 2
APPLICATIONS RECEIVED BY REVIEW TYPE
FY2014 - FY2018

	FY2014	FY2015	FY2016	FY2017	FY2018
Nonsubstantive*	117	194	171	186	154
Substantive Individual	114	129	148	89	142
Comparative	2	0	0	0	0
TOTALS	233	323	319	275	296

* Includes 1 swing bed application.

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
FY2014 - FY2018

	FY2014	FY2015	FY2016	FY2017	FY2018
Applications Received	235	326	320	275	296
Processed within 15 Days	235	324	318	272	295
Percent Processed within 15 Days	100%	99%	99%	99%	99%

Note: Includes 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
FY2014- FY2018

	FY2014	FY2015	FY2016	FY2017	FY2018
Nonsubstantive	40	42	38	41	36
Substantive Individual	117	112	104	116	102
Comparative	116	N/A	N/A	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
FY2014 - FY2018

	FY2014	FY2015	FY2016	FY2017	FY2018
Emergency CONs Issued	2	2	0*	0	0
Percent Issued within 10 Working Days	100%	100%	N/A	N/A	N/A

*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
FY2014- FY2018

	Nonsubstantive		Substantive Individual		Comparative	
	Issued	Issued on Time	Issued	Issued on Time	Issued	Issued on Time
FY2014	119	100%	130	100%	6	100%
FY2015	195	100%	118	100%	0	N/A
FY2016	169	100%	138	100%	0	N/A
FY2017	167	100%	99	100%	0	N/A
FY2018	174	100%	107	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
FY2014- FY2018

	Approved	Approved w/ Conditions	Disapproved	Percent Disapproved	TOTAL
FY2014	222	28	7	3%	257
FY2015	261	53	1	0.3%	315
FY2016	226	81	0	0%	307
FY2017	205	61	0	0%	266
FY2018	214	65	2	0.7%	281

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

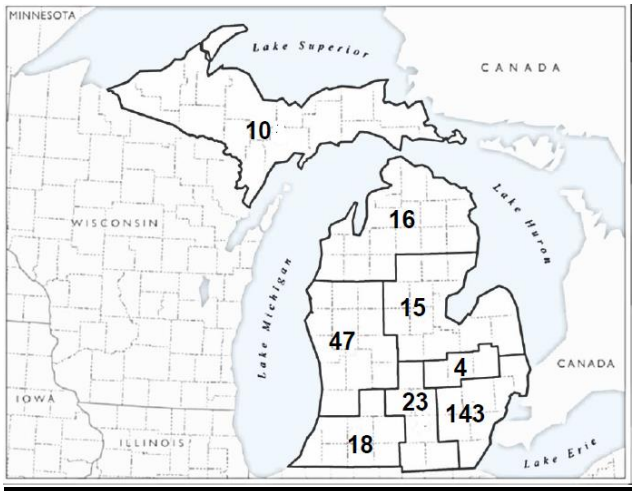
The Director issues a final decision on a CON application following either a proposed decision or the completion of a hearing, if requested, on a proposed decision. Pursuant to Section 22231(1) of the Public Health Code, the Director may issue a decision to approve an application, disapprove an application, 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 FY2014- FY2018*	
FY2014	256
FY2015	316
FY2016	303
FY2017	272
FY2018	276

FIGURE 2
FY 2018 FINAL DECISIONS ISSUED BY HEALTH SERVICE AREAS



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

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 projects in the 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 2017, the covered capital expenditure threshold was $3,187,500 and as of January 1, 2018, the covered capital expenditure threshold was increased to $3,252,500. The threshold is updated in January of every year.

TABLE 9 *FINAL DECISIONS ACTIVITY CATEGORY* *FY2014 - FY2018*					
Approved	**FY2014**	**FY2015**	**FY2016**	**FY2017**	**FY2018**
Acquire, Begin, or Replace a Health Facility	47	68	26	47	56
Change in Bed Capacity	46	34	42	26	40
Covered Clinical Services	191	214	240	167	180
Covered Capital Expenditures	47	33	49	65	32
Disapproved					
Acquire, Begin, or Replace a Health Facility	4	0	0	0	1
Change in Bed Capacity	5	1	0	0	0
Covered Clinical Services	0	1	0	0	0
Covered Capital Expenditures	5	1	0	0	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 *COMPARISON OF FINAL DECISIONS BY DECISION TYPE* *FY2014 - FY2018*				
	Approved	**Approved With Conditions**	**Disapproved**	**Totals**
Number of Final Decisions				
FY2014	223	28	5	256
FY2015	261	53	2	316
FY2016	224	79	0	303
FY2017	208	64	0	272
FY2018	210	65	1	276
Total Project Costs				
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
FY2017	$ 1,069,086,777	$ 307.391,790	$ 0	$ 1,376,478,567
FY2018	$1,590,933,280	$544,275,880	$200,000,000	$2,335,209,160

Note: Final decisions include emergency CON applications.

In FY2018, one (1) CON application received final decision of disapproval from the Department. This project was to begin operation of a new acute care hospital with 200 beds in n HSA-1.

CERTIFICATE OF NEED ACTIVITY SUMMARY COMPARISON

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

TABLE 11 *CON ACTIVITY COMPARISON FY2014 - FY2018*				
	Number of Applications	**Difference from Previous Year**	**Total Project Costs**	**Difference from Previous Year**
Letters of Intent Processed				
FY2014	333	(24%)	$1,282,834,192	(23%)
FY2015	435	31%	$2,894,486,078	126%
FY2016	442	2%	$1,527,863,597	(47%)
FY2017	341	(23%)	$1,864,251,305	22%
FY2018	397	16%	$2,660,753,511	43%
Applications Submitted				
FY2014	235	(28%)	$ 904,601,983	(41%)
FY2015	326	39%	$2,526,962,926	179%
FY2016	320	(2%)	$1,235,892,460	(51%)
FY2017	275	(14%)	$1,598,240,431	29%
FY2018	296	8%	$2,575,451,177	61%
Final Decisions Issued				
FY2014	256	(17%)	$1,140,856,082	(11%)
FY2015	316	23%	$2,322,741,030	104%
FY2016	303	(4%)	$1,314,654,311	(43%)
FY2017	272	(10%)	$1,376,478,567	5%
FY2018	276	2%	$2,335,209,160	70%

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
FY2014 - FY2018

	FY2014	FY2015	FY2016	FY2017	FY2018
Amendments Received	63	84	76	67	80
Amendment Decisions Issued	60	88	76	68	75
Percent Issued within Required Time Frame	99%	100%	97%	100%	100%

NEW CERTIFICATE OF NEED CAPACITY

Table 13 provides a comparison of existing covered services, equipment and facilities already operational to new capacity approved in FY 2018. Eighty one (81) of the 272 CON approvals in FY 2018 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
FY2018

Covered Clinical Services/Beds	Existing Sites	Existing Units/Beds	New Sites	New Units/Beds
Air Ambulances	14	17	0	0
Cardiac Catheterization Services	60	229	0	2
Primary PCI	1	N/A	0	N/A
Elective PCI	14	N/A	0	N/A
Open Heart Surgical Services	34	N/A	0	N/A
Surgical Services	254	1392	9	24
CT Scanners Services	256	388	3	10
MRI Services	275	310	20	7
PET Services	96	27	2	0
Lithotripsy Services	85	10	4	1
MRT Services	69	121	0	2
Transplant Services	6	N/A	0	N/A
Hospitals	183	26,047	2	29
NICU Services	21	640	0	0
SCN Services	15	91	0	0
Extended Care Services Program (Swing Beds)	32	293	0	4
Nursing Homes/HLTCU	471	48,533	1	58
Psychiatric Hospitals/Units	67	2,697	1	134
Psychiatric Flex Beds	4	46	0	0

Note: The source for the existing site and unit/bed information for Table 13 was the 2017 CON Annual Survey, and CON applications approved but not yet operational. Table 13 does not account for projects expired, facilities closed and beds delicensed and returned to the various bed pools since the last survey period for CY 2017. New sites include mobile host sites for CT, Lithotripsy, MRI and PET services.

COMPLIANCE ACTIONS

Table 14 shows there were 272 projects requiring follow-up for FY 2018 based on the Department's Monthly Follow-up/Monitoring Report as shown below.

TABLE 14 FOLLOW UP AND COMPLIANCE ACTIONS FY2014 - FY2018					
	FY2014	**FY2015**	**FY2016**	**FY2017**	**FY2018**
Projects Requiring 1-yr Follow-up	350	251	314	303	272
Approved CONs Expired	97	95	51	78	118
Compliance Orders Issued	6	30	10	54	48

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, settlement agreements offered or remedies for non-compliance. The Department completed a statewide compliance review of cardiac catheterization and MRT services. Other compliance orders issued included covered capital expenditure project, Lithotripsy and Air Ambulance services.

ANALYSIS OF CERTIFICATE OF NEED PROGRAM FEES AND COSTS

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

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

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

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

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

Table 15A *NUMBER OF CON APPLICATIONS BY FEE FY2014*	
CON Fee	**FY2014A**
*$ 0**	0
$1,500	5
$5,500	8
$8,500	7
TOTAL	20

TABLE 15B *NUMBER OF CON APPLICATIONS BY FEE FY2014 – FY2018*					
CON Fee	**FY2014B**	**FY 2015**	**FY2016**	**FY2017**	**FY2018**
*$ 0**	3	6	1	1	1
$3,000	103	146	166	95	123
$8,000	70	91	96	93	86
$11,000	23	36	27	42	30
$15,000	16	47	30	44	54
TOTAL	215	326	320	275	292

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 APPLICATION FEES FY2014 – FY2018*					
CON Fee Category	**FY2014**	**FY 2015**	**FY2016**	**FY2017**	**FY2018**
Complex Project	8	3	0	9	2
Expedited Review	27	38	42	31	52
*LOI Waiver**	37	34	69	23	77
*Amendment**	32	44	54	56	80
Annual Survey (Facilities)	1,191	1,107	1,099	1,056	1052

*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 FY2014– FY2018*					
	FY2014	**FY2015**	**FY2016**	**FY2017**	**FY2018**
Program Cost	$1,967,395	$2,115,182	$2,051,035	$1,972,166	$2,382,030
Fees/Funding	$1,823,772	$2,620,083	$2,350,168	$2,293,095	$2,607,045
Fees % of Costs	93%	100%+	100%+	100%+	100%+

Source: MDHHS Budget and Finance Administration.

CERTIFICATE OF NEED COMMISSION ACTIVITY

During FY2018, the CON Commission revised the review standards for Surgical Services and Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services.

The revisions to the CON Review Standards for Surgical Services received final approval by the CON Commission on September 21, 2017 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 November 17, 2017. The final language changes include the following:

- Updated the Department name throughout the document.
- Section 4(3)(a): Added language regarding commitment letters and the use of historical surgical cases for initiation.
- Section 11(2)(e): Added new language regarding commitment letters and the use of historical surgical cases for initiation as shown below. Less regulation will ease the process for the applicant when using its own data to initiate:
    - (e) SUBSECTION 11(2)(d) SHALL NOT APPLY IF THE PROPOSED PROJECT INVOLVES THE INITIATION OF A SURGICAL SERVICE AT A NEW FSOF OR A NEW ASC AT A NEW GEOGRAPHICAL SITE UTILIZING THE HISTORICAL SURGICAL CASES OF THE APPLICANT AND THE NEW SERVICE IS OWNED BY THE SAME APPLICANT. THE APPLICANT FACILITY COMMITTING SURGICAL DATA HAS COMPLETED THE DEPARTMENTAL FORM THAT CERTIFIES THE SURGICAL CASES WERE PERFORMED AT THE COMMITTING FACILITY AND THE SURGICAL CASES WILL BE TRANSFERRED TO THE PROPOSED SURGICAL FACILITY FOR NO LESS THAN 3 YEARS SUBSEQUENT TO THE INITIATION OF THE SURGICAL SERVICE PROPOSED BY THE APPLICANT.
- Other technical edits

The revisions to the CON Review Standards for UESWL Services received final approval by the CON Commission on March 27, 2018 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 29, 2018. The final language changes include the following:

- Updated the Department name throughout the document.
- Section 3(1)(c)(iii) and (vii): FSOF and ASC sites can't typically meet these requirements. The change is for administrative feasibility. (Note: The option for a contractual agreement was removed in 1998.)
    - EITHER on-site OR THROUGH A CONTRACTUAL AGREEMENT WITH ANOTHER HEALTH FACILITY, IV supplies and materials for infusions and medications, blood and blood products, and pharmaceuticals, including vasopressor medications, antibiotics, and fluids and solutions.
    - EITHER on-site OR THROUGH A CONTRACTUAL AGREEMENT WITH ANOTHER HEALTH FACILITY, A 23-hour holding unit.
- Section 3(2): Added requirements to convert from mobile to fixed UESWL services. The change is consistent with other CON covered mobile modalities that offer conversion.
    - (2) AN APPLICANT PROPOSING TO INITIATE A FIXED UESWL SERVICE THAT MEETS THE FOLLOWING REQUIREMENTS SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH SUBSECTION (1)(B):
    - (a) THE APPLICANT IS CURRENTLY AN EXISTING MOBILE UESWL HOST SITE.

- (b) THE APPLICANT HOSPITAL HAS PERFORMED AN AVERAGE OF AT LEAST 500 PROCEDURES ANNUALLY FOR THE PAST THREE YEARS PRIOR TO SUBMITTING AN APPLICATION.
- (c) THE APPLICANT HOSPITAL OPERATES AN EMERGENCY ROOM THAT PROVIDES 24-HOUR EMERGENCY CARE SERVICES AND AT LEAST 80,000 VISITS WITHIN THE MOST RECENT 12-MONTH PERIOD FOR WHICH DATA, VERIFIABLE BY THE DEPARTMENT, IS AVAILABLE.
- (d) THE APPLICANT HOSPITAL SHALL INSTALL AND OPERATE THE FIXED UESWL UNIT AT THE SAME SITE AS THE EXISTING HOST SITE.
- (e) THE APPLICANT HOSPITAL SHALL CEASE OPERATION AS A HOST SITE AND NOT BECOME A HOST SITE FOR AT LEAST 12 MONTHS FROM THE DATE THE FIXED SERVICE BECOMES OPERATIONAL.

- Section 4(2): Removed the volume requirement for replacement. This is similar to other CON covered clinical services.
- Section 4(3): Modified as follows. This will still allow for conversion from fixed to mobile, but the service will have to demonstrate compliance with the volume requirement. If a host site was converted to a fixed unit for better access to UESWL services at that site, then converting it back to a mobile unit seems to defeat that purpose. This language was originally written to convert fixed units to mobile.

  (3) An applicant PROPOSING TO REPLACE 1 existing fixed UESWL unit with 1 mobile UESWL unit SHALL DEMONSTRATE THAT THE PROPOSED PROJECT MEETS ALL OF 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.
- Section 4(4): 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 UESWL service to a new location in certain situations that are unforeseen to the applicant (same as MRI and CT language).
  - (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 UESWL service and its unit(s) to a new site in certain situations that are unforeseen to the applicant (same as MRI and CT language):
  - (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.
- Section 6 has been modified to allow for the acquisition of a fixed or mobile UESWL service not meeting volume requirements by an entity if the UESWL service is 1) owned by the applicant, 2) is under common control by the applicant, or 3) has a common

parent as the applicant. The acquisition of an UESWL service does not change the location of the service. The service would have to meet all other applicable UESWL standards and project delivery requirements. Reduced regulation allows for facilities to more easily realign their assets when part of a larger health system.

- Section 7(4) has been removed. This will give mobile routes more flexibility to change the route to accommodate changes that may be caused by facilities converting to a fixed unit.
- Appendix A: The factor for calculating projected UESWL procedures has been updated.
- Other technical edits.

The following review standards were reviewed with an anticipated completion in FY2019:

Hospital Beds: Proposed action was taken by the Commission at its March 27, 2018 meeting. The standards were submitted to the joint legislative committee (JLC) and a Public Hearing was held. The Commission took final action at its June 14, 2018 Commission meeting and were submitted to the JLC and Governor for the required 45-day review period. Standards will become effective in FY2019.

Cardiac Catheterization Services: Proposed action was taken by the Commission at its June 14, 2018 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 20, 2018 Commission meeting and were submitted to the JLC and Governor for the required 45-day review period. Standards will become effective in FY2019.

Open Heart Surgery Services: Proposed action was taken by the Commission at its June 14, 2018 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 20, 2018 Commission meeting and were submitted to the JLC and Governor for the required 45-day review period. Standards will become effective in FY2019.

Psychiatric Beds and Services is being reviewed by an informal workgroup.

Megavoltage Radiation Therapy (MRT) is being reviewed by a standard advisory committee (SAC).

APPENDIX I - CERTIFICATE OF NEED COMMISSION

James B. Falahee, Jr., JD, CON Commission Chairperson (Replaced Suresh Mukherji, MD as Chairperson 3/27/18)
Thomas Mittlebrun, III, Vice-Chairperson
Denise Brooks-Williams
John Dood (Replaced Gail J. Clarkson, RN, NHA)
Tressa Gardner, DO (Replaced Kathleen Cowling, DO)
Debra Guido-Allen, RN
Robert L. Hughes
Melanie Lalonde (Replaced Jessica A. Kochin)
Amy McKenzie, MD (Replaced Marc D. Keshishian, MD)
Melissa Oca, MD (Replaced Luis A. Tomatis, MD)
Stewart Wang (Replaced Suresh Mukherji, MD)

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

STATE OF MICHIGAN
DEPARTMENT OF ATTORNEY GENERAL

DANA NESSEL
ATTORNEY GENERAL

MEMORANDUM

March 14, 2019

TO: James Falahee
CON Commission Chair

FROM: Carl J. Hammaker, III CJH
Assistant Attorney General
Corporate Oversight Division

CC: Elizabeth Nagel
Joseph E. Potchen

RE: Legal Report for the March 21, 2019 Commission Meeting

We currently have two pending cases in the Michigan Administrative Office of Hearings and Rules.

On July 10, 2018, the Department issued its decision to expire CON 13-0375. CON 13-0375 was an approved project to make a change to the bed capacity at the Hickory Ridge of Temperance facility by adding 20 nursing home beds into a newly constructed addition. The matter is currently adjourned while the parties explore settlement. A status conference is scheduled for April 17, 2019.

On October 5, 2018, the Department issued a proposed decision to disapprove CON Application No. 18-0050 to begin operation of a new nursing home, Regency at East Ann Arbor. Formal discovery is ongoing. A status conference is scheduled for April 30, 2019.

In addition to these cases, we continue to work with MDHHS staff to assist in developing standards and providing legal advice on various matters.

CJH/cms

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

Attachment Q

	2018						2019					
	July	August	September	October	November	December	January	February	March	April	May	June
Commission Meetings			Meeting			Meeting	Special Meeting – Cancelled due to weather		Meeting			Meeting
Air Ambulance Services				Public Comment Period					Discussion/ Report			
Bone Marrow Transplantation (BMT) Services				SAC Nomination & Selection Period				BMTSAC Mtg.	BMTSAC Mtg.	BMTSAC Mtg.	BMTSAC Mtg.	BMTSAC Mtg.
Computed Tomography (CT) Scanner Services				Public Comment Period					Discussion/ Report			
Megavoltage Radiation Therapy (MRT) Services/Units		SAC Meeting		SAC Meeting	SAC Meeting				Report/Draft Language Presented/ Potential Proposed Action	Public Hearing		Report/ Final Action
Neonatal Intensive Care Services/Beds (NICU)				Public Comment Period					Discussion/ Report			
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups				Public Comment Period					Discussion/ Report			

	2018						2019					
	July	August	September	October	November	December	January	February	March	April	May	June
Psychiatric Beds and Services	Workgroup Meeting	Workgroup Meeting	Workgroup Meeting	Workgroup Meeting	Workgroup Meeting	Presentation/ Draft Language Presented/ Proposed Action; Workgroup Meeting	Workgroup Meeting	Public Hearing	Report/ Final Action Workgroup Meeting			Report/Draft Language Presented/ Potential Proposed Action
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units				Public Comment Period					Discussion/ Report			
New Medical Technology Standing Committee	Department Monitoring				Department Monitoring				Department Monitoring			
FY2018 CON Annual Report									Present Report to Commission			

For Approval March 21, 2019. 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), Policy, Planning & Legislative Services, Office of Planning, 5th Floor South Grand Bldg., 333 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	2021
Cardiac Catheterization Services	December 26, 2018	2020
Computed Tomography (CT) Scanner Services	December 9, 2016	2019
Heart/Lung and Liver Transplantation Services	September 28, 2012	2021
Hospital Beds	November 28, 2018	2020
Magnetic Resonance Imaging (MRI) Services	October 21, 2016	2021
Megavoltage Radiation Therapy (MRT) Services/Units	September 14, 2015	2020
Neonatal Intensive Care Services/Beds (NICU)	December 9, 2016	2019
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups	March 20, 2015	2019
Open Heart Surgery Services	December 26, 2018	2020
Positron Emission Tomography (PET) Scanner Services	September 14, 2015	2020
Psychiatric Beds and Services	December 9, 2016	2021
Surgical Services	November 17, 2017	2020
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	May 29, 2018	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.