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

Thursday, June 13, 2019

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

APPROVED MINUTES

I. Call to Order

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 9:34 a.m.)
Lindsey Dood
Debra Guido-Allen, RN
Robert Hughes (arrived at 9:34 a.m.)
Melanie LaLonde
Amy McKenzie, MD (arrived at 9:36 a.m.)
Stewart Wang, MD

B. Members Absent:

Tressa Gardner, DO
Melisa Oca, MD

C. Department of Attorney General Staff:

Carl Hammaker

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

Tulika Bhattacharya
Beth Nagel
Tania Rodriguez
Brenda Rogers

II. Review of Agenda

Motion by Commissioner Guido-Allen, seconded by Commissioner Lalonde to approve the agenda as presented. Motion carried.

III. Declaration of Conflicts of Interests

None.

IV. Review of Minutes of March 21, 2019

Motion by Commissioner Mittelbrun, seconded by Commissioner Guido-Allen to approve the minutes as presented. Motion carried.

V. Megavoltage Radiation Therapy (MRT) Services/Units – Public Hearing Summary

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

A. Public Comment

None.

B. Commission Discussion

None.

C. Commission Action

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

VI. Bone Marrow Transplantation Services Standard Advisory Committee (BMTSAC) – Final Report and Draft Language

BMTSAC Co-Chairperson Philip Stella, MD provided the report (Attachment C).

A. Public Comment

1. David Walker, Spectrum Health
2. Tracy Dietz, Henry Ford Health System (HFHS)

3. Greg Yanik, MD, University of Michigan

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Brooks-Williams, seconded by Commissioner Mittelbrun to determine that new standards are necessary for Immune Effector Cell Therapy (IECT) Services, take proposed action on the language (Attachment D) as presented and move forward to Public Hearing and to the JLC. Motion carried in a vote of 9 - Yes, 0 - No, and 0 - Abstained.

VII. Psychiatric Beds and Services Workgroup – Final Report and Draft Language

Psychiatric Beds and Services Workgroup Chairperson Laura Hirshbein, MD, PhD, provided the report (Attachment E).

A. Public Comment

1. Tracy Dietz, HFHS

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Dood, seconded by Commissioner Wang to take proposed action on the language (Attachment F) as presented and move forward to Public Hearing and to the JLC. Motion carried in a vote of 8 - Yes, 0 - No, and 1 - Abstained.

VIII. Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services/Units Services – Draft Language

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

A. Public Comment

None.

B. Commission Discussion

None.

C. Commission Action

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

IX. Legislative Update

Chairperson Falahee provided an update.

X. Administrative Update

A. Planning & Access to Care Section Update

Ms. Nagel provided an update on seating the NH-HLTCU SAC & CT Workgroup.

B. CON Evaluation Section Update

Ms. Bhattacharya provided an update on the following items:

1. Compliance Report (Attachment H)
2. Quarterly Performance Measures (Attachment I)

XI. Legal Activity Report

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

XII. Future Meeting Dates: September 19, 2019 and December 5, 2019

XIII. Public Comment

None.

XIV. Review of Commission Work Plan

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

A. Commission Discussion

None.

B. Commission Action

Motion by Commissioner Brooks-Williams, seconded by Commissioner Guido-Allen to accept the Work Plan as presented with updates from today's meeting. Motion carried in a vote of 9 - Yes, 0 - No, and 0 - Abstained.

XV. Adjournment

Motion by Commissioner Brooks-Williams, seconded by Commissioner LaLonde to adjourn the meeting at 11:17 a.m. Motion Carried in a vote of 9 - Yes, 0 - No, and 0 - Abstained.

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

Date: May 7, 2019

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 Megavoltage Radiation Therapy (MRT) Services/Units Standards

---

Public Hearing Testimony

Pursuant to MCL 333.22215 (3), the Certificate of Need (CON) Commission "...shall conduct a public hearing on its proposed action." The Commission took proposed action on the Psychiatric Beds and Services Standards at its March 21, 2019 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed Psychiatric Beds and Services Standards on April 25, 2019. Written testimony was accepted for an additional seven days after the hearing. Testimony was received from three organizations.

Written Testimony:

1.) *Joseph Cacchione, MD, President, Ascension Medical Group and Paul J. Chuba, MD, PhD, FACR, Medical Director, Radiation Oncology – Ascension Michigan*
- Supports the proposed language.

2.) *Dr. Benjamin Movsas, Chair, Radiation Oncology; Dr. Steven Kalkanis, Medical Director, Henry Ford Cancer Institute; and Bob Riney, President & Chief Operating Officer, Henry Ford Health System – Henry Ford Health System (HFHS)*
- Supports the proposed language.

3.) *Gwen G. Sandefur, MHSA, President, Spectrum Health Hospital Group – Spectrum Health*
- Supports the proposed language.

Department Recommendation:

The Department supports the language as presented at the March 21, 2019 CON Commission meeting.

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

SUMMARY OF SAC FOR

CHIMERIC ANTIGEN RECEPTOR CELLS (CAR-T)

The BMT SAC was charged to review if cellular therapies, such as, but not limited to CAR-T cells should be considered for regulation under CON BMT services or under separate standards or if no regulation is necessary under CON at this time. If regulation is recommended under BMT services, then review and recommend any necessary changes to the BMT Services CON Standards. If regulation is recommended under separate standards, then make a recommendation for new standards. The SAC had representation from Providers, Consumer Groups, Payers, Purchasers and Experts in the Field.

CAR-T cells are genetically modified patient cells, which are programmed to eliminate cancer cells. The therapy is currently FDA approved for the treatment of certain types of Non-Hodgkin's Lymphoma and patients with Acute Lymphoblastic Leukemia. These are likely the first of many complex cellular therapies for the treatment of malignant diseases.

The committee first defined the types of cells to be included. These standards were felt to apply to immune effector cells used to modulate an immune response for therapeutic intent, such as natural killer cells, T cells, and B cells. These would include, but not be limited to CAR-T cells. It was also strongly recommended that these forms of cellular therapy should not be restricted to BMT centers. However given the complex nature of CAR-T cell therapy and other cellular therapies the committee recommended these therapies should be regulated by the CON under separate standards. This would allow maintenance of quality programs throughout the state.

The new standards would have only one requirement and that would be to have accreditation by FACT (Foundation for the Accreditation for Cellular Therapies) under the Immune Effector Cell Pathway. This is an accreditation process, separate from bone marrow and stem cell transplantation, that encompasses multiple forms of cellular therapy. This is the accreditation recommended by CMS and the Association of American Cancer Institutes (AACI) for all centers involved in cellular therapies. Putting this under CON review would provide regulatory

oversight. It would prevent opening of independent programs who do not have the quality metrics to provide safe administration of these cells. The committee voted unanimously to approve these recommendations.

BMT SAC Member Name, Name of Organizations Member is Representing, Telephone Email

Philip J Stella, MD - **Co-Chair** Trinity Health - Michigan **Expert** (734) 712-5948 philip.stella@stjoeshealth.org

Joseph Uberti, MD - **Co-Chair** McLaren Health Care **Expert** (313) 576-8760 ubertii@karmanos .org

Tricia Baird, MD FAAFP MBA Priority Health **Payer** (616) 464-8268 tricia.baird@priorityhealth.com

Synnomon Harrell International Union, UAW **Consumer** (313) 926-5321 sharrell@uaw.net

Ishmael A. Jaiyesimi, MS, DO, FACP Beaumont Hospital - Royal Oak **Expert** (248) 551-6900 Ishmail.Jaiyesimi@beaumont.edu

Daniel Lebovic, MD Ascension Michigan **Expert** (313) 884-5522 Daniel.lebovic@ascension.org

Edward M. Peres, MD Henry Ford Health System **Expert** (313) 916-4642 eperes1@hfhs.org

Natalie Pirkola Ford Motor Company **Purchaser** (313) 390-0206 npirkola@ford.com

Gordan Srkalovic, MD, PhD, FACP Sparrow Health System **Provider** (517) 364-9426 gordan.srkalovic@sparrow.org

Burton Vanderlaan MD BCBSM **Expert** (616) 258-3025 BVanderLaan@bcbsm.com

Stephanie Williams, MD Spectrum Health Systems **Expert** (616) 486-5933 stephanie.williams@spectrumhealth.org

Gregory A. Yanik, MD, BS University of Michigan Health System **Expert** (734) 764-3243 gyanik@umich.edu

2019

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

CERTIFICATE OF NEED (CON) REVIEW STANDARDS
FOR IMMUNE EFFECTOR CELL THERAPY (IECT) 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 TO INITIATE, REPLACE OR ACQUIRE IECT SERVICES UNDER PART 222 OF THE CODE. THE CON COMMISSION ADDED IECT SERVICES AS A COVERED CLINICAL SERVICE PURSUANT TO MCL 333.22215. 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(C) OF THE CODE, BEING SECTION 333.22225(2)(C) OF THE MICHIGAN COMPILED LAWS.

SECTION 2. DEFINITIONS

Sec. 2. (1) AS USED IN THESE STANDARDS:

(a) "CERTIFICATE OF NEED COMMISSION" OR "COMMISSION" MEANS THE COMMISSION CREATED PURSUANT TO SECTION 22211 OF THE CODE, BEING SECTION 333.22211 OF THE MICHIGAN COMPILED LAWS.

(b) “CHIMERIC ANTIGEN RECEPTOR (CAR) T CELLS” MEANS A GENETICALLY MODIFIED T CELL USED IN IMMUNE EFFECTOR CELL THERAPY (IECT).

(c) "CODE" MEANS ACT NO. 368 OF THE PUBLIC ACTS OF 1978, AS AMENDED, BEING SECTION 333.1101 ET SEQ. OF THE MICHIGAN COMPILED LAWS.

(d) "DEPARTMENT" MEANS THE MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES (MDHHS).

(e) "DEPARTMENT INVENTORY OF IECT SERVICES" MEANS THE LIST MAINTAINED BY THE DEPARTMENT OF: (i) THE IECT SERVICES OPERATING PURSUANT TO A VALID CON ISSUED UNDER PART 222; AND (ii) IECT SERVICES THAT ARE NOT YET OPERATIONAL BUT HAVE A VALID CON ISSUED UNDER PART 222. THE LIST SHALL SPECIFY THE SITE AT WHICH THE IECT SERVICE IS AUTHORIZED.

(f) "EXISTING IECT SERVICE," MEANS ANY OF THE FOLLOWING: (I) AN IECT SERVICE LISTED ON THE DEPARTMENT INVENTORY, (II) A PROPOSED IECT SERVICE UNDER APPEAL FROM A FINAL DECISION OF THE DEPARTMENT, OR (III) A PROPOSED IECT SERVICE THAT IS PART OF A COMPLETED APPLICATION UNDER PART 222 (OTHER THAN THE APPLICATION UNDER REVIEW) FOR WHICH A PROPOSED DECISION HAS BEEN ISSUED AND WHICH IS PENDING FINAL DECISION.

(g) “IMMUNE EFFECTOR CELL THERAPY (IECT)” OR “CELLULAR THERAPY” MEANS CELLULAR IMMUNOTHERAPIES, AND OTHER TYPES OF BOTH AUTOLOGOUS AND ALLOGENEIC CELLS DERIVED FROM IMMUNE EFFECTOR CELLS TO TREAT CERTAIN THERAPEUTIC INDICATIONS. FOR PURPOSES OF CON, THIS TERM DOES NOT INCLUDE THERAPEUTIC CANCER VACCINES REGULATED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER) OR ADOPTIVE IMMUNOTHERAPEUTIC PRODUCTS THAT ARE CURRENTLY FDA APROVED AND ARE GIVEN TO PATIENTS IN THE OUTPATIENT SETTING, AS THESE STANDARDS PRODUCTS HAVE DIFFERENT MECHANISMS OF ACTION AND THEREFORE THESE STANDARDS SHALL NOT APPLY.

(h) “IMMUNE EFFECTOR CELL THERAPY SERVICE” OR “IECT SERVICE” MEANS THE INFUSION OR TRANSFER OF IMMUNE EFFECTOR CELLS AND/OR IMMUNE EFFECTOR CELL

THERAPIES INTO PATIENTS. THIS DEFINITION DOES NOT INCLUDE BONE MARROW OR STEM CELL TRANSPLANTATION.

(i) “IMMUNE EFFECTOR CELLS” MEANS CELLS FROM THE HUMAN BODY THAT HAVE DIFFERENTIATED INTO A FORM CAPABLE OF MODULATING OR EFFECTING AN IMMUNE RESPONSE SUCH AS, BUT NOT LIMITED TO, B CELLS, DENDRITIC CELLS, NATURAL KILLER CELLS, AND T CELLS. THIS DEFINITION INCLUDES CAR T CELLS. FOR PURPOSES OF THESE STANDARDS, IMMUNE EFFECTOR CELLS TO BE USED IN IECT SERVICES MUST BE COLLECTED AND PROCESSED AT A FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY (FACT) ACCREDITATED FACILITY.

(j) "INSTITUTIONAL REVIEW BOARD" OR "IRB" MEANS AN INSTITUTIONAL REVIEW BOARD AS DEFINED BY PUBLIC LAW 93-348 WHICH IS REGULATED BY TITLE 45 CFR 46.

(k) "MEDICAID" MEANS TITLE XIX OF THE SOCIAL SECURITY ACT, CHAPTER 531, 49 STAT. 620, 42 U.S.C. 1396 TO 1396G AND1396I TO 1396U.

(2) THE DEFINITIONS OF PART 222 SHALL APPLY TO THESE STANDARDS.

SECTION 3. REQUIREMENTS TO INITIATE AN IECT SERVICE

Sec. 3. INITIATE AN IECT SERVICE MEANS TO BEGIN OPERATION OF AN IECT SERVICE AT A SITE THAT DOES NOT PROVIDE IECT SERVICES AND IS NOT LISTED ON THE DEPARTMENT INVENTORY AS OF THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT. AN APPLICANT PROPOSING TO INITIATE AN IECT SERVICE SHALL DEMONSTRATE THE FOLLOWING REQUIREMENTS.

(1) AN APPLICANT PROPOSING TO INITIATE AN IECT SERVICE SHALL AGREE TO OBTAIN FACT ACCREDITATION FOR IECT WITHIN 3 YEARS OF CON APPROVAL. THE APPLICANT SHALL ALSO AGREE TO MAINTAIN FACT ACCREDITATION FOR CELLULAR THERAPY FOR THE LIFE OF THE SERVICE.

(2) AN APPLICANT SHALL SPECIFY THE FACT ACCREDITED SITE AT WHICH THE IECT SERVICE WILL BE PROVIDED.

(3) AN APPLICANT PROPOSING TO INITIATE AN IECT SERVICE SHALL CERTIFY THAT IT WILL ONLY OFFER CELLULAR THERAPIES THAT HAVE FOOD AND DRUG ADMINISTRATION (FDA) APPROVAL OR ARE OFFERED AS PART OF A CLINICAL OR INVESTIGATIONAL TRIAL. THE CLINICAL OR INVESTIGATIONAL TRIAL SHALL BE FOR NEW NON-FDA APPROVED PRODUCTS OR NEW INDICATIONS OF CURRENTLY AVAILABLE COMMERCIAL PRODUCTS. THE CLINICAL OR INVESTIGATIONAL TRIAL SHALL BE CONDUCTED THROUGH APPROPRIATE IRB APPROVED PROTOCOLS.

SECTION 4. REQUIREMENTS FOR APPROVAL – ACQUISITION OF AN IECT SERVICE

SEC 4. ACQUISITION OF AN IECT SERVICE MEANS THE ACQUISITION (INCLUDING PURCHASE, LEASE, DONATION, OR OTHER ARRANGEMENT) OF AN EXISTING IECT SERVICE. AN APPLICANT PROPOSING TO ACQUIRE AN EXISTING IECT SERVICE SHALL DEMONSTRATE THE FOLLOWING:

(1) THE EXISTING IECT SERVICE IS FACT ACCREDITED FOR IECT AND SHALL AGREE TO MAINTAIN FACT ACCREDITATION FOR CELLULAR THERAPY FOR THE LIFE OF THE SERVICE.

(2) THE APPLICANT AGREES AND ASSURES TO COMPLY WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS.

SECTION 5. REQUIREMENTS TO REPLACE IECT SERVICES

SEC. 5. REPLACEMENT OF AN IECT SERVICE MEANS RELOCATING AN EXISTING IECT SERVICE TO A NEW GEOGRAPHIC LOCATION. THE TERM DOES NOT INCLUDE THE REPLACEMENT OF AN EXISTING IECT SERVICE AT THE SAME SITE. AN APPLICANT REQUESTING TO REPLACE AN EXISTING IECT SERVICE SHALL DEMONSTRATE EACH OF THE FOLLOWING.

(1) AN APPLICANT PROPOSING TO REPLACE AN EXISTING IECT SERVICE SHALL DEMONSTRATE THAT THE EXISTING IECT SERVICE IS FACT ACCREDITED FOR IECT AND SHALL AGREE TO OBTAIN FACT ACCREDITATION, AND THE NEW SERVICE SHALL MEET THE REQUIREMENTS OF SECTION 3.

(2) THE EXISTING IECT SERVICE TO BE REPLACED HAS BEEN IN OPERATION FOR AT LEAST 36 MONTHS AS OF THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT.

(3) THE IECT SERVICE SHALL CEASE OPERATION AT THE ORIGINAL SITE PRIOR TO BEGINNING OPERATION AT THE NEW SITE.

SECTION 6. REQUIREMENTS FOR MEDICAID PARTICIPATION

SEC. 6. 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 7. PROJECT DELIVERY REQUIREMENTS TERMS OF APPROVAL FOR ALL APPLICANTS

SEC. 7. AN APPLICANT SHALL AGREE THAT, IF APPROVED, THE IECT SERVICE SHALL BE DELIVERED IN COMPLIANCE WITH THE FOLLOWING TERMS OF APPROVAL:

(1) COMPLIANCE WITH THESE STANDARDS. AN APPLICANT SHALL IMMEDIATELY REPORT TO THE DEPARTMENT ANY CHANGES IN THE IECT SERVICE THAT MAY AFFECT ITS ABILITY TO COMPLY WITH THESE STANDARDS.

(2) COMPLIANCE WITH THE FOLLOWING QUALITY ASSURANCE REQUIREMENTS:

(a) THE APPLICANT SHALL OBTAIN FACT ACCREDITATION WITHIN 3 YEARS OF CON APPROVAL AND SHALL MAINTAIN FACT ACCREDITATION THROUGHOUT THE LIFE OF THE SERVICE AS LONG AS THE SERVICE PROVIDES CELLULAR THERAPIES FOR WHICH FACT ACCREDITATION IS REQUIRED OR RECOMMENDED. THE APPLICANT SHALL IMMEDIATELY NOTIFY THE DEPARTMENT IF IT'S FACT ACCREDITATION IS SUSPENDED, REVOKED, EXPIRED OR OTHERWISE LIMITED.

(b) AN APPLICANT SHALL CERTIFY THAT IT WILL ONLY OFFER CELLULAR THERAPIES THAT HAVE FDA APPROVAL OR ARE OFFERED AS PART OF A CLINICAL OR INVESTIGATIONAL TRIAL. THE CLINICAL OR INVESTIGATIONAL TRIAL SHALL BE FOR NEW NON-FDA APPROVED PRODUCTS OR NEW INDICATIONS OF CURRENTLY AVAILABLE COMMERCIAL PRODUCTS. THE CLINICAL OR INVESTIGATIONAL TRIAL SHALL BE CONDUCTED THROUGH APPROPRIATE IRB APPROVED PROTOCOLS.

(3) COMPLIANCE WITH THE FOLLOWING ACCESS TO CARE REQUIREMENTS:

(A) THE IECT SERVICE SHALL ACCEPT REFERRALS FOR IECT SERVICES FROM ALL APPROPRIATELY LICENSED HEALTH CARE PRACTITIONERS.

(B) THE IECT SERVICE SHALL PARTICIPATE IN MEDICAID AT LEAST 12 CONSECUTIVE MONTHS WITHIN THE FIRST TWO YEARS OF OPERATION AND CONTINUE TO PARTICIPATE ANNUALLY THEREAFTER.

(C) THE IECT SERVICE SHALL NOT DENY IECT SERVICES TO ANY INDIVIDUAL BASED ON ABILITY TO PAY OR SOURCE OF PAYMENT.

(D) THE OPERATION OF AND REFERRAL OF PATIENTS TO THE IECT SERVICE SHALL BE IN CONFORMANCE WITH 1978 PA 368, SEC. 16221, AS AMENDED BY 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

(4) COMPLIANCE WITH THE FOLLOWING MONITORING AND REPORTING REQUIREMENTS:

(a) 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, DEMOGRAPHIC AND DIAGNOSTIC INFORMATION, PRIMARY AND SECONDARY DIAGNOSES, LENGTH OF STAY, THE VOLUME OF CARE PROVIDED TO PATIENTS FROM ALL PAYOR SOURCES, AND OTHER DATA REQUESTED BY THE DEPARTMENT AND APPROVED BY THE CON COMMISSION. THE APPLICANT SHALL PROVIDE THE REQUIRED DATA ON AN INDIVIDUAL BASIS FOR EACH DESIGNATED FACT ACCREDITED 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.

(b) THE IECT SERVICE SHALL PROVIDE THE DEPARTMENT WITH TIMELY NOTICE OF THE PROPOSED PROJECT IMPLEMENTATION CONSISTENT WITH APPLICABLE STATUTE AND PROMULGATED RULES.

(5) 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 8. DEPARTMENT INVENTORY OF IECT SERVICES

SEC. 8. THE DEPARTMENT SHALL MAINTAIN, AND PROVIDE ON REQUEST, A LISTING OF THE DEPARTMENT INVENTORY OF IECT SERVICES.

SECTION 9. EFFECT ON PRIOR POLICIES; COMPARATIVE REVIEWS

SEC. 10. (1) PROJECTS REVIEWED UNDER THESE STANDARDS SHALL NOT BE SUBJECT TO COMPARATIVE REVIEW.

Michigan Certificate of Need Psychiatric Bed Workgroup
Charges and Recommendations
Laura Hirshbein, MD, PhD, Chair
17 May 2019

The Michigan Certificate of Need Psychiatric Bed Workgroup met six times between August 2018 and March 2019. Approximately 90 people attended one or more of the public meetings. Several sub-workgroups were formed within the bigger group to address the charges of the workgoup. The following represents our conclusions on the charges made by the Certificate of Need Commission.

1. *Determine if modifications are necessary to Section 2(1)(s) to consider adding Nurse Practitioners and Physician Assistants individually to the definition of "Mental Health Professional" and include as part of "Mental Health Professional" in Section 15(1) – Project delivery requirements – additional terms of approval for child/adolescent service.*

Recommendation: The Workgroup noted that the way the standard is written, it appears that there is nothing to be gained by adding advanced practice providers (NP/PA) to the definition of "Mental Health Professional." The only place in the standard in which the specific mental health professionals are listed is in Section 14.1, which identifies individuals who must be included in a licensed child/adolescent psychiatric service. Although it is not the intent of the standard, it appears that identifying advanced practice providers within the category of mental health professionals would require facilities to have this type of provider on staff. At this point, we would not recommend making this change. There is nothing within the CON standards to prevent a facility from employing advanced practice providers.

Although there does not seem to be a need to add the advanced practice provider to the CON standard, we would like to respectfully suggest that all the regulatory bodies within the State of Michigan strive toward a consistent standard for what advanced practice providers are able to do (especially as stated in the Michigan Mental Health Code).

2. *Review potential options for flexibility to transfer beds and/or create units with existing child/adolescent and adult beds*.

Recommendation: The Workgroup understands that a proposal to allow for transfer of child/adolescent beds to facilities without an existing child/adolescent unit (but with an emergency department) was heard at the CON Commission. The Workgroup endorses that proposal (changes reflected in Sections 7 and 8).

3. *Review the methodology for determining the inpatient psychiatric bed need in the state, including the proper percentage of psychiatric beds that should be allocated to the special pool for psychiatric beds*.

Recommendations: The Workgroup spent a considerable amount of time reviewing the potential methodology options for determining need for psychiatric beds in the state of Michigan. We reviewed a number of challenges, including the fact that the need for psychiatric services in the state has increased at a much higher rate in the past 5 years than in the past (which rendered past predictions inaccurate). Going forward, the Workgroup has endorsed changes in Section 3 of the CON standards as follows:

- We recommend that the current methodologies for predicting inpatient psychiatric bed need for both adult and child/adolescent beds be retired. We propose a new bed need methodology that incorporates a time series approach to predict future patient days and a normative approach to distribute those patient days to the HSAs (Health Service Areas). The proposed methodology can be used for both adult and child/adolescent beds. While the proposed methodology is not without flaws, we believe that it is a more justifiable approach and potentially more accurate than the methodologies currently in place.
- We also recommend that the CON Commission and MDHHS work with the current psychiatric facilities in an effort to collect additional data via the CON Annual Survey or MIDB.
- We recommend an increase of the Special Pool Bed number to 7.5% of the total bed need in the state for existing categories of Developmentally Disabled, Geriatric Psychiatry, and Med-Psych. We have also recommended adding a new category of High Acuity that would be 10% of the total bed need in the state. The minimum for all of the categories that can include child/adolescent beds should be increased to 50.

4. *Review the comparative review criteria*.

Recommendations: A subgroup of the Psychiatric Bed Need Workgroup did a detailed analysis of the specific criteria for comparative review and proposed significant changes. These include more emphasis on access for indigent and high acuity populations. These revisions are in line with the identified need for patients who have been difficult to place throughout the state with a focus on access, quality, and cost. The formulas for comparative review have been simplified. Section 11 has been rewritten to reflect these changes.

5. *Review criteria for the special pool beds*.

Recommendations: The Workgroup agreed that the special pool beds offered a useful mechanism to allow facilities to address needs within the state and their areas. The recommendation was to increase the percentage of the state bed need formula to increase the

number of special pool beds. The group also recommended a revision of the standard for Med-Psych beds, as well as a new category of special pool bed: the High Acuity unit.

- The standard for Med-Psych units is proposed to be revised to include both units within general hospitals (where the medical services are in the same overall facility) and free-standing psychiatric units with collaborative agreements with medical service hospitals.
- A High Acuity unit was defined to capture patient populations that are hard to place. These populations are defined as demonstrating 3 or more symptoms to a moderate degree or 2 or more symptoms to a severe degree: confusion, irritability, boisterousness, poor impulse control, uncooperativeness, hostility, verbal threats, physical threats, attacking objects. High acuity also includes patients who are unable to refrain from harming themselves or others during this episode of illness or who have a history of harming themselves or others while on an inpatient psychiatric unit. [A sample screening form that could be used by Emergency Departments and/or inpatient psychiatric facilities is included as an attachment to this report.]
- The High Acuity criteria were developed from two validated scales used in acute psychiatric settings, the Excited Component of the Positive and Negative Syndrome Scale (PANSS-EC) and the Brøset Violence Checklist (BVC). The cutoffs to identify a patient as high acuity reflect a higher likelihood for aggressive behaviors or need for higher staffing or emergency medications.

6. *Add clarifying language, as appropriate, in each subsection of Section 8 to assist in understanding which subsection(s) apply under what circumstances (e.g., adding new beds from dept. inventory, adding new beds under high occupancy, relocate beds, etc).*

Recommendation: The Workgroup reviewed this language with MDHHS professionals and modifications to Section 8 have been submitted.

7. *Add minimum occupancy requirements in last 12-months prior to application submission, as in hospital beds standards, for the existing psych hospital/unit before a new entity can acquire the facility, replace the facility, or relocate beds*.

Recommendation: The Workgroup recommended lowering minimum occupancy to 60% for adult beds and 40% for child beds as reflected in Sections 6, 7, and 10.

8. *Consider any technical or other changes from the Department, e.g., updates or modifications consistent with other CON review standards and the Public Health Code*.

Recommendation: Throughout this process, the Workgroup consistently came up against issues around provider availability, continuum of care gaps, and inadequate reimbursement for many

patients' hospitalizations. The Workgroup recommends continuing work in these areas on the state level.

PSYCHIATRIC PROPOSED BED NEED – NEW METHODOLOGY

Results

Adult

HSA	BEDS (avg)	OCC Adj	Patient Days	BEDS (pred)	BEDS (curr)	DIFF
1	42.6	0.7	282,824	1107	1,273	166
2	27.2	0.7	47,072	185	176	-9
3	25.3	0.7	49,522	194	152	-42
4	51.7	0.7	94,343	370	362	-8
5	33.8	0.7	32,598	128	135	7
6	29.3	0.7	42,143	165	117	-48
7	14.5	0.65	23,748	101	32	-69
8	28.5	0.7	16,455	65	57	-8

Child/adolescent

HSA	BEDS (avg)	OCC Adj	Patient Days	BEDS (pred)	BEDS (curr)	DIFF
1	29	0.7	43,776	173	148	-25
2	16	0.65	7,106	30	16	-14
3	6	0.65	8,075	35	6	-29
4	33	0.7	16,003	61	79	18
5	0	0.65	5,129	25	0	-25
6	33	0.7	6,354	26	33	7
7	0	0.65	3,637	17	0	-17
8	6	0.65	2,310	10	6	-4

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.~~ “AVERAGE OCCUPANCY RATE” IS CALCULATED AS FOLLOWS:

(i) CALCULATE THE NUMBER OF PATIENT DAYS DURING THE MOST RECENT, CONSECUTIVE 12-MONTH PERIOD, AS OF THE DATE OF THE APPLICATION, FOR WHICH VERIFIABLE DATA ARE AVAILABLE TO THE DEPARTMENT.

(ii) CALCULATE THE TOTAL LICENSED BED DAYS FOR THE SAME 12-MONTH PERIOD AS IN (i) ABOVE BY MULTIPLYING THE TOTAL LICENSED BEDS BY THE NUMBER OF DAYS THEY WERE LICENSED.

(iii) DIVIDE THE NUMBER OF PATIENT DAYS CALCULATED IN (i) ABOVE BY THE TOTAL LICENSED BED DAYS CALCULATED IN (ii) ABOVE, THEN MULTIPLY THE RESULT BY 100.

(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~~16.

(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~~ 6 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).~~ THE NUMBER OF CHILD/ADOLESCENT INPATIENT PSYCHIATRIC BEDS NEEDED IN A PLANNING AREA SHALL BE DETERMINED BY THE FOLLOWING FORMULA:

(a) TABULATE THE YEARLY NUMBER OF CHILD/ADOLESCENT PATIENT DAYS FOR THE MOST RECENT FIVE YEARS OF DATA FROM THE CON ANNUAL SURVEY.

(b) CONSTRUCT A LINEAR REGRESSION MODEL WITH YEAR AS THE INDEPENDENT

VARIABLE AND YEARLY PATIENT DAYS AS THE DEPENDENT VARIABLE. IF THE COEFFICIENT OF DETERMINATION (R^2) OF THE LINEAR MODEL IS 0.5 OR GREATER, USE THE REGRESSION PARAMETERS TO PREDICT THE STATEWIDE PATIENT DAYS IN THE PLANNING YEAR. IF THE COEFFICIENT OF DETERMINATION OF THE LINEAR MODEL IS LESS THAN 0.5, CALCULATE THE STATEWIDE PATIENT DAYS IN THE PLANNING YEAR BY TAKING THE MEAN OF THE MOST RECENT THREE YEARS OF DATA.

(c) DIVIDE THE TOTAL PATIENT DAYS OBTAINED IN SUBSECTION (B) BY THE STATEWIDE PLANNING YEAR POPULATION AGE 0-17. THE RESULT IS THE UTILIZATION RATE FOR THE POPULATION AGE 0-17 IN THE PLANNING YEAR.

(d) MULTIPLY THE UTILIZATION RATE OBTAINED IN SUBSECTION (C) BY THE PLANNING YEAR POPULATION AGE 0-17 IN EACH PLANNING AREA. THE RESULT IS THE UNADJUSTED NUMBER OF CHILD/ADOLESCENT PATIENT DAYS FOR EACH PLANNING AREA IN THE PLANNING YEAR.

(e) USING THE MOST RECENT DATA FROM THE DEPARTMENT INVENTORY OF BEDS, CALCULATE THE AVERAGE NUMBER OF LICENSED CHILD/ADOLESCENT BEDS PER FACILITY FOR EACH PLANNING AREA.

(f) FOR PLANNING AREAS WITH AN AVERAGE NUMBER OF BEDS PER FACILITY LESS THAN 20, DIVIDE THE UNADJUSTED PLANNING AREA PATIENT DAYS BY 0.65. FOR PLANNING AREAS WITH AN AVERAGE NUMBER OF BEDS PER FACILITY OF 20 OR MORE, DIVIDE THE UNADJUSTED PLANNING AREA PATIENT DAYS BY 0.70. THE RESULT IS THE OCCUPANCY-ADJUSTED NUMBER OF CHILD/ADOLESCENT PATIENT DAYS FOR EACH PLANNING AREA IN THE PLANNING YEAR.

(g) FOR EACH PLANNING AREA, DIVIDE THE OCCUPANCY-ADJUSTED NUMBER OF CHILD/ADOLESCENT PATIENT DAYS FROM (F) BY 365 (OR 366 FOR LEAP YEARS). ROUND THE VALUES UP TO THE NEAREST WHOLE NUMBER. THE RESULT IS CHILD/ADOLESCENT BED NEED IN THE PLANNING YEAR.

(2) THE NUMBER OF ADULT INPATIENT PSYCHIATRIC BEDS NEEDED IN A PLANNING AREA SHALL BE DETERMINED BY THE FOLLOWING FORMULA:

(a) TABULATE THE YEARLY NUMBER OF ADULT PATIENT DAYS FOR THE MOST RECENT FIVE YEARS OF DATA FROM THE CON ANNUAL SURVEY.

(b) CONSTRUCT A LINEAR REGRESSION MODEL WITH YEAR AS THE INDEPENDENT VARIABLE AND YEARLY PATIENT DAYS AS THE DEPENDENT VARIABLE. IF THE COEFFICIENT OF DETERMINATION (R^2) OF THE LINEAR MODEL IS 0.5 OR GREATER, USE THE REGRESSION PARAMETERS TO PREDICT THE STATEWIDE PATIENT DAYS IN THE PLANNING YEAR. IF THE COEFFICIENT OF DETERMINATION OF THE LINEAR MODEL IS LESS THAN 0.5, CALCULATE THE STATEWIDE PATIENT DAYS IN THE PLANNING YEAR BY TAKING THE MEAN OF THE MOST RECENT THREE YEARS OF DATA.

(c) DIVIDE THE TOTAL PATIENT DAYS OBTAINED IN SUBSECTION (B) BY THE STATEWIDE PLANNING YEAR POPULATION AGE 18+. THE RESULT IS THE UTILIZATION RATE FOR THE POPULATION AGE 18+ IN THE PLANNING YEAR.

(d) MULTIPLY THE UTILIZATION RATE OBTAINED IN SUBSECTION (C) BY THE PLANNING YEAR POPULATION AGE 18+ IN EACH PLANNING AREA. THE RESULT IS THE UNADJUSTED NUMBER OF ADULT PATIENT DAYS FOR EACH PLANNING AREA IN THE PLANNING YEAR.

(e) USING THE MOST RECENT DATA FROM THE DEPARTMENT INVENTORY OF BEDS, CALCULATE THE AVERAGE NUMBER OF LICENSED ADULT BEDS PER FACILITY FOR EACH PLANNING AREA.

(f) FOR PLANNING AREAS WITH AN AVERAGE NUMBER OF BEDS PER FACILITY LESS THAN 20, DIVIDE THE UNADJUSTED PLANNING AREA PATIENT DAYS BY 0.65. FOR PLANNING AREAS WITH AN AVERAGE NUMBER OF BEDS PER FACILITY OF 20 OR MORE, DIVIDE THE UNADJUSTED PLANNING AREA PATIENT DAYS BY 0.70. THE RESULT IS THE OCCUPANCY-ADJUSTED NUMBER OF ADULT PATENT DAYS FOR EACH PLANNING AREA IN THE PLANNING YEAR.

(g) FOR EACH PLANNING AREA, DIVIDE THE OCCUPANCY-ADJUSTED NUMBER OF ADULT PATIENT DAYS FROM (F) BY 365 (OR 366 FOR LEAP YEARS). ROUND THE VALUES UP TO THE NEAREST WHOLE NUMBER. THE RESULT IS ADULT BED NEED IN THE PLANNING YEAR.

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~~5. 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~~6. Requirements for approval to replace beds

Sec. ~~7~~6. 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.

(6) THE APPLICANT SHALL COMPLY WITH THE FOLLOWING REQUIREMENTS, AS APPLICABLE:

(a) THE EXISTING PSYCHIATRIC HOSPITAL OR UNIT SHALL HAVE AN AVERAGE OCCUPANCY RATE OF AT LEAST 60% FOR ADULT BEDS AND 40% FOR CHILD/ADOLESCENT BEDS.

(b) IF THE AVERAGE OCCUPANCY RATE FOR THE EXISTING PSYCHIATRIC HOSPITAL OR UNIT IS BELOW 60% FOR ADULT BEDS OR 40% FOR CHILD/ADOLESCENT BEDS, THEN THE APPLICANT PSYCHIATRIC HOSPITAL OR UNIT SHALL REDUCE THE APPROPRIATE NUMBER OF LICENSED BEDS TO ACHIEVE AN AVERAGE ANNUAL OCCUPANCY RATE OF AT LEAST 60% FOR ADULT BEDS OR 40% FOR CHILD/ADOLESCENT BEDS. THE APPLICANT PSYCHIATRIC HOSPITAL OR UNIT SHALL NOT EXCEED THE NUMBER OF BEDS CALCULATED AS FOLLOWS:

(i) FOR ADULT BEDS, AS OF THE DATE OF THE APPLICATION, CALCULATE THE NUMBER OF PATIENT DAYS DURING THE MOST RECENT, CONSECUTIVE 36-MONTH PERIOD WHERE VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT, AND DIVIDE BY .60.

(ii) DIVIDE THE RESULT OF SUBSECTION (i) ABOVE BY 1095 (OR 1096 IF THE 36-MONTH PERIOD INCLUDES A LEAP YEAR) AND ROUND UP TO THE NEXT WHOLE NUMBER OR 10, WHICHEVER IS LARGER. THIS IS THE MAXIMUM NUMBER OF BEDS THAT CAN BE LICENSED AT THE EXISTING LICENSED PSYCHIATRIC HOSPITAL OR UNIT SITE AFTER REPLACEMENT.

(iii) FOR CHILD/ADOLESCENT BEDS, AS OF THE DATE OF THE APPLICATION, CALCULATE THE NUMBER OF PATIENT DAYS DURING THE MOST RECENT, CONSECUTIVE 36-MONTH PERIOD WHERE VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT, AND DIVIDE BY .40.

(iv) DIVIDE THE RESULT OF SUBSECTION (iii) ABOVE BY 1095 (OR 1096 IF THE 36-MONTH PERIOD INCLUDES A LEAP YEAR) AND ROUND UP TO THE NEXT WHOLE NUMBER OR 10, WHICHEVER IS LARGER. THIS IS THE MAXIMUM NUMBER OF BEDS THAT CAN BE LICENSED AT THE EXISTING LICENSED PSYCHIATRIC HOSPITAL OR UNIT SITE AFTER REPLACEMENT.

Section ~~8~~7. Requirements for approval of an applicant proposing to relocate existing licensed inpatient psychiatric beds

Sec. ~~8~~7. (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~~8(11).

(7) THE APPLICANT SHALL COMPLY WITH THE FOLLOWING REQUIREMENTS, AS APPLICABLE:

(a) THE SOURCE PSYCHIATRIC HOSPITAL OR UNIT SHALL HAVE AN AVERAGE OCCUPANCY RATE OF AT LEAST 60% FOR ADULT BEDS AND 40% FOR CHILD/ADOLESCENT BEDS.

(b) IF THE SOURCE PSYCHIATRIC HOSPITAL OR UNIT DOES NOT HAVE AN AVERAGE OCCUPANCY RATE OF AT LEAST 60% FOR ADULT BEDS AND 40% FOR CHILD/ADOLESCENT BEDS, THEN THE SOURCE PSYCHIATRIC HOSPITAL OR UNIT SHALL REDUCE THE APPROPRIATE NUMBER OF LICENSED BEDS TO ACHIEVE AN AVERAGE OCCUPANCY RATE OF AT LEAST 60% FOR ADULT BEDS AND 40% FOR CHILD/ADOLESCENT BEDS UPON COMPLETION OF THE RELOCATION(S). THE SOURCE PSYCHIATRIC HOSPITAL OR UNIT SHALL NOT EXCEED THE NUMBER OF BEDS CALCULATED AS FOLLOWS:

(i) FOR ADULT BEDS, AS OF THE DATE OF THE APPLICATION, CALCULATE THE NUMBER OF PATIENT DAYS DURING THE MOST RECENT, CONSECUTIVE 36-MONTH PERIOD WHERE VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT, AND DIVIDE BY .60.

(ii) DIVIDE THE RESULT OF SUBSECTION (i) ABOVE BY 1095 (OR 1096 IF THE 36-MONTH PERIOD INCLUDES A LEAP YEAR) AND ROUND UP TO THE NEXT WHOLE NUMBER OR 10, WHICHEVER IS LARGER. THIS IS THE MAXIMUM NUMBER OF BEDS THAT CAN BE LICENSED AT THE SOURCE PSYCHIATRIC HOSPITAL OR UNIT SITE AFTER THE RELOCATION.

(iii) FOR CHILD/ADOLESCENT BEDS, AS OF THE DATE OF THE APPLICATION, CALCULATE THE NUMBER OF PATIENT DAYS DURING THE MOST RECENT, CONSECUTIVE 36-MONTH PERIOD WHERE VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT, AND DIVIDE BY .40.

(iv) DIVIDE THE RESULT OF SUBSECTION (iii) ABOVE BY 1095 (OR 1096 IF THE 36-MONTH PERIOD INCLUDES A LEAP YEAR) AND ROUND UP TO THE NEXT WHOLE NUMBER OR 10, WHICHEVER IS LARGER. THIS IS THE MAXIMUM NUMBER OF BEDS THAT CAN BE LICENSED AT THE SOURCE PSYCHIATRIC HOSPITAL OR UNIT SITE AFTER THE RELOCATION.

(4) A SOURCE HOSPITAL SHALL APPLY FOR MULTIPLE RELOCATIONS ON THE SAME APPLICATION DATE, AND THE APPLICATIONS CAN BE COMBINED TO MEET THE CRITERIA OF (7)(b) ABOVE. A SEPARATE APPLICATION SHALL BE SUBMITTED FOR EACH PROPOSED RELOCATION.

Section ~~9~~8. Requirements for approval to increase beds

Sec. ~~9~~8. An applicant proposing an increase in the number of adult or child/adolescent beds shall demonstrate or provide the following:

(1) AN APPLICANT PROPOSING NEW BEDS IN A PSYCHIATRIC HOSPITAL OR UNIT, EXCEPT AN APPLICANT MEETING THE REQUIREMENTS OF SUBSECTION (3), (9), or (10) SHALL DEMONSTRATE THAT t~~T~~he 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) AN APPLICANT PROPOSING NEW BEDS IN A PSYCHIATRIC HOSPITAL OR UNIT, EXCEPT AN APPLICANT MEETING THE REQUIREMENTS OF SUBSECTION (3), (9), or (10) SHALL DEMONSTRATE THAT t~~T~~he 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. THIS SUBSECTION SHALL NOT APPLY IF ADDING BEDS FROM A SPECIAL POPULATION GROUP CONTAINED IN THE ADDENDUM TO THESE STANDARDS. 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~~ AN APPLICANT MAY APPLY FOR THE ADDITION OF NEW BEDS if all of the following SUBSECTIONS are met~~:~~. FURTHER, AN APPLICANT PROPOSING NEW BEDS AT AN EXISTING LICENSED PSYCHIATRIC HOSPITAL OR UNIT SITE SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH THE NEEDED PSYCHIATRIC HOSPITAL BED SUPPLY IF THE APPLICATION MEETS ALL OTHER APPLICABLE CON REVIEW STANDARDS AND AGREES AND ASSURES TO COMPLY WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS.

(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. THIS SUBSECTION SHALL NOT APPLY IF ADDING BEDS FROM A SPECIAL POPULATION GROUP CONTAINED IN THE ADDENDUM TO THESE STANDARDS.

(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~~7, 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~~7(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/adolescent 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~~9. Requirements for approval for flex beds

Sec. ~~10~~9. 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~~5(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~~10. Requirements for approval for acquisition of a psychiatric hospital or unit

Sec. ~~11~~10. 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.

(3) THE APPLICANT SHALL COMPLY WITH THE FOLLOWING REQUIREMENTS, AS APPLICABLE:

(a) THE EXISTING PSYCHIATRIC HOSPITAL OR UNIT SHALL HAVE AN AVERAGE OCCUPANCY RATE OF AT LEAST 60% FOR ADULT BEDS AND 40% FOR CHILD/ADOLESCENT BEDS.

(b) IF THE AVERAGE OCCUPANCY RATE FOR THE EXISTING PSYCHIATRIC HOSPITAL OR UNIT IS BELOW 60% FOR ADULT BEDS OR 40% FOR CHILD/ADOLESCENT BEDS, THE APPLICANT SHALL AGREE TO ALL OF THE FOLLOWING:

(i) THE PSYCHIATRIC HOSPITAL OR UNIT TO BE ACQUIRED WILL ACHIEVE AN AVERAGE OCCUPANCY RATE OF AT LEAST 60% AVERAGE ANNUAL OCCUPANCY FOR ADULT BEDS OR 40% ANNUAL AVERAGE OCCUPANCY FOR CHILD/ADOLESCENT BEDS FOR THE REVISED LICENSED BED COMPLEMENT DURING ANY CONSECUTIVE 12-MONTH PERIOD BY THE END OF THE SECOND YEAR OF OPERATION AFTER COMPLETION OF THE ACQUISITION.

(A) CALCULATE AVERAGE OCCUPANCY RATE FOR ADULT BEDS AS FOLLOWS:

(1) 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.

(B) CALCULATE AVERAGE OCCUPANCY RATE FOR CHILD/ADOLESCENT BEDS AS FOLLOWS:

(1) 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.

(C) FLEX BEDS APPROVED UNDER SECTION 9 SHALL BE COUNTED AS EXISTING ADULT INPATIENT PSYCHIATRIC BEDS.

(c) IF THE PSYCHIATRIC HOSPITAL OR UNIT TO BE ACQUIRED DOES NOT ACHIEVE AN AVERAGE ANNUAL OCCUPANCY RATE OF AT LEAST 60% FOR ADULT BEDS OR 40% FOR CHILD/ADOLESCENT BEDS, AS CALCULATED ABOVE, DURING ANY CONSECUTIVE 12-MONTH PERIOD BY THE END OF THE SECOND YEAR OF OPERATION AFTER COMPLETION OF THE ACQUISITION, THE APPLICANT SHALL RELINQUISH SUFFICIENT BEDS AT THE EXISTING PSYCHIATRIC HOSPITAL OR UNIT TO RAISE ITS AVERAGE OCCUPANCY TO 60% FOR ADULT BEDS OR 40% FOR CHILD/ADOLESCENT BEDS. THE REVISED NUMBER OF LICENSED BEDS AT

THE PSYCHIATRIC HOSPITAL OR UNIT SHALL BE CALCULATED AS FOLLOWS. HOWEVER, THE PSYCHIATRIC HOSPITAL OR UNIT SHALL NOT BE REDUCED TO LESS THAN 10 BEDS.

(i) FOR ADULT BEDS, AS OF THE DATE OF THE APPLICATION, CALCULATE THE NUMBER OF PATIENT DAYS DURING THE MOST RECENT, CONSECUTIVE 12-MONTH PERIOD WHERE VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT, AND DIVIDE BY .60.

(ii) DIVIDE THE RESULT OF SUBSECTION (i) ABOVE BY 365 (OR 366 IF THE 12-MONTH PERIOD INCLUDES A LEAP YEAR) AND ROUND UP TO THE NEXT WHOLE NUMBER OR 10, WHICHEVER IS LARGER. THIS IS THE MAXIMUM NUMBER OF BEDS THAT CAN BE LICENSED AT THE EXISTING LICENSED PSYCHIATRIC HOSPITAL OR UNIT SITE AFTER ACQUISITION.

(iii) FOR CHILD/ADOLESCENT BEDS, AS OF THE DATE OF THE APPLICATION, CALCULATE THE NUMBER OF PATIENT DAYS DURING THE MOST RECENT, CONSECUTIVE 12-MONTH PERIOD WHERE VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT, AND DIVIDE BY .40.

(iv) DIVIDE THE RESULT OF SUBSECTION (iii) ABOVE BY 365 (OR 366 IF THE 12-MONTH PERIOD INCLUDES A LEAP YEAR) AND ROUND UP TO THE NEXT WHOLE NUMBER OR 10, WHICHEVER IS LARGER. THIS IS THE MAXIMUM NUMBER OF BEDS THAT CAN BE LICENSED AT THE EXISTING LICENSED PSYCHIATRIC HOSPITAL OR UNIT SITE AFTER ACQUISITION.

Section ~~12~~11. Additional requirements for applications included in comparative review

Sec. ~~12~~11. (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~~TRANSPORTATION ASSISTANCE TO PATIENTS WHO REQUIRE THESE SERVICES. AN APPLICANT PROPOSING A NEW FACILITY WILL BE AWARDED 3 POINTS IF IT SUBMITS SITE PLANS OR SERVICE CONTRACTS TO DEMONSTRATE IT WILL INLCUDE ANY OF THESE SERVICES AS PART OF ITS PROPOSED PROJECT.

(~~g~~c) 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 FOR ~~due to a pattern of licensure deficiencies at~~ any psychiatric hospital or unit owned or operated by the applicant in this state.

(~~h~~d) A qualifying project will have points awarded based on the ~~percentage of the hospital's indigent volume as set forth in the following table~~ RANKING OF THE APPLICANT'S MEDICAID DAYS AS MEASURED AS A PERCENTAGE OF TOTAL DAYS AS SET FORTH IN THE FOLLOWING TABLE. FOR PURPOSES OF SCORING, THE APPLICANT'S MEDICAID PERCENTAGE WILL BE THE CUMULATIVE OF ALL TITLE XIX AND HEALTH MICHIGAN INPATIENT PSYCHIATRIC DAYS DIVIDED BY THE CUMULATIVE OF ALL INPATIENT PSYCHIATRIC DAYS AT ALL CURRENTLY LICENSED MICHIGAN HOSPITALS UNDER COMMON OWNERSHIP OR CONTROL WITH THE APPLICANT. FOR PURPOSES OF EVALUATING THIS CRITERION, AN APPLICANT SHALL SUBMIT THE MOST RECENT REVIEWED AND ACCEPTED MEDICAID COST REPORT FOR EACH CURRENTLY LICENSED HOSPITAL UNDER COMMON OWNERSHIP OR CONTROL IN MICHIGAN.

~~| 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.~~

MEDICAID DAYS	POINTS AWARDED
APPLICANT WITH HIGHEST PERCENT OF MEDICAID DAYS	10 POINTS
ALL OTHER APPLICANTS	APPLICANT'S PERCENT OF MEDICAID DAYS DIVIDED BY THE HIGHEST APPLICANT'S PERCENT OF MEDICAID DAYS, THEN MULTIPLIED BY 10
EXAMPLE BELOW	
THE HIGHEST APPLICANT HAS 58.3% MEDICAID DAYS	10 POINTS
APPLICANT WITH 55.3% MEDICAID DAYS	(.553 / .583) X 10 = 9 POINTS
APPLICANT WITH 51.3% MEDICAID DAYS	(.513 / .583) X 10 = 9 POINTS

PERCENTAGES OF DAYS SHALL BE ROUNDED TO THE NEAREST 1/1000 AND POINTS AWARDED SHALL BE ROUNDED TO THE NEAREST WHOLE NUMBER, I.E. NUMBERS ENDING IN .5 OR HIGHER, ROUND UP, AND NUMBERS ENDING IN .4 OR LOWER, ROUND DOWN.

(i~~e~~) 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

(f) A QUALIFYING PROJECT WILL BE AWARDED POINTS BASED ON THE APPLICANT'S TOTAL PROJECT COSTS PER BED. FOR PURPOSES OF THIS CRITERION, TOTAL PROJECT COSTS SHALL BE DEFINED AS THE TOTAL COSTS FOR CONSTRUCTION AND RENOVATION, SITE WORK, ARCHITECTURAL/ ENGINEERING AND CONSULTING FEES, CONTINGENCIES, FIXED EQUIPMENT, CONSTRUCTION MANAGEMENT AND PERMITS. POINTS SHALL BE AWARDED IN ACCORDANCE WITH THE TABLE BELOW:

COST PER BED	POINTS AWARDED
APPLICANT WITH THE LOWEST COST PER BED	10 POINTS
ALL OTHER APPLICANTS	APPLICANT'S COST PER BED DIVIDED BY THE LOWEST APPLICANT'S COST PER BED, THEN MULTIPLIED BY 7
EXAMPLE BELOW	
THE LOWEST COST APPLICANT IS $698,000 PER BED	7 POINTS
APPLICANT WITH $710,000 PER BED	($698,000 / $710,000) X 7 = 7 POINTS
APPLICANT WITH $975,000 PER BED	($698,000 / $975,000) X 7 = 5 POINTS

POINTS SHALL NOT BE AWARDED UNDER THIS SECTION FOR ANY PROJECT THAT PROPOSES TO ADD BEDS AT A LEASED FACILITY. COSTS SHALL BE ROUNDED TO THE NEAREST WHOLE DOLLAR AND POINTS AWARDED SHALL BE ROUNDED TO THE NEAREST WHOLE NUMBER, I.E. NUMBERS ENDING IN .5 OR HIGHER, ROUND UP, AND NUMBERS ENDING IN .4 OR LOWER, ROUND DOWN.

(g) A QUALIFYING PROJECT WILL BE AWARDED 1 POINT FOR EACH DESIGN FEATURE IN THIS SUBSECTION (MAXIMUM OF 3 POINTS) THAT APPLICANT PROPOSES TO INCLUDE IN THE PROPOSED PROJECT TO REDUCE STRESS, FOSTER DIMINISHED AGGRESSION, AND REDUCE PATIENT RISK:

(i) DESIGN FEATURES AS SHOWN ON THE FLOOR PLAN SUBMITTED WITH THE CON APPLICATION TO ALLOW THE APPLICANT TO CREATE ONE OR MORE SUBUNITS WITHIN A

LARGER UNIT FOR CLINICAL OR PROGRAMMATIC PURPOSES, INCLUDING DOOR OR WALL SYSTEMS PERMITTED UNDER THE MINIMUM DESIGN STANDARDS FOR HEALTHCARE FACILITIES IN MICHIGAN TO SUBDIVIDE INPATIENT PSYCHIATRIC SPACE ON A TEMPORARY OR FLEXIBLE BASIS;

(ii) GARDENS OR OTHER OUTDOOR AREAS TO ALLOW INPATIENTS DIRECT DAILY ACCESS TO OUTDOOR SPACE AND DAYLIGHT; AND

(iii) A FLOOR PLAN DESIGNED TO HELP REDUCE PATIENT RISK BY OPTIMIZING OBSERVATION OF PATIENTS IN THE FACILITY IN COMMUNAL AREAS, HALLWAYS, AND PATIENT ROOMS. FOR PURPOSES OF THIS CRITERIA, APPLICANTS SHALL SUBMIT PROPOSED FLOOR PLANS THAT SHOW UNOBSTRUCTED SIGHT LINES FROM NURSE STATIONS OR THE EQUIVALENT TO ALL PATIENT ROOM CORRIDORS AND ALL COMMON AREAS UTILIZED FOR PATIENT CARE.

(h) A QUALIFYING PROJECT WILL BE AWARDED 3 POINTS IF THE APPLICANT HAS OR PROPOSES TO DEVELOP, WITH CREDIBLE DOCUMENTATION ACCEPTABLE TO THE DEPARTMENT, A TELEHEALTH AND/OR TELEMEDICINE PROGRAM TO FACILITATE INPATIENT ADMISSION OF PSYCHIATRIC PATIENTS OR TO ASSIST IN THE DIAGNOSIS, TREATMENT OR PROVISION OF OTHER INPATIENT SUPPORT AND SERVICES NECESSARY AND APPROPRIATE FOR THE ADMISSION OR RETENTION OF A PSYCHIATRIC HOSPITAL INPATIENT WITH THE FOLLOWING FEATURES:

(i) THE EXISTING OR PROPOSED TELEHEALTH AND/OR TELEMEDICINE PROGRAM COMPLIES OR WILL COMPLY WITH MICHIGAN COMPILED LAWS SECTION 333.16283 TO 333.16288;

(ii) THE PROPOSED PROJECT INCLUDES INFRASTRUCTURE NECESSARY OR APPROPRIATE FOR THE PSYCHIATRIC TELEHEALTH AND/OR TELEMEDICINE SERVICES INCLUDING HIGH-SPEED INTERNET CONNECTIONS, INTEGRATION OF THE TELEHEALTH AND/OR TELEMEDICINE SERVICES WITH THE ELECTRONIC HEALTH RECORD OF THE PSYCHIATRIC INPATIENT, AND PHYSICAL PLANT DESIGN ELEMENTS NECESSARY OR APPROPRIATE FOR COMPLIANCE WITH APPLICABLE STATE AND FEDERAL PRIVACY LAWS; AND

(iii) THE APPLICANT HAS OR PROPOSES A PLAN TO FACILITATE WORKFORCE TRAINING AND TECHNICAL ASSISTANCE TO SUPPORT OPERATION OF THE TELEHEALTH AND/OR TELEMEDICINE PROGRAM.

(i) A QUALIFYING PROJECT WILL BE AWARDED 3 POINTS IF THE APPLICANT ALREADY HAS, OR THE PROPOSED PROJECT WILL HAVE COMPREHENSIVE PSYCHIATRIC CRISIS SERVICES FOR THE PURPOSE OF DIVERTING PATIENTS TO A LOWER ACUITY SETTING INCLUDING ANY OF THE FOLLOWING: 24-HOUR PATIENT/FAMILY CRISIS TELEPHONE LINES, WALK-IN CRISIS SERVICES, OR A CRISIS STABILIZATION UNIT. AN APPLICANT SHALL SUBMIT SITE PLANS OR CONTRACTS TO DEMONSTRATE IT CURRENTLY HAS OR WILL INCLUDE ANY OF THESE SERVICES AS PART OF ITS PROPOSED PROJECT.

(j) A QUALIFYING PROJECT WILL BE AWARDED POINTS BASED ON THE GEOGRAPHIC LOCATION OF THE PROJECT IN ACCORDANCE WITH THE FOLLOWING TABLE. FOR PURPOSES OF EVALUATION, THIS CRITERIA WILL CONSIDER THE PROXIMITY OF THE PROPOSED PROJECT TO EXISTING BEDS OF THE SAME TYPE AS THOSE PROPOSED IN THE APPLICATION, INCLUDING BOTH OPERATING AND CON-APPROVED BUT NOT YET OPERATIONAL BEDS ON THE DATE OF APPLICATION.

PROXIMITY TO EXISTING BEDS OF THE SAME TYPE	POINTS AWARDED
LESS THAN 30 MILES	0
BETWEEN 30 AND 60 MILES	1
BETWEEN 60 AND 90 MILES	2

GREATER THAN 90 MILES	3

FOR PURPOSES OF SCORING THIS CRITERIA, THE APPLICANT SHALL SUBMIT DATA USING THE MICHIGAN STATE UNIVERSITY GEOCODER LOCATED ON THE DEPARTMENT'S WEBSITE AND THE DEPARTMENT'S INVENTORY OF BEDS AT THE TIME THE APPLICATION IS DEEMED SUBMITTED.

(k) A QUALIFYING PROJECT THAT PROPOSES BEDS UNDER THE ADDENDUM FOR SPECIAL POPULATION GROUPS, SECTION 7 FOR HIGH ACUITY PSYCHIATRIC PATIENTS, WILL BE AWARDED BASED ON THE PERCENTAGE OF BEDS LOCATED IN PRIVATE ROOMS PROPOSED AS PART OF THE PROJECT, SUPPORTED BY THE FLOOR PLANS PROVIDED IN THE APPLICATION, IN ACCORDANCE WITH THE TABLE BELOW.

PERCENTAGE OF HIGH ACUITY BEDS LOCATED IN PRIVATE ROOMS	POINTS AWARDED
APPLICANT WITH HIGHEST PERCENTAGE OF HIGH ACUITY BEDS LOCATED IN PRIVATE ROOMS	7 POINTS
ALL OTHER APPLICANTS	APPLICANT'S PERCENT OF BEDS LOCATED IN PRIVATE ROOMS DIVIDED BY THE HIGHEST APPLICANT'S PERCENT OF BEDS LOCATED IN PRIVATE ROOMS, THEN MULTIPLIED BY 7
EXAMPLE BELOW	
THE APPLICANT WITH THE HIGHEST PERCENTAGE OF BEDS IN PRIVATE ROOMS IS 90.0%	7 POINTS
APPLICANT WITH 80.0% OF BEDS IN PRIVATE ROOMS	(.800 / .900) X 7 = 6 POINTS
APPLICANT WITH 70.5% BEDS IN PRIVATE ROOMS	(.750 / .900) X 7 = 5 POINTS

PERCENTAGES OF BEDS IN PRIVATE ROOMS SHALL BE ROUNDED TO THE NEAREST 1/1000 AND POINTS AWARDED SHALL BE ROUNDED TO THE NEAREST WHOLE NUMBER, I.E. NUMBERS ENDING IN .5 OR HIGHER, ROUND UP, AND NUMBERS ENDING IN .4 OR LOWER, ROUND DOWN.

(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~~12. Requirements for approval -- all applicants

Sec. ~~13~~12. (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~~13. Project delivery requirements - terms of approval for all applicants

Sec. ~~14~~13. 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.

(iv) ADOPT AND MAINTAIN A POLICY THAT INCLUDES A PLAN FOR PROVIDING INPATIENT PSYCHIATRIC SERVICES TO EXISTING OR POTENTIAL PSYCHIATRIC INPATIENTS WHOSE LENGTH OF STAY AT APPLICANT'S PSYCHIATRIC HOSPITAL EXCEEDS, OR MAY EXCEED, 45 CONSECUTIVE INPATIENT DAYS IN ACCORDANCE WITH APPLICABLE MEDICARE, MEDICAID, CMH, OR OTHER THIRD-PARTY PAYOR MEDICAL NECESSITY CRITERIA FOR INPATIENT PSYCHIATRIC ADMISSIONS AND AN APPROPRIATE CARE PLAN.

(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~~ 9 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~~14. Project delivery requirements - additional terms of approval for child/adolescent service

Sec. ~~15~~14. (1) In addition to the provisions of Section ~~14~~13, 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~~15. Department inventory of beds

Sec. ~~16~~15. 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~~16. Planning areas

Sec. ~~17~~16. 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~~17. Effect on prior CON review standards; comparative reviews

Sec. ~~18~~17. (1) These CON review standards supercede and replace the CON Review Standards for Psychiatric Beds and Services, approved by the CON Commission on ~~September 21, 2016~~MARCH 21, 2019 and effective on ~~December 9, 2016~~MAY 24, 2019.

(2) Projects involving replacement beds, relocation of beds, flex beds under Section ~~10~~9, or an increase in beds, approved pursuant to Section ~~7~~6(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~~5(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, 7 and ~~7~~ 8 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) "HIGH ACUITY PSYCHIATRIC UNIT" MEANS A DISTINCT PSYCHIATRIC UNIT FOR INDIVIDUALS WHO ARE CURRENTLY EXHIBITING THREE OR MORE TO A MODERATE DEGREE OR TWO OR MORE TO A SEVERE DEGREE OF THE FOLLOWING: CONFUSION, IRRITABILITY, BOISTEROUSNESS, POOR IMPULSE CONTROL, UNCOOPERATIVENESS, HOSTILITY, VERBAL THREATS, PHYSICAL THREATS, OR ATTACKING OBJECTS. THIS TERM ALSO INCLUDES PATIENTS WHO ARE UNWILLING OR UNABLE TO STOP ATTEMPTS AT SELF HARM OR SUICIDE OR PATIENTS WHO HAVE A HISTORY OF VIOLENCE TO SELF OR OTHERS ON AN INPATIENT PSYCHIATRIC UNIT.

(d) "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~~ 850 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 DEVELOPMENTAL DISABILITY, GERIATRIC AND MEDICAL

PSYCHIATRIC poolS ~~is~~ ARE based on ~~five~~ SEVEN AND A HALF percent of the statewide bed need for psychiatric inpatient beds rounded up to the next ten WITH A MINIMUM OF 50 CHILD/ADOLESCENT BEDS IN EACH SPECIAL POOL, AS APPLICABLE. THE NUMBER OF BEDS IN THE HIGH ACUITY POOL IS BASED ON TEN PERCENT OF THE STATEWIDE BED NEED FOR PSYCHIATRIC INPATIENT BEDS ROUNDED UP TO THE NEXT TEN WITH A MINIMUM OF 50 CHILD/ADOLESCENT BEDS. 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~~ 160 adult beds and ~~20~~ 50 child/adolescent beds.

(b) Geriatric psychiatric beds will be allocated ~~110~~ 160 adult beds.

(c) Medical psychiatric beds will be allocated ~~110~~ 160 adult beds and ~~20~~ 50 child/adolescent beds.

(d) HIGH ACUITY PSYCHIATRIC BEDS WILL BE ALLOCATED 220 ADULT BEDS AND 50 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, 6 and ~~6~~7. 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.

(5) BEDS APPROVED UNDER SUBSECTIONS 4, 5, 6, AND 7 SHALL NOT BE CONVERTED TO OR UTILIZED AS GENERAL PSYCHIATRIC BEDS.

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 ONE OF THE FOLLOWING SETTINGS:

(i) a licensed hospital licensed under part 215 of the code, OR

(ii) AN ADULT OR CHILD/ADOLESCENT PSYCHIATRIC SERVICE OR UNIT WITH A WRITTEN COLLABORATIVE AGREEMENT WITH A LICENSED HOSPITAL LICENSED UNDER PART 215 OF THE CODE THAT IS PROVIDED AS PART OF THE APPLICATION AND INCLUDES ALL OF THE FOLLOWING:

(A) PROCEDURES FOR JOINT CREDENTIALING CRITERIA AND RECOMMENDATIONS FOR PHYSICIANS APPROVED TO TREAT MEDICAL PSYCHIATRIC PATIENTS

(B) PROVISIONS FOR REGULARLY HELD JOINT PSYCHIATRIC AND MEDICAL CONFERENCES TO INCLUDE REVIEW OF ALL MEDICAL PSYCHIATRIC CASES.

(C) A MECHANISM TO PROVIDE FOR APPROPRIATE TRANSFERS BETWEEN FACILITIES AND AN AGREED UPON PLAN FOR PROMPT CARE.

(D) CONSULATION ON FACILITIES, EQUIPMENT, STAFFING, ANCILLARY SERVICES, AND POLICIES AND PROCEDURES FOR THE PROVISION OF MEDICAL PSYCHIATRIC TREATMENT.

(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, INCLUDING CONTRACTED 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. REQUIREMENTS FOR APPROVAL FOR BEDS FROM THE STATEWIDE POOL FOR SPECIAL POPULATION GROUPS ALLOCATED TO HIGH ACUITY PSYCHIATRIC PATIENTS

SEC 7. 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 HIGH ACUITY PSYCHIATRIC PATIENTS AS COMPARED TO SERVING THESE NEEDS IN A GENERAL PSYCHIATRIC UNIT(S).

(1) AN APPLICANT PROPOSING TO BEGIN OPERATIONS OF A NEW ADULT OR CHILD/ADOLESCENT PSYCHIATRIC SERVICES 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 SHALL BE OPERATED AS PART OF A SPECIALIZED PROGRAM EXCLUSIVELY FOR ADULT OR CHILD/ADOLESCENT PATIENTS CLASSIFIED AS HIGH ACUITY.

(b) THE APPLICANT SHALL SUBMIT EVIDENCE WITH CREDIBLE DOCUMENTATION ACCEPTABLE TO THE DEPARTMENT OF THE FOLLOWING:

(i) THE PROPOSED UNIT SHALL CONSIST OF A MAJORITY OF PRIVATE ROOMS AND SHALL INCLUDE ENVIRONMENTAL SAFETY MEASURES THAT MEET STANDARDS FROM THE JOINT COMMISSION AND THE CENTERS FOR MEDICARE AND MEDICAID SERVICES THROUGHOUT THE ENTIRE UNIT.

(ii) THE PROPOSED UNIT SHALL HAVE A PHYSICAL ENVIRONMENT DESIGNED TO MINIMIZE NOISE AND LIGHT REFLECTIONS TO PROMOTE VISUAL AND SPATIAL ORIENTATION.

(iii) THE PROPOSED UNIT'S STAFF SHALL BE SPECIALLY TRAINED IN THE TREATMENT OF HIGH ACUITY PATIENTS WITH NON-VIOLENT INTERVENTION MODALITIES SUCH AS NON-ABUSIVE PSYCHOLOGICAL AND PHYSICAL INTERVENTION, CRISIS INTERVENTION INSTITUTE TRAINING OR SIMILAR PROGRAMS.

(iv) THE PROPOSED UNIT SHALL DEMONSTRATE A PLAN FOR THE SAFE MANAGEMENT OF AGITATED OR AGGRESSIVE PATIENTS

(c) THE PROPOSED BEDS WILL SERVE ONLY HIGH ACUITY PSYCHIATRIC PATIENTS.

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

Section ~~7~~8. Acquisition of psychiatric beds approved pursuant to this addendum

Sec. ~~7~~8. (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.

(4) AN APPLICANT PROPOSING TO ACQUIRE PSYCHIATRIC BEDS FROM THE STATEWIDE POOL FOR SPECIAL POPULATIONS ALLOCATED TO HIGH ACUITY PSYCHIATRY SHALL MEET THE FOLLOWING:
(a) THE PROPOSED UNIT SHALL CONSIST OF A MAJORITY OF PRIVATE ROOMS AND SHALL INCLUDE ENVIRONMENTAL SAFETY MEASURES THAT MEET STANDARDS FROM THE JOINT COMMISSION AND THE CENTERS FOR MEDICARE AND MEDICAID SERVICES THROUGHOUT THE ENTIRE UNIT.
(b) THE PROPOSED UNIT SHALL HAVE A PHYSICAL ENVIRONMENT DESIGNED TO MINIMIZE NOISE AND LIGHT REFLECTIONS TO PROMOTE SPATIAL ORIENTATION.
(c) THE PROPOSED UNIT'S STAFF SHALL BE SPECIALLY TRAINED IN THE TREATMENT OF HIGH ACUITY PATIENTS WITH NON-VIOLENT INTERVENTION MODALITIES SUCH AS NON-ABUSIVE PSYCHOLOGICAL AND PHYSICAL INTERVENTION, CRISIS INTERVENTION INSTITUTE TRAINING OR SIMILAR PROGRAMS.
(d) THE PROPOSED UNIT SHALL DEMONSTRATE A PLAN FOR THE SAFE MANAGEMENT OF AGITATED OR AGGRESSIVE PATIENTS.
(e) THE PROPOSED BEDS WILL SERVE ONLY HIGH ACUITY PSYCHIATRIC PATIENTS.

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

Section ~~8~~9. Project delivery requirements -- terms of approval for all applicants seeking approval under section 3(1) of this addendum

Sec. ~~8~~9. (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 aN 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~~ 13 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 aN 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~~ 13 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 aN 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~~ 13 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.

(5) AN APPLICANT FOR BEDS FROM THE STATEWIDE POOL FOR SPECIAL POPULATION GROUPS ALLOCATED TO HIGH ACUITY 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 INITATION OF BEDS APPROVED, AND THEREAFTER, 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 AN 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 HIGH ACUITY PSYCHIATRIC PATIENTS.

(b) THE HIGH ACUITY UNIT SHALL CONSIST OF A MAJORITY OF PRIVATE ROOMS AND SHALL INCLUDE ENVIRONMENTAL SAFETY MEASURES THAT MEET STANDARDS FROM THE JOINT COMMISSION AND THE CENTERS FOR MEDICARE AND MEDICAID SERVICES THROUGHOUT THE ENTIRE UNIT.

(c) THE HIGH ACUITY UNIT SHALL HAVE A PHYSICAL ENVIRONMENT DESIGNED TO MINIMIZE NOISE AND LIGHT REFLECTIONS TO PROMOTE VISUAL AND SPATIAL ORIENTATION.

(d) THE PROPOSED UNIT'S STAFF SHALL BE SPECIALLY TRAINED IN THE TREATMENT OF HIGH ACUITY PATIENTS WITH NON-VIOLENT INTERVENTION MODALITIES SUCH AS NON-ABUSIVE PSYCHOLOGICAL AND PHYSICAL INTERVENTION, CRISIS INTERVENTION INSTITUTE TRAINING OR SIMILAR PROGRAMS.

(e) THE PROPOSED UNIT SHALL DEMONSTRATE A PLAN FOR THE SAFE MANAGEMENT OF AGITATED OR AGGRESSIVE PATIENTS.

(f) THE HIGH ACUITY UNIT SHALL ESTABLISH AND MAINTAIN WRITTEN POLICIES AND PROCEDURES FOR EACH OF THE FOLLOWING:

(i) PATIENT ADMISSION CRTIERIA THAT DESCRIBE MINIMUM AND MAXIMUM CHARACTERISTICS FOR PATIENTS APPROPRIATE FOR ADMISSION TO THE UNIT FOR HIGH ACUITY PATIENTS.

(ii) QUALITY ASSURANCE AND ASSESSMENT PROGRAM TO ASSURE THAT SERVICES FURNISHED TO HIGH ACUITY PATIENTS MEET PROFESSIONALLY RECOGNIZED STANDARDS OF HEALTH CARE FOR PROVIDERS OF SUCH SERVICES AND THAT SUCH SERVICES WERE REASONABLE AND MEDICALLY APPROPRIATE TO THE CLINICAL CONDITION OF THE HIGH ACUITY PATIENT RECEIVING SUCH SERVICES.

(III) ORIENTATION AND ANNUAL EDUCATION/COMPETENCIES FOR ALL STAFF, WHICH SHALL INCLUDE CARE GUIDELINES, SPECIALIZED COMMUNICATION AND PATIENT SAFETY.

(g) 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 13 OF THE CON REVIEW STANDARDS FOR PSYCHIATRIC BEDS AND SERVICES.

Section ~~9~~10. Comparative reviews, effect on prior CON review standards

Sec. ~~9~~10. (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.

(4) PROJECTS PROPOSED UNDER SECTION 7 SHALL BE CONSIDERED A DISTINCT CATEGORY AND SHALL BE SUBJECT TO COMPARATIVE REVIEW ON A STATEWIDE BASIS.

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR URINARY EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY (UESWL) SERVICES

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

Section 1. Applicability

Sec. 1. These standards are requirements for approval to initiate, replace, expand, or acquire an UESWL service/unit under Part 222 of the Code. Urinary extracorporeal shock wave lithotripsy is a covered clinical service for purposes of Part 222 of the Code. The Department shall use these standards in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

Section 2. Definitions

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

(a) "Central service coordinator" OR "CSC" means the organizational unit that has operational responsibility for a mobile UESWL service and its unit(s) and that is a legal entity authorized to do business in the state of Michigan.

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

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

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

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

(ii) Experienced interventional radiologic support.

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

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

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

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

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

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

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

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

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

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

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

(n) "Planning area" means the state of Michigan.

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

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

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

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

(1) An applicant proposing to initiate a UESWL service shall demonstrate each of the following:
(a) The capability to provide complicated stone disease treatment on-site.
(b) At least 1,000 procedures are projected pursuant to the methodology set forth in Section 10(1).
(c) The proposed UESWL service shall be provided at a site that provides, or will provide, each of the following:
(i) On-call availability of an anesthesiologist and a surgeon.
(ii) On-site Advanced Cardiac Life Support (ACLS)-certified personnel and nursing personnel.
(iii) Either on-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.
(iv) On-site general anesthesia, EKG, cardiac monitoring, blood pressure, pulse oximeter, ventilator, general radiography and fluoroscopy, cystoscopy, and laboratory services.
(v) On-site crash cart.
(vi) On-site cardiac intensive care unit or a written transfer agreement with a hospital that has a cardiac intensive care unit.
(vii) Either on-site or through a contractual agreement with another health facility, a 23-hour holding unit.

(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 hospital 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. Requirements to replace an existing UESWL unit(s)

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

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

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

(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 MOBILE unit AND 500 PER FIXED UNIT during the most recent continuous 12-month period for which the Department has verifiable data.
(b) The proposed mobile unit will serve at least 1 host site that is located in a region other than the region in which the fixed UESWL unit proposed to be replaced is located currently.
(c) At least 100 UESWL procedures are projected in each region in which the proposed mobile UESWL unit is proposed to operate when the results of the methodology in Section 10 are combined for the following, as applicable:
(i) All licensed hospital sites committing MIDB data pursuant to Section 11, as applicable, that are located in the region identified in subsection (c).
(ii) All sites that receive UESWL services from an existing UESWL service and propose to receive UESWL services from the proposed mobile unit and that are located in the region identified in subsection (c).
(d) A separate application from each host site is filed at the same time the application to replace a fixed unit is submitted to the Department.
(e) The proposed mobile UESWL unit is projected to perform at least 1,000 procedures annually pursuant to the methodology set forth in Section 10.

(4) An applicant proposing to replace an existing fixed UESWL service and its unit(s) to a new site shall demonstrate that the proposed project meets all of the following:
(a) The UESWL service to be replaced has been in operation for at least 36 months as of the date an application is submitted to the Department unless the applicant meets the requirement in subsection (d)(i) or (ii).
(b) The site to which the UESWL service will be replaced meets the requirements of Section 3(1)(c).
(c) The proposed new site is in the state of Michigan and within a 25-mile radius of the existing site of the UESWL service to be replaced.
(d) The UESWL service and its unit(s) to be replaced performed an average of at least ~~1,000~~500 procedures per unit in the most recent 12-month period for which the Department has verifiable data unless one of the following requirements are met:

(i) the owner of the building where the site is located has incurred a filing for bankruptcy under chapter 7 within the last three years;

(ii) the ownership of the building where the site is located has changed within 24 months of the date of the service being operational; or

(iii) the 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.

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

(5) An applicant proposing to replace a fixed UESWL unit(s) of an existing UESWL service TO A NEW SITE shall demonstrate that the proposed project meets all of the following:

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

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

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

(d) Each existing UESWL unit(s) at the service from which a unit is to be replaced performed at least an average of ~~1,05~~00 procedures per fixed unit in the most recent 12-month period for which the Department has verifiable data.

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

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

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

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

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

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

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

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

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

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

(1) The applicant shall not be required to be in compliance with the volume requirement applicable to the seller/lessor on the date the acquisition occurs if the proposed project meets one of the following:

(a) It is the first acquisition of the existing fixed or mobile UESWL service for which a final decision has not been issued after May 2, 1998.

(b) The existing fixed or mobile UESWL service is owned by, is under common control of, or has a common parent as the applicant, and the UESWL service shall remain at the same site.

(2) For any application for proposed acquisition of an existing fixed or mobile UESWL service, except an application approved pursuant to subsection (1), an applicant shall be required to demonstrate that the UESWL service and its unit(s) to be acquired performed an average of at least 1,000 procedures per MOBILE unit AND 500 PER FIXED UNIT in the most recent 12-month period for which the Department has verifiable data.

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

(a) For any application for proposed acquisition of an existing fixed or mobile UESWL unit(s), an applicant shall be required to demonstrate that the UESWL unit(s) to be acquired performed an average of at least 1,000 procedures per MOBILE unit AND 500 PROCEDURES PER FIXED UNIT in the most recent 12-month period for which the Department has verifiable data.

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

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

Section 7. Additional requirements for approval for mobile UESWL services

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

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

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

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

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

(c) A SEPARATE CON APPLICATION HAS BEEN SUBMITTED BY THE CSC AND EACH PROPOSED HOST SITE.

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

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

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

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

(3) A central service coordinator proposing to add, or an applicant proposing to become, a host site on either an existing or a proposed mobile UESWL service shall demonstrate that it meets ALL OF the FOLLOWING:

(a) THE requirements of Section 3(1)(C).
(b) THE NORMAL ROUTE SCHEDULE, THE PROCEDURES FOR HANDLING EMERGENCY SITUATIONS, AND COPIES OF ALL POTENTIAL CONTRACTS RELATED TO THE MOBILE UESWL SERVICE AND ITS UNIT(S) SHALL BE INCLUDED IN THE CON APPLICATION SUBMITTED BY THE CENTRAL SERVICE COORDINATOR OR THE APPLICANT HOST SITE.

Section 8. Requirements for Medicaid participation

Sec. 8. An applicant shall provide verification of Medicaid participation. An applicant that is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of service if a CON is approved.

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

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

(1) Compliance with these standards.

(2) Compliance with the following quality assurance standards:
(a) The medical staff and governing body shall receive and review at least annual reports describing activities of the UESWL service, including complication rates, morbidity data, and retreatment rates.
(b) An applicant shall accept referrals for UESWL services from all appropriately licensed health care practitioners.
(c) An applicant shall develop and utilize a standing medical staff and governing body rule that provides for the medical and administrative control of the ordering and utilization of UESWL services.
(d) An applicant shall require that each urologist serving as a UESWL surgeon shall have completed an approved training program in the use of the lithotripter at an established facility with UESWL services.
(e) An applicant shall establish a process for credentialing urologists who are authorized to perform UESWL procedures at the applicant facility. This shall not be construed as a requirement to establish specific credentialing requirements for any particular hospital or UESWL site.
(f) A urologist who is not an active medical staff member of an applicant facility shall be eligible to apply for limited staff privileges to perform UESWL procedures. Upon request by the Department, an applicant shall provide documentation of its process that will allow a urologist who is not an active medical staff member to apply for medical staff privileges for the sole and limited purpose of performing UESWL procedures. In order to be granted staff privileges limited to UESWL procedures, a urologist shall demonstrate that he or she meets the same requirements, established pursuant to the provisions of subsection (e), that a urologist on an applicant facility's active medical staff must meet in order to perform UESWL procedures.
(g) An applicant shall provide UESWL program access to approved physician residency programs for teaching purposes.

(3) Compliance with the following access to care requirements:
(a) An applicant, to assure appropriate utilization by all segments of the Michigan population, shall:
(i) Not deny any UESWL services to any individual based on inability to pay or source of payment,
(ii) Provide all UESWL services to any individual based on clinical indications of need for the services, and
(iii) Maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually.
(b) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter.
(c) The operation of and referral of patients to the UESWL service shall be in conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).
Compliance with selective contracting requirements shall not be construed as a violation of this term.

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

(a) Each UESWL unit~~, whether fixed or mobile,~~ shall perform at least an average of 1,000 procedures per MOBILE unit AND 500 PER FIXED UNIT per year in the second 12 months of operation and annually thereafter. The central service coordinator shall demonstrate that a mobile UESWL unit approved pursuant to these standards performed at least 100 procedures in each region that is served by the mobile unit. For purposes of this requirement, the number of UESWL procedures performed at all host sites in the same region shall be combined.

(b) The applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to, annual budget and cost information; operating schedules; and demographic, diagnostic, morbidity and mortality information; primary diagnosis code; whether the procedure was a first or retreatment UESWL procedure; what other treatment already has occurred; outpatient or inpatient status; complications; and whether follow-up procedures (e.g., percutaneous nephroStomy) were required, as well as the volume of care provided to patients from all payor sources. An applicant shall provide the required data on a separate basis for each host site or licensed site in a format established by the Department and in a mutually-agreed-upon media. The Department may elect to verify the data through on-site review of appropriate records.

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

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

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

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

(c) Each mobile UESWL service shall establish and maintain an Operations Committee consisting of the central service coordinator's medical director and members representing each host site and the central service coordinator. This committee shall oversee the effective and efficient use of the UESWL unit, establish the normal route schedule, identify the process by which changes are to be made to the schedule, develop procedures for handling emergency situations, and review the ongoing operations of the mobile UESWL service and its unit(s) on at least a quarterly basis.

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

(e) If the host site will not be performing the lithotripsy procedures inside the facility, it must provide a properly prepared parking pad for the mobile UESWL unit of sufficient load-bearing capacity to support the vehicle, a waiting area for patients, and a means for patients to enter the vehicle without going outside (such as a canopy or enclosed corridor). Each host site also must provide the capability for maintaining the confidentiality of patient records. A communication system must be provided between the mobile vehicle and each host site to provide for immediate notification of emergency medical situations.

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

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

Section 10. Methodology for projecting UESWL procedures

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

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

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

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

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

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

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

Section 11. Requirements for MIDB data commitments

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

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

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

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

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

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

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

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

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

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

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

Section 12. Effect on prior planning policies; comparative reviews

Sec. 12. (1) These CON review standards supersede and replace the CON review standards for urinary extracorporeal shock wave lithotripsy (UESWL) services approved by the CON Commission on ~~September 25, 2014~~MARCH 27, 2018 and effective on ~~December 22, 2014~~MAY 29, 2018.

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

APPENDIX A

Factor For Calculating Projected UESWL Procedures

(1) Until changed by the Department, the factor to be used in Section 10(1)(b) used for calculating the projected number of UESWL procedures shall be 1.104[A1].

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

(a) Steps for determining statewide UESWL adjustment factor:

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

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

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

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

(i) For each hospital, assign urban/rural status based on the county classifications found in Appendix C. "Metropolitan statistical area counties" will be assigned "urban" status, and "micropolitan statistical area" and "rural" counties will be assigned "rural" status.

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

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

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

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

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

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

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

APPENDIX B

Counties assigned to each region are as follows:

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

APPENDIX C

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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

APPENDIX D

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

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

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

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

CERTIFICATE OF NEED

2nd 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	2nd Quarter	Year-to-Date
Approved projects requiring 1-year follow up	81	150
Approved projects contacted on or before anniversary date	50	95
Approved projects completed on or before 1-year follow up	62%	
CON approvals expired	15	26
Total follow up correspondence sent	226	427
Total approved projects still ongoing	311	

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.

- The Department is 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 and MRI Utilization List 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

2nd 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	2nd Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Letters of Intent Received	88	N/A	160	N/A
Letters of Intent Processed within 15 days	88	100%	158	99%
Letters of Intent Processed Online	88	100%	160	100%

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

Activity	2nd Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Applications Received	41	N/A	110	N/A
Applications Processed within 15 Days	41	100%	110	100%
Applications Incomplete/More Information Needed	29	71%	59	54%
Applications Filed Online*	38	100%	99	100%
Application Fees Received Online*	15	39%	40	40%

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

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

Activity	2nd Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Nonsubstantive Applications	30	100%	60	100%
Substantive Applications	26	100%	61	100%
Comparative Applications	2	100%	4	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	2nd 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	2nd Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Amendments	25	100%	49	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	2nd Quarter	Year-to-Date
Refunds Issued Pursuant to Section 22231	0	0

Other Measures

Activity	2nd Quarter		Year-to-Date	
	No.	Percent	No.	Percent
FOIA Requests Received	58	N/A	176	N/A
FOIA Requests Processed on Time *	58	100%	176	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.

STATE OF MICHIGAN
DEPARTMENT OF ATTORNEY GENERAL

DANA NESSEL
ATTORNEY GENERAL

MEMORANDUM

June 4, 2019

TO: James Falahee
CON Commission Chair

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

CC: Elizabeth Nagel
Joseph E. Potchen

RE: Legal Report for the June 13, 2019 Commission Meeting

We currently have one pending case in the Michigan Office of Administrative Hearings and Rules.

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. The matter is set for a status conference on June 12, 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/

DRAFT - Certificate of Need (CON) Commission Work Plan - DRAFT

Attachment K

	2019											
	January	February	March	April	May	June	July	August	September	October	November	December
Commission Meetings			Special Meeting/ Meeting			Meeting			Meeting			
Bone Marrow Transplantation (BMT) Services		BMTSAC Mtg.	BMTSAC Mtg.	BMTSAC Mtg.		Report/Draft Language/ Proposed Action	Public Hearing		Report/ Final Action			
Computed Tomography (CT) Scanner Services			Discussion/ Report			CT Workgroup Mtg.	CT Workgroup Mtg.	CT Workgroup Mtg.	CT Workgroup Mtg. or Report/Draft Language/ Proposed Action			
Megavoltage Radiation Therapy (MRT) Services/Units			Report/Draft Language/ Proposed Action	Public Hearing		Report/ Final Action						
Neonatal Intensive Care Services/Beds (NICU)			Discussion/ Report				SAC Nomination & Selection Period					
Nursing Home and HLTCU Beds and Addendum (NH-HLTCU)			Discussion/ Report	SAC Nomination & Selection Period			NH-HLTCU SAC Mtg.	NH-HLTCU SAC Mtg.	NH-HLTCU SAC Mtg.	NH-HLTCU SAC Mtg.	NH-HLTCU SAC Mtg.	NH-HLTCU SAC Mtg.
Psychiatric Beds and Services	Workgroup Meeting	Public Hearing/ Workgroup Meeting	Report/ Final Action/ Workgroup Meeting			Report/ Draft Language Presented/ Proposed Action	Public Hearing		Report/Final Action			
Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services/Units	Public Comment Period		Discussion/ Report	Dept. Drafting Language	Dept. Drafting Language	Draft Language Presented/ Proposed Action	Public Hearing		Report/Final Action			
New Medical Technology Standing Committee	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring	Department Monitoring

For Approval June 13, 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) at, 517-335-6708 or 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	2022
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	May 24, 2019	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.